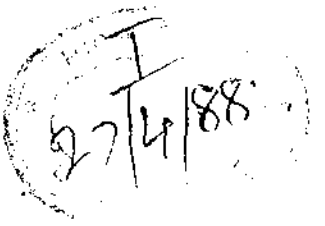

REPORT OF

THE COMMISSION OF INQUIRY

(Re. DEATHS OF PATIENTS IN J. J. HOSPITAL AT BOMBAY IN JANUARY-FEBRUARY 1986 DUE TO ALLEGED REACTION OF DRUGS)

HEADED BY

THE HONOURABLE MR. JUSTICE B. LENTIN
JUDGE, HIGH COURT AT BOMBAY

[*Price*—Rs. 50]

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I
27/4/88

COMMISSION OF INQUIRY

Headed by the Hon'ble Mr. Justice B. Lentin

(*Re.* Deaths of patients in J. J. Hospital in January–February 1986 due to alleged drug reaction)

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22/4/88.

COMMISSION OF INQUIRY

Headed by the Hon'ble Mr. Justice B. Lentin

(*Re.* Deaths of patients in J. J. Hospital in January-February 1986 due to alleged drug reaction)

FOREWORD

These pages describe and illustrate the ugly facets of the human mind and human nature, projecting errors of judgment, misuse of ministerial power and authority, apathy towards human life, corruption, nexus and *quid pro quo* between unscrupulous licenceholders, analytical laboratories, elements in the Industries department controlling the awarding of rate contracts, manufacturers, traders, merchants, suppliers, the FDA and persons holding ministerial rank.

None of this will be palatable in the affected quarters. But that cannot be helped.

STATISTICAL DATA

I

21st February 1986	..	The present Commission of Inquiry was appointed *vide* Government Notification No. JJH-2088/712/MED-4.
24th March 1986	..	Receipt of the President of India's letter of assent dated 18th March 1986 to my functioning as Commission of Inquiry.
24th April 1986	..	Secretary to the Commission was appointed.
30th April 1986	..	Counsel for the Commission were appointed.
6th May 1986	..	Commission was provided with office premises to house its office.
12th May 1986	..	Publication of Commission's Notification dated 12th May 1986 calling for information from members of public in English and regional language newspapers.
12th May 1986	..	Regulations of Procedure were framed.
13th May 1986	..	Commission's letter to Government calling for Statement of Case.
5th June 1986	..	Regulations of Procedure were published in Government Gazette.
11th June 1986	..	Preliminary sitting when further directions were given.
23rd June 1986	..	Production of files and documents by PSI Nikam and recording of evidence commenced.
30th June 1986	..	As the then Counsel for Government was unable to open the case of the Government, at my request, Counsel for the Commission Mr. N. A. Shah did so, on the basis of the record produced.
3rd July 1986	..	Written intimation was given to the next of kin of the deceased persons inviting them to participate in the Inquiry.
17th July 1986	..	Inspection of J. J. Hospital by Commission and Counsel.
24th July 1987	..	Recording of evidence concluded; and Inspection of FDA and its Laboratory by Commission and Counsel.
27th July 1987	..	Commencement of submissions by Government Advocates and other parties.
24th August 1987/ 9th November 1987	..	Submissions of Mr. N. A. Shah.

II

Documents and files produced and perused	2424
Witnesses called by Government	80
Witnesses called by Commission by issuing Witness Summons	17
Persons to whom Notice under Section 8-B of the Commissions of Inquiry Act, 1952 was issued.	20
Witnesses called by parties before the Commission	23
Pages of evidence recorded	3732
Documents and files seized	387
Documents, files and articles exhibited	678

III

APPEARANCES

(1) Initially Mr. R. S. More with Mr. M. K. Patwardhan and Mr. R. S. More with Mr. C. S. Kotwal, thereafter Mr. R. S. More with Mr. V. T. Tulpule and thereafter Mr. V. T. Tulpule with Mr. V. C. Gupte, for Government.

(2) Mr. P. P. Hudlikar with Mr. T. H. Sardar for M/s. Chem Med Analytical Lab. and M/s. Semit Products.

(3) Mr. R. C. Shah with Miss S. R. Shah for Jethalal C. Soni, Proprietor of M/s. Ganesh Chemicals.

(4) Miss Pratima Patel for Mahendra R. Doshi, partner of H. M. Chemicals.

(5) Mr. M. V. Rajadhyaksha with Mr. D. D. Madon i/b M/s. Mulla & Mulla Craigie Blunt and Caroe for M/s. Kailash & Co., and M/s. Haresh Chemicals.

(6) Mr. C. S. Gosalia for M/s. Alpana Pharma Pack.

(7) Mr. U. S. Mirajkar with D. U. Mirajkar for M/s. Apex Laboratories.

(8) Mr. P. K. Thakkar for Relatives of Deceased.

(9) Mr. P. K. Jadhav and Mr. Sunil Kale with Mr. N. V. Pradhan for A. K. Chavan.

(10) Mr. K. K. Singhvi and thereafter Mr. K. S. Ghag for Bhai Sawant.

(11) Mr. K. H. Joshi for Dr. R. D. Kulkarni.

(12) Mr. V. L. Pradhan for S. M. Dolas.

(13) Mr. P. S. Mahajan and Mr. S. D. Vyas for S. D. Bhirud.

(14) Mr. D. R. Dhanuka with K. R. Dhanuka for Shivajirao Patil Nilangekar.

(15) Mr. V. M. Parshurami for Dr. B. W. Hiray.

(16) Mr. B. G. Pradhan for V. C. Sane.

(17) Mr. S. D. Mokashi for G. N. Patil.

(18) Mr. M. D. Rijhwani for Trustees of Rural Upliftment Organisation.

(19) Mr. M. P. Savla i/b M/s. M. P. Savla & Co. for—

(1) M. L. Patwari, (2) Mrs. K. M. Patwari, (3) B. R. Chajer, (4) J. L. Patwari, and (5) Susbilkumar Morarka.

(20) Mr. N. A. Shah with Mr. J. P. Devadhar for the Commission.

IV

Oral submissions were made by (1) Government Advocate Mr. Tulpule, (2) Mr. Hudlikar for Chem Med and Semit, (3) Mr. R. C. Shah for M/s. Ganesh Chemicals, (4) Miss Pratima Patel for M/s. H. M. Chemicals, Mahendra Doshi and Girish Doshi, (5) Mr. M. V. Rajadhyaksha for M/s. Kailash & Co. and Haresh Chemicals, (6) Mr. Gosalia for M/s. Alpana Pharma Pack, (7) Mr. D. U. Mirajkar for M/s. Apex Analytical Laboratories, (8) Mr. P. K. Thakkar for the next of kin of the deceased, (9) Mr. V. L. Pradhan for S. M. Dolas, (10) Mr. K. S. Ghag for Health Minister Mr. Bhai Sawant and (11) Mr. A. P. Namjoshi, President of Small Drugs Manufacturers Organisation of India, and (12) Mr. N. A. Shah, Counsel assisting the Commission.

Here I may state that as appearing hereafter, Dr. Hiray's Advocate Mr. Parshurami chose not to exercise his client's right to make submissions though invited to do so.

On behalf of Dr. R. D. Kulkarni's Advocate Mr. K. H. Joshi, Mr. Gupte assisting Mr. Tulpule stated that Mr. K. H. Joshi had requested him to inform me that Mr. K. H. Joshi did not desire to make any submissions on behalf of Dr. R. D. Kulkarni. Mr. Gupte made a further statement that he had received a similar request from Mr. Bhirud through Asstt. Commr. Raykar for being conveyed to me.

Likewise, V. C. Sane's learned Advocate Mr. V. G. Pradhan conveyed to me through Mr. Tulpule and Mr. Rajadhyaksha in Court that he would not be making any submissions before me as he had no instructions from his client V. C. Sane to do so.

Mr. Tulpule added that as requested by me before he commenced his arguments on 27th July 1987, he had informed V. C. Sane and others including their respective advocates (except Commr. Bhirud) on 3 occasions that they were at liberty to make their submissions before me if they so desired before the Commission's learned Counsels started making his submissions. Mr. Tulpule further added that as desired by me, he had also conveyed to all of them (except Commr. Bhirud) that if they did not make their submissions before the Commission's learned Counsel commenced his, they would not be allowed to make a grievance of the same.

V

Written submissions were handed in by (1) Mr. Rajadhyaksha for M/s. Kailash & Co. and M/s. Haresh Chemicals (Ex. 665), (2) Mr. D. U. Mirajkar for M/s. Apex Analytical Laboratories (Ex. 666), (3) Mr. P. K. Thakkar for the next-of-kin of the deceased (Ex. 667), (4) Mr. V. L. Pradhan for S. M. Dolas (Ex. 668),

(5) Mr. N. V. Pradhan for A. K. Chavan (Ex. 669), (6) Mr. K. S. Ghag for Health Minister Bhai Sawant (Ex. 670), (7) Mr. A. P. Namjoshi, President of Small Drugs Manufacturers Organisation of India (Ex. 671), and (8) Mr. F. K. Solapurwala, Proprietor of ROC Pharmaceuticals (Ex. 672).

Written submissions with covering letters received from Dr. B. W. Hiray and Dr. Shaligram on 10th November 1987 and 13th November 1987 respectively are numbered as Ex. 674 (colly) and Ex. 675 (colly) respectively.

NATURE OF INQUIRY

An inquiry under the Commissions of Inquiry Act, 1952 may be conducted in public or in camera. Under Section 8 of the Act, the discretion lay with me. I exercised it against the latter. My reason was simple. An inquiry of this nature, involving no State or Defence secrets, was better allowed to unfold itself not within the cloistered doors of secrecy but within full public gaze with access to one and all either by their presence or following its course through the press. Secrecy breeds suspicion, and suspicion breeds contempt. A public inquiry would therefore ensure public confidence in the work of the Commission to arrive at the truth without fear or favour, regardless of power, position, influence and importance of several witnesses. I therefore decided this would be a public inquiry.

YARDSTICK APPLIED

The yardstick applied by this Commission was to ascertain the facts and to arrive at the truth. There was no lis before the Commission as in a civil proceeding nor was there any accused person as in a criminal proceeding. Witnesses were examined as called by Government and others were summoned so as to assist the Commission as witnesses and not as accused persons. To certain witnesses, notice were issued under Section 8-B of the Act so as to give them the opportunity of explaining circumstances appearing against them. The evidence oral and documentary was evaluated by me on probabilities which would lead to an irresistible inference one way or the other.

PROCEDURE FOLLOWED

The Indian Evidence Act and the Code of Civil Procedure were followed. However witnesses were given the liberty to be represented by advocates of their choice and to cross-examine. No document was taken on record as an exhibit except by consent of parties or when produced from official custody or was proved. Certain documents were merely marked 'X' for identification until they were proved. If they were not proved, their contents were disregarded, unless the contents were otherwise admitted. Though, the contents of certain documents were strictly not proved, they were marked as exhibits but only to the limited extent as to the existence of such documents and not for the correctness of their contents.

The weapon of cross-examination was allowed to all parties including witnesses so that not only could the truth emerge but the interest of the party cross-examining could also be protected.

At the conclusion of the evidence, Government Counsel Mr. Tulpule was invited to first make his submissions, so that whatever Government had to say for or against any party could be noted and replied to by such party. Oral submissions were made by Government Counsel Mr. Tulpule. Thereafter the other parties were invited to make their submissions. Oral and written submissions were made by them as stated earlier. Thereafter, Mr. N. A. Shah the learned Counsel assisting the Commission was invited to make his submissions.

Thereafter such of the parties who were present were invited to give a permissible rejoinder. I use the word " permissible " because under the Civil Procedure Code, a rejoinder can never be a re-argument but must be confined either to a point of law newly raised or to an aspect which was misquoted by Counsel assisting the Commission.

Since none of these attributes were present, I did not permit Chem Med's Advocate Mr. Hudlikar to advance a rehash of his arguments already advanced. Government Advocate Mr. Tulpule contented himself by inviting me to make a note of 3 points which I did in his own words, namely—

" Rahim's noting never shown to Mr. Tulpule, (sic)".

" Sane's appointment was made by the Establishment Board and not by Dr. Hiray. "

" Appointment of Director E. S. I. S. Dr. Hulsure, made by M. P. S. C. and not by Shri Bhai Sawant. "

Dr. Hiray's Advocate Mr. Parshurami though present did not indicate that he wanted to say anything.

However on 10th November 1987, i.e. the day following the conclusion of the submissions, I received a letter dated 10th November 1987 from Dr. Hiray making a grievance that I did not hear arguments which his Advocate wanted to advance. Dr. Hiray enclosed his written submissions with his said letter (Ex. 674 colly). This grievance was repeated by Dr. Hiray at a press conference summoned by him on 11th November 1987 in a city hotel. The Commission's attention to this press conference was drawn by a Reporter of the Times of India and the Commission's reaction was sought and given. The report of the press conference and the Commission's reaction appeared in the Times of India on 12th November 1987. A xerox copy of the relevant cutting is marked Ex. 676.

This grievance of Dr. Hiray was totally unwarranted and without foundation. Before Mr. N. A. Shah commenced his submissions on 24th August 1987, I had invited all the advocates representing the various parties to make their submissions, including Mr. Parshurami representing Dr. Baliram Hiray. However Mr. Parshurami declained the invitation on the ground that—

> " he is instructed by his client Dr. Baliram Hiray to state that he does not desire to make any submissions (a) because what was issued to his client, Dr. Hiray, was a witness summons and (b) as the matter is subjudice because the prosecution for perjury is pending before the learned Metropolitan Magistrate. "

This was recorded by me in open Court in Mr. Parshurami's presence and in his own words at page 3187 of the notes of evidence.

Even after Mr. N. A. Shah concluded his submissions, I enquired of all the Counsel present, including Mr. Parshurami whether any of them wanted to make any submissions by way of a permissible rejoinder. However Mr. Parshurami though present did not give the slightest indication that he wanted to do so.

On 13th November 1987 I received a letter from Dr. Shaligram that Government's Councel had not advanced certain arguments on his behalf as set out by him in the annexure to his letter (Ex. 675 colly). Dr. Shaligram like any other witness was also given the liberty of being represented by an advocate of his choice. He himself could have, if he wanted to, advanced his arguments after Mr. Tulpule finished and before the Commission Counsel started his.

In making my Report, I have gone through and carefully considered all the arguments, written and oral, advanced by the parties, by Counsel assisting the Commission as also the written submissions sent to me by Dr. Hiray on 10th November 1987 and by Dr. Shaligram on 13th November 1987.

COUNSEL'S ROLE IN ASSISTING THE COMMISSION

Presence of Counsel to assist the Commission is of vital importance in order to collect the facts and ferret out the truth from witnesses interested in thwarting the Commission or otherwise not willing to co-operate or coming ready with pre-planned lies, as indeed was the case of most of the witnesses examined before this Commission. It is for this reason that the Commission was required to have its own independent machinery whereby the relevant and requisite material could be gathered and/or elicited from the witnesses by cross-examination so that their veracity could be tested. Moreover the public may be interested in giving information to the Commission which may be true or untrue or a little of both. Such information must be investigated and sifted to ascertain its relevancy and where the truth lies.

Thus a Commission of Inquiry should have an independent Counsel of its choice for assistance. Though such Counsel is not part of the Commission, he will render assistance to the Commission to arrive at the truth. Counsel assisting the Commission is therefore in the nature of an amicus curiae. His role is to go through the myriad of files, documents and papers and to bring on the recrod of the Commission the relevant facts, marhall them, and bring them to the Commission's notice for its consideration. There his task ends. Any view expressed or submission made by the Commission's Counsel must necessarily be his own and which may or may not coincide with the view of the Commission. Ultimately, it is for the Commission to arrive at its own findings, for just as the Commission is not bound to accept submissions made by or on behalf of the parties appearing before it, the Commission is not bound to accept submissions made by Counsel assisting it.

In all this I was more than fortunate in the Counsel of my choice Mr. N. A. Shah ably assisted by Mr. J. P. Deodhar.

STATEMENT OF CASE

The Statement of Case presented by the then Government Advocate at the commencement of the inquiry was hopelessly defective. It unfolde nothing of any consequence and not even the sequence of events. As a result, the task of the narration of events fell upon the Commission's Counsel Mr. N. A. Shah which he called out from the Government and FDA files produced before the Commsission.

WITNESSES

For the purpose of my Report, it has become unnecessary to deal with the evidence of each and every witness. Only the evidence of such witnesses as is necessary has been dealt with. I have chosen to ignore the other witnesses whose minor aberrations pale into the utter insignificance in the light of the immensity of the ramifications revealed by the witnesses whose evidence I have dealt with in this Report.

I have also ignored the evidence of "tainted" witnesses unless such portion of their evidence is corroborated in material particulars either by their own admissions or unimpeachable documentary evidence or other reliable oral evidence.

Further, care has been taken to draw an irresistible inference against a witness when no other explanation was possible.

PERJURY NOTICES

During the course of the inquiry, I was constrained to order the Commission's Secretary Mr. Gadagkar to issue perjury notices against 4 witnesses, namely ex-Commissioner V. C. Sane, G. N. Patil, Jr. Commr. Dolas and ex-Health Minister Dr. Baliram Hiray on 13th March 1987, 19th May 1987, 26th May 1987 and 16th June 1987 respectively. Perjury notices were thereuopn issued to these 4 witnesses on 19th March 1987, 25th May 1987, 16th June 1987 and 23rd June 1987 respectively. After arguments those notices were made absolute by me on 3rd April 1987, 16th June 1987, 2nd July 1987 and 7th July 1987, respectively. Prosecutions against them were filed in the Addl. Chief Metropolitan Magistrate, Esplanade Court. These prosecutions are pending.

V. C. Sane's Review Petition against my order dated 3rd April 1987 was dismissed by me on 21st May 1987.

Dr. Hiray's Write Petition No. 773 of 1987 for setting aside my order dated 7th July 1987 was dismissed by the Division Bench of the Bombay High Court on 12th August 1987. Against that order, Dr. Hiray has filed a petition for special leave to appeal in the Supreme Court.

TRAVAILS OF THE COMMISSION

I

Apparently this Inquiry was not exactly welcomed in certain quarters. As a result, the Commission was plagued with attemps at denigration, harassment, threats and attempted bribery. Unfortunately for the persons concerned, none of this succeeded.

II

On 4th August 1986, one Bandu Shingre addressed a letter to me questioning the propriety of my conducting this Commission on the ground that two of my cousins Dr. F. E. Udwadia and Dr. T. E. Uadwadia are Honoraries in the J. J. Hospital. A sepaking order was passed by me on 5th August 1986, repudiating the insinuations of Bandu Shingre and recroding the statement made by the then Advocate-General Mr. A. V. Savant conveying the Chief Minister's support to the Commission.

III

On 11th August 1987, it came to my notice that on 24th July 1987, the Chief Metropolitan Magistrate Mr. Velkar had addressed a letter to Mr. Soman, the then Commissioner of Police, asking him to take special steps under my directions to execute the warrants against Dr. Baliram Hiray and G. N. Patil. No such directions whatsoever had been given by me to Mr. Velkar either directly or indirectly, orally or in writing. This was admitted by Mr. Velkar before the learned Acting Chief Justice Mr. S. K. Desai as recorded by him in his letter dated 13th August 1987. All this forms part of the recrod of the Commission at pages 3182–3191 of the notes of evidence and at Ex. 664 and 664-A.

IV

On 12th November 1987 a report appeared in the issue of the Free Press Journal concerning the Commission's Counsel Mr. Navnit Shah, attributing a statement to Mr. Nihal Ahmed, Opposition leader in the State Assembly as under :—

" * * * * *

" Ahmed said Shah had visited his residence once to meet common Opposition candidate for the Presidency Krishna Iyer. " That was only time I met Shah ", Ahmed told FPJ.

* * * * * ".

On 13th November 1987, Commission's Counsel Mr. N. A. Shah addressed a letter to the Editor of the Free Press Journal pointing out that as a result of this report, an e roneo us impression was sought to be created because he, i.e. Mr. N. A. Shah, had never met Mr. Nihal Ahmed at any time, much less had he ever gone to his residence for any purpose whatsoever. Mr. N. A. Shah further stated that he has not and never had been in politics, nor does he belong or ever belonged to any political party and that he has no political leanings and never had any one way or the other. Mr. N. A. Shah further stated that Mr. Nihal Ahmed was mistaking him for another person of the same name, *viz.* another Navnit Shah, a former M. L. A. belonging to the P. S. P. to which Mr. Ahmed also belonged. Commission's Counsel Mr. N. A. Shah further stated that Mr. Nihal Ahmed was not the only person to make this mistake because during the Samyukta Maharashtra Movement, the other Mr. Navnit Shah was the only non-Marathi speaking candidate elected to the Legislative Assembly when many mistaking Commission's Councel Mr. N. A. Shah for the other Mr. Navnit Shah had sent their congratulations to the Commission's Counsel Mr. N. A. Shah instead of to the other Mr. Navnit Shah. A copy of Mr. N. A. Shah's letter dated 13th November 1987 to the Editor was sent by him to the Commission for information. The cutting from the Free Press Journal and copy of Mr. N. A. Shah's letter and its publication in the Free Press Journal are Ex. 677 (colly).

In this Report I have used only simple medical words and have avoided elaborately worded medical jargon and instead have used its equivalent in simple language within the comprehension of the average lay person.

ACKNOWLEDGEMENTS

I acknowledge my gratitude to the Chief Minister Mr. S. B. Chavan for his support to the Commission; the Government of Maharashtra for providing office accommodation; the Commissioner of Police for arranging for security in the Courtroom and Chamber; Mr. R. H. Kumavat, Dy. Secretary, Medical Education and Drugs Department, for his unfailing courtesy and promptness in assisting the Commission whenever requested; the Hon'ble the then Chief Justice Mr. M. H. Kania, and the Hon'ble the Ag. Chief Justice Mr. S. K. Desai for putting at my disposal such of the Court staff selected by me; my learned Sister Mrs. Sujata Manohar, J. and my learned borther V. P. Tipnis J. for placing at short notice and at great incovenience to themselves the services of their Personal Assistants; Miss K. R. Bharucha, Prothonotary and Senior Master, and Mr. R. G. Sindhkar, Registrar, High Court, Bombay for the correspondance carried out by them with Government and to the former, also for temporarily sparing me the services of her Stenographer; and various police constables for their silent unobtrusive alertness.

I acknowledge my deep gratitude to Mr. N. M. Shetty, Mr. B. B. Sabnis, Mr. T. M. Vijaykumar, Mr. A. B. Shaikh and Mrs. Harsha V. Ahuja for their individual and collective contribution in transcribing this Report which would otherwise never have been ready within the 3 weeks at my disposal for its preparation.

My special thanks go to the Commission's staff who have ungrudgingly toiled without a thought for themselves and in particular Superintendent Mr. V. J. More, Clerk Mr. J. J. Ruben, Sheristedar Mr. G. S. Toskar and Peon Mr. H. N. Indulkar.

It is difficult to find words appropriate enough to express my appreciation of the epic work done by Mr. N. A. Shah ably assisted by Mr. J. P. Devadhar and by the Commission's Secretary Mr. R. K. Gadagkar, ill-health and hospitalisation notwithstanding. To them my deep and unflagging thanks.

Finally, but by no means the least, it would be ungracious of me not to acknowledge the role played by the press for its part in bringing awareness of the state of things to the door-step of those unable to attend the proceedings.

Note.—On 26th November 1987 a booklet in Marathi addressed to the Commission's Secretary Mr. Gadagkar at the Commission's office was received by him by post purporting to contain certain statements made by G. N. Patil, Secretary, Bhausaheb Hiray Smaranika Samiti Trust regarding Dr. Hiray's evidence and perjury proceedings. Comment is unnecessary. That booklet is marked Ex. 678.

CHAPTER I

Introduction

1. In January 1986, tragedy struck the J. J. Hospital. Four departments were affected, Neurology, Neurosurgey, Nephrology and Ophthalmology.

2. It started with Bapu Thombre. He died on 21st January 1986. He was followed by 13 others. The last was Dawood Dholakia on 7th February 1986. They were all patients in the J. J. Hospital. They all died unnatural and untimely deaths. Their ages ranged from 10 to 76. Two of them were well on their way to recovery. To the astonishment of the doctors, they too died. The common drug administered to all 14 was glycerine, otherwise a harmless drug in therapeutical doses used down the years by the Medical profession the world over including the J. J. Hospital to combat oedema or swelling of the brain.

3. But this glycerine was not harmless. It was lethal. It was contaminated with diethylene glycol, a deadly poison. As a result, all these patients developed anuria leading to renal cortical necrosis. It was irreversible. Dialysis was of no avail. They did not ask to be born; they did not choose to die. They died. They died as they had lived quietly and in poverty.

4. Little could they know that by their deaths they would arouse an outcry of public indignation which would lay bare lack of probity in public life, malaise and corruption in places high and low indulged in contempt of the laws of God and man.

5. All is over bar the shouting. It is time to pause and forage into the murky waters of lies, deceit, intrigue, ineptitude and corruption to salvage the truth which led to this ghastly and tragical episode.

6. To that end, in so far as is relevant to this Inquiry, hereunder the set up of the J. J. Hospital and the sequence of events.

CHAPTER II

SET UP OF THE J. J. HOSPITAL IN SO FAR AS THE PRESENT INQUIRY IS CONCERNED

Complex

1. The total complex admeasures over 43 acres on which a total number of 57 buildings stand including the main Building and C. J. Ophthalmology.

Units

2. There are 11 departments (Units), namely :—

(1) Medical Department,
(2) Surgery Department,
(3) Obstetrics Department,
(4) Paediatrics Department,
(5) Ophthalmology,
(6) Nephrology Department with A.K.D.,
(7) Cardiology Department,
(8) Cardio Thoracic Department,
(9) Neurology Department,
(10) Neurosurgery Department,
(11) Plastic Surgery Department.

Wards and beds

3. Every department (Unit) has its own ward comprising of a separate male and female ward. Every department is headed by a consultant who is an honorary or a full time professors, with a lecturer or reader under him. Every department has a Registrar or Houseman. There are in all 40 wards with a total of 1,339 beds.

Procedure for transferring patients

4. Whenever a patient is to be transferred from one department to another, a reference is made by the Registrar or Houseman of that department under the directions of the consultant. Thereupon the Houseman or consultant of the other department to whom a reference is made examines the patient. If it is decided to transfer the patient to the other department, he will either be transferred to the receiving ward or kept in the same ward of the parent department, but treatment will be given to him by the receiving department.

Ward Register

5. A ward register is maintained in which is kept a record of such examination and the receiving or retention in the parent ward of such patient. This is also entered on the first page of the indoor casepapers.

Staff as on January/February 1986

6. 329 Full time doctors.
80 Honorary doctors.
21 Medical Officers.
208 Resident doctors.
575 Nursing staff.
500 Class III servants.
1274 Class IV servants.

Medical Store and Floor Pharmacies

7. The Hospital has a Medical Store on the ground floor of the main building and 6 floor pharmacies, out of which four are on the 1st, 2nd, 3rd and 4th floors of the main building and 2 in other buildings. The timings of the Medical Store are 9-00 a.m. to 1-00 p.m., and of the floor pharmacies 8-30 a.m. to 2-30 p.m. (on working days). On Saturdays the respective timings are 9-00 a.m. to 12-00 noon. On Sundays the Medical Store and floor pharmacies are closed.

Procedure of Floor Pharmacies

8. Floor pharmacies send indents to Medical Store every 15 days for their collective requirements. They maintain a bin card for every drug. Stock taking is done every 15 days. The area of the floor pharmacies on the 1st, 2nd and 3rd floors of the main building is 10′ × 15′. Only the floor pharmacy on the 1st floor has a refrigerator. The area of the floor pharmacy on the 4th floor is slightly smaller. In the C. J. Building, the floor pharmacy is on the ground floor with an area of 10′ × 10′. In the building in which the paediatrics department is situate, the area of the floor pharmacy is 10′ × 10′.

9. Floor pharmacies make one day's supplies of medicines to the wards and do not stock or supply bulky drugs.

Medical Store

10. Medical Store is supervised by the Pharmacology Department. It has a cold room and 3 sections, namely AB, C and D. In these sections drugs are stored according to the annual consumption cost. Drugs costing more than Rs. 10,000 a year are stored in section AB. Drugs costing less than Rs. 10,000 a year are stored in section C and other drugs including bulky drugs are stored in section D, irrespective of their cost. Glycerol is stored in section D on a separate rack which can accommodate 300 bottles at a time. Fresh stock is placed behind the existing stock. Medical Store supplies drugs to the wards on weekly indents received from various wards. During the closure hours of Medical Store and floor pharmacies, supplies can be obtained by the wards from the Casualty Department on the ground floor in the main building.

Staff of Medical Store and Floor Pharmacies

11. (1) 1 pharmacist, in-charge,
(2) 1 senior pharmacist,
(3) 5 pharmacists, and
(4) 22 compounders.

Duties of Pharmacist in-charge

12. Pharmacist's duties comprise of (*a*) overall administration of Medical Store, (*b*) supervision over receipts and issuance of drugs, (*c*) supervision of records of Medical Store and (*d*) preparing proposals for the procurement of drugs.

Procedure for withdrawal of drugs

13. Drugs are withdrawn by issuing circulars.

Telephone facility in Medical Store and Floor Pharmacies.

14. Medical Store has a telephone having a direct line. It also has another line through the operator. However there is no telephone facility in the Pharmacology Department which supervises Medical Store, nor is there any telephone facility in the floor pharmacies.

Bin Card

15. Medical Store maintains a bin card for every drug wherein the receipt and delivery of the drug concerned is required to be mentioned contemporaneously, but is not. Every bin card has an order point which shows the level reached by the concerned drug necessitating a fresh order to be placed for the supply of that drug. Every bin card has also an order-size, indicating the quantity to be ordered. As soon as the stock of a particular drug depletes, the compounder must inform the pharmacist, whose duty it is to make a proposal indicating the quantity to be purchased and the source of purchase. The source of purchase is determined on the basis of rate contracts awarded by the Industries Department of the Government of Maharashtra. The purchase therefore can be made only from rate-contracted firms, i.e. initially from the main contractor, and failing him from the alternate supplier.

16. Whenever the Industries Department awards rate contracts to contractors in the backward area by way of reservation (the percentage being 33), the Hospital is required to place an order to the extent of such percentage with such rate contractor in that area. If the said 33 per cent is divided between 2 or more contractors, the said 33 percentage is also required to be proportionately divided between such rate contractors and the Hospital is not allowed to exceed such proportion while placing an order.

17. The purchase proposal of the pharmacist must be approved by the Professor of Pharmacology. Local purchases cannot be made by Medical Store. That can only be done by the Dean in exceptional circumstances and not exceeding Rs. 10,000 in one year.

18. There is no routine practice in Medical Store to check the quality of drugs, nor is Medical Store otherwise equipped to check the quality. The total number of items handled by Medical Store range from 600 to 800 at a given point of time. The total annual budget of J. J. Hospital for purchase of drugs and medicines is Rs. one crore and 50 lakhs. There is no system of auditing or check as to what happens to the drugs once they leave Medical Store or the floor pharmacies.

Out Patient Department and Resident Hospital

19. The daily attendance ranges from 1,800 to 2,400 persons. In the resident hospital, the daily admissions range from 90 to 100, discharges from 90 to 100 and deaths from 3 to 5.

Nursing Staff

20. The nursing staff works in 3 shifts, namely from 7-00 a.m. to 2-30 p.m. from 1-00 p.m. to 8-00 p.m. and from 8-00 p.m. to 8-00 a.m.

The Relevant Department

21. The present Commission of Inquiry is concerned with Neurosurgery, Neurology, Ophthalmology, Nephrology, Pathology and Pharmacology departments.

Neurosurgery Department (Ward 25)

22. Neurosurgery department is situate in the main building and comprises of Units 1 and 2. Unit 1 was headed by Dr. S. N. Bhagwati (an Honorary) with Dr. S. L. Panda as Reader. Unit 2 is headed by *Dr. M. J. Virani* with Dr. D. A. Palande as Lecturer. Both these Units have a common ward, namely Ward 25 and a common nursing staff.

Neurology Department (Ward 24)

23. Neurology Department is situate in the main building and has two Units. However the concerned Unit is Unit 2 headed by *Dr. S. M. Katrak.*

Ophthalmology Department (Ward 26)

24. Ophthalmology Department is situate in the C. J. Building, about a furlong away from the main building. The ophthalmology ward is Ward No. 26 having total capacity of 100 beds. Ophthalmology department comprises of Units 1 and 2. Unit 1 has 52 beds and was at the material time headed by Dr. (Miss) M. A. Kamble. The other staff which manned this Unit were the Registrar Dr. (Mrs.) Neeta Shah, the Lecturer Dr. Shaikh and House Surgeons Dr. (Mrs.) Asha Menon and Dr. (Miss) Parul Shah. Unit 2 was headed by Dr. (Mrs.) P. G. Hingorani. The other staff which manned Unit 2 comprised of Dr. R. M. Shanbhag, Associate Professor, Dr. (Mrs.) Pushpa H. Gaikwad, Lecturer, Dr. (Mrs.) Jyoti S. Padaley (*nee* Jyoti Dekate) and Dr. S. M. Lele. Unit 2 has 48 beds.

25. On the ground floor of the C. J. Building is the O.P.D. waiting room and floor pharmacy. On the 1st floor is the operating theatre and the male ward which is a part of Ward 26. On the 2nd floor is the female ward which is also a part of Ward 26. On the 3rd floor are the jail and septic wards.

26. The nursing staff for Ward No. 26 is common and comprises of sister Smita R. Jadhav, staff nurse Miss Gulab N. Manjrekar, Miss Sheela R. Bhalerao, Mrs. Archana D. Chikane, Shobha Ravi Varma and Vasanti S. Mahamulkar.

27. The first shift (7-30 a.m. to 2-30 p.m.) has 3 staff nurses plus one nurse for the operation theatre and one nurse for O.P.D. The second shift (1-00 p.m. to 8-00 p.m.) has one staff nurse and 2 student nurses. The third shift (8-00 p.m. to 8-00 a.m.) has one staff nurse and one student nurse. The burden on the nursing staff is unmanagable as they have to look after the patients in this department from the ground to the 3rd floors as also the patients in the jail and septic wards. The pressure on this staff is even greater at nights when the lift is not available, assuming it is available to them during the course of the day which more often is not. Over and above this they are expected to maintain the requisite records.

Nephrology Department (A.K.D., Ward 22)

28. The Nephrology Department is situate in the main building and is headed by Dr. A. L. Kripalani with a Lecturer Dr. (Mrs.) R. A. Sirsat and 2 Registrars Dr. P. P. Pargaonkar and Dr. Farhed Kapadia.

Pathology Department

29. The Pathology Department is headed by Dr. U. L. Wagholikar.

Pharmacology Department

30. The Pharmacology Department is headed by Dr. R. D. Kulkarni, Professor of Pharmacology with Dr. S. V. Shaligram, also Professor of Pharmacology. At the material time, there were 3 Associate Professors, namely Dr. (Mrs.) P. S. Worlikar, Dr. (Mrs.) M. S. Kelkar and Dr. A. P. Saraf and a Lecturer Dr. (Mrs.) U. V. Mujamdar. All were in full time service. Till September 1984, Medical Store which is under Pharmacology Department was in the charge of Dr. (Mrs.) Kelkar, and thereafter in the charge of Dr. (Mrs.) Worlikar.

31. The Pharmacology Department has 3 different units :—

(*a*) Clinical Pharmacology Unit established in 1969 for evaluating new drugs and training personnel in methods of human evaluation of drugs. Bio Availability Study is done mainly in this Unit.

(*b*) Drug Information Centre established in 1978 for getting information of drugs which would be available at short notice and

(*c*) Adverse Drug Reaction Monitoring Cell established in 1982 by reason of the concern for increase in drug reaction. This Cell is also a part of a training centre for the National Adverse Reaction Registry.

CHAPTER III

DEATHS FROM 1st JANUARY 1986 TO 2nd FEBRUARY 1986

1. During this period 45 patients dies in the J. J. Hospital out of which 13 are the subjectmatter of the present Inquiry. However during the course of these proceedings it transpired that a 14th patient one Laxmibai D. Varadkar had also succumbed. The names of these 14 patients appear almost immediately hereafter.

2. Out of the remaining patients, glycerol was administered to 7, but they died of other causes. Their names are :

(1) Mahadev Govind Shinde (Ex. S-26),
(2) Daji Bapu Vichare (Ex. S-27),
(3) Gopinath Ambu Mahatre (Ex. S-28),
(4) Bhagwat Pitambar Rane (Ex. S-29),
(5) Dhanajirao Jadhav (Ex. S-30),
(6) Balram Mahadik (Ex. S-31) and
(7) Tukaram Sakpal (Ex. S-32).

3. Ex. G to Ex. S and Ex. S-25 are the files of the 14 patients who die. Their names, ages and dates of death are as under :—

Name	Age	Date of death
(1) Bapu Thombre (Ex. I)	.. 33 years	21st January 1986
(2) Ramesh Shinde (Ex. H)	.. 20 years	24th January 1986
(3) Hemant Ranade (Ex. G)	.. 20 years	24th January 1986
(4) Tanveer Baig (Ex. J)	.. 10 years	25th January 1986
(5) Vithal Bhokare (Ex. M)	.. 44 years	25th January 1986
(6) Bittal Kevat (Ex. K)	.. 50 years	27th January 1986
(7) Vithal Gharge (Ex. O)	.. 50 years	27th January 1986
(8) Shailendra Joshi (Ex. L)	.. 22 years	28th January 1986
(9) Sopan Tawar (Ex. N)	.. 18 years	28th January 1986
(10) Rajendrakumar Mishra (Ex. Q)	.. 33 years	30th January 1986
(11) Ramji Balu Kasar (Ex. P)	.. 60 years	1st February 1986
(12) Abdul Kadar Shaikh (Ex. R)	.. 60 years	2nd February 1986
(13) Dawood Dholakia (Ex. S) (Discharged against medical advice on 6th February 1986).	.. 76 years	7th February 1986
(14) Laxmibai D. Varadkar (Ex. S-25)	.. 55 years	24th January 1986

4. Composite charts departmentwise containing the material particulars regarding these 14 patients appear hereunder.

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CHART SHOWING THE PARTICULARS OF 14 PATIENTS WHO DIED AT J. J. HOSPITAL IN JANUARY-FEBRUARY 1986

Department : Neuro Surgery.

Ward No. 25, Dr. S. N. Bhagwati, Unit No. I, Dr. Panda.

Serial No.	Name and Age of the patient	Brief History	Dates on which the suspect drugs were administered	Date of Death	Remarks
1	Bapu Anand Thomre .. Age 33 years (Ex. I)	(315) Had a history of fall. Medico legal case. Admitted on 15th January 1986 in General Surgical Ward. Transferred to Ward 25, Unit I on 16th January 1986. Referred to Nephrology Department on 20th January 1986 as patient had not passed urine throughout the day and night. (717) Given lasix and no dialysis in view of head injury and his parameters did not indicate the necessity for dialysis.	(Ex. 91) *Glycerol* : 18th January 86 to 20th January 86. *Mannitol* : 16th January 86 to 20th January 86. *Diamox* : Nil.	(Ex. 91) 22nd January 86 at 8-30 a.m.	(825) He was autopsied by the Forensic Medicine Department. Kidney showed acute cortical necrosis indicative of diethylene glycol poisoning.
2	Hemant D. Ranade .. Age 20 years (Ex. G)	(317) Medico legal case. Had scooter accident Swollen Brain. Initially admitted in G.T. Hospital for 3 days. Admitted in Ward 25 on 20th December 1985. Operated on 26th December 1985. Passed no urine on 19th January 1986. On 20th January 1986 signs of vomitting and abdominal pain. (318) At 4-00 a.m. on 20th January 1986 emergency Nephrology Registrar summoned. Removed to Nephrology Department on 20th January 1986 at 12-30 p.m. (717) Had high renal parameters given haemodialysis on 20th January 1986, 21st January 1986 and 22nd January 1986 (blood taken out of the body passed through an artificial kidney and on purification put back into the body).	(Ex. 91) *Glycerol* : 21st December 85 to 25th December 85, 28th December 85, 29th December 85, 1st January 86 to 20th January 86. *Mannitol* : 20th December 85 to 1st January 86. *Diamox* : 1st January 86 to 15th January 86.	(Ex. 91) 24th January 86 at 6-45 a.m.	(822) Kidney biopsy indicates glycol poisoning. (826) He was not autopsied.
3	Ramji Balu Kasar .. Age 60 years (Ex. P)	(319) Had History of abnormal behaviour drowsiness and convulsions. Admitted to Medical Ward No. 9 on 14th January 1986. Transferred to Ward 25 on 17th January 1986 at 11-30 p.m. Brain Tumor—1st operation done at 9-30 p.m. on 20th January 1986, 2nd operation at 10-30 a.m. on 21st January 1986. On 27th and 28th January 1986 passed no urine. (718) Transferred to Nephrology Department on 27th January 1986 at 11-00 p.m. Given antibiotics and haemodialysis on 28, 29, 30 and 31st January, 1986.	(Ex. 91) *Glycerol* : 19th January 86 to 20th January 86 (1st dose only), 24th January 86 and 25th January 86. *Mannitol* : 17th January 86 to 24th January 86. *Diamox* : Nil.	(Ex. 91) 1st February 1986 at 7-25 a.m.	(824) Kidneys Autopsy showed acute defused tubular necrosis indicative of diethylene glycol poisoning, liver had also centrilobular hepatic necrosis indicative of diethylene glycol poisoning.

The figures in brackets denote page numbers of the notes of evidence.

Serial No.	Name and age of the patient	Brief History	Dates on which the suspect drugs were administered	Date of Death	Remarks
Ward No. 25, Unit II, Dr. Virani J. J.					
4	Ramesh Parshuram Shinde Age 20 years. (Ex. H)	(328) Met with vehicular accident at Mangaon Swollen Brain. Admitted in emergency casualty on 15th January 1986. Same night transferred to Ward 25, Unit II referred to Nephrology Department on 16th January 1986. On 21st January 1986 at 3-10 p.m. transferred to Nephrology Department because of anuria. (719) Given lasix, antibiotics and sodabicarb. Put on Peritonial dialysis on 21st January 1986—given blood transfusion-did not respond.	(Ex. 91) *Glycerol* : 16th January 86 (2 Oz.) to 20th January 86. *Mannitol* : 15th January 86. *Diamox* : 16th January 86 to 20th January 86.	(681)24th January 86 at 0.45 midnight	R.D. Kulkarni. (115) There is no stoppage of glycerol shown in the treatment card. (681) Dr. Palande sats that the patient was given the conventional medical management treatment for brain oedema (i.e. swelling of the brain) and contusion. (822) Kidney biopay indicates glycol poisoning.
5	Shailendra M. Joshi .. Age 22 years. (Ex. L)	(332) Had a history of generalised head-aches, bulging of the right eye and deterioration of vision in both eyes. Admitted on 16th January 1986. C.T.S. can revealed Brain Tumor. On 20th January, 1986 operated at 9-00 a.m. Referred to Nephrology Department on 23rd January 1986. On 25th January 1986 given peretonial dialysis. Dialysed till 27th January 1986-did not respond.	(Ex. 91) *Glycerol* : 16th January 86 (2Oz) 19th January 86, 21st January 86 to 23rd January 86. *Mannitol* : (50 cc) 19th January 86, 20th January 86 to 23rd January 86. *Diamox* : Nil.	28th January 86 at 6-45 a.m.	(683) On 23rd January 86 he was vomitting continuously and passed less urine. Nephrology Registrar opined that the investigations were showing higher reading, due to dehydration therapy induced by mannitol or glycerol. He advised stoppage of drugs which was done No improvement. on 24th January 86 renal parameter still gone up. (825) Kidneys showed defused bilateral cortical necrosis indicative of diethylene glycol poisoning. His adrehal gland showed massive haemorrage indicative of diethylene glycol, poisoning.
6	*Sopan S. Tawar* .. Age 18 years. (Ex. N)	*(336) Had Brain Tumer, Admitted* in Ward 23 on 29th November 1985, operated on 23rd November 1985. Again operated on 4th December 1985. Tumor found cancerous. He was put on radio therapy for 5-6 weeks. Since 24th January 1986 stopped passing urine. On 25th January 1986 at 1-00 p.m. transferred to Nephrology Department for haemodialysis. (318) Urinary output Nil. On 27th January 1986 put on artificial kidney dialysis. (720) He had anuria and was dehydrated. (721) On 28th January 1986 his Blood Pressure started falling and thereafter his condition became serious.	(Ex. 91) *Glycerol* : 25th November 85 to 3rd December 85 24th December 85 to 20th January 86. *Injection Mannitol* : (50 cc) 22th November 85 to 3rd December 85. *Diamox* : 30th December 85 to 2nd January 86.	28th January 86 at 8-00 a.m.	(824) Renal Cortical Necrosis produced by and the result of glycol poisoning.

Serial No.	Name and age of the patient	Brief History	Dates on which the suspect drugs were administered	Date of Death	Remarks
7	Vithal S. Garge Age 50 years (Ex. O.)	Progressive weakness of the left half of the body for 3 months and left sided focal convulsions. Admitted on 5th November 1985 under Dr. Kapoor in Ward 9. Transferred to Ward 25, Unit II on 6th December 1985. On 7th December 1985 operated by Dr. Parikh. Biopsy revealed cancerous growth. Referred to Tata Memorial for radio therapy. On 22nd January 1986 referred to Nephrology Department and was removed to Nephrology Department on 24th January 1986. (721) Complained pain in the loins. Given haemodialysis on 23, 24 and 25 January 1986–also given treatment for bronchial asthama.	(Ex. 91) *Glycerol* 14th December 85 to 16th December 85 21st December 85 to 22nd January 86. *Mannitol* : 6th December 85 to 11th December 85 (50 cc.) *Diamox* : Nil. *Sodabicarb* : 22nd January 86 ,23rd January 86 and 24th January 86 (50 cc 6 hourly)	27th January 86 at 2-00 a.m.	(682) Dr. Palande says that on 22nd January 86 he developed breathlessness and complained of abdominal pain.

Department : Ophthalmology.

Ward No. 26, Unit I, Dr. M. A. Kamble.

Serial No.	Name and Age of the patient	Brief History	Dates on which the *suspect drugs were* administered	Date of Death	Remarks
1	Laxmibai D. Varadkar Age 55 years. (Ex. S-25)	*Ex. S-25.*—Admitted on 10th January 1986 at 11-30 a.m. Mature cataract operated on 14th January 1986. *Ex. S-35,39.*—Discharged on 18th January 1986 against Medical advice. On 20th January 1986 oliguria which slowly went into fatal anuria by 21st January 1986.	(749) None of the suspect drugs were administered to her.	24th January 86 at 12-30 p.m.	(850) Discharged on 18th January 86 re-admitted on 23rd January 86. (749) She had the same kind of necrosis. (805) In the opinion of Kriplani she could have developed cortical necrosis as a result of contaminated glycerol even though it is not mentioned in the case papers. (826) Her autopsy showed defused cortical necrosis of both kidneys and centrilobular hapatic necrosis indicative of diethylene glycol poisoning.

Department : Ophthalmology

Ward No. 26, Unit No. I, Dr. M. A. Kamble.

Serial No.	Name and age of the patient	Brief History	Dates on which the suspect drugs were administered	Date of Death	Remarks
1	Rajendra Mishra Age 33 years (Ex. Q) (Ex. 102).	(459) Suffering from adherent glucoma of the right eye. Admitted on 18th November 1985. Operated on 26th November 1985. (612) On 25th January 1986 complained of weakness, backpain, distension, nausea and vomitting. (613) Emergency Registrar diagnosed his case as of Erosive gastritis inflammation of the stomach. (403) On 27th January 1986 at 11-15 p.m. transferred to Nephrology Department (Ward No. 20) (724) Given Peritoneal dialysis on 28th January 1986 (28 cycles) and haemodialysis on 28th January 86 and 29th January 1986.	(Ex. 102) (460) *Glycerol* 19th January 86 to 24th January 86 *Mannitol* : Nil *Diamox* : 7th December 85 to 3rd January 86, 19th January 86 to 23rd January 86.	(724) 30th January 86 at 2-30 a.m.	(670) Dr. Asha Menon says that on 27th January 86 at about 7/7-30 when examined he was in bad shape, he was disoriented, he was starring into space with a blank expression, there was distension of the abdomen and slightly dehydrated. (465) In the nurses' order, book under dates 10th and 11th January 1986 there is a vertical line in red ink. (474) Over-writing/double writing in nurses' order book under dates 18th to 21st January, 1986. Entries under 25th and 26th January, 1986 diagonally struct off and 27th January 86 vertically scored off at the instance of Dr. Kamble. (475) In treatment and diet card (Ex. 19) there is a blue line against entry dated 24th January 86 pertaining to oral glycerol. (565) Stoppage of glycerol on 25th January 86 at the instance of Dr. M. A. Kamble. (824) Renal Cortical necrosis was produced by and as a result of diethylene glycol poisoning.
2	Vithal Bhokare Age 44 years (Ex. M) Chart (Ex. 103)	(611) Suffering from irrodocylities with mature cataract with secondary glucoma in the left eye. Admitted on 20th December 1985. (466) On 18th January 1986 operated for left eye. Schioz's Intracap Extraction by Dr. V. S. Gawai (R.M.O.) (601) On 19th January 1986 his condition was satisfactory. On 24th January 1986 he complained of vomitting. Started talking irrelevantly and appeared dehydrated. Jadhav (467) During the night of 24th and 25th January 1986 he fell off the bed. Medical Registrar summoned at different times to examine him. Police report regarding his falling of the bed made. Thereafter he was kept on the floor on a mattress to prevent falling. Suddenly stopped passing urine. (468) On 25th January 1986 transferred to Nephrology Department at 12-45 p.m. (723) Started Haemodialysis on 25th January 1986 but he pulled out the catheter within 5 minutes with the result lost some blood and had to be given blood transfusion.	(Ex. 103) *Glycerol* 24th December 85 to 10th January 86, 12th January 86 to 21st January 86, 23rd January 86 to 25th January 86. *Mannitol* 17th January 86 to 18th January 86. *Diamox* 24th December 85 to 10th January 86, 12th January 86 to 21st January 86 23rd January 86 to 24th January 86. (2nd and 3rd dose on 20th January 86 and the dosage on 21st January 86 was of accetazolomide).	25th January 86 at 10-45 p.m.	(476) In the nurses' order book there are over-writing under date 23rd January 86 regarding glycerol and amphicillin. Over-writing under date 24th January 86 in respect of Wymesone and diamox (who did it not known). (826) Autopsied by the Forensic Medicine Department—Kidneys showed bilateral cortical necrosis indicative of diethylene glycol poisoning. His autopsy also showed oedema and congestion of lungs and brain indicative of secondary damage due to kidney failure as a result of diethylene glycol poisoning.

Department : Ophthalmology

Serial No.	Name and Age of the patient	Brief History	Dates on which the suspect drugs were administered	Date of Death	Remarks
Ward No. 26, Unit No. II, Dr. A. H. Dastoor.					
3	Dawood Dholakia Age 76 years. (Ex. S) (Ex. 101-Chart)	(537) Suffering from advanced glaucoma in both eyes. (457) Admitted on 20th January 1986 at 1-20 p.m One eye was beyond repair and the other was amenable to treatment. (538) Could not be operated on 24th January 1986 for want of urgent blood sugar report. Thereafter he developed anuria and became semiconscious. On 29th January 1986 transferred to Nephrology Department (Ward 20) (Referred to Nephrology Department twice on 28th January 1986). (724) Put on haemodialysis on 29th January 1986, 30th January 1986, 31st January 1986, 3rd February 1986, 5th February 1986 and 6th February 1986.	(458) *Glycerol* : 20th January 86 to 27th January 86. *Mannitol* : Nil *Diamox* : 20th January 86 to 27th January 86.	7th February 1986	(724) Discharged against Medical advice on 6th February 86 at 11-00 p.m. (475) On Nurses Order Book there are overwriting in respect of glycerol and diamox under date 22nd January 86 (who did it not known). (539) Even though on 24th January 86 the glycerol and diamox ordered to be stopped they were administered.
Ward No. 26, Unit No. II, Dr. R. H. Shanbhag.					
4	Abdul Kadar Sheikh .. Age 60 years. (Ex. R) (Ex. 98 Chart of Treatment)	(450) Admitted on 23rd January 1986 at 12-15 noon for left eye mature cataract with simple glaucoma (474) Developed Oliguria i.e. Secretion of less urin from 25th January, 1986. (552) On 26th January 1976 found difficulty in passing urine. On 28th January 1986 Urologist was summoned, who advised transfer. On 28th January 1986 transferred to Nephrology Department. (725) Given haemodialysis from 28th January 1986 to 1st February 1986. Responded initially but from 31st January 1986 his mental state deteriorated.	(450) *Glycerol* : 23rd January 86 to 27th January 86. (470) Glycerol given on 28th January 86 at 6-00 a.m. *Mannitol* : 23rd January 86. *Diamox* : 23rd January 86 to 27th January 86.	(725) 2nd February 86 at 10-15 a.m.	(471) Jadhav says that on 3rd February 86 erasures were made by Staff Nurse Bhalerao in nurses Order Book at the instance of Dr. M. A. Kamble. (472) On 4th February 86 restoration was done in the Nurses Order Book by Staff Nurse at the instance of Sister Jadhav. (473) Page 11 of Ex. R show that mannitol was given for 5 days from 23rd January 86. But Nurses Order Book shows that mannitol was given only 23rd January 86. (485) Nurses Order Book as recorded in the case of Abdul Kadar does not show correct position. Jadhav says that Night Nurse told that at 6-00 a.m. on 28th January 86 dose has been given. (524) In Nurses Order Book there is no entry for stopping glycerol. (529) Ravi Varma (Night Nurse) denise having given glycerol on 28th January 86 at 6-00 a.m. (825) Kidney autopsy showed acute tubular necrosis indicative of diethylene glycol poisoning. Lever also showed diethylene glycol affection.

Serial No.	Name and age of the patient	Brief History	Dates on which the suspect drugs were administered	Date of Death	Remarks
5	Bittal Kawat Age 50 years (Ex. X) (Ex. 100-Chart)	(455) Suffered from optical Keratoplasty in the left eye. Admitted on 2nd January 1986 at 11-10 a.m. Operated on the left eye on 3rd January 1986. (551) Developed abdominal pain on 21st January 1986-Emergency Surgical Registrar summoned on 21st January 1986. X-ray showed distended large bowel loop : there was sub-acute intestinal obstruction. Emergency Surgical Registrar summoned again on 22nd January 1986 at 3-30 p.m. Transferred to Emergency Surgical Ward 19B on 22nd January 1986 at 4-30 p.m. (726) Anuria since 22nd January 1986. Given haemodialysis on 24th January 1986, 25th January 1986 and 27th January 1986 did not respond.	(456) *Glycerol* : 4th January 86 to 20th January 86. *Mannitol* : Nil *Diamox* : Nil.	(475) 27th January 86 at 5-45 p.m.	(476) In Nurses Order Book there is over-writing in respect of glycerol under date 22nd January 86. Mrs. Jadhav says that Staff Nurses told her that it was done the instance of Dr. Kamble. But later on she says that Staff Nurses took the name of Abdul Kadar only. (825) Kidney showed bilateral cortica-necrosis indicative of diethylene glycol poisoning. His autopsy showed centri-lobular hepatic necrosis.

Department : Neurology

Dr. Katrak

Serial No.	Name and Age of the patient	Brief History	Dates on which the suspect drugs were administered	Date of Death	Remarks
1	Tanveer U. Baig Age 10 years (Ex. J)	(349) History of headache from 1st January 1986. Vomitting from 3rd January 1986 and had become unconscious from 11th January 1986. Admitted in Ward 38 on 14th January 1986 at 6-35 a.m. Transferred to Ward 24 same day. Condition improved from 15th January 1986 till 20th January 1986. On 21st January 1986 became breathless. (713) Transferred to Nephrology Department (Ward 20) at 2-10 a.m. on 22nd January 1986. Given peritoneal dialysis immediately. As the dialysis got infected it was terminated on 23rd January 1986 at 11-00 a.m. (715) He had both Oremia and anuria	(Ex. J) *Glycerol* : 14th January 86 to 21st January 86. *Mannitol* : 20th January 86 to 21st January 86, 24th January 86. *Diamox* : 15th January 86 to 21st January 86.	25th January 86 at 3-15 a.m.	*Dr. Katrak* : (354) Patient's report received at 8-00 p.m. on 21st January 86 and the initial call was sent to the Emergency Surgical Registrar at 9-10 p.m. delay not explained. (823) Renal cortical necrosis was produced by and was the result of diethylene glycol poisoning.

CHAPTER IV

Hereunder the 11 questions set out in the Government Notification of 21st February 1986 and my answers in brief against each question—

(1) Whether such deaths of patients occurred due to certain deficiency or defect in the line of treatment or due to any negligence on the part of the doctors/para-medical/ other ancillary staff who were connected with the care of the patients at any stage or at any level and if so, who are responsible ?

The deaths did not occur due to any deficiency or defect or negligence in the line of treatment on the part of the doctors/para-medical/other ancillary staff who were connected with the care of the patients at any stage or at any level. Hence the question of fixing responsibility does not arise.

(2) Whether such deaths of patients occurred due to administration of adulterated, sub-standard, contaminated or defective drugs during the course of their treatment ?

Yes, However such glycerol was not administered with the knowledge that it was adulterated/substandard/contaminated/defective.

(3) If so, whether there was any negligence or dereliction of duty on the part of doctors/para-medical/other ancillary staff who were connected with the care of the same patients in identifying and withdrawing the offending drug promptly from use, to avoid further danger to the safety of patients ?

(*a*) In *identifying* the offending drug, there was no negligence or dereliction of duty on the part of the doctors/para-medical/other ancillary staff who were connected with the care of the patients except on the part of the then Dean Dr. R. S. Chandrikapure and Superintendent Dr. V. G. Deshmukh.

(*b*) Regarding negligence or dereliction of duty in promptly *withdrawing* the offending drug, there was no negligence on the part of the Neurology Department (Ward 24), or the Neurosurgery Department (Ward 25) but there was gross negligence on the part of the Pharmacology Department (Medical Store) and the Ophthalmology Department (Ward 26) and the then Dean Dr. Chandrikapure and Superintendent Dr. Deshmukh.

(4) Whether adequate curative and preventive measures in respect of affected patients were taken by the concerned doctors/para-medical/other ancillary staff who were connected with the care of the patients ? If not, who were responsible ?

Yes. Except that the then Dean Dr. Chandrikapure and Superintendent Dr. Deshmukh failed to take preventive measures for which the responsibility must lie on them.

(5) If certain deaths have occurred due to administration of any adulterated/sub-standard/contaminated/ defective drugs, the causes and circumstances which resulted in administration of such drugs to the patients ?

(*a*) Death occurred due to administration of adulterated/substandard/contaminated/defective glycerol.

(*b*) The evidence shows that pure glycerol is customarily given orally with no side effects in certain cases to prevent oedema and was administered under the belief that it was a standard drug.

(*c*) However the adulterated/substandard/contaminated/defective glycerol was administered in ignorance of the fact that it was so.

(6) Whether the prescribed procedure for procurement, storage, as well as inspection of quality of these drugs at the J.J. Hospital was followed ? If not, the reasons therefore and the persons responsible for it ?

(*a*) As far as the J. J. Hospital was concerned, the correct procedure for *procurement* was followed except that in the case of Alpana Pharma Pack the order was not restricted to 11%.

(*b*) If by the word " procurement " it is intended to cover procurement by Government for J. J. Hospital, the prescribed procedure was not followed by Government, namely the Industries Department.

(*c*) There does not appear to be any prescribed procedure laid down by Government for storage.

(*d*) Looking to the available storage facility of stock at the J. J. Hospital, the storage was proper.

(*e*) There was no procedure for inspection of the quality of drugs. In any event, inspection of the quality of drugs could not have been followed as there was no facility for such inspection except by the F.D.A.

(*f*) The persons responsible for placing the order for glycerol with Alpana Pharma Pack in excess of the permitted 11% are Pharmacist Jamadagni and Associate Professor of Pharmacology Dr. (Mrs.) Worlikar. F.D.A. is also responsible for not carrying out the requisite inspection.

(7) Whether any breach of provisions of Drugs and Cosmetics Act, 1940, was committed by manufacturer/distributor/supplier of these drugs and if so, who are responsible ?

Yes. There were gross violations of the provisions of the Drugs and Cosmetics Act, 1940 and the Rules by the manufacturer, namely Ganesh Chemicals, the middleman (if " distributor " can be so called), namely H. M. Chemicals and Kailash and Co., and the supplier, namely Alpana Pharma Pack.

(8) Whether statutory and effective control was exercised by the authorities responsible for implementing the provisions of Drugs and Cosmetics Act, 1940, and if not who are responsible ?

No. Various F.D.A. Officers were responsible for the breach of the provision of the Act and the Rules.

(9) Whether there was any administrative lapse on the part of the J. J. Hospital authorities; Directorate of Medical Education and Research in promptly assessing the gravity of the situation in J. J. Hospital, Bombay, and reporting to the higher authorities ?

Yes. On the part of the Dean Dr. Chandrikapure and Superintendent Dr. Deshmukh, and Officers of the F.D.A.

(10) Adequacy or otherwise of the existing statutory and administrative procedures/measures in J. J. Hospital/Directorate of Medical Education and Research/Office of the Commissioner of Food and Drugs Administration, to prevent and to effectively deal with such incidents; and to suggest remedial measures to avoid such incidents in future ?

(*a*) By far and large, the administrative and statutory provisions are adequate except *inter alia* the manner in which Medical Store operates and the total lack of adequate inter-communication facility in the J. J. Hospital.

(*b*) In 1973 Dr. Surinder P. S. Pruthi made his Project Report on J. J. Group of Hospitals wherein in Chapter 3 at pages 20-39 (Ex. 25) he has dealt with purchase and storage of drugs in the J. J. Hospital.

(*c*) Though the recommendations made by Dr. Surinder P.S. Pruthi have been accepted by Government, even so surprisingly still the same have not been implemented in toto except to the limited extent that Medical Store has been placed in charge of the Professor of Pharmacology. This by itself is not enough as will appear from this Report.

(*d*) Remedial measures and improvements are recommended later in this Report.

(11) Such other matters as may be germane to the above.

See Recommendations.

CHAPTER V

1. Hereunder a resume of the material events at the J. J. Hospital from 24th January 1986.

FRIDAY, 24TH JANUARY 1986

2. The attention of the Honorary Head of Neurosurgery Unit 2, Dr. M. J. Virani (Witness No. 18) was drawn by his Lecturer Dr. D. A. Palande (Unit 1) (Witness No. 42) to the latter's suspicion on the presence of contaminants in certain drugs namely mannitol, gerramycin, diamox and glycerol. By 24th Nephrology had 7 cases of renal failure out of which 1 of Dr. Bhagwati's patients (Unit 1) had died on 21st January. His name was Bapu Thombre. In the morning of 24th one more case of Sopan Tawar was referred to Nephrology. Thus by that morning, there was a total number of 8 cases of renal failure referred to Nephrology. That morning, the topic of discussion between the Head of Nephrology Dr. Kripalani (Witness No. 47), Dr. (Mrs.) Sirsat (Witness No. 43) and the resident doctors of Nephrology was the apparently inexplicable cases of renal failure referred to their Nephrology Department and which had resulted in deaths. Not unnaturally they could come to no conclusion or ascertain the cause of the deaths as the case papers had gone to the postmortem department and the postmortem result was not immediately available. That night another patient Ramesh Shinde died.

Dr. Palande draw Dr. Virani's attention to the contaminants in mannitol, diamox and glycerol.

Discussion between Dr. Kripalani and Dr. (Mrs.) Sirsat and Resident Doctors of Nephrology.

Thus ended Friday, the 24th January.

SATURDAY, 25TH JANUARY 1986

(1) In the early hours Tanveer Baig died. All the earlier cases where anti-oedema drugs, namely diamox/glycerol/mannitol had been administered were re-referred to Nephrology. From the case papers of Bittal Kevat, Vithal Gharge, Sopan Tawar and Shailendra Joshi available in Nephrology, glycerol was discovered to be the common drug administered to them.

(2) That morning, 3 decisions were taken in the Nephrology Department by Dr. Palande and the Nephrology doctors, Dr. (Mrs.) Sirsat and Dr. Farhad Kapadia; namely (*i*) to stop administration of the suspect drugs, (*ii*) to give dialysis to the affected patients and (*iii*) to inform the authority accordingly, for which purpose Dr. Palande was requested to contact the Hospital's Superintendent Dr. Deshmukh who resides in the campus and in hierarchy ranks immediately after the Dean.

Dr. Palande, Dr. (Mrs.) Sirsat and Dr. Farhad Kapadia discussion by.

3. Thereupon from Nephrology itself, Dr. Palande immediately telephoned the Superintendent and informed him of the steps decided. Superintendent Dr. Deshmukh admits that he received this telephone call. According to him he told Dr. Palande to inform the Dean and Medical Store that the suspect drugs were not to be administered and that Dr. Palande should take these drugs into his own custody. This version of the Superintendent is denied by Dr. Palande.

Dr. Palande's telephone call to Superintendent Dr. Deshmukh.

4. A premature red alert to the Dean would have landed Dr. (Mrs.) Sirsat in trouble had her suspicion been unfounded. Hence after the meeting in the Nephrology Department, Dr. (Mrs.) Sirsat went to the Neurosurgery Department at about 10.30 a.m. She examined Sopan Tawar and Shailendra Joshi and advised the line of treatment. After seeing and confirming her findings regarding the affected patients and her suspicion regarding mannitol, glycerol and diamox, she returned to her Nephrology Department at about 11.00 a.m. and telephoned the Dean at his residence and apprised him of the situation. She told the Dean :—

Dr. (Mrs.) Sirsat's visit to Neurosurgery and her telephone to the Dean.

(*i*) that mannitol, acetazolamide (diamox) and glycerol were the suspect drugs,

(*ii*) that in the last week her Nephrology Department had received 7 cases of anuria with uremia from Neurosurgery and Neurology,

(*iii*) that all of them had received one or all of the suspect drugs,

(*iv*) that 4 of them had died despite adequate treatment being given to them in her Nephrology Department,

(*v*) that the situation was grave and urgent remedial measures must be taken. The Dean told her to stop those drugs in the affected wards. According to the Dean, Dr. (Mrs.) Sirsat replied that this had been done.

5. Thereafter one of Dr. (Mrs.) Sirsat's resident doctors, Dr. Farhad Kapadia put up a notice on the board outside the resident doctors' canteen on the 5th floor that these drugs were suspected and should not be administered.

Dr. (Mrs.) Sirsat's letter to Pharmacology/Superintendent.

6. At 11.30 a.m. Dr. (Mrs.) Sirsat wrote a letter to the Pharmacology Department with a copy to the Superintendent Dr. Deshmukh at his residence in the campus. However, the Pharmacology Department was closed, Saturday being a half day, and the Superintendent refused to accept delivery of the copy.

Dr. (Mrs.) Sirsat tells Dr. Pargaonkar to warn doctors of Ophthalmology.

7. At 11-40 a.m. Dr. (Mrs.) Sirsat's Nephrology Department got a call from Ophthalmology regarding Vithal Bokhare. He was the second patient to be affected in that Department, the first being Bittal Kevat who had received only glycerol out of the suspect drugs. Thus it was realised that Ophthalmology had also been affected. Since Vithal Bokhare was the second patient to be affected in Ophthalmology, Dr. (Mrs.) Sirsat was convinced that the mischievous drug was glycerol. Thereupon she told her Registrar Dr. Pargaonkar (Witness No. 44) to go to Ophthalmology and warn the doctors not to administer the suspect drugs.

Dr. Pargaonkar and Dr. (Miss) Parul Shah.

8. This information was accordingly conveyed by Dr. Pargaonkar to Dr. (Miss) Parul Shah in Ophthalmology where he also examined Vithal Bokhare, as also that cases had been referred to Nephrology by the Neurology and Neurosurgery Departments. He returned to Nephrology and apprised Dr. (Mrs.) Sirsat what he had done in Ophthalmology.

Dr. Palande

Dr. Palande instructs Unit 1 to discontinue suspect drugs.

9. In his Ward No. 25 Dr. Palande instructed the staff sister to discontinue the suspect drugs and to keep the order books and case papers ready for his perusal. He gave the same intructions to the Registrar of Unit No. 1 and to the staff sister of Ward No. 24. Dr. Palande went to the Pharmacology Department but it was closed, Saturday being a half day.

Dr. Palande asks Jamadagni for alternate supplies and Jamadagni's reply.

10. Dr. Palande then went to Medical Store. He asked pharmacist Jamadagni for alternate supplies. Jamadagni replied he had none and nothing could be done till Monday.

Dr. Palande's instructions to staff sister Ward 25.

11. Dr. Palande returned to his Ward No. 25 and went through the case papers. His suspicion fell on glycerol as the most likely drug. Acetazolamide (diamox) was not available in his ward. He instructed the staff sister to keep all the glycerol bottles aside and to instruct all the ward nurses not to administer glycerol. He also instructed the sister to put up a notice to this effect on the notice board. It was done. Dr. Palande also told the sister to prepare a chart from the order book.

Dr. (Mrs.) Sirsat message to Dr. Panda suspect drugs stopped in Unit I.

12. In the afternoon Dr. Panda's Unit No. 1 (Neurosurgery) got a message from Dr. (Mrs.) Sirsat that the suspect drugs were mannitol, glycerol and acetazolamide. Thereupon instructions were given to the ward sister and other personnel in Unit No. 1 not to administer those 3 drugs until further notice. Administration of these 3 drugs in Unit No. 1 was stopped.

Dr. (Mrs.) Sirsat's telephone to Dr. Kripalani.

13. At 1-00 p.m., Dr. (Mrs.) Sirsat telephoned Dr. Kripalani but he was out. She again telephoned him at 5-30 p.m. at his residence. He was not at home. She left a message for Dr. Kripalani to contact her.

14. At 3-30 p.m., in the campus Dr. Palande accidentally met the Superintendent Dr. Deshmukh who was going out shopping. Dr. Palande told the Superintendent all that had transpired, including the non-availability of the alternate supplies. The Superintendent proceeded to go shopping. Superintendent goes shopping.

15. After Dr. Panda's discussion with Dr. Palande about the stoppage of the suspect drugs, Dr. Panda instructed his Registrar to stop administering glycerol, mannitol and diamox. Dr. Panda's instructions for stoppage.

16. Dr. Palande informed Dr. Virani (Ward No. 18) that Shailendra Joshi and Sopan Tawar from Ward No. 25 were undergoing dialysis. This sterengthened Dr. Virani's suspicion that since these two patients were receiving more or less the same treatment as the other two patients, the culprit could be some contaminant. Thereupon Dr. Virani ordered Dr. Palande to inform the Dean and the Superintendent that he was stopping routine admission in his Ward No. 25 till the culprit drug was ascertained. Dr. Virani's suspicion strengthened. Routine admissions in Ward 25 stopped.

17. Dr. (Miss.) M. A. Kamble (Ward No. 38) was at the relevant time Associate Professor of Ophthalmology and Head of Unit No. 1, Ward No. 26. On 25th January in the course of her rounds, D. (Miss.) Kamble examined Vithal Bokhare at 11-30 a.m. and referred him to Nephrology for further management as in his case papers there were references to Medical Registrar on call and his blood urea was very high. After examination by the Nephrology Registrar Dr. Pargaonkar, the patient was transferred to Nephrology for further management. That day during her morning round Dr. (Miss) Kamble came to know for the first time that Vithal Bokhare had developed anuria. From his case papers she found that he had developed anuria on 24th January. On 25th January only one patient, namely Vithal Bokhare, in her Unit had anuria. Dr. (Miss) Kamble Associate Professor of Ophthalmology (Patient Vithal Bokhare) Dr. (Miss) Kamble.

18. Dr. (Miss) Kamble examined Rajendrakumar Mishra (Ex. Q) at 12-00 noon. He had been admitted to Ward No. 26, Unit No. 1, on 18th November 1985 and was there till 11-15 p.m. on 27th January. Dr. (Miss) Kamble told Dr. (Mrs.) Asha Menon who was with her to examine Rajendrakumar Mishra and to write a reference to the Medical Registrar on call. She instructed Dr. (Mrs.) Asha Menon to remain with Rajendrakumar Mishra and accompanied by Dr. Shaikh went to the 2nd floor of Ward No. 26, namely the female ward. Dr. (Miss) Kamble (Patient Rajendrakumar Mishra)

19. During that time, pursuant to the call, the emergency Registrar came to Rajendra Mishra. The case papers do not disclose the time of his arrival. In the female ward, Dr. (Miss) Parul Shah told Dr. (Miss) Kamble between 12 noon and 12-30 p.m. that the Nephrology Registrar Dr. Pargaonkar had examined Vithal Bokhare. Dr. (Miss) Kamble told Dr. (Miss) Parul Shah to transfer Vithal Bokhare according to the instructions of the Nephrology Registrar and thereafter to join her in the round of the female ward. Dr. (Miss) Parul Shah did so. Dr. (Miss) Kamble and Dr. (Miss) Parul Shah. Dr. Pargaonkar (Patient Vithal Bokhare)

20. After finishing her round in the female ward on the 2nd floor, Dr. (Miss) Kamble came down to the 1st floor ; she saw patient Vithal Bokhare was on a trolly preparatory to being transferred to Nephrology. Thereafter she went to her room on the ground floor. Saturday, being a half day, she went home at 2-00 p.m. Dr. (Miss) Kamble (Patient Vithal Bokhare)

21. Dr. Palande telephoned Dr. Virani in the evening and apprised him of all that had transpired and the steps he (Dr. Palande) had taken. Dr. Palande apprises Dr. Virani.

22. In response to the message left by Dr. (Mrs.) Sirsat at Dr. Kripalani's residence earlier in the day, on his return home, Dr. Kripalani contacted Dr. (Mrs.) Sirsat over the telephone at about 11-00 p.m. She apprised him of all that had transpired inter alia to wit that more cases of renal failure had been referred to Nephrology from Neurosurgery and one from Ophthalmology, she gave the names of the patients, namely Sopan Tawar (Ex. N), Shailendra Joshi (Ex. L) and Vithal Bokhare (Ex. M), reminded him about the increased number of renal failure cases from Neurosurgery and their failure to respond to treatment, that the previous day they had discussed Dr. Kripalani's telephone to Dr. (Mrs.) Sirsat at 11-00 p.m. She apprises him of the situation

that these cases might be the result of contaminated drug-induced renal failure, and that the new cases of renal failure had confirmed her opinion that these and the earlier cases of renal failure were due to contaminated drug infection.

Dr. Kripalani's suspicions confirmed.

But other probabilities not entirely ruled out.

Dr. Kripalani satisfied about correctness of treatment and Dr. (Mrs.) Sirsat's steps taken by her.

23. Dr. Kripalani was surprised at the new cases of renal failure and after Dr. (Mrs.) Sirsat's telephone call to him that night, his suspicions were confirmed in the direction of mannitol, glycerol and diamox at the same time not ruling out the probability of some other drug or some disease like meningitis as being the cause of the deaths. From this conversation with Dr. (Mrs.) Sirsat over the telephone, Dr. Kripalani was satisfied that the treatment given to the patients in Nephrology was the correct treatment and the steps taken by Dr. (Mrs.) Sirsat were the correct steps.

Thus ended Saturday, the 25th January.

SUNDAY, 26TH JANUARY 1986

Dean's incidental visit.

1. The Dean went to the Hospital to attend the flag-hoisting ceremony in the morning. Thereafter he incidentally went to the wards, viz. the Nephrology Department at 11.00 a.m. for 10-15 minutes. He enquired from the Registrar about the treatment being given to the stricken patients. He did not know how many patients needed dialysis nor did he make any enquiries to that end. He saw 3 patients and their case papers and treatment cards. He talked to Dr. Palande and the Superintendent, who told him that the suspect drugs had been stopped. The Superintendent who accompanied the Dean, did nothing. Thereafter they went homes as it was a Sunday and a holiday.

Dr. Palande and Superintendent Dr. Deshmukh.

Superintendent's reply to Dr. Palande that nothing could be done till Monday.

2. Dr. Palande (Ward No. 42) also attended the flag-hoisting ceremony. He told the Superintendent that as far as his ward was concerned, noting fresh had occurred. The Superintendent replied that nothing could be done till Monday. After the flag-hoisting ceremony, Dr. Palande went to his ward and satisfied himself that his instructions of the previous day had been carried out.

3. In the morning Dr. Katrak's Registrar (Neurology Ward No. 24), had instructed his (Dr. Katrak's) House Physicians not to use mannitol, glycerol or diamox.

Dr. (Miss) Kamble.

4. At about 11-30 a.m. after the flag-hoisting ceremony, Dr. (Miss) Kamble took her round in the Ophthalmology ward. When she examined Rajendrakumar Mishra that day and the next day, he did not complain of any symptoms indicative of anuria.

Thus ended Sunday, the 26th January.

MONDAY, 27TH JANUARY 1986

Dr. Kripalani and Dr. (Mrs.) Sirsat.

1. That morning at 9-30 Dr. Kripalani came to know that Vithal Gharge had died. Dr. (Mrs.) Sirsat while apprising him of the situation with the available case papers showed him the two undelivered letters of the 25th to the Pharmacology Department and the Superintendent. She, Dr. Kripalani and the Nephrology resident doctors examined all the patients in their ward and the afflicted patients in Neuro-surgery, namely Sopan Tawar and Shailendra Joshi. All this was till 10-30 a.m.

Discussion between Dr. Kripalani, Dr. (Mrs.) Sirsat and Nephrology resident doctors.

2. Thereafter Dr. Kripalani, Dr. (Mrs.) Sirsat and the Nephrology resident doctors had a discussion amongst themselves. Dr. Kripalani asked the typist to type out in his name Dr. (Mrs.) Sirsat's letter of the 25th January sent to Pharmacology Department and the Superintendent (which that day could not be delivered to the former as it was closed, and had been refused by the latter). While it was being typed out, Dr. Kripalani went to give a scheduled lecture in the hospital premises. Dr. Kripalani went to the Dean's office, but the Dean had left to attend the lecture. Dr. Kripalani then went to the lecture theatre; on the way he met the Dean. He told the Dean what had transpired over the week-end and the steps taken so far by Dr. Kripalani's Department. While he was delivering his lecture, Dr. (Mrs.) Sirsat

and Dr. Pargaonkar went to the Forensic and the Pathology Department to find out the autopsy report on Tanveer Baig and the histology from the biopsy of Hemant Ranade and Ramesh Shinde. In the Forensic Department they were unable to find out the doctors who had carried out the postmortems. In the Pathology Department they met the Head, Dr. Wagholikar. Dr. Wagholikar promised he would examine the organs and have a discussion with the person who had performed the postmortem and would thereafter give Dr. (Mrs.) Sirsat his opinion after 2 hours. That conversation took place round about 11.00 a.m.

Dr. (Mrs.) Sirsat and Dr. Pargaonkar visit to Forensic and Pathology Department.

3. After Dr. Kripalani's lecture got over at 12.00 noon, Dr. (Mrs.) Sirsat apprised him of what she had done that morning including that the autopsy report was probably that of cortical necrosis. Dr. Kripalani returned to his Nephrology Department, completed his round and returned to the typist who had kept the letter ready for his signature in quadruplicate, i.e. for sending to the Dean, the Superintendent, Professor of Pharmacology and the fourth intended as Dr. Kripalani's office copy. Dr. Kripalani signed the three letters and sent them to the Professor of Pharmacology and the Superintendent; he personally delivered the Dean's letter (Ex. 6) to the Dean himself.

Dr. Kriplani's letter to Dean, Superintendent, Professor of Pharmacology.

Delivery of letter by Dr. Kripalani personally to Dean.

4. In these letters, Dr. Kripalani stated that a large number of patients had developed sudden on-set of anuria in the past week, that all of them were on anti-oedema measures; the suspect drugs were stated to be mannitol, diamox and glycerol, that the fatality rate was very high despite vigorous haemodialysis; that Dr. Kripalani had requested that these three drugs be checked and replaced with a fresh batch immediately. In the left-hand margin of this letter Dr. Kripalani also made an endorsement that all the patients had come from Ward Nos. 23, 24 or 25 (i.e. Neurology and Neurosurgery) and that out of 10 such cases, six had died and postmortem had been done on all.

Ex. 6

Contents of Dr. Kripalani's letter.

5. While the letter was being dispatched, Dr. (Mrs.) Sirsat went back to Dr. Wagholikar at the Pathology Department. He told her that the kidneys of Tanveer Baig showed bilateral cortical necrosis and he also had meningo-encephalitis suspected to be of virus origin. Dr. (Mrs.) Sirsat told Dr. Wagholikar that about 10 cases from Neurology, Neurosurgery and Ophthalmology had unexpectedly developed anuria and acute renal failure which was suspected by Nephrologists to be drug-induced, the suspect drugs being glycerol, mannitol and diamox (acetazolamide); that the response of the patients to dialysis was unsatisfactory and their condition was serious and that five patients had died; that boipsies of kidneys had been done on two patients and autopsies on four patients had been requisitioned. Dr. (Mrs.) Sirsat wanted to know the reports of the biopsies that had been done. Dr. Wagholikar told Dr.(Mrs.) Sirsat that none of the three suspect drugs in their pure form could have caused the cortical necrosis. Dr. Wagholikar's findings were merely on gross examination, i.e. by visual inspection of the kidneys. Dr. Wagholikar said he would require histo-pathological examination of the kidneys to ascertain the cause of cortical necrosis. Dr. (Mrs.) Sirsat told him (Dr. Wagholikar) that a needle biopsy had been done in the case of 2 patients (Hemant Ranade and Ramesh Shinde). That was because the patient Hemant Ranade was related to a doctor in the J. J. Hospital who refused permission for postmortem; in the case of Ramesh Shinde a needle biopsy was done as an early report was wanted. Dr. Wagholikar promised to give Dr. (Mrs.) Sirsat a report the following day as it would take some time for the tissue to be processed for microscopic examination. All this was conveyed by Dr. (Mrs.) Sirsat to Dr. Kripalani. By then it was 1-30 p.m. Thereafter Dr. Kripalani went and met the Dean.

Dr. (Mrs.) Sirsat and Dr. Wagholikar

Dr. (Mrs.) Sirsat and Dr. Wagholikar

Dr. Kripalani and Dr. (Mrs.) Sirsat.

6. On Dr. Kripalani's letter to the Dean (Ex. 6) the Dean made an endorsement to Dr. (Mrs.) Worlikar (Associate Professor of Pharmacology and in charge of Medical Store) (Ward No. 9) to investigate and take necessary action. This letter was received by Dr. (Mrs.) Worlikar between 2 and 2-30 p.m. It was then that she came to know that mannitol, diamox and glycerol were the suspect drugs. She immediately showed that letter to Dr. Shaligram (Head of Pharmacology) and had a discussion with him for about 5 to 10 minutes.

Dr. Chandrikapure Ex. 6 Dean's endorsement to Dr. (Mrs.) Worlikar. Discussion between Dr. (Mrs.) Worlikar and Dr. Shaligram (Head of Pharmacology)

They decided that since this was a serious matter, a circular should be issued to the wards that administration of these 3 drugs be stopped immediately.

Dr. (Mrs.) Worlikar and Dr. R. D. Kulkarni Ex. 6

7. On her way to Medical Store, she met Dr. R. D. Kulkarni outside her room. She apprised Dr. Kulkarni of Dr. Kripalani's letter (Ex. 6) and that she was on her way to Medical Store to issue the circular. Dr. Kulkarni told her that Dr. (Mrs.) Mujumdar was going to the wards to investigate the matter as he knew about the drug reaction from Dr. Palande. Dr. (Mrs.) Worlikar proceeded to Medical Store.

A. K. Jamadagni, Pharmacist.

8. At Medical Store, Pharmacist A. K. Jamadagni (Witness No. 8) came on duty at 9-00 a.m. as usual. Till 1-00 p.m. he was occupied with the work of making proposals for fresh orders. From 1-00 p.m. till 2-00 p.m. came the lunch break. From 2-00 p.m. he did his routine work. At about 2-30 p.m. he received Dr. Kripalani's letter dated 27th January (Ex. 7) to the Professor of Pharmacology with copies marked to the Dean and the Superintendent with the Dean's endorsement " Dr. Worlikar, for necessary action ". According to Jamadagni, he came to know that glycerine was one of the suspect drugs.

Cheking by Dr. (Mrs.) Worlikar and Jamadagni.

9. On reading this letter, Jamadagni started for Dr. (Mrs.) Worlikar who herself was on her way to Medical Store. They ran into each other. They both went to Medical Store and for 10–15 minutes checked the batches of the drugs named by Dr. Kripalani which had been issued to the various wards. Dr. (Mrs.) Worlikar dictated a circular (Ex. 8) to Pharmacist Jamadagni. At 2-45 p.m. it was issued in triplicate. It asked the ward sisters to stop the use of the 3 drugs named by Dr. Kripalani giving the batch numbers and the names of the manufacturers. One of them was glycerol Batch No. 27 of Alpana Pharma. The signature of each ward sister was to be obtained at the foot of the circular. According to Jamadagni, he also instructed the compounders in Medical Store to stop issuing these drugs and to isolate them. According to Jamadagni, this was done.

Ex. 8
Dr. (Mrs.) Worlikar's stoppage circular.

Dr. Shaligram checks nephro-toxicity in his room.

10. At 2-15 p.m. Dr. Shaligram went to Dr. Kulkarni's room but he was not there. Dr. Shaligram thereupon returned to his room and devoted his time in checking up the nephro-toxicity of the 3 drugs, *viz.* mannitol, diamox and glycerol.

Jamadagni's oral message to some floor pharmacies.

11. At about 2-30 p.m. Jamadagni sent an oral message to the floor harmacpies which were open not to issue the suspect drugs.

Jamadagni receives stoppage circular from wards.

12. At about 5-00 p.m. Jamadagni received the three copies of the circular back with the signatures of the various ward sisters at the foot and reverse of each copy. He informed Dr. (Mrs.) Worlikar accordingly. He closed Medical Store at 5-00 p.m. and not at the usual hour of 4-00 p.m.

Dr. (Mrs.) Worlikar informs Dr. Kulkarni about stoppage circular.

13. Dr. (Mrs.) Worlikar informed Dr. Kulkarni about the circular which had been issued to the wards.

False date given by Dean about his telephone call to Dr. (Miss) Sankholkar Dy. Director of Medical Education and Research.

14. Coming to the Dean, according to him that afternoon he telephoned Dr. (Miss) Sankholkar, Dy. Director of Medical Education and Research and told her that a few drug reaction deaths had taken place in Nephrology which were noticed from Saturday, the 25th, that the patients had developed anuria and the drugs were glycerol, mannitol and acetazolamide (diamox). However the Dean later admitted that though he came to learn of the deaths on Saturday, the 25th, he contacted Dr. (Miss) Sankholkar on Tuesday, the 28th. This is corroborated by Dr. (Miss) Sankholkar.

Ex. 47
Dr. (Mrs.) Worlikar's unsuccessful efforts for alternate supply of mannitol. She apprises Dr. Kulkarni.

15. Dr. (Mrs.) Worlikar worte a letter (Ex. 47) to Dr. Kripalani asking him for further details regarding the investigation and drug therapy received by the patients. In the afternoon she telephoned other rate contract suppliers for alternate supply of mannitol, but was unsuccessful. A little after 5-00 p.m. she met Dr. Kulkarni and apprised him of the situation and the steps she had taken.

Dr. Palande, Dean and Dr. Kulkarni.

16. Monday, the 27th was Dr. Palande's (Ward No. 42) Unit's operation day. He was assisting Dr. Virani in his operation. At 2-00 p.m. Dr. Palande came out of the operation theatre and went to the Dean's office to enquire about the alternate supplies of the drugs. However the Dean was on the 6th floor in a meeting. So

Dr. Palande went there. A meeting was in progress in the surgery department. He asked the Dean what steps were being taken to secure alternate supply of the drugs. The Dean directed him to the Professor of Pharmacology Dr. R. D. Kulkarni. Dr. Palande thereupon went to the Pharmacology Department and met Dr. Kulkarni. He narrated to Dr. Kulkarni all that had transpired on Saturday, the 25th January, that certain patients in Ophthalmology had also been affected and calls had been sent to Nephrology and that the only departments which had been affected were Neurosurgery, Neurology and Ophthalmology. Dr. Kulkarni expressed surprise at what Dr. Palande told him. They had a discussion as to which drug could be the mischievous drug. After knowing that the common drug was glycerol and the damage irreversible, Dr. Kulkarni opined that there must be some adulteration in the glycerol to have caused the irreversible damage. Their discussion was that glycerine, being an expensive commodity in short supply, was more likely to have been adulterated, and that there was a likelihood of industrial glycerine having been supplied, and that glycols do cause kidney damage of this nature which is irreversible, and that this could be confirmed by analytical tests.

Discussion Dr. Palande Dr. Kulkarni.

Dr. Kulkarni's opinion

17. While this discussion was in progress, Dr. Kulkarni sent for Dr. (Mrs.) Mujumdar who was in charge of the Adverse Reaction Monitoring Cell and told her to go to the wards for investigation. Dr. Kulkarni told her that the suspect drugs were mannitol, acetazolamide, glycerol and gentamycin. Dr. Kulkarni asked her to collect information as fast as possible from the nurses' order book and from the nurses on duty if the case papers of the deceased patients had gone to the record section.

Directions by Dr. Kulkarni to Dr. (Mrs.) Mujumdar.

18. Dr. (Mrs.) Mujumdar immediately left for Ward No. 25 i.e. Dr. Palande's ward where she saw three patients, Shailendra Joshi, Sopan Tawar and Ramji Kasar. They were in a coma. She collected information about their drug therapy from their case papers and from the sister on duty. She found from the ward sister that the drugs mentioned in the case papers had been administered to these three patients

Dr. (Mrs.) Mujumdar's activities para 8

19. Regarding the patients who had expired, Dr. (Mrs.) Mujumdar collected information from the nurses' order book. Dr. Palande had left with the ward sister a chart containing the names of all the patients suspected by him to have suffered drug reaction. As the ward sister declined to part with the chart, Dr. (Mrs.) Mujumdar copied it down. The notes which she made from the nurses' order book regarding the deceased patients, Vithal Gharge, Ramesh Shinde and Bapu Thombre pertained to the drug therapy given to them. She was in Ward No. 25 till 5-15 p.m. that day.

Dr. (Mrs.) Mujumdar's activities continued.

20. From the nurses' order book pertaining to the three dead patients and the case papers pertaining to the three living patients in Ward No. 25, Dr. (Mrs.) Mujumdar came to the conclusion that glycerol had been given to all these six patients, that mannitol was given to 5 patients and that acetazolamide and gentamycin had been given only to one or two patients. Thus the common drug given to all these six patients was glycerol.

Dr. (Mrs.) Mujumdar's activities continued.

21. After leaving Ward No. 25, Dr. (Mrs.) Majumdar went to Wards 17 and 18 (Surgery) where she discovered that glycerol and acetazolamide were not used, that mannitol had been used on one patient who had been discharged, and that gentamycin was used but no reaction was reported. After gathering this information, Dr. (Mrs.) Mujumdar went to her Pharmacology Department round about 5-30 p.m.

Dr. (Mrs.) Mujumdar's activities continued

22. Between 3 and 3-30 p.m. Dr. Palande met Dr. Wagholikar at the Pathology Department and discussed the kind of damage caused to the kidneys as that would give a clue to the cause of the kidney damage. Dr. Palande gave Dr. Wagholikar the nemes of the suspect drugs and the details of the afflicted patients. Dr. Kulkarni was of the view that if pure glycerol was adulterated with glycol, irreversible kindey damage would result.

Dr. Palande and Dr. Wagholikar's discussion.

23. At 4-00 p.m. Dr. (Mrs.) Worlikar, came to Dr. Shaligram's room and told him that she had issued a circular and had written a letter to Dr. Kripalani and had not informed FDA. She also told him that she was trying to get supplies of the 3 drugs from other suppliers.

Dr. (Mrs.) Worlikar meets Dr. Shaligram.

Talk between Dr. Shaligram and Dr. Kulkarni Ex. 6 Dr. Shaligram's scepticism.

24. Between 4-30 p.m. and 4-45 p.m. Dr. Shaligram met Dr. R. D. Kulkarni and told him about Dr. Kripalani's letter (Ex. 6) and that they were stopping these drugs and ordering replacements. Dr. Kulkarni was of the view that out of the 3 drugs, glycerine could be responsible for the reaction. Dr. Shaligram was however sceptical as nobody would think of glycerine.

Talk between Dr. (Mrs.) Mujumdar and Dr. Kulkarni.

25. At 5-30 p.m. Dr. (Mrs.) Mujumdar told Dr. Kulkarni that glycerine had been administered to all the patients in Neurology, Neurosurgery and Ophthalmology but that the other three drugs had not been administered to all the patients afflicted with drug reaction, that several patients in the surgery ward had received gentamycin but had not suffered any drug reaction and that in the surgery department mannitol had been given to only one patient but she could not meet him as he had been discharged; that in the surgery department several patients had been administered gentamycin but there was no adverse reaction.

Dr. Kulkarni's suspicions against Batch 27 aroused on what Dr. Palande told him.

26. Dr. Kulkarni's suspicions against glycerol (Batch No. 27) were aroused on 27th January because (*a*) the patients were suffering from acute renal failure, (*b*) they had acidosis and the necropsy result of the kidney indicated cortical necrosis, (*c*) commercial glycerine sometimes contains ethylene glycol, (*d*) standard medical glycerine was at that time in short supply. Dr. Kulkarni did not talk to anybody from the Nephrology Department. It was Dr. Palande (Neurosurgery) who gave Dr. Kulkarni all the symptoms on which Dr. Kulkarni based his suspicions and finally his conviction that the killer drug was glycerine Batch No. 27. Dr. Palande also told Dr. Kulkarni that the kidney necropsy had shown cortical necrosis and that three other drugs were also under suspicion, namely diamox, mannitol and gentamycin. Those three drugs, namely diamox, mannitol and gentamycin would not cause cortical necrosis. The damage caused to the deceased persons would *rule out diamox and gentamycin as the cause. Dr. Kulkarni would also* rule out likewise pure glycerine. The other drugs, namely mannitol and gentamycin, would have produced the same lethal results had they been contaminated as was the glycerine from Batch No. 27. Diamox could not have been thus contaminated because it is in the form of tablets. Gentamycin had been given to many patients who suffered no reaction. At that time there was no strong reason to suspect mannitol. Diamox was ruled out as it does not cause cortical necrosis and was given to very few patients, none of whom died.

Dr. Wagholikar's conclusion renal cortical necrosis due to diethylene glycol.

27. Dr. Wagholikar saw the kidneys of Tanveer Usman Baig who had *died on* 25th January. These kidneys showed renal cortical necrosis. In order to ascertain the cause, histo-pathology process of the tissues of the kidneys and other organs was started. The conclusion arrived at was that the renal necrosis was produced by and was the result of diethylene glycol.

Thus ended Monday, the 27th January.

TUESDAY, 28th JANUARY 1986

1. This was the day the resident doctors struck work for one day.

Dr. (Miss) Kamble-Her astonishment and surmise—Her instructions for stoppage of mannitol, diamox and glycerol and meeting in her room at 10-30 a.m.

2. At 9-00 a.m. Dr. (Miss) M. A. Kamble went to Ward No. 26. Her lecturer Dr. Shoukat Ali Shaikh informed her that Rajendrakumar Mishra had been transferred to Nephrology Department on the night of 27th January as he had developed uremia. This struck her as somewhat unusual because Rajendrakumar Mishra was the second person from her ward who has been transferred to Nephrology, the first person being Vithal Bhokare. Thereupon she contacted Dr. Shanbhag, in charge of Unit No. 2 and enquired of him whether any patient from Unit No. 2 had been transferred to Nephrology. *He told Dr. (Miss)* Kamble that one patient Bittal Kevat was transferred from Unit No. 2 to Surgical Ward as he was having intestinal obstruction and thence to Nephrology. At the same time Dr. Shanbhag also told her that another patient in Unit No. 2 namely Abdul Kadar was having urinary problem and the treatment given to him and Bittal Kevat. She remembered the treatment *which had been* given to her patients Vithal Bhokare and Rajendrakumar Mishra and realised that the drugs commonly administered to all these four patients were mannitol, diamox and glycerol. She thought that therefore these four patients might have suffered adverse drug reaction due to drug contamination from any of these three drugs. Thereupon b*wtween 9-30 and 10-30* a.m. she *told* the sister-in-charge Jadhav to immediately stop administering these three drugs. At the same time Dr. (Miss) Kamble informed all the staff members of Ophthalmology Department to discontinue the administration of these three drugs.

The staff members were Dr. Shanbhag, Dr. (Mrs.) Gaikwad, Dr. Shaikh, Dr. (Miss) Dekate and Dr. Dastoor. She also told them that she would be holding a meeting that day at 10-30 a.m. in her room. All of them attended that meeting. The meeting was minuted in the presence of those assembled and they signed those minutes in token of their attendance (Ex. 106-A). She retained the original minutes with her which she produced (Ex. 106-A). This meeting lasted half an hour. Ex. 106-A

3. At about 11-00 a.m., after the meeting was over, Dr. (Miss) Kamble sent her lecturer Dr. Shaikh to Nephrology to see the condition of the patients transferred there. She told Dr. Shaikh to discuss those patients with the Nephrologists. She also told Dr. Shaikh to go to the Pharmacology Department and see the Professor of Pharmacology and inform him that certain patients had developed adverse drug reaction or reaction due to drug contamination by reason of these three drugs. Accordingly Dr. Shaikh went to the Nephrology and Pharmacology Department. Some time after 11-30 a.m. Dr. Shaikh returned to the Ophthalmology Department and informed Dr. (Miss) Kamble that their two patients, namely Bittal Kevat and Vithal Bhokare, had died in the Nephrology Department and that the condition of Rajendrakumar Mishra was serious, Dr. Shaikh also informed her what had happened in the Pharmacology Department, namely that he had met Dr. Shaligram who told him that there was going to be a meeting in the Nephrology Department that day between 11-00 a.m. and 11-30 a.m. in connection with these three drugs, namely mannitol, diamox and glycerol. By then Dr. (Miss) Kamble received a circular dated 28th January from the Pharmacology Department to that effect. Dr. (Miss) Kamble's instructions to Dr. Shaikh and his movements.

4. Dr. (Miss) Kamble immediately wrote a letter (Ex. 28) to the Dean stating all the facts which had come to her knowledge. The Dean received it the same day. Ex. 28 Dr. (Miss) Kamble writes to Dean.

5. At 9-00 a.m. Dr. (Mrs.) U. V. Mujumdar went to Dr. Palande's Ward No. 25 (Neurosurgery) and collected information about two more patients, namely Hemant Ranade and Nasiruddin. She learnt from the nurses' order book (and perhaps from Dr. Palande's chart), that Hemant Ranade had received glycerol but not Nasiruddin and that Hemant Ranade had died. Thereafter she went to Ward No. 24 (Neurology) and saw the nurses' order book of Tanveer Usman Baig who had died and found that he had received glycerol, mannitol and acetazolamide. She was in Ward Nos. 25 and 24. She could not get any information from any resident doctor by reason of the one-day resident doctors' strike that day. She was in Wards 25 and 24 for about 2 hours. Thence she went to Ward No. 20 (Nephrology), but the sister-in-charge did not have the information which Dr. (Mrs.) Mujumdar wanted regarding the drug therapy. She then went to AKD (Artificial Kidney Dialysis Centre) and asked for Dr. Kripalani. She was directed to where a meeting was in progress. Dr. (Mrs.) Mujumdar. Her movements.

6. At 9-30 a.m. Dr. (Mrs.) Worlikar went to Medical Store. She and Jamadagni started segregating the remaining stock of glycerol Batch No. 27 and the remaining stock of mannitol. This took about 20 to 30 minutes. Dr. (Mrs.) Worlikar and Jamadagni segregate Batch No. 27 in Medical Store.

7. At 11-30 a.m. Dr. Shaligram (who was also conducting animal tests) convened a meeting of the heads of Neurology, Neurosurgery and Ophthalmology in the Nephrology Department. This meeting was in pursuance of a letter dated 28th January 1986 written by Dr. Shaligram to Dr. Kripalani (Ex. 72). Amongst those present were Dr. Kripalani, Dr. (Mrs.) Sirsat, Dr. Bhagwati, Dr. Palande, Dr. (Miss) Kamble, Dr. Shaligram and Dr. (Mrs.) Worlikar. Dr. (Mrs.) Mujumdar was invited to participate. Dr. Shaligram convenes meeting in Nephrology Deptt. Glycerol prime suspect. Decision taken. Ex. 72

8. The possible involvement of the three suspect druges was discussed. It became apparent that the only drug which could be involved was glycerol because that was the common drug administered to all the patients. Dr. Shaligram pointed out that glycol could be the contaminant in glycerol that was administered to the patients. Dr. Kripalani knowing that glycol is a toxic drug, suggested that the investigations should be pursued to definitely know whether the particular glycerol was contaminated or not. The conclusion arrived at was that the drug reaction, namely anuria, was caused by glycerol as that was the common drug received by the patients who had developed anuria. Hence suspicion fell primarily on glycerol with diamox to be the least likely drug. It was felt that no drug could be positively incriminated without positive proof that it was the culprit drug. Hence to be on the safe side it was decided (*i*) to stop the use of not only of glycerol but also of

diamox and mannitol, (*ii*) to purchase these three drugs on emergency basis, (*iii*) to inform the FDA, (*iv*) to perform animal toxicity tests, (*v*) to send these drugs to a private laboratory for analysis. Knowing full well that the Forensic Department of the J. J. Hospital would take a long time in carrying out the requisite tests, both Dr. Kripalani and Dr. Bhagwati suggested to Dr. Shaligram that the tests be carried out by a private laboratory as expeditiously as possible at the personal expenses of Dr. Kripalani and Dr. Bhagwati. Dr. Kripalani informed the gathering that he would make a report of this meeting to the Dean which he did and sent a copy to Dr. Shaligram. The meeting terminated at 12-30 p.m.

Movements of Dr. Kripalani. Dr. Kapadia and Dr. (Mrs.) Sirsat in Pathology. Finding is glycol poisoning. Steps taken by Dr. Kripalani.

9. After the Nephrology meeting, Dr. Kripalani, Dr. Farhad Kapadia and Dr. (Mrs.) Sirsat went to Pathology at about 1-00 p.m. and met Dr. Wagholikar. He was taking photographs of the organs of one of the afflicted patients, Bittal Kevat. His kidneys showed the same finding of cortical necrosis. Thereafter they saw histopathological slides of another patient Hemant Ranade, whose biopsy tissues had been sent to Pathology Department earlier. The finding from the slide was consistent with glycol poisoning. In view of this Dr. Kripalani decided that all the patients who had received glycerol should be administered sodabicarb (2 grams 2 hourly) and 3 litres of fluid per day. Dr. Kripalani sent a handwritten note to that effect to Ophthalmology Department. Regarding the Neurosurgery Department, Dr. (Mrs.) Sirsat met Dr. Palande and informed him about the treatment recommanded by Dr. Kripalani. She informed the Lecturer and Registrar of the Neurology Department about the line of treatment suggested by Dr. Kripalani.

Dr. (Miss.) Kamble's surprise.

10. During Dr. Palande's conversation with Dr. (Miss) Kamble after the Nephrology meeting, he told her that Ward No. 26 had received the circular in the evening of 27th January. Dr. (Miss) Kamble expressed surprise and told him that she did not know anything about it. When he found that the circular had been received by Ward No. 26, he enquired from the sister why it had not been brought to the notice of Dr. (Miss) Kamble. The sister said that she also did not know anything about the circular. From the enquiry as to who had received this circular in Ophthalmology, it was discovered that this circular had been received in Ward No. 26 by the evening staff.

Dr. (Miss) Kamble issues office order and circular. Ex. 108. Ex. 107. Dr. (Miss) Kamble's visit to Dean.

11. After the meeting, Dr. (Miss) Kamble returned to her Ward No. 26 and issued an office order dated 28th January 1986 (Ex. 108) between 12-30 p.m. and 1-00 p.m. At about 2-00 p.m. she also issued a circular (Ex. 107). The same afternoon of 28th January she want to the Dean's office and told him about the drug reaction in her ward and about the patients transferred from her ward to Nephrology. The Dean told her that he was aware of those facts.

Dr. Wagholikar's diagnosis of glycol poisoning confirmed. His discussion with Dr. Kripalani. Killer—Diethylene glycol. Meeting in Nephrology.

12. At 11-00 a.m. Dr. Wagholikar saw the special stained slides of the biopsies of Hemant Ranade and Ramesh Shinde, which confirmed the diagnosis of glycol poisoning. He sent word to Dr. Kripalani who saw the slides and discussed with Dr. Wagholikar which of the glycols could be responsible. As there were no oxalate crystals in these kidneys, they concluded that the killer drug was diethylene glycol. At 11-00 a.m., a meeting was convened in Nephrology Department. The Dean did not attend as he was busy with post-graduate registration. It was decided to stop all the suspect drugs and to inform the Dean accordingly.

Dr. (Mrs.) Mujumdar Her movements in Wards 26 and 25, and information she collected. Prepared chart.

13. After the 11-30 meeting, Dr. (Mrs.) Mujumdar went to Ward No. 26 (Ophthalmology). On the way she met Dr. Palande who accompanied her to Ward No. 26. There she collected information from the nurses' order book about five patients, namely Rajendra Mishra, Vithal Sadhu Bhokare, Bittal A. Kevat, Dawood Haji Dholakia and Abdul Kadar Shaikh. Out of them Rajendra Mishra and Dawood Haji Dholakia had been taken to AKD for dialysis. Adbul Kadar Shaikh had been sent for some investigation. Vithal Sadhu Bhokare and Bittal A. Kevat had expired. She did not see the case papers of Rajendra Mishra and Dawood Haji Dholakia as their case papers had, according to the normal practice, gone with them to AKD, where they were undergoing dialysis. In Ward No. 26 Dr. Palande told her that in his Ward No. 25 he had kept some samples of the suspect drugs. Thereupon he and Dr. (Mrs.) Mujumdar went to Ward No. 25 to collect the samples. She took these samples to her department of Pharmacology and handed them over to Dr. (Mrs.) Worlikar. The information collected by her from Ward No. 26 (Ophthalmology) was that all the patients had received glycerol,

only one had received mannitol, four had received acetazolamide and none had received gentamycin. Glycerol was the common drug. That evening Dr. (Mrs.) Mujumdar prepared a chart (Ex. 81) based on the information which she had collected. She showed that chart to Dr. Kulkarni and told him that all these patients except Nasiruddin had received glycerol and that she would attend the autopsy conference the following day. She kept the chart with her because she would have had to complete that after the autopsy conference the following day. The corrected chart is Ex. 82. Ex. 81. Ex. 82

14. The Dean received a letter from the Honorary Professor, Neurosurgery, Dr. Virani requesting that patients requiring intracranial surgery be directed to other hospitals until the matter of drug contamination was sorted out. The Dean accordingly gave instructions to Supdt. Dr. Deshmukh. Ex. 11 Dr. Virani's letter to Dean.

15. The Dean telephonically informed Dr. Kate, Director of Medical Education and Research, regarding the steps taken until then, that the five patients who had been transferred from other departments (*i.e.* 4 from the Neurosurgery and one from Ophthalmology) had died and had been subjected to postmortem. Dean's telephone to Director, Medical Education.

16. When Dr. Palande went to the ward in the morning, he learnt that Shailendra Joshi had died that morning and that his body had been sent for postmortem. He gave this information to Dr. Virani at about 9-00 a.m. or 9-30 a.m. when Dr. Virani came to the ward for his round. After completing their round, Dr. Palande discussed with Dr. Virani other patients who were affected and that a letter should be sent to the Dean for stopping admission of patients requiring brain surgery until further requisite drugs were made available. Dr. Palande and Dr. Virani.

17. Thereafter Dr. Palnde went to the Pathology Department and met Dr. Wagholikar. He told Dr. Wagholikar that Shailendra Joshi had expired. Dr. Wagholikar said he knew about it. Dr. Palande told Dr. Wagholikar that a proper postmortem be performed on Shailendra Joshi to ascertain the type of kidney damage. That day he also attended the meeting in the AKD. Dr. Palande and Dr. Wagholikar.

18. Dr. Dr. Palande went to the Ophthalmology Department with Dr. (Mrs.) Mujumdar. He then came to know from the sister in Ward No. 26 that in Ward No. 26 (Ophthalmology) glycerol had been administered till the morning of 28th January. He asked the siter how this was possible despite the fact that Nephrology had sent word to the Ophthalmology Department on 25th January not to administer it. She replied that she was not on duty on Saturday, the 25th and that she did not know anything about it until 28th January after the first dose of glycerol was administered at 6-00 a.m. She told him that she came to know about it that morning in the meeting held in the Ophthalmology Department. Dr. Palande goes to Ward No. 26 and is surprised to learn that first dose of glycerol was administered at 6-00 a.m.

19. In the afternoon Dr. (Mrs.) Mujumdar told Dr. Kulkarni that she had visited the Neurosurgery, Neurology and Ophthalmology wards, that she had more information of the drugs administered to the affected patients and that she had personally told all the sisters in-charge of those wards not to administer these three durgs. Dr. (Mrs.) Mujumdar talks with Dr. Kulkarni.

20. Dr. (Miss) Sankholkar is the Deputy Director of Medical Education since 13th February 1986. Between 1-30 and 2-00 p.m. Dr. (Miss) Sankholkar received a telephone message from the Dean Dr. Chandrikapure that 6 to 7 patients had developed drug reaction which was noticed on Saturday the 25th, when they developed anuria, that most of them belonged to Neurosurgery and had undergone surgery, that they were put on dialysis, that 2 patients had died and the others were under treatment, that the postmortem on the two patients revealed that the changes in the organs were due to severe drug reaction that the Department of Pharmacology was investigating into the matter, that all the drugs had been sent to FDA for analysis and (this was incorrect) that he, the Dean, would be submitting a written report of the incident to Dr. (Miss) Sankholkar's office the same evening. Dr. (Miss) Sankholkar immediately dictated to her P.A. what Dr. Chandrikapure had told her. The note was thereafter signed by her. As Dr. B. R. Kate, Director of Medical Education was not in his office, the note was submitted to his P.A. between 3 and 4 p.m. It was received by Dr. Kate the following day. Dean telephones Dy. Director of Medical Education, Dr. (Miss) Sankholkar and her note to Director Dr. Kate.

21. When Dr. Kulkarni visited Medical Store, he found that glycerine from Batch No. 27 was in D section where medicines are kept unlocked. Dr. Kulkarni instructed pharmacist Jamadagni to keep these bottles under lock and key in C section where medicines are kept under lock and key. Dr. Kulkarni's instructions to Jamadagni.

Dr. (Mrs.) Worlikar's call to FDA.

22. At about 1-00 p.m. Dr. (Mrs.) Worlikar took some bottles of the suspect drugs from Medical Store to Pharmacology for testing. Thereafter Dr. (Mrs.) Worlikar went back to Medical Store at 1-15 p.m. and telephoned FDA. She spoke to Assistant Commissioner Raykar and told him that there have been some deaths in the J. J. Hospital and that they suspected 3 drugs, namely glycerol, diamox and mannitol and requested him to have the samples collected as early as possible from the J. J. Hospital.

Dr. (Mrs.) Worlikar contacts Italab.

23. After speaking to Assistant Commissioner Raykar, Dr. (Mrs.) Worlikar contacted Italab for testing the samples of glycerol and mannitol. She was told to send the samples to Italab the next day.

Dr. (Mrs.) Worlikar apprises Dr. Shaligram.

24. At about 2 or 2-30 p.m. Dr. (Mrs.) Worlikar told Dr. Shaligram that she had contacted FDA and that their officers would be coming to the J. J. Hospital to collect the samples.

Dr. Shaligram and Dr. (Miss) Kamble's letter to Dr. Shaligram and copy to Dean.

25. At 3 or 3-30 p.m. a lecturer from Ophthalmology came to Dr. Shaligram with a letter dated 28th January 1986 addressed to him by Dr. (Miss) Kamble and samples of acetazolamide, glycerol and mannitol. A copy of Dr. (Miss) Kamble's letter was marked to the Dean for information (Ex. 76). Dr. Shaligram told the lecturer to keep the samples with Dr. (Mrs.) Worlikar. Dr. Shaligram told Dr. (Mrs.) Worlikar that the samples stated by Dr. (Miss) Kamble in her letter Ex. 76. Ex. 76 should be included in the samples to be sent to the FDA.

FDA collects samples. Ex. 8.

26. In response to Dr. (Mrs.) Worlikar's telephone call to FDA, Drug Inspectors Vadnere and Dube from FDA came to Pharmacology at 3-30 p.m. Dr. (Mrs.) Worlikar gave them a typed letter (Ex. 8) signed by her for checking glycerine, mannitol and diamox. She took the FDA Inspectors to Medical Store where they collected samples of glycerol Batch No. 27, mannitol and diamox under the supervision of Assistant Commissioner Raykar who had by then arrived.

Dr. Shaligram's experiments.

27. Not having rats or rabbits at hand, Dr. Shaligram was carrying out tests of the samples of acetazolamide and glycerol Batch Bo. 27 on mice to ascertain nephrotoxicity. None of the mice died.

Pharmacopoeial test—Samples failed in acidity and glucose.

28. The Pharmacopoeial test was carried out by the pharmacy post-graduate students in Dr. Kulkarni's Department on glycerine from Batch No. 27 supplied by Alpana Pharma. This test revealed that the samples failed in respect of acidity and glucose. They orally told Dr. Kulkarni of their conclusion which was based on the test data seen by Dr. Kulkarni.

FDA draws sample from Batch 27.

29. The Drugs Inspector drew a sample from Batch No. 27 in the presence of the Pharmacist Jamadagni and the Associate Professor Dr (Mrs.) Worlikar.

Dr. R. D. Kulkarni sends samples to Dr. Sane.

30. In the evening Dr. R. D. Kulkarni sent the samples from Alpana Pharma's Batch No. 21 and Batch No. 27 and a sample of Chem Med's glycerol for detailed analysis to Dr. R. T. Sane, Professor of Chemistry, Ruia College.

Dean's telephone to Dr. Kate.

31. That evening the Dean telephonically requested Dr. Kate to inform all Government Medical Colleges in the State. Dr. Kate told the Dean to do so.

Thus, ended Tuesday, the 28th January.

WEDNESDAY, 29th JANUARY 1986

Dr. (Miss) Kamble holds meeting. Ex. 114-A

1. At 9-30 a.m. Dr. (Miss) Kamble held a meeting in her chamber of all the resident doctors. At the end the proceedings were minuted by her in the presence of all assembled and their signatures taken on the original minutes (Ex. 114-A). At this meeting it was decided (i) not to prescribe these 3 drugs, (*ii*) to carry out certain investigations on patients who had received these 3 drugs in the ward and who were still in the ward, and (*iii*) to be on the look out for certain clinical features in those patients.

Dr. Kulkarni tells Dr. Shaligram Batch 27 failed in acidity and glucose tests.

2. At 10-00 a.m. Dr. S. V. Shaligram met Dr. R. D. Kulkarni. Dr. Kulkarni told him that the glycerine of Alpana Pharma Batch No. 27 failed in the acidity and glucose tests.

3. Dr. B. R. Kate is the Director, Medical Education and Research, Government of Maharashtra. He is in charge of the Medical Colleges and Hospitals in the State of Maharashtra and looks after the Medical Education. Dr. Kate is not directly concerned with administration of Government Hospitals and Deans are not expected to make regular reports to him. It is only when something untoward happens, that the Dean of such hospital must make a report to Dr. Kate, who would thereupon take action on such report. On 29th January 1986 when Dr. Kate attended his office at 10·15 a.m., he found a note dated 28th January 1986 signed by Dr. (Miss) P. C. Sankholkar, Dy. Director of Medical Education and Research, Bombay. From this note Dr. Kate gathered that there was some drug reaction in the J. J. Hospital and that two patients had died. He appointed what came to be known as Choube Committee.

Dr. Kate gets Dr. (Miss) Sankholkar's note on 28th.

4. At 10-30 a.m. Dr. (Miss) Kamble held meeting with all the staff members of her Ophthalmology Department. Dr. Dastoor, Dr. Shanbhag, Dr. (Mrs.) Padaley, Dr. (Mrs.) Gaikwad, Dr. Shaikh and Dr. Gawai attended. At the end the proceedings were minuted by her in the presence of all and their signatures taken on the minutes (Ex. 117). At this meeting it was decided that patients who had received glycerol would be monitored and no further routine surgery would be done and that the blood of patients who had received glycerol would be sent for investigation.

Dr. (Miss) Kambles Ophthalmology meeting and decision taken.

Ex. 117

5. At 10-30 a.m. from Medical Store, Dr. (Mrs.) Worlikar issued a hand-written circular (Ex. 9) to all the wards recalling all the bottles of glycerine supplied by Alpana Pharma. The circular was sent by Jamadagni to all the ward sisters. It was received back by him the same day with the signatures of the ward sisters at the foot and reverse of the circular. If any ward was closed that day (e.g. operation theatre), the circular was sent to such ward the next day.

A. K. Jamadagni and Dr. (Mrs.) Worlikar Ex. 9.
Dr. (Mrs.) Worlikar issues recall circular.

6. Between 11-00 and 11-30 a.m. Dr. Kripalani had a meeting with Dr. Kulkarni regarding the antidote to be given to the affected patients, and decided not to dialyse patients who had not exhibited the symptoms of renal failure, as such an expedient would be unscientific and in the nature of experimentation.

Dr. Kripalani and antidote measures.

7. That morning the Dean held a meeting of the College Council where all the professors and heads of departments were present. The Dean apprised the Council of the actions taken by him so far. Dr. (Mrs.) Renu Patel (Professor of Paediatrics) drew the Dean's attention that her department had not received the circular dated 27th January 1986 stopping the administration of the suspect drugs. The Dean thereupon issued a fresh circular (Ex. 12) again to all the departments of the J. J. and other hospitals attached to the Grant Medical College. He also telephonically gave information to all Government Medical Colleges in the State.

Dean holds meeting of College Council.
Dr. (Mrs.) Renu Patel's grievance.
Fresh circular issued. Ex. 12.

8. Dr. R. D. Kulkarni made an oral report to the Dean that the sample of mannitol and diamox did not contain any contaminant and that he suspected contamination in the glycerol sample, but as there were no facilities in the department for analysis he would be sending the glycerol sample for analysis to a private laboratory.

Dr. Kulkarni's oral report to Dean.

9. At 1-30 p.m. Dr. Kulkarni and Dr. (Mrs.) Worlikar went to the Pathology Department to see the kidneys of the affected patients. Dr. Kripalani, Dr. Palande, Dr. Wagholikar and many resident Pathologists were also present there. Dr. Wagholikar showed them 6 kidneys and told them that what they were seeing in those kidneys was a rare abnormality, namely cortical necrosis. This meeting lasted an hour.

Dr. Kulkarni, Dr. (Mrs.) Worlikar Dr. Kripalani, and Dr. Palande go to Pathology.
Dr. Wagholikar shows 6 kidneys and pronounces cortical necrosis.

10. That afternoon the Dean telephoned Dr. Kate and informed him that drug reaction had been noticed, that some patients had died and that he had informed Dr. (Miss.) Sankholkar accordingly. The Dean did not tell Dr. Kate when the drug reaction was first noticed, nor did Dr. Kate ask. Dr. Kate took it for granted that the incident of drug reaction must have been of recent origin, namely of the past two or three days. Dr. Kate did not ask the Dean when the drug reaction was first detected but asked what steps the Dean had taken with regard to the detection of drug reaction. The Dean replied that he had withdrawn all the three drugs, namely mannitol, glycerol and diamox. Dr. Kate did not ask when these drugs were withdrawn. Dr. Kate gave no information to the Secretary, Medical Education, Mr. Tripathi, that day as according to him he was busy with fixing up the composition of the Choube Committee and was awaiting a detailed written report from the Dean. Dr. Kate contacted the Secretary Mr. Tripathi the next day.

Dean telephoned Dr. Kate—*Suppressio Veri and suggestio falsi.*

Ex. 12 Dean.

11. At 12 noon Medical Store received a circular (Ex.12) from the Dean for stopping the use of mannitol, diamox and glycerine. The Dean however admits that this circular was received by the departments on 3rd or 4th February 1986.

Dr. (Mrs.) Worlikar Ex. 9 Samples of mannitol and Batch 27 sent to Italab.

12. After issuing the recall circular (Ex. 9), Dr. (Mrs.) Worlikar went to the Dean at about 12 noon to get his signature on a letter prepared by her that day, viz. 29th January 1986, to Italab for testing the samples of glycerine Batch No. 27 and mannitol. These were sent to Italab along with the letter signed by the Dean.

Death Conference *in Pathology.* Conclusion : renal cortical necrosis produced by diethylene glycol poisoning.

13. At 1-30 p.m. there was a meeting (Death Conference) in the Pathology Department. Several doctors were present, *including* Dr. (Mrs.) Mujumdar, Dr. Kripalani, Dr. Palande, Dr. (Mrs.) Sirsat, Dr. (Miss) Kamble and Dr. Wagholikar, and other members from the Pathology, Pharmacology, Nephrology, Neurology, Neurosurgery and Ophthalmology Departments. The kidneys and organs of the autopsied patients were displayed. The result of the discussion was that the renal cortical necrosis had been produced by, and was the result of diethylene glycol poisoning, and that the prognosis of the affected patients was grave and their recovery unlikely. Their further conclusion was that in the absence of any knowledge of an antidote to diethylene glycol poisoning, nothing more could be done than what was being done.

14. Autopsies on Sopan Tawar and Nasiruddin Shaikh were performed. The conclusion drawn *was that* Nasiruddin Shaikh's case was not of glycol poisoning.

Thus ended Wednesday, the 29th January.

THURSDAY, 30TH JANUARY 1986

Dr. Kate's visit to Secretary Tripathi.

1. Dr. Kate paid a visit to G. C. Tripathi, Secretary, Medical Education and Drugs at his office in Mantralaya and informed him of the death that had taken place in the J. J. Hospital and the formation of the Choube Committee.

Dr. Kulkarni tells his suspicion to Dean.

2. Dr. Kulkarni told the Dean that he suspected that glycerine Batch No. 27 could have been adulterated by ethylene glycol, vinyl chloride, carbolic acid or diethylene glycol.

Dr. Wagholikar. Rajendra kumar Mishtra autopsided. Renal cortical necrosis due to diethylene glycol.

3. The autopsy on Rajendrakumar Mishra *was performed*. It showed renal cortical necrosis produced by and as a result of diethylene glycol poisoning. The liver showed extensive necrosis.

Dean's conversation with Dr. Kate.

4. At 4-00 p.m. the Dean informed Dr. Kate that till then 8 patients had died, that the suspect drugs were being tested by the Pharmacology Department of the J. J. Hospital and the FDA and that a detailed report would follow.

And *vice versa*.

5. During the course of the day Dr. Kate informed the Dean of the appointment of the Choube Committee to which the Dean should extend his co-operation.

Thus, ended Thursday, the 30*th January*.

FRIDAY, 31ST JANUARY 1986

News report.

1. The Maharashtra Times published a news report of the deaths in the J. J. Hospital.

10 Dead.

2. By 31st January, 10 afflicted patients had died.

Ex. 77 Dr. Shaligram's report to Dean.

3. Dr. Shaligram made a signed report (Ex. 77) to the Dean regarding all the steps which had been taken by Medical Store.

Visit of Dr. Kate and Secretary Tripathi.

4. At 10-30 a.m. Dr. Kate and Secretary Mr. Tripathi came to the hospital. They were there for about two hours. The Dean *explained* to them what had transpired and the measures taken by him. They called the various doctors, namely Dr. Kripalani (Pharmacology), Dr. Wagholikar (Pathology), Dr. Palande (Neuro-surgery), Dr. (Mrs.) Sirsat (Nephrology), Dr. (Miss) M. A. Kamble (Ophthalmology), Dr. Virani (Neurosurgery) and pharmacist Jamadagni, who narrated the measures taken by them.

5. That day Dr. Shaligram started the glycerol and the mannitol tests on rats and rabits. He tested the glycerol on 24 rats divided into 3 groups of eight each. One group received B.D.H. pure glycerol 10 ccs. per kg. twice a day for 7 days. No rat from this group died. The second group received Alpana Pharma glycerol Batch No. 27, 5 ccs. per kg. twice a day for 7 days. One rat died on the third day, the other 7 survived. The third group of eight rats received 10 ccs. per kg. of Alpana Pharma's glycerol, Batch No. 27 for 7 days. One rat died on the fifth day, the other 7 survived. At the end of the 7th day all the rats were killed so as to examine their blood and organs. The blood was examined for two indicators of kidney function, namely urea and creatinine. Creatinine is a blood constituent which goes up in the case of kidney damages; the same is the case of urea. From the examination of the blood of the sacrificed rats it was found that compared to the rats which were given B.H.D. pure glycerine, in the rats which had been given Alpana Pharma glycerine, creatinine and urea had been raised. From the urine tests it was discovered that the B. D. H. pure glycerol-fed rats excreted more urine than the rats fed on Alpana Pharma's glycerol. Dr. Wagholikar's report shows that the kidneys of the B. D. H. glycerol treated rats were virtually normal whereas the kidneys of the rats treated with Alpana Pharma's glycerol showed various types of kidney damage, and at least two rats amongst those showed cortical necrosis of the type which was observed by him in the human kidneys of those patients who had died after administration of Alpana Pharma's glycerol Batch No. 27. Even the other rats showed extensive tubular damage.

Dr. Shaligram's tests on rats and rabbits.

6. That day Dr. Shaligram started the tests on rabbits. There were 7 rabbits divided into two groups of 4 and 3. Four rabbits were given Alpana Pharma's glycerol Batch No. 27 in a dose of 5 cc. per kg. once a day. The other group of 3 rabbits received B. D. H. pure glycerol. Of the 4 rabbits which were given Alpana Pharma's glycerol, one died on the 3rd day, and the other died on the 6th day. From the other group of 3 rabbits which were given B. D. H. pure glycerol, none of them died. All the living rabbits were sacrificed and their blood collected. It showed that in the Alpana Pharma glycerol-treated rabbits the urea and creatinine were high and the kidneys showed extensive damage. The blood of the B.D.H. glycerol-treated rabbits did not show any elevation of urea or creatinine, and their kidneys did not show any damage.

Dr. Shaligram's tests on rabbits.

7. Dr. Kulkarni made a report (Ex. 29) that glycerine samples sent to Dr. Sane showed presence of some contaminant and its identification was in progress.

Ex. 29
Dr. Kulkarni reports to Dean Identification of contaminants in progress.

8. The Dean sent for and for the first time saw the plastic dark blue bottles of glycerol Batch No. 27, but could not see the contents.

Dean sees glycerol bottles, Batch 27.

9. The Dean gave directions to all the departments to carefully preserve the hospital records of the patients involved, and instructed Dr. Kulkarni (Pharmacology) to keep the three suspect drugs under lock and key.

Dean's direction to preserve records. Dr. Kulkarni to keep suspect drugs under lock and key.

10. As a result of the news report, Health Minister Bhai Sawant, the Director of Medical Education Dr. Kate and Secretary Mr. Tripathi visited the Hospital at 2-30 p.m. They were there for an hour. The Health Minister suggested the inclusion of two more names in the composition of the Choube Committee.

Health Minister's visit to J. J. Hospital.

11. The Director of Medical Education Dr. Kate and the Secretary, Department of Medical Education came to the Dean's office. Dr. Kripalani and Dr. Wagholikar were sent for. Dr. Kulkarni informed the Director and the Secretary of the steps taken by him from 27th January. The Director asked Dr. Kulkarni to give a written report. Dr. Kulkarni did so then and there. In his report Dr. Kulkarni set out the facts in brief, including the fact that the suspect sample showed the presence of a contaminant, that further tests for identification of the contaminant were in progress, that chemical analysis did not reveal any vinyl chloride or carbolic acid contamination, that Dr. Sane's report revealed that the sample from Batch No. 27 contained diethylene glycol which is a very highly nephro-toxic agent which would cause renal cortical necrosis and capillary haemorrhages. According to medical literature, presence of diethylene glycol over 5 per cent produces definite nephro-toxicity resulting in renal failure. For his part Dr. Kulkarni would not

Visit of Dr. Kate and Secretary Tripathi to Dean's office.

Dr. Kulkarni's written report.

consider even the least percentage of diethylene glycol in glycerine to be safe. According to Dr. Sane's report, the presence of diethylene glycol in Batch No. 27 was 18 per cent. Diethylene glycol in such a large quantity could positively result in definite toxic reaction resulting in definite renal failure. According to the Indian Pharmacopoeia a bottle of standard glycerine must contain minimum 98 per cent glycerine with not more than 2 per cent moisture. In Batch No. 21 the glycerine was 91 per cent and the moisture 4·5 per cent. In Batch No. 27 of Alpana Pharma the glycerine was 09 per cent and the moisture 23 per cent. With the combination of 09 per cent glycerine, 23 per cent moisture and 18 per cent diethylene glycol, the toxic effect of diethylene glycol would be manifest resulting in renal failure.

Thus ended Friday, the 31st January.

1ST FEBRUARY 1986

Dr. Wagholikar Ramji Kasar autopsied Diethylene glycol poisoning.

1. The autopsy on Ramji Balu Kasar was performed. His kidneys showed acute defused tubular necrosis indicative of diethylene glycol poisoning. His liver showed centrilobular hepatic necrosis, indicative of diethylene glycol poisoning.

2. The Choube Committee made its preliminary report that deaths were caused due to some contaminant in the glycerol and which contaminant was being identified.

2ND FEBRUARY 1986

Dr. Wagholikar Abdul Kadar Shaikh autopsied Diethylene glycol affection.

The autopsy on Abdul Kadar Shaikh was performed. It showed acute tubular necrosis indicative of diethylene glycol poisoning. The liver showed eivdence of alcohol-induced cirrhosis in which there was evidence of diethylene glycol affection.

5TH FEBRUARY 1986

Dr. Shaligram's report on toxicity tests on animals.

Ex. 26.

1. Dr. S. V. Shaligram sent Dr. Kulkarni his report regarding the toxicity test carried out by him on rabbits, rats, cats, and mice. The report disclosed that mannitol and acetazolamide did not have any adverse effect on mice and rabbits; uptil 10 ml/kg of glycerol there was no adverse effect on mice; all the 8 rats given 10 ml/kg of standard glycerine were surviving and one out of 8 rats given 5 ml/kg of the test glycerol had died; and the test on rabbits and cats was in progress. Subsequently Dr. Kulkarni learned from Dr. Shaligram that rabbits who had been given the test glycerol died but the mice survived.

Records taken to Mantralaya.

2. Mr. Budhwant, Dy. Secretary, Medical Education Department, and Dr. Kate visited the hospital, took charge of the hospital records and took them to Mantralaya. Some case papers pertaining to the patients were with the Pathology Department and others were in the record section. The Dean called for those case papers.

6TH FEBRUARY 1986

Ex. 14 Informal Report

The Dean received a letter dated 6th February 1986 from Dr. R. D. Kulkarni (Pharmacology) setting out the informal report of the Chemical analysis of glycerol done by R. T. Sane (Professor of Chemistry, Ruia College). The extraction and infrared spectrometry showed the presence of diethylene glycol; the approximate composition of the glycerol sample was—

Diethylene glycol	18·5 per cent (Nephro-toxic)
Water	21 per cent
Glycerol	9 per cent
Polyglycol	51 per cent

Diethylene glycol : 18.5 per cent.

Commercial glycerol used.

The letter ended that commercial glycerol with impurities had been used during manufacture instead of pure glycerol.

7TH FEBRUARY 1986

The Choube Committee made its final report.

12TH FEBRUARY 1986

Three decisions were taken at a Cabinet meeting, namely (*a*) to hold the present inquiry; (*b*) to ask the C.I.D. to investigate, and (*c*) to take action against erring officials of the J. J. Hospital and the FDA. Cabinet meeting decisions.

13TH FEBRUARY 1986

1. 106 bottles of glycerol (Batch No. 27) were sealed in a cupboard in 'D' Section of Medical Store. Bottles sealed.

2. Transfer orders were passed by Government; the Dean was transferred to Miraj, Dr. R. D. Kulkarni to Aurangabad, Dr. (Miss) Kamble to Nagpur and Pharmacist Jamadagni to Poona. Transfer orders.

20TH FEBRUARY 1986

Dr. Sane submitted his formal Report which was in conformity with his earlier informal Report. Dr. Sane's formal Report.

21ST FEBRUARY 1986

A Notification was issued by Government appointing the present Commission to inquire and report on 11 questions set out in that Notification. G.N.

18TH MARCH 1986

Pending the Commission's Report, Government ordered the suspension of the investigation by the CID.

23RD JUNE 1986

Government Analyst Dr. Pilankar made his toxicity report. Ex. 246.

Thus comes to an end the narration of events.

CHAPTER VI

I shall now deal with the Questions seriatim.

Question (*a*).—" Whether such deaths of patients occurred due to certain deficiency or defect in the line of treatment or due to any negligence on the part of the doctors/ para-medical/other ancillary staff who were connected with the care of the patients at any stage or at any level and if so, who are responsible? "

This question must be answered in the negative.

1. Glycerine is a standard drug recognised as such under Indian Pharmacopoeia. For years it has been used with success the world over, including the J. J. Hospital, to reduce intra-cranial pressure. Until 25th January 1986 when suspicion fell for the first time that Alpana Pharma's glycerol was one of the drugs not of standard quality and its administration was stopped from that day itself in the Neurology and Neuro-surgery Departments, the doctors and staff of the J. J. Hospital had no knowledge, or any reason nor the means of knowing or suspecting that the killer glycerol Batch No. 27 was not standard medicinal glycerine it was supposed and expected to be. Hence there was no negligence on their part in disseminating or administering that drugs, proceeding as they did and as they were entitled to on the footing that Batch No. 27 was indeed standard medicinal glycerine. The fact that glycerine is a recognised and standard drug under I.P. and has been successfully used as an anti-oedema measure was a complete justification for the doctors in prescribing this drug on the justifiable assumption that it was of standard medicinal quality and not contaminated, as discovered later. There is not even the remotest whisper of evidence that the normal doses were exceeded. In these circumstances there was no deficiency in the line of treatment nor any negligence on the part of the doctors and staff in administering this drug in the genuine belief that it was a standard drug. Thus question (*a*) must be answered in the negative.

CHAPTER VII

Question (*b*).—" Whether such deaths of patients occurred due to administration of adulterated, substandard, contaminated or defective drugs during the course of their treatment? "

1. In order to answer this question, it must first be ascertained which of the 3 suspect drugs was the killer drug. Was it acetazolamide (diamox), mannitol or glycerol?

2. There is overwhelming evidence on record including two Charts (Exhibits 81 and 82) prepared by Dr. (Mrs.) Mujumdar which rules out acetazolamide and diamox as the killer drugs. On analysis, acetazolamide was found to be of standard quality. Mannitol did fail in the pyrogen test. However such mannitol did not cause the deaths, because at worst it would cause a mild fever which would subside as soon as the defective mannitol was withdrawn. Moreover it was not given to all the patients who died. Ex. 81and 82

3. Overwhelming and uncontrovertible evidence points to one drug and one drug alone as the killer drug. It was the common drug administered to all the 14 patients who died—glycerol Batch 27 supplied by Alpana Pharma.

4. Pure glycerine must contain not less than 98% glycerine and not more than 2% moisture. As against this, the composition of glycerol sold by Alpana Pharma to J. J. Hospital was:

Diethylene (Nephro-toxic)	18.5%
Water	21.00%
Polyglycol	51.00%
Glycerol	9.00%

To call such a concoction glycerol is a mistake. It can more correctly be described as diethylene glycol with a dash of glycerine.

5. The report dated 3rd February 1986 (Exhibit 291) of the Government Analyst Dr. Pilankar on Batch No. 27 shows it to be substandard. Dr. Sane's report dated 7th February 1986 (Exhibit 35) establishes that it was toxic and contaminated with diethylene glycol. This is corroborated by none other than the manufacturer himself, viz., Jethalal Soni, the proprietor of Ganesh Chemicals. It is this glycerine through various middlemen was ultimately sold by the repacker Alpana Pharma to the J. J. Hospital. It makes no difference that Chem Med Laboratory purported to certify it to be of standard quality. Even assuming that Chem Med's certificate (Exhibit 212) is correct (which it is not as will be established later in this Report), it is worthless even at face value, for no toxicity test had been called for nor carried out by Chem Med. Ex. 291 Ex. 35 Ex. 212

6. The report dated 19th June 1986 (Exhibit 369) of the Government Analyst Dr. Pilankar shows that the 3 samples analysed were found to contain diethylene glycol in the percentage of 13.872, 14.404 and 13.358. Dr. Pilankar says that the test carried out by him on Batch No. 27 by the gas liquid chromatograph method revealed the presence of diethylene glycol to the extent of 13% and glycerine to the extent of 8.5% only. Ex. 369

7. Diethylene glycol has two major targets in the human body. The liver and the kidneys. In the liver the damage is restricted mostly to the centrilobular zones of hepatic lobules. (This is the central zone of the hepatic lobules which is a part of the liver). The damage is characterised by the swelling of the cells and the resultant death of the cells. It is different from hepatitis which is commonly caused by viruses known as infective hepatitis or jaundice, and from which 95% of such patients recover. The liver damage in the case of diethylene glycol poisoning has comparatively less significance because the patients die of renal failure before the liver failure becomes manifest. In the absence of any major disease in other organs, a combination of kidney damage and liver damage is pathagnomonic (i.e. one of the diagnostic criteria of glycol poisoning). This was substantiated by animal experiments and chemical analysis of Alpana Pharma's glycerol Batch 27.

8. The worst affected however are the kidneys. The damage is characterised by tubular nephropathy (damage to the tubules of the kidney). The damage has a specific histopathologic appearance which is very diagnostic, that is, suggestive of poisoning.

In the later phases, there is a destruction of the phases in the kidneys where the formation of urine first starts (glomeruli) and cortical necrosis is said to have taken place. Its clinical manifestation is anuria and renal failure. While in the vast majority of cases renal failure is reversible, renal failure caused by diethylene glycol poisoning is irreversible despite dialysis and medical treatment. This irreversibility must result in death and thus it was with these 14 patients.

9. Even if the presence of diethylene glycol is 3% or less, there is a danger of damage to the kidneys, if not always death. A normal healthy kidney will no longer remain so if a person is given even a single dose of one ounce diethylene glycol in the percentage of 18.5. A single dose of glycerol containing as much as 18.5% diethylene glycol (as in Batch No. 27) would certainly cause damage to the kidneys and other organs, if not always death. The cause of death of these patients was cortical necrosis or tubular necrosis of the kidneys. As a result of the presence of diethylene glycol in Alpana Pharma's Batch No. 27, the livers and kidneys of the deceased patients were primarily damaged and the damage was irreversible. There was also secondary damage to the brain and the lungs as a result of diethylene glycol.

10. It is manifest that glycerine Batch No. 27 containing diethylene glycol was the only drug which caused the deaths. Amongst those who died there were some who had pre-existing diseases. Two patients had hypertension, one had diabetes, one had chronic obstructive pulmonary disease, one had goitre and one had ascoriasis (infection caused by round worms in the stomach). None of the above pre-existing diseases could cause renal failure. Even so, these patients who had these pre-existing diseases developed renal failure, which could only be attributed to glycerol Batch 27 and not to any of the pre-existing diseases. The postmortem reports reveal that organs were affected by contamination by some chemical which caused depression of the central nervous system and acute necrosis of the kidneys which were irreversible. The evidence reveals that dialysis was of no use. This indicates that apart from head injuries suffered by some patients, there were other organs which were also affected, namely, the liver, brain and lungs. If kidneys were affected, dialysis could sustain life. Hence none of the pre-existing diseases caused irreversible cortical necrosis which ultimately caused the death of these patients who had been administered the common drug of glycerol contaminated with diethylene glycol. This is what Dr. (Mrs.) Sirsat has to say about cortical necrosis in her evidence:

> " 75. Cortical necrosis is the death of the kindey cortex; there is necrosis of the glomerulus, proximal tubules and blood vessels supplying the glomerulus. Modual is inner part of the kidney. There are different blood supply lines to the cortex and modula. In cortical necrosis modula is not involved. There can be selective necrosis of the cortex, but not necessarily of modula. In these 13 cases the necrosis was only of the cortex. In the case of these 13 patients capillaries were also damaged. "
>
> " 76. Necrosis of the cortex is irreversible. The irreversibility would depend upon the extent of the damge and the cause of the damage.
>
> Q: —Will cortical necorosis occur if standard pure unadulterated durgs are administered in larger quantities than required ?
>
> A. No.
>
> Acute tubular necrosis can occur with some drugs; it would be reversible. Drug induced intertial nephritis can occur but can be reversible. Focal necrosis is the involvement of the small area of the kidneys. "

Necrosis is death of tissues. Cortex is the outer cover. In 13 cases necrosis was only of the cortex and capillaries were also damaged. Necrosis of cortex is irreversible. Other kinds of necrosis can be reversible.

11. Thus it was the common drug, namely Alpana Pharma's glycerol Batch No. 27, administered to all the deceased patients that was the killer drug, containing as it did the lethal poison of diethylene glycol.

12. Having established that Alpana Pharma's glycerol was the killer drug, I proceed to consider Question (*b*).

13. Alpana Pharma's glycerol Batch 27 was adulterated and contaminated with diethylene glycol. It therefore also became a substandard and defective drug. The resultant deaths were directly due to the manufacture and ultimate supply to the J. J. Hospital of this glycerol, and not due to its administration till suspicion fell on it on 25th January 1986. By then irreversible damage had been done in ignorance of the fact that it was a lethal poison as set out earlier.

Question.—(*c*)—" If so, whether there was any negligence or dereliction of duty on the part of doctors/ para-medical/other ancillary staff who were connected with the care of the same patients in identifying and withdrawing the offending drug promptly from use, to avoid further danger to the safety of patients ?"

1. As will appear later from the discussion while answering question (*d*), there was no negligence or dereliction of duty on the part of doctors/para-medical/other ancillary staff in identifying or withdrawing the killer drug.

2. However regarding the withdrawal of the offending drug, the Dean Dr. Chandrikapure and the Superintendent Dr. Deshmukh must take the primary responsibility in their utter failure to do either. To that end they are guilty of negligence and dereliction of duty.

3. The evidence of the Dean Dr. Chandrikapure and the Superintendent Dr. Deshmukh even at face value makes for startling reading. Difficult though it may be, of them I shall endeavour to speak in measured terms and restrained vocabulary in deference to their noble profession.

4. Starting with the Dean Dr. Chandrikapure, on his own showing, despite Dr. (Mrs.) Sirsat's frantic telephone call to him on Saturday 25th January at 11 a.m. and despite her telling him that 4 or 5 patients had already died due to drug reaction and that other patients had likewise been effected, and though on his own admission he did consider drug reaction as also what Dr. (Mrs.) Sirsat told him to be serious matters for concern, he did nothing. It was his day off; so he did nothing. As the highest authority in the Hospital it was the Dean or the Supdt. who alone could have given immediate directions to Medical Store not to further disseminate the suspect drugs. He did neither. He left it to Dr. (Mrs.) Sirsat. Despite the seriousness of the situation, the Dean did not visit the Hospital on the lame excuse that there were competent people in the hospital to handle the situation. Who they were the Dean discreetly does not care to say. He did not even telephone the Head of Departments or any doctors to narrow down the suspect drugs or for the purpose of taking any action.

5. Suspect drugs which were commonly administered to the patients freely should have been a matter of grave concern to the Dean and which he should at once have brought to the notice of the higher authorities. He did nothing of the kind on the lame excuse that it did not strike him to do so as the Director of Medical Education Dr. Kate is usually out of Bombay on week-ends. The Dean admitted that he did not even ascertain whether Dr. Kate was in Bombay that Saturday. It did not even strike him to contact Dr. (Miss) Sankholkar This is too ridiculous for words. Thus on Saturday the 25th January while drugs suspected to be contaminated were floating in the Hospital and were being freely administered as routine drugs, the Dean was enjoying his Saturday off at home.

6. The following day, Sunday the 26th was the flag-salutaion function at the Hospital. The Dean went to the Hospital essentially to attend that function. After it was over he incidentally went to the Nephrology Department at 11.00 a.m. for 10-15 minutes to see whether any patient was on dialysis, but did not see any patient being dialysed. He did not go to the affected departments or make on-the-spot enquiries or find out how many more patients afflicted by the suspect drugs needed treatment or dialysis. He did not talk to any doctor, professor or lecturer connected with Nephrology Department nor did he even visit the Neurosurgery or Ophthalmology Departments. Thus on Sunday, the 26th except paying a brief and perfunctory visit to Nephrology for about 15 minutes, the Dean did nothing. He did not bother to visit the affected departments, viz. Neurology, Neurosurgery and Ophthalmology, from where the patients were being sent to Nephrology for dialysis.

7. From the Dean's own lips there is his revelation that from 25th till 27th January he did nothing except to abdicate his responsibility to Dr. (Mrs.) Sirsat on 25th and on the afternoon of 27th to issue his circular-and that too after virtually being goaded into doing so by the Head of the Nephrology Dr, A. L. Kriplani,

According to the Dean that morning he tried to contact the Heads of Departments, but they were not available. There is nothing to commend this version, such as it is, except the Dean's *ipse dixit*. Thereafter he did nothing.

8. Thus for 2 vital days, 25th and 26th January the Dean enjoyed his holidays and did nothing Rome burnt and Nero fiddled.

9. For that matter on 29th when the Dean telephoned Dr. Kate in the afternoon, he significantly did not even tell him when the drug reaction was first noticed. Suppressio veri and suggestio falsi.

10. There is also the Dean's admission from his own lips that the stoppage circular issued by him on 29th January (Exibit 12) was received by the departments as late as 3rd or 4th February. This is a further indication of the total inaction on the part of the Dean whose duty it should have been to ensure that the same was received by all the wards immediately it was issued.

11. The Dean admitted that only 2 persons could have ordered the stoppage of the supply of the suspect drugs, viz. he himself and Superintendent Dr. Deshmukh. There is nothing to commend the Dean's *ipse dixit* that he gave oral instructions to the heads of all departments on 27th January that the three suspect drugs must be withdrawn. Not a single head of any department or anyone has come forth in corroboration for that matter. On this own admission the Dean did not even know that the killer glycerol was administered till 28th January or that all the wards had not received his circular. He knew nothing, he did nothing and was good for nothing.

12. Superintendent Dr. Deshmukh's track record is no better. His evidence makes equally bizarre reading. Taking his evidence at face value, it is manifest that after he received Dr. Palande's frantic telephone call on Saturaday, the 25th at mid-day, like the Dean, he too did nothing. Even assuming what Superintendent Dr. Deshmukh says is correct, namely that on Saturday, the 25th January he did tell Dr. Palande over the telephone to inform the Dean and Medical Store, that by itself shows that there by the Superintendent abdicated his duty and responsibility of doing himself what he told Dr. Palande to do. It was for the Superintendent himself to have brought the emergent situation to the notice of the Dean. The Superintedent failed to do so. It was for the Superintendent himself to have given instructions to Medical Store, for it was the Superintendent and not Dr. Plaande, who had the requisite authority to order Medical Store to stop further supplies to the wards and to recall the supplies already made. All this, on the showing of the Superintendent himself, he failed to do.

13. There emerges from his own lips a course of conduct which like the Dean's borders on the grotesque. He resides in the campus itself. On Saturdays he does not attend the Hospital and stays at home or visits the wards or the operation theatres. The first is nearer the truth because surprisingly enough on that fateful Saturday despite Dr. Palande's telephone call to him he stayed at home. The specious excuse that he gives is that necessary action had been taken by the doctors concerned. He compounds negligence and dereliction of duty by the brutality of his observation that every death that takes place is no signal for him to rush to the Hospital, and that there was nothing he could have done about the deaths which had already taken place. Of course, he had to admit the obvious, namely that every death does not take place due to drug reaction nor does drug reaction take place everyday in the Hospital, that the deaths reported to him by Dr. Palande over the telephone that afternoon were unusual deaths. Even so Superintendent Dr. Deshmukh like the Dean moved not a finger to prevent dissemination of the suspect drugs or recall hem. He cannot be heard he had no power to do so.

14. What is worse, in the afternoon of Saturday the 25th, though Dr. Deshmukh was at home in the campus he refused to take delivery of a letter of that date jointly addressed by Dr. (Mrs.) Sirsat to him and the Dean. That afternoon Dr. (Mrs.) Sirsat had given 2 letters to the sister-in-charge Rozario of the AKD. One letter was from Dr. (Mrs.) Sirsat jointly to the Dean and the Superintendent and the other to the Pharmacology Department. Sister Rozario gave those letters for delivery to ward-boy Gautam Pawar in the A.K.D. who was free. The letters were not put in an envelope. They were open letters. Both the letters came back. The Pharmacology Department was closed and when the ward-boy Pawar offered to Superintendent at his residence the letter intended for him, he refused to accept it. Pawar thereupon brought back the letters to Sister Rozario who told Dr. (Mrs.) Sirsat why these letters had come back.

15. I do not believe Superintendent Dr. Deshmukh when he says no such letter was sought to be delivered to him. There is no reason, and none was suggested by Dr. Deshmukh himself, why ward-boy Pawar, Sister Rozario and Dr. (Mrs.) Sirsat should conspire against him. It is true that Pawar is no longer at the J. J. Hospital. Even so he had his roots there; he was born in the campus and his father was for several years working in the J. J. Hospital. He had no animus against the Superintendent. He had no reason to falsely implicate him. For that matter neither had Dr. (Mrs.) Sirsat nor Sister Rozario, who are even today at the J. J. Hospital of which even today Dr. Deshmukh is the Superintendent. Dr. Deshmukh's refutation of the attempted delivery of this letter is false and is a cover-up for his insensitivity in refusing it.

16. According to Superintendent Dr. Deshmukh he functioned only in the absence of the Dean. Hence according to him even though his post might be equivalent to that of a Civil Surgeon of a district and even though he is supposed to be on duty day and night, it was for the Dean to take steps in an emergency. Pray, then what was the necessity for Dr. Palande's frantic telephone call to the Superintendent? Why did the Superintendent not tell Dr. Palande that he, the Superintendent, was powerless. What then is the necessity for the Superintendent to have his residence in the campus itself unless it is to enable him to be at hand round the clock? If in an emergency the Superintendent does not respond, why is he there at all? I shall not pause to comment at any length on the absurdity of such protestations. Dr. Deshmukh did not even bother to call up the Dean and ask for instructions, as the Superintendent being in the campus would be the man on-the-spot. In the morning of Saturday the 25th, he stayed at home and went for shopping in the afternoon.

17. What is even worse is that the following day, Sunday the 26th, after the flag-salutation ceremony was over, the Superintendent told Dr. Palande that nothing could be done until Monday, namely the following day. Till Sunday, the 26th, Superintendent Deshmukh did not even know the names of the suspect drugs. On Monday, the 27th also the Superintendent did nothing. Dr. Kripalani wrote his letter that day (Exhibit 6) to the Dean and the Superintendent urging them to take action. This letter was not even attended to by the Superintendent. Ex. 6

18. Neither the Dean nor the Superintendent did anything to identify the drugs from 25th, right until the time the killer drug was identified and that too by somebody else. They did nothing to withdraw the drugs except for a belated routine circular sent by the Dean in the afternoon of 27th. They did not bother to find out if any follow-up action was taken, much less take it themselves, or to ascertain whether the circulars were acted upon or even received by all the wards. The Dean did nothing for any practical purpose and the Superintendent did nothing for any purpose.

19. Now what does one say to such conduct established from the lips of the Dean and the Superintendent themselves, not pawns but the highest authorities in the Hospital. The captain and his lieutenant failed in their duties and abdicated their responsibilities and abandoned ship in the hours of crisis.

20. These two worthies were as negligent, inefficient, brutal, cynical and lazy in doing their duty, as they were incalculable in their capacity for shrugging off responsibility, knowing neither thought nor remorse. They are unfit to hold any post involving responsibility.

21. Coming to the doctors and the para-medical and other ancillary staff, the evidence does not disclose any negligence on their part either in identifying or withdrawing the offending drug.

22. All the 14 deaths which took place were from Neurosurgery, Neurology and Ophthalmology Departments. All the 14 patients suffered mainly from diseases of the brain or eyes. The treatment included administration of standard drugs prescribed by standard text books and administered for a number of years the world over, including the J. J. Hospital. One of such drug is standard medicinal glycerol given orally. There was no existing renal disease in any of the patients nor did they exhibit any symptoms which could have attracted renal diseases. A state of shock may attract renal failure. However none of the 14 patients who had died were in a state of shock to which renal failure could be attributed. Yet, for no apparent

reason all the 14 coming from 3 different departments developed manifestations of nephro toxicity resulting in—

1 death from Neurology,

7 deaths from Neurosurgery (3 had brain injuries and 4 had brain tumor),

6 deaths from Ophthalmology (these patients suffered from various eye diseases). Out of these 14 patients 13 were male and one female; the youngest was aged 10, the eldest 75. All of them succumbed, irrespective of sex or age.

23. The early clinical manifestations of nephro toxicity appeared within 1 to 7 days after the first exposure to nephro toxic chemical. Diethylene glycol is a nephro toxic chemical used for industrial (and never for medicinal) purposes. In all these 14 patients the average time was 4 to 5 days when the early clinical manifestations of nephro toxicity made themselves manifest, namely ;—

Vomitting	.. 8 cases
Gastrointestinal bleeding	.. 2 cases
Abdominal pain	..2 cases
Gourding and rigidity of abdomen	.. 1 case
Abdominal distension (Diarrhoea)	.. 1 case
	14 cases

These are normal reactions. Within the average time of 4-5 days of the manifestation of these symptoms, it would cross no one's mind that they could be caused by a spurious or sub-standard drug, much less would anyone think of identifying the drug. So far so good.

24. However after these early manifestations, the manifestations of renal failure appeared in an average time of 2-3 days. In 13 cases the manifestations of renal failure occurred in the following forms :—

Oliguria (Secretion of less urine in relation to fluid intake.)	.. 1 case
Oliguria and anuria (Urine output of less than 100 cc in 24 hours.)	.. 11 cases
Raised urea	.. 12 cases
Acidosis (Presence of acids in blood beyond normal limit.)	.. 5 cases
Unstable blood pressure	.. 1 case

These were renal manifestations suggestive of kidneys being affected. Deaths occurred within 1 to 5 days from these renal manifestations and the average of these deaths was 3 to 5 days.

25. The early normal reactions, namely gastrointestinal bleeding, abdominal pain, gourding and rigidity of abdomen and abdominal distension were suggestive of the alimentary system being affected (i.e. from mouth to anus).

26. The manifestations of symptoms of renal failure due to a defective drug must in these circumstances have been farthest from the mind of any doctor or medical staff. They had no reason to doubt, much less suspect, that the drugs indented by the J. J. Hospital and administered to the patients were not of standard quality. For that matter, there was no previous incident in India of renal failure having been caused by drug contamination. It is true that in 1937 in the U.S.A. and in South Africa in 1969 there were cases of renal failure caused by drug contamination. However there is nothing to suggest that the doctors or the medical staff of the J. J. Hospital attending to these patients were aware of those cases or had the slightest inkling that the drug prescribed by them and administered under their instructions were any other than the normal standard drugs and particularly glycerine which in its standard form is the most innocuous of all and which for years on end was used in the J. J. Hospital, as indeed it is the world over.

27. Acute renal failure followed within 3 days after the symptoms of renal failure made themselves manifest. It is this acute renal failure that led the doctors to diagnose the damage to the kidneys. The patients were immediately put on the only remedial step known to medical science-dialysis. The manner and the promptness with which dialysis was done, cannot be faulted. The credit must go to Dr. A. L. Kripalani and his Nephrology team. Full marks to Dr. Kripalani, Dr. (Mrs.) Sirsat and their team in Nephrology.

28. The doctors and the medical staff did not, as indeed they could not, know the cause of the damage to the kidneys because in the Neurology and Neurosurgery departments, acute renal failure is not entirely unknown. In fact in these two departments, it is a common occurrence.

29. In Opthalmology renal failure can never appear due to any form of treatment given in that department. If such a case had occurred in Ophthalmology to the knwoledge of Nephrology it would have put the latter to inquiry for such an unusual occurrence. The first case of renal failure took place in Ophthalmology on 22nd January 1986 in the case of Bittal Kevat. Even so suspicion did not, as indeed it could not, fall upon any drug contamination because Bittal Kevat was a surgical case where kidney failure is not unknown, and was transferred to Ward No. 19 (Surgical) as he had abdominal pain.

30. It was only when the first 5 to 6 cases of renal failure took place that the doctors started regarding it as something unusual. Their suspicions deepened when more cases of renal failure occurred in Ophthalmology. And after 2 such subsequent occurrences they became almost certain that the kidney disease was hospital-acquired. It must indeed stand to the credit of the doctors that they became certain merely from the analysis of the case papers which showed that the common drug given to all the 14 patients who succumbed was glycerol Batch No. 27. Even so they were under the impression (for which no fault can be found with them) that the renal failure was an untoward reaction to a normal standard drug and not to any substandard or contaminated drug which in their slightest imagination they never thought the J. J. Hospital would purchase-least of all a drug contaminated with a lethal nephrotoxic chemical such as diethylene glycol.

31. It was at the meeting on 28th January in A.K.D. that Dr. (Mrs.) Worlikar suggested that the mischievous drug could be glycerol as could have been contaminated with glycol. Dr. Kripalani concurred. For this the credit must go to Dr. (Mrs.) Worlikar.

32. Even so the first factor which pinpointed and confirmed the drug being contaminated with a lethal chemical became possible only after post mortem examinations were carried out. Except for Bapu Thombre whose death took place on 21st January, the other deaths took place on and after 24th January, namely—

On 24th January	..	..	.. 2 deaths
On 25th January	..	..	.. 2 deaths
On 27th January	..	..	.. 1 death
On 28th January	..	..	.. 2 deaths

Suspicion was confirmed only when the postmortem results were made available, the first being on 29th January pertaining to Tanveer Baig. Credit must go to Dr. Kripalani for his insistence on post mortems. Credit must also go to Dr. Wagholikar and his staff who performed the autopsies with meticulous diligence and exactitude, even to the extent of preparing photo documentation. Credit must also go to Dr. Palande and again to Dr. Kripalani and Dr. Wagholikar in identifying the fatal drug and thereby preventing further casualties.

33. In these circumstances, it is manifest that prior to 29th January, it was not possible for the doctors or the medical staff to have identified the killer drug.

34. All this is brought to the forefront by the evidence of Dr. Bhagwati [p. 390-(12-14)]; Dr. Kripalani [p] 793 (11), p. 797 (15), p. 798 (16)]; Dr. Palande [p. 683-684 (11), p. 685 (13), p. 693 (28)]; Dr. [Mrs. Sirsat [p. 727 (26), p. 728 (28), p. 744(67)]; Dr. Shaligram [p. 280 (7)]; Dr. Panda [p. 323 (28), p. 324 (32), p. 326 (39)] and Dr. Virani [p. 340 (48-49)].

35. There is overwhelming evidence to indicate that neither Dr. Palande, nor Dr. Bhagwati's Unit No. I, nor Dr. Virani's Unit No. II (Neurosurgery), nor, Dr. Katrak's Neorology Department (Unit No. II) could have suspected glycerol, an otherwise innocent drug, as the killer drug. To that end, hereunder the following particulars.

Name of patient	Refereed to Nephrology on	Date of death
Hemant Ranade (Dr. Bhagwati's patient) ..	20-1-1986	24-1--1986
Ramesh Shinde (Dr. Virani's patient) ..	Do.	Do.
Bapu Thombre (Dr. Bhagwati's patient) ..	Do.	21-1-1986
Tanveer Baig (Dr. Katrak's patient) ..	21-1-1986	25-1-1986
Bittal Kevat (Patient of Dr. Hingorani-Unit II. He came via Ward 19 (surgical) suspected to require abdominal operation).	22-1-1986	27-1-1986
Vithal Gharge (Dr. Virani's patient) ..	Do.	Do.
Shailendra Joshi (Dr. Virani's patient) ..	23-1-1986	28-1-1986
Vithal Bhokare (Dr. (Miss) Kamble's Unit No. I.)	24-1-1986	25-1-1986
Sopan Tawar (Dr. Virani's patient) ..	Do.	28-1-1986
Rajendrakumar Mishra (Dr. (Miss) Kamble's patient.)	25-1-1986	30-1-1986
Ramji Balu Kasar (Dr. Bhagwati's patient')	26-1-1986	1-2-1986
Abdul Kadar Shaikh (Dr. Hingorani's patient)	Do.	2-2-1986
Dawood Dholakia (Dr.(Miss) Kamble's patient) Discharged against medical advice on 6th February 1986.	28-1-1986	In the night of 7/8-2-1986

36. The summary of the above is that prior to 24th January 1986, 7 cases were referred or transferred to Nephrology. In the morning of 24th January 1986 Hamant Ranade died. Later the same day, Vithal Bhokare and Sopan Tawar were referred to Nephrology. In the morning of 25th January Tanveer Baig and Vithal Bhokare died and Rajendrakumar Mishra was referred to Nephrology. On 26th January, Ramji Kasar and Abdul Kadar Shaikh were referred to Nephrology. On 27th January Bittal Kavat and Vithal Gharge died. On 28th January Dawood Dholakia was referred to Nephrology. The same day, Shailendra Joshi and Sopan Tawar died. On 30th January Rajendrakumar Mishra died. On 1st February, Ramji Kasar died. On 2nd February Abdul Kadar Shaikh died. In the night of 7th/8th February Dawood Dholakia (who had been discharged against medical advice on 6th February 1986) died. These aspects bring to the forefront that until the killer drug, namely glycerol Batch No. 27, was actually identified as such, neither the Neurology nor Neurosurgery had or could have had the slightest inkling as to the lethal nature of glycerol, an otherwise harmless drug. In these circumstances, the part of question(c) insofar as it pertains to identifying the offending drug, must be answered in the negative.

37. Coming to the latter part of question(c) pertaining to the prompt withdrawal of the offending drug, there is overwhelming evidence which indicated that at the earliest point of time, namely 25th January, everyone connected with the Neurology and Neurosurgery Departments were convinced that it was dangerous to use the 3 suspect drugs and they could not be used. For that matter, in Neurosurgery and Neurology, instructions had been given at the earliest piont of time, namely 25th and 26th January 1986 respectively for the withdrawal of the 3 suspect drugs from that day onwards and the 3 suspect drugs were in fact withdrawn. To these 2 departments must go the credit for promptly withdrawing the suspect drugs.

38. As against that the responsibility for failure to withdraw the suspect drugs must fall squarely on the Dean Dr. Chandrikapure and Superintendent Dr. Deshmukh. I need not repeat what I have already stated about them earlier in this Report. However on this aspect I shall add a rider.

39. The Dean must take his fair share of negligence and dereliction of duty in failing to promptly withdraw the suspect drugs. It was his duty to do so. In that duty he failed. In a shoddy attempt to vindicate his total intertia, he took shelter under Clause (1) of Government Resolution dated 23rd July 1974 (Exhibit 5), Ex. 5 which sets out the duties and responsibilities inter alia of Deans. Clause (1) of that G. R. states.——

"He will be responsible for order, discipline and efficient management of the ..... Hospital, subject to the control of the Director of Medical Education and Research and will carry out the executive duties connected with the administration of the.....Hospital....."

According to the Dean, withdrawing of a drug did not form part of his duties as it did not embrace "efficient management of the.....Hospital". I fail to see how such a construction can possibly be placed by the Dean on these words, except to lay unction on his own conscience. I fail to see how the Hospital can be efficiently managed if the highest authority in that Hospital (and in this case the Dean of the J. J. Hospital) did not consider it his duty to withdraw a spurious or otherwise, offending drug in the interest of the patients for whose care and well being the Hospital is intended, and whose care and well being should have been the Dean's primary concern.

40. Similarly the Dean cannot wash away his responsibility and failure in withdrawing the suspect drugs merely on the excuse that the patients were in the charge of competent doctors. Doctors attending a patient can at best not administer a spurious or defective drug but they cannot super-impose their authority over that of the Dean in ordering its withdrawal from the entire Hospital. It was indisputably the primary duty of the Dean to have ordered the immediate stoppage and withdrawal of the 3 suspect drugs and ordered their being taken charge of and sealed and to have prevented further dissemination. In this essential, vital duty, the Dean lamentably failed. It was a gross administrative dereliction on his part, which no amount of self-justification can avail him.

41. Likewise Superintendent Dr. Deshmukh must also take his fair share of negligence and dereliction of duty in failing to promptly withdraw the suspect drugs. I use the word promptly out of politeness, for in fact, he took no steps at all. He too, like the Dean, did nothing which is amply demonstrated by the evidence of the Superintendent himself. He admits that at about mid-day of 25th January 1986, Dr. Palande telephoned him and told him that there had been a few cases of adverse reaction to certain drugs and asked him what action should be taken. It was the first time that he came to know of the drug reaction in J. J. Hospital. According to the Superintendent, he told Dr. Palande to take 4 steps immediately, namely (1) inform the Dean, (2) stop all these drugs, (3) inform the Medical Store and, (4) take charge of drugs in Dr. Palande's custody. Dr. Palande told the Superintendent that he had already taken those steps. The Superintendent thereafter goes on to say that the same day at about 3.00 p.m. Dr. Palande again told him that the the four steps which the Superintendent had suggested had already been taken and that the Dean was informed by Dr. (Mrs.) Sirsat about the adverse drug reaction. Thereupon the Superintendent did not take any action. The Superintendent goes on to say that the following day, namely Sunday the 26th January (Republic Day), at the flag-hoisting ceremony the Dean asked Dr. Palande and the Superintendent if the suspect drugs had been stopped whereupon Dr. Palande and the Superintendent replied in the affirmative. Until then the Superintendent had not been informed which were the suspect drugs but from the 5-minute discussion between him, Dr. Palande and the Dean that day he came to know that they were mannitol, glycerol, gentamycin and diamox.

42. Regarding Dr. Kripalani's letter dated 27th January 1986 (Exhibit 6) to the Ex. 6 Professor and Head of Pharmacology, a copy whereof was marked by Dr. Kripalani to the Superintendent, the Superintendent admitted that he did not take the two steps desired by Dr. Kripalani in his letter because it did not fall within his jurisdiction to do so and because the letter was addressed to the Professor and Head of the Pharmacology Department. This is a surprising explanation coming from a presumbly responsible second highest authority of the J. J. Hospital. If this was so, what was the necessity of Dr. Palande telephoning the Superintendent on the 25th or Dr. Kripalani sending a copy of Exhibrt 6 to the Superintendent. Surely it stands to reason that they did so because the Superintendent himself, residing in the campus, would be entitled to take the matter in his own hands and forthwith issue the requisite

circulars. The mental make up of the Superintendent is revealed from his own lips when he says that naturally he was perturbed and disturbed when he came to know of drug reaction from Dr. Palande's telephone call on 25th January but this state of disturbance and perturbation lasted but a few minutes and when he read Dr. Ex. 6 Kripalani's letter (Exhibit 6), the Superintendent's state of disturbance and perturbation had passed.

43. The Superintendent agreed that drug reaction particularly in a large hospital like the J. J. Hospital would be a matter of grave concern. Even so he had no conversation with the Dean after reading Dr. Kripalani's letter (Exhibit 6) because according to the Superintendent the Dean had been apprised of the entire situation by Dr. (Mrs.) Sirsat's telephone call of the 25th and because the Dean had a discussion with him on 26th. He also admits that after reading Dr. Kripalani's letter (Exhibit 6) he had no conversation with Dr. Kripalani because the Dean was taking the necessary step; he left it all to the Dean. The Dean however did not tell him that he was taking any steps but the Superintendent was watching what was going on. The Superintendent ultimately had to admit—

" ....I did not take any concrete steps, or for that matter, any steps at all."

44. The above evidence of the Superintendent and ultimately his pathetic admission that he took no steps whatsoever must put beyond the pale of controversy, the Superintendent's total negligence and dereliction of duty in withdrawing the suspect drugs.

45. It is futile for the Superintendent to say that though in the administrative management of the J. J. Hospital and in hierarchy he is immediately after the Dean, it is only in the absence of the Dean that he takes administrative decisions, that drug reaction would not be an administrative problem and that in a situation such as the present he would consider it within his function merely to advise the stoppage of suspect drug suspected of causing reaction.

46. Excuses, excuses and more excuses, when faced with his inexorable negligence in taking no action whatsoever for withdrawing the suspect drugs.

47. Even assuming drug reaction as commonly understood is not an " administrative " problem, ordering the withdrawal of a spurious or offending drug was an administrative matter within the cognizance of the Superintendent. To confuse " administrative problem " or " administrative decisions " with lack of basic humanity is a mistake.

48. The Superintendent says that when Dr. Palande told him that he had taken the requisite precautions, the Superintendent assumed that Dr. Palande had done so in his own unit and that Dr. (Mrs.) Sirsat had done so in her own unit (namely Nephrology). Even assuming any such assumption on the part of the Superintendent was justified, there was nothing for him to assume that drugs had been ordered to be withdrawn from the other departments and particularly from Ophthalmology, where the killer glycerol had been administered till 28th January.

49. To explain away his failure in ordering withdrawal of the suspect drugs, the Superintendent seeks to equate his post to that of a Civil Surgeon whose main duties are (*a*) to be in charge of the hospital for technical and administrative duties, (*b*) to pay periodical visits to medical stores guiding medical officers in the medico-legal wards, (*c*) examination of candidates sent for medical examination, (*d*) to be in charge of national programmes, (*e*) to inspect subordinate hospitals, etc. The Superintendent loftily says it is not the duty of the Civil Surgeon to attend to all emergencies at odd hours but admits that in the case of a problem or emergency connected with the hospital, the Civil Surgeon is bound to attend to it even on bank holidays and at odd hours, if informed. After equating his post to that of a Civil Surgeon, Superintendent Dr. Deshmukh does a volte-face and says that his duties at the J. J. Hospital were not the same as those of the Civil Surgeon because the latter is in-charge of the entire institution which the Superintendent is not. He would consider drug reaction in a Hospital to be a serious matter depending upon the degree of the reaction of the drugs and the number of persons who died as a result of the drug reaction (on a given day). According to him, a sufficient number would be 4 or 5 persons dying of drug reaction. And even if there was no casualty but a sufficient number of patients were affected by drug reaction, he would consider it to be a serious problem. He does not consider 5 patients to be a sufficient number but over 5 patients would be a serious problem. Unadulterated rubbish.

50. After spouting all this nonsense, he admitted that if a drug is contaminated, spurious, adulterated or otherwise substandard, he would consider even 2 cases of reaction to be a serious problem. He also admitted that if as a result of his enquiries he found that the problem was urgent, he would ask that the suspect drugs be stopped, would inform Medical Store about it and ask the doctor concerned to inform the Medical Store about the drug reaction. Then pray, why did he not do all this?

51. According to him the nature of his powers are limited. According to him as Superintendent he only performed glorified clerical jobs (taking the phraseology from p. 3 of the Project Report on the J. J. Group of Hospitals, 1973, Exhibit 25).

52. I do not agree that the Superintendent is a glorified clerk. This self-denigration by the Superintendent is not out of self-pity for lack of authority but is a desperate endeavour to absolve himself from his responsibility, his negligence and dereliction of duty in not withdrawing the suspect drugs. He is expected to be on duty round the clock. Instead of doing his duty the Superintendent even went to the length of refusing to accept the letter dated 25th January 1986 sent to him by Dr. (Mrs.) Sirsat which was sought to be delivered to him by the ward-boy Pawar at the behest of Sister Rozario. When he received Dr. Palande's telephone call on the 25th he knew that the Medical Store was open.

53. At no time did Superintendent Dr. Deshmukh raise a little finger to have the suspect drugs withdrawn. Even though when Dr. Palande telephoned him on 25th, he knew that Medical Store was open, he did nothing. In his own words, he was watching. And while he watched the patients died.

54. Finally came the admission from reluctant but not repentful lips that irrespective of power or authority, he did not want to take any action on what had been told to him by Dr. Palande in the morning of 25th January.

55. Nothing more need be said, self-condemned as the Superintendent does stand.

56. Nor can pharmacist Jamadagni be absolved of his responsibility in not promptly withdrawing the suspect drugs. Despite Dr. Palande's warning to him on 25th January, he did not bother to obtain or even attempt to obtain the requisite authorisation either from the Dean or from the Superintendent even though the Superintendent resides in the campus and was at his residence that day, and even though on 25th January itself Jamadagni knew that alternate supplies were required. As a pharmacist Jamadagni knew or should have known that alternate supplies are not suddenly called for unless something is radically wrong with the drug on hand. Even though the Professor of Pharmacology Dr. Shaligram resides in the campus, Jamadagni did not bring or attempt to bring this fact to Dr. Shaligram's attention. Jamadagni also did not even bother to contact Dr. (Mrs.) Worlikar who is his immediate superior. Aa a pharmacist Jamadagni knew or should have realised the gravity of the situation on Saturday the 25th. Yet on that date he shut shop as usual at 12 noon and went home.

57. Even on Monday 27th January though pharmacist Jamadagni came to the Medical Store at 9-00 a.m. he did his usual work till 2-00 p.m. when he received Dr. Kripalani's letter of that day (Exhibit 6) addressed to the Professor and Head of Pharmacology with a copy to the Dean and the Superintendent. Jamadagni, read that letter wherein Dr. Kripalani had brought it to the pointed attention of the Professor and Head of Pharmacology that a large number of patients had developed sudden onset of anuria in the past week, that all of them had been on anitoedema measures, namely mannitol, diamox and glycerol and that the fatality rate was very high despite vigorous dialysis. In this letter, Dr. Kripalani made a request that these drugs should be checked and that all the stocks should be replaced immediately. The letter ended with the exhortation that the matter be treated as very urgent. At the foot of this letter, Dr. (Mrs.) Worlikar made an endorsement to, Jamadagni to notify all wards and to stop the use of the 3 drugs mentioned in that letter. In this letter there was also an endorsement by Dr. Kripalani that all patients had come from Wards 23, 24 or 25 (*i.e.* Neurology and Neurosurgery), that out of 10 such cases, 6 had died and that post mortem had been done on all. Pharmacist Jamadagni read this letter and what did he do? Nothing. He read Dr.(Mrs.) Worlikar's endorsement to him notify all wards and to stop the use of the 3 drugs. What did Jamadagni do? Nothing. Ex. 6

58. There is no doubt that Jamadagni knew the seriousness of the situation in the afternoon of 25th itself when Dr. Palande asked him for replacement of the suspect drugs. As a pharmacist, he should know that drugs are not lightly replaced unless something is radically wrong with them. Yet in the morning of 27th pharmacist Jamadagni issued 25 bottles. Assuming however that he came to know of the gravity of the situation even in the afternoon of 27th January by reason of the circular which Dr. (Mrs.) Worlikar dictated to him, he did not send anyone to collect the suspect drugs from the wards until 30th January. It is not as if he had to send someone to all the 40 wards in the Hospital but only to 3 departments, namely Neurosurgery, Neurology and Ophthalmology, where the suspect drugs were and which Jamadagni could have found from the records in Medical Store. If this had been done the glycerine would not have been used in Ophthalmology till 28th January. Even after he received the circular of 27th January he took no steps to withdraw the 25 bottles which he had issued in the morning of 27th. Even after
Ex. 6 reading Dr. Kripalani's letter (Exhibit 6), he made no enquiry either from Medical Store or from the floor pharmacies whether the 3 suspect drugs had been supplied to any of the wards before Dr. Kripalani's letter came to his notice. The excuse given by him is that he was busy drafting the stoppage circular to the wards. Surely it did not take him days on end to draft that circular.

59. There is no doubt that in any event, Jamadagni was aware of the gravity of the situation on 27th when Dr. (Mrs.) Worlikar came to Medical Store and dictated the stoppage circular to him that day.

60. The totally slipshod manner in which pharmacist Jamadagni go the withdrawals from the various wards is borne out by the slipshod manner in which the bin cards have been maintained. No regular entries were made as and when the bottles were returned to Medical Store. Apparently they were just dumped in one place without any tally and on 6th February 1986 compounder Soudi made a
Ex. 39 consolidated entry of glycerine in the bin card (Exhibit 39) that 182 bottles were received from the wards. Out of these 182 bottles 106 were of Batch No. 27. According to the bin card, 37 bottles of Batch No. 27 were lying unused in Medical Store. It is therefore uncertain whether the 106 bottles included those 37 bottles or not. Perhaps they did because on 13th February 197 bottles were sealed, out of which 106 bottles were of Batch No. 27. The consolidated entry on 6th February 1986 in the bin card was prepared for the benefit of the Choube Committee, as by then that Committee had been appointed. Perhaps if that Committee had been appointed later, the consolidated entry would also have been made later.

61. From the haphazard and slipshod way in which the bin cards are maintained, it is not possible to say even today if all the bottles were returned to Medical Store, despite the fact that by 6th February 1986 glycerol had been identified as the killer drug. To illustrate, 4 bottles of Batch No. 27 have been shown to have been received by Medical Store in the bin card from Ward 38-B on 28th Janaury 1986, whereas the same 4 bottles are shown to have been received by Medical Store on 6th February 1986. This, says compounder Soudi is a mistake. Greater the reason therefore that adequate mesures should have been taken to ensure that each and every bottle of glycerol, Batch No. 27, issued by Medical Store to the wards returned back to Medical Store. Even the sealing of the reutrned bottles in Medical Store was not done till 13th February 1986 being the date of the Cabinet decision. To this day, there is no complete account of the withdrawal of Batch No. 27 which can be accounted for.

62. For that matter, there is Jamadagni's admission that there was no proper accounting of glycerol bottles, that he himself could not say if some bottles are still lying in the wards, that there is no written record of the number of bottles sent from Medical Store and how many bottles were consumed. There is his evidence that there were no red entries in the bin card until 6th February 1986 (namely till after the Choube Committee started its first sitting on 3rd February 1986). It is therefore manifest that the red entries in this bin card have been made after 6th February 1986. Jamadagni has further admitted that the maximum use of glycerol was in 3 wards, namely Neurology, Neurosurgery and Ophthalmology. Even so, on his own admission, he took no steps till 29th January 1986 to recall the glycerol from any wards, including these 3 departments. Jamadagni cannot wish away his responsibility merely by his assertion that even in cases of adulterated and contaminated drugs it is not the practice of Medical Store to have drugs collected from the wards because the responsibility to do so is on the wards.

63. Jamadagni's nelgigence and dereliction of duty in not promptly withdrawing the suspect drug is established.

64. There is overwhelming evidence of dereliction of duty on the part of the Pharmacology Department in not withdrawing the suspect drugs promptly. Medical Store is under the Pharmacology Department. On Monday the 27th, Pharmacology Department concerned itself with collecting data, looking up textbooks and conducting experiments on animals. No doubt all this was laudable but for the fact that the priorities got mixed up as the first normal reaction and expedient of prudence and urgency demanded preventing Medical Store from further disseminating the suspect drugs and to recall them from the wards. No one from the Pharmacology Department though of doing anything of the kind or of physically taking charge of the suspect drugs from the affected wards or sealing the remaining stock in Medical Store. For that matter on 27th Medical Store issued 25 bottles of Batch No. 27. Even the stoppage circular dated 27th, January (Exhibit 8) sent by pharmacist Exh. 8 Jamadagni after 2-45 p.m. to the various wards was a terse handwritten note as under :—

"Please stop the use of the following drugs immediately—

Inj. Mannitol	B. No. 5059 Mfg. by Haffkine.
Glycerine	B. No. 27 Mfg. by Alpana.
Tab Acetazolamide	B. No. A2 Mfg. by Vikas Pharam.

with immediate effect."

The nurses in the various wards had to sign this circular and were inexplicably expected to memorise the names of the manufacturers, the suspect drugs and batch numbers. The dire urgency of the situation was not reflected in this circular. The words " with immediate " effect convey nothing of the suspicion that the drugs are not of standard quality. Dispute with the suppliers, say over charges, could also be a cause for immediate withdrawal. This was a most undesirable way of stopping administration of the suspect drugs. The receiving nurses could not even keep this circular and were expected to pass on its contents to the relieving nurses. On the contrary, every ward should have been given a copy of this important circular because that would have eliminated all chances of receiving nurse's failure to pass on the message to the relieving nurse. The circular doses not even bother to say why the 3 drugs mentioned therein should be stopped. Nothing has been mentioned in the circular which would read as a warning that the drugs mentioned therein should not be used as they were suspected to be contaminated. It is inconceivable that such a perfunctory circular should have met with the approval of Dr. (Mrs.) Worlikar and Dr. Shaligram, as it did. They were satisfied that by issuing such a terse and almost meaningless circular, the Pharmacology Department had done its job.

65. This is not all. The Pharmacology Department was in duty bound to have immediately informed the FDA on the 27th instead of 28th January 1986.

66. No attempt was made by the Pharmacology Department on 27th itself to ascertain from the records as to which wards the suspect drugs were sent and would be found. This could have been done by referring to the bin card, and the written indents received by the Medical Store from the wards. However inexplicably no one thought of that simple expedient. If this had been done, though advisable, it might not even had been necessary to go to each and every ward for a physical check which exercise of course no one ever bothered to embark on. Till this day its not possible to know for certain whether all bottles of Batch No. 27 were in fact returned by the wards to Medical Stores and it is not unlikely that bottles of Batch No. 27 may still be lying in the wards, though hopefully not.

67. If this is not negligence and dereliction of duty, pray, what is ?

68. Nor can the Professor of Pharmacology Dr. Shaligram be obsolved of his negligence and dereliction of duty in not promptly withdrawing the suspect drugs. For that matter he did nothing in that direction, taking shelter behind the skirt of Dr. (Mrs.) Worlikar (Associate Professor of Pharmacology) and throwing the responsibility on her.

69. There is Dr. Shaligram's evidence that at about 2-00 p.m. on 27th January he came to know that several patients had developed anuria and that the mortality rate amongst them was quite higher. At about 2-00 p.m. that day Dr. (Mrs.) Worlikar

Ex. 6 came to him with Dr. Kripalani's letter (Exhibit 6). There was some talk between him and Dr. (Mrs.) Worlikar as to what was to be done. He told Dr. (Mrs.) Worlikar that several of the anuria cases were from Neurosurgery, that they seem to be post-operative cases, that anuria is not uncommon in such cases and that unless there is any other cause for anuria, most anuria cases recovered. He further told Dr. (Mrs.) Worlikar that since Dr. Kripalini's letter mentioned that 6 out of 10 anuria patients had died, it was a serious matter and that as desired by Dr. Kripalani, the drugs mentioned by him would be stopped. He told Dr. (Mrs.) Worlikar to write to Dr. Kripalani that they were complying with his demands and that they would need more information, that they would inform the FAD as also Dr. R. D. Kulkarni.

70. Dr. Shaligram however seeks to absolve himself from all responsibility and throws the blame on Dr. (Mrs.) Worlikar on the ground (1) that he was not in-charge of Medical Store (2), officially he had nothing to do with Medical Store and (3) that it was not his duty or function to exercise any control over Medical Store which he seldom visited and never gave instructions to.

71. To that end, he is directly contradicted by the evidence of Dr. (Mrs.) Worlikar (Associate Professor of Pharmacology) when she says that as far as Medical Store was concerned, she had to report to Dr. Shaligram if she had any problem and that Dr. Shaligram would periodically convene meetings to review the position if there was any problem regarding any drug. While she visited Medical Store every day or in any event every alternate day, except on Saturdays and Sundays, Dr. Kulkarni and Dr. Shaligram visited Medical Store occasionally. In this she is corroborated by Dr. Kulkarni.

72. The attempt of Dr. Shaligram to absolve himself by dissociating himself from Medical Store is as unworthy as his attempt to throw the blame on his Associate Professor Dr. (Mrs.) Worlikar. A man who takes shelter behind a woman is less of a man and more of a coward. In the meeting of 28th January which took place in Dr. Kripalani's Nephrology Department, Dr. Shaligram was also present, along with Dr. (Mrs.) Worlikar, Dr. Bhagwati, Dr. Palande, Dr. (Mrs.) Sirsat, Dr. (Miss) Kamble, Dr. (Mrs.) Mujumdar and Dr. Kripalani. At this meeting, Dr. Shaligaram informed the persons assembled about the receipt by him of Dr. Kripalani's letter
Ex. 6 dated 27th January 1986 (Exhibit 6); that he had stopped the drugs and that they had assembled to discuss what was happening to the patients. There is no reason why Dr. Shaligram should have stated at that meeting that he had stopped the drug if he had nothing to do with Medical Store and unless he has in-charge of Medical Store. He would not have dared attempt a piece of bravado in the presence of his peers who knew who was who and what was what. Further on 31st January, Dr Shali-
Ex. 77 gram made a written Report (Exhibit 77) signed by him to the Dean regarding all the steps which had been taken by Medical Store. There is no reason why he should have done anything of the kind if he had nothing to do with Medical Store and unless he was in-charge of Medical Store. However realising this slip on his part he attempted to give a twist and said that he merely signed the Report at the behest of Dr. (Mrs.) Worlikar because Dr. Kulkarni was busy elsewhere. He did not recollect that there was any urgency in sending this Report to the Dean.

73. He admitted that he did not consider Dr. Kripalani's letter dated 27th January to be frivolous or unworthy of credit, and that Dr. Kripalani, himself a leading doctor, would not take statements without valid reasons. On 27th or even on 28th January, he did not personally make sure that the 3 suspect drugs were not administered to any patient in any of the wards. He admitted that he did consider it imperative to immediately instruct Medical Store not to issue the 3 suspect drugs and also to give immediate instructions to the ward sisters to forthwith stop further administration of these 3 drugs. His excuse however for not doing so was that for the implementation of such instructions he relied on Dr. (Mrs.) Worlikar and pharmacist Jamadagni. He admitted that his post is higher than Dr. (Mrs.) Worlikar's. Even during the presence of Dr. (Mrs.) Worlikar he would not give instructions to Medical Store but he would tell Dr. (Mrs.) Worlikar what was to be done and she would give the requisite instructions to Medical Store and he would ensure from her that those instructions were carried out by Medical Store.

74. Pausing here for a moment, pray why would Dr. Shaligram do so if he was not in-charge of Medical Store? What was the reason or necessity for him to ensure from Dr. (Mrs.) Worlikar that his instructions were carried out by Medical Store

unless he was in-charge of Medical Store? The entire attempt of Dr. Shaligram to dissociate himself from Medical Store and to lay the entire burden on Dr. (Mrs.) Worlikar is far from creditable and must fail.

75. Connected with the evidence of withdrawal of the drugs is the evidence of compounder Soudi. Like Jamadagni, Soudi's evidence also shows that proper records were not maintained by the Medical Store, that contemporaneous entries were not made in bin-cards and other records, and that proper account of the returned bottles has never been done more so in view of the fact that no checking was done. Like Jamadagni, Soudi's evidence also indicates that the records maintained by Medical Store do not inspire the slightest confidence, either in the manner in which they were maintained or their accuracy.

76. Soudi is yet another witness who cannot absolve himself from his fair share of negligence and dereliction of duty in not promptly withdrawing the suspect drugs.

77. He admits after issuing the bin-card, that the entry under date 20th August 1985 shows a balance of 1441 bottles of glycerine, that the next entry under date 21st August 1985 shows a balance of 1440 bottles of glycerine and that it was a mistake in showing one bottle less in the follow up entry on 21st August 1985. He further admits that in the bin-card, 96 bottles of glycerine are shown less between 8th August 1985 and 17th September 1985, than the quantity of glycerine actually in hand and that Medical Store had during this period 96 bottles of glycerine more than what is shown in the bin-card. This he attempts to attribute to these 96 bottles kept aside for want of space and hence by mistake was not being shown in the bin-card. Soudi also admits that all the entries in the bin-card have not been made in respect of the glycerine returned by the wards to Medical Store. This lapse he sought to explain away by saying that the bin-card was lying before this commission. This is a total facetious explanation as the bin-card came to be produced before this Commission several months later. Realising this he attempted by retraction by saying that these entries remained to be made because " a police officer " (whose name he does not know) who came to the J.J. Hospital in the first week of February 1986 told him not to make them. So be it, for whatever both explanations are worth.

78. Soudi goes on to say that 197 bottles of glycerine which were returned by the various wards were kept in a sealed cupboard in Medical Store. Out of these 197 bottles, 106 bottles were of Alpana Pharma's batch No. 27 and out of the remaining 91 bottles 70 bottles were of Alpana Pharma's batch Nos. 19, 20 and 21 and the balance 21 bottles belonged to other suppliers.

79. After consulting the bin-card, Soudi stated that between 27th December 1985 and 17th January 1986, 283 bottles of glycerine were issued by Medical Store to various wards, of these 234 bottles were used in the wards. Thus, 49 bottles of glycerine remained in the wards. However, 197 bottles of glycerine had been returned by various wards to Medical Store which were sealed by Medical Store. He was unable to give any particulars about these 197 bottles. He admitted that all bottles of batch No. 27 had not been released by Medical store to the wards. He was also unable to say whether any bottles of Alpana Pharma including batch No. 27 remained with Medical Store when between 27th December 1985 and 27th January 1986 it issued 283 bottles in the aggregate. He himself never went to any ward to check how many bottles of glycerine were lying there.

80. Soudi tells a deliberate falsehood when he says that entries in the bin-card are made from day-to-day from the indents. This is not so, as revealed to the contrary by Jamadagni's oral evidence and incontrovertible documentary evidence viz. the bin-card itself. Soudi was the only person to make entries pertaining to glycerol in the Issue Register. After 27th January 1986 nobody inspected the Issue Register or the bin-card.

81. Soudi went on to say that on 27th January 1986 the glycerine which was issued by ' D ' Section was Alpana Pharma's glycerine, but even after looking at the bin-card could not say what was the balance of batch No. 27 in ' D ' Section on 27th January 1986. He started by saying that on that day batch No. 27 was issued by Medical Store because there was no other batch of any other supplier with Medical Store. That statement he admitted to be not correct.

82. Soudi admitted that he had not made any record that he had stopped issuing batch No. 27 from 28th January 1986 and had started issuing Chem Pack's glycerine. After looking at the bin card he admitted that he had issued 19 bottles of glycerine

on 28th January 1986 and 5 bottles of glycerine on 29th January 1986 but affected to say from memory that that glycerine was supplied by Chem Pack, which according to him he remembered because on 28th January 1986 he had been instructed to stop the supply of Alpana Pharma's glycerine and to issue Chem Pack's glycerine. Nobody asked him how many bottles of Alpana Pharma glycerine were lying in 'D' Section on 28th January 1986. On that day he did not count the number of bottles lying in 'D' Section nor did he try to ascertain the names of the suppliers.

83. Soudi goes on to say that on 29th January 1986 the wards started returning glycerol bottles of batch No. 27 to Medical Store along with their memos. Those bottles were in Soudi's charge. He admitted that he made all the red ink entries in the bin card on one day viz. 6th February 1986, but tried to justify himself by saying that on 6th February 1986 he was more free from other work and because by 6th February 1986 all the glycerine bottles had been returned to Medical Store. None of this can militate from his negligence in not keeping a contemporaneous record of the returned bottles in the bin card and making the entries on one day viz. 6th February 1986. Soudi finally admitted that 13 bottles of glycerine were received by him from Ward No. 19 on 7th February 1986 and not on 6th February 1986 as written by him in the bin card and that this entry pertaining to these 13 bottles as also all the other red-ink entries were made by him not on 6th February 1986 as shown in the bin card but were made by him thereafter. Even after 6th February 1986 Soudi received glycerine bottles from the wards but failed to enter them in the bin card on the ground that the bin card had been taken away by the FDA or police. Assuming that was so, Soudi should have kept a separate record of such glycerine bottles received after 6th February 1986. He failed to do so.

84. After denying that he had put an incorrect date of 28th January 1986 in the bin card to show that things were done properly, he admitted that when he put that date in the bin card, he did so with realisation that the he was putting an incorrect date in order to show that the sample bottles were given by him to Dr. Kulkarni, FDA, Dr. Kale and Italab on that day. His excuse for putting the incorrect date is puerile, namely that if he had put the correct date on the bin card it would have resulted in making a lot of corrections and interpolations. That was not so because Soudi finally had to admit that the only correction required would have been the correction of the date 28th January 1986.

85. Soudi also admitted that the entries under date 28th January 1986 in the bin card were actually made by him on 7th or 8th February 1986 so as to have a record of how many bottles were given and to whom. He also admitted that he did realise that the record was an incorrect record with another puerile rider that the incorrectness would be in regard to 28th January 1986 only. Even this explanation, such as it is, does not bear scrutiny in the light of his own admission that he considered this not to be a minor but a serious matter and that even so he knowingly put the wrong date of 21st January 1986 in the bin card.

86. Soudi also admitted that the last entry in the bin card pertaining to the return of 4 bottles from Ward No. 38-B was a duplication of an earlier entry but subscribed the duplication as his mistake. So be it.

87. Soudi admitted that all the bottles returned to Medical Store are not accounted for in the bin card. He admitted that the bin card is an incomplete record. He admitted that there is no record to account for all the glycerol bottles sent by Medical Store to the various wards. He admitted that there is no record to account for the bottles returned by the various wards to Medical Store. Soudi also failed in his duty to bring to the notice of Pharmacist Jamadagni or Dr. (Mrs.) Worlikar that all the glycerol bottles issued by Medical Store were not accounted for.

88. Such is not and can never be the manner of maintaining a bin card, particularly in an emergent situation such as this.

89. Apart from anything else, Soudi's own admissions drew him into the net of negligence and dereliction of duty in not promptly withdrawing the suspect drugs.

90. Nor can Dr. (Mrs.) Worlikar (Associate Professor of Pharmacology) absolve hereself of her fair share of negligence and the dereliction of duty in not promptly withdrawing the suspect drugs.

91. She was concerned with the day-to-day supervision of Medical Store. Even though she was alive to the gravity of the situation, it did not strike her to check or get checked from the record of Medical Store how many bottles of glycerine had been issued to various wards. This could have been done by the simple expedient of going through the recent indents received by Medical Store from Neurology, Neurosurgery and Opthalmology. Dr. (Mrs.) Worliker failed to do so or give directions to that end.

92. Dr. (Mrs.) Worlikar gave no information to the FDA at the earliest point of time viz. 27th January but waited till 28th January to do so as Dr. Shaligram required her to get information from the wards whether other drugs had been administered to the patients and if so their dosage as also the dosages of the suspect drugs administered to the patients. In his letter dated 27th January 1986 (Exh. 6) Exh. 6
Dr. Kripalani had specified the suspect drugs in no uncertain terms. There was no suspicion against any other drug. Nor does even Dr. (Mrs.) Worlikar say so. Hence, the reason for her wanting information about other drugs is inexplicable. Further, if she required the dosage of the suspect drugs administered to the patients, the easiest thing for her was to have got such information from the wards herself or have deputed somebody for the purpose for that matter. She does not even say that she had asked the wards to supply her this information Then what on earth was she waiting for instead of promptly informing FDA on the 27th itself instead of doing so in the afternoon of 28th.

93. Despite the gravity of the situation of which she was well aware, it was only on 29th January 1986 at about 11-00 a.m. that from Medical Store she issued the recall circular (Exh. 9). Why Dr. (Mrs.) Worlikar should have waited till 29th Exh. 9
January 1986 to do this, is incomprehensible when on 28th itself she knew that three wards viz. Neurology, Neurosurgery and Opthalmology were affected by the suspect drugs. She should hereself have gone or deputed somebody to go at least to these 3 affected wards to collect suspect drugs. She did nothing of the kind, and on the 29th issued her belated perfunctory recall circular (Exh. 9). Exh. 9

94. Dr. (Mrs.) Worlikar failed to ensure that withdrawals of the suspect drugs was properly and expeditiously effected and that they were promptly returned to Medical Store. She could have done this by the simple expedient of checking the bin cards or by visiting at least the affected wards viz. Neurology, Neurosurgery and Ophthalmology. She did not even ensure that her recall circular (Exhibit 9) was Exh. 9
received by all the wards.

95. The question I ask myself is: Can all this be dismissed as errors of judgment, or has she attracted to herself the charge of negligence and dereliction of duty in not promptly withdrawing the suspect drugs?

96. I find myself with no alternative but to answer this question against Dr. (Mrs.) Worlikar. To dismiss Dr. (Mrs.) Worlikar's conduct as mere errors of judgment would be a mistake. It is not a single error. There are numerous such errors as detailed above which indicate a consistent course of conduct which no average person of ordinary prudence could repeat over and over again. Negligence in this direction is nearer the answer than mere errors of judgment.

97. Dr. (Mrs.) Worlikar herself is a medical practitioner and Associate Professor of Pharmacology. On 27th January 1986 she was well aware of the gravity of the situation as also the fact that Dr. Mujumdar had been deputed by Dr. Kulkarni to the wards to pin-point the suspect drugs. Further, there is Dr. Kripalani's letter Exh. 6
dated 27th January 1986 (Exhibit 6) on which the Dean had made an endorsement to Dr. (Mrs.) Worlikar to investigate and take necessary action. It is unfortunate that even so no investigation was done by Dr. (Mrs.) Worlikar and no action was taken by her except to belatedly inform FDA in the afternoon of 28th January and to send her belated and perfunctory recall circular on 29th. She knew that immediate replacement of the drugs was required. Hence, as a doctor she had knowledge that the drugs already supplied to the wards should not be allowed to be used. Normally drugs are not suddenly required to be replaced for same fanciful reason but for grave reasons like contamination, actual or suspected and the like. Dr. (Mrs.) Worlikar herself went to Medical Store realising the urgency of the situation on the 27th itself. What did she do there? She merely dictated the circular of 27th January. Even that is a badly worded and misleading circular not projecting the urgency of the situation. The manner in which the cir ular was sent to the wards was perfunctory. It is impossible to expect the receiving nurses to memorise the contents of such a circular

containing the na mes of the suspect drugs, batch numbers, the names of the manufacturers and to pass on such information to the relieving nurses. Dr. (Mrs.) Wor ikar as a trained medical praetitioner and Associate Professor of Pharmacology, and even as an average person of reasonable prudence, should have known that the urgency and gravity of the situation of which she was aware should also be brought to the notice of the receiving nurses viz. that under no circumstances the drugs should be administered because they were suspected to be adulterated. It was not even
Exh. 8 stated in that circular (Exhibit 8) that the 3 drugs were suspected to be not of standard quality. As a medical practitioner and Associate Professor of Pharmacology Dr. (Mrs.) Worli kar should have realised that greater the urgency and seriousness of a situation, the greater should have been her efforts to promptly arrest the spread of deaths
Exh. 8 and d isaster. None of this is reflected in her circular (Exhibit 8) nor in her actions aimed towards the prompt withdrawal of the suspect drugs.

98. On the aspect of withdrawal of the suspect drugs, except for issuing the circular
Exh. 8 dated 27th January 1986 (Exhibit 8) what else did Dr. (Mrs.) Worlikar do? For all practical purposes, nothing except 15—20 minutes taken for segregating the stock on 28th January 1986 at Medical Store, telephoning alternate suppliers and the FDA on 28th January 1986 and giving her letter at 3-30 p.m. to the Drugs Inspctor
Exh. 9 for checking the suspect drugs and issuing belated recall circular (Exhibit 9) on 29th January.

Exh. 9 99. Even her belated recall circular (Exhibit 9) of 29th January is as perfunctory
Exh. 9 as her earlier circular of the 27th (Exhibit 8). Her recall circular (Exhibit 9) reads as under:—

" Urgent

Please return all stocks of glycerol AP B. No. 27 immediately to Medical Store. Replacement is available."

The same comments made by me earlier in respect of her circular of 27th January
Exh. 9 apply with equal force to her recall circular of 29th January (Exh. 9). After issuing her
Exh. 9 circular (Exh. 9) she did nothing of any consequence by way of withdrawing the drugs except on 11th or 13th February 1986 she sealed the glycerine bottles, but did not try to check whether the bottles tallied with the bin card or not nor did she ascertain or get ascertained whether all the bottles of batch No. 27 were accounted for.

100. On 25th January 1986 glycerine bottles were issued to Wards Nos. 6, 12, 18 and 44. Dr. (Mrs.) Worlikar admitted that there is no record that these wards returned those bottles to Medical Store. She has also no knowledge about the red ink entries in the bin card. She has also no personal knowledge about the return of the bottles except what is stated in the bin card on which as stated earlier no reliance can be placed.

101. However much can be said in favour of Dr. (Ms.)Worlikar by way of mitigation. Her work in other directions in this tragic episode has been commendable, as appears in the chronology of events set out earlir in this Report. Further she acted under the directions of her senior Dr. Shaligram and it was he who should have given Dr. (Mrs.) Worlikar appropriate directions, which Dr. Shaligram failed to do. If she did not give the requisite information to the FDA on 27th January itself, it was under the directions of her senior Dr. Shaligram as reluctantly admitted by Dr. Shaligram himself at page 307 of his evidence. It is also on record that before she herself took any step she had discussed Dr. Kripalani's letter dated 27th January 1986 with Dr. Shaligram and had acted according to his (Dr. Shaligram's) instructions.

102. In the circumstances, Dr. Shaligram's negligence assumes far greater proportion than that of Dr. (Mrs.)Worlikar. In the light thereof, it is but fit and proper that a generous view be taken of Dr. (Mrs.) Worlikar in this respect.

103. This brings me to the role played by Ophthalmology. At the relevant time, until her transfer on 14th February 1986, Unit I of Ophthalmology having 52 beds was headed by Dr. (Miss) Kamble. Sisters Jadhav and Mahamulkar were in-charge of Ward No. 26. The staff nurses were Bhalerao and Chikane.

104. Indisputably, there are certain erasures and over-writings in the Nurses' Order Books. The version of sister Jadhav and nurses Bhalerao and Chikane is that the tampering was done by Bhalerao under the orders of Dr. (Miss) Kamble on 3rd February 1986. To that end, the role played or alleged to have been played by them is of some importance.

105. The evidence of sister Jadhav indicates that the circular dated 27th January 1986 was received in Ward No. 26 by staff nurse Mahamulkar and sister Jadhav came to know of this circular on 28th January 1986 at 7-30 a.m. when she came on duty. In the nurses' order book which has been tampered with, though a number of patients are mentioned, it ultimately boils down to Abdul Kadar Shaikh being shown to have received glycerol on 27th and 28th January. Erasures and over-writings have been done by someone on 3rd February 1986. This according to nurse Jadhav and sisters Bhalerao and Chikane, was reported on 4th February 1986 to sister Jadhav by Chikane and Bhalerao. Thereupon, sister Jadhav at once got the original notings restored in the nurses' order book to show the correct position that on 27th and 28th January glycerine was *not* administered to Abdul Kadar Shaikh before Dr. (Miss) Kamble allegedly got the tampering done to show that glycerol *was* administered to Abdul Kadar Shaikh on those two days. Here it may be stated that Abdul Kadar Shaikh was not the patient of Dr. (Miss) Kamble.

106. On the aspect of erasures and over-writings in the nurses' order book (Exh.97) the evidence of sister Jadhav, staff nurses Chikane and Bhalerao and Dr. (Miss) Kamble are relevant. I shall first take up the evidence of sister Jadhav. Exh. 97

107. Smita Ram Jadhav is the sister-in-charge of Ophthalmology, Ward No. 26 since August 1985. On 4th February 1986 she came to know of certain erasures and over-writings in the nurses' order book. She questioned her staff nurses Bhalerao and Chikane who told her that the nurses' order book had been taken by the Head of the Department Dr. (Miss) Kamble and that the over-writings and erasures had been done by them at her instance. Sister Jadhav admonished the two staff nurses and directed them to restore the entries to what they were. Nurses Bhalerao and Chikane did so. In the case of Abdul Kadar Shaikh there were several erasures and over-writings. For the convenience of this Commission, sister Jadhav prepared a Chart (Exh. 98) showing the treatment which had been given to Abdul Kadar Shaikh. Exh. 98
Since 4th February 1986 the nurses' order book remained in her cupboard in Ward No. 26. The cupboard was accessible to any staff member.

108. Nurse Jadhav was unable to say who had put the vertical lines in red ink against the treatment given under dates 10th and 11th January. This is something which is never done in the nurses' order book. Nor is it the practice to delete in red ink or otherwise the treatment given to a patient. Treatment once written is never scored off by delineation. She cannot say who has scored off various entries in the nurses' order book. There are also delineations in blue ink denoting the scoring off of treatment given to patients. Such delineations are never made. Nurse Jadhav does not know who did all this.

109. She deposed that glycerol batch No. 27 was administered to Abdul Kadar Shaikh at 6-00 a.m. on 28th January. That was the first dose of that day. She admitted that the stoppage of glycerol to Abdul Kadar as shown in the case papers (Exh. R) as 27th January, was incorrect. She did not know who has written the Exh. R
stoppage date in Exh. R. The stoppage date of 27th January which she saw for the first time in the case papers (Exh. R) was put after 28th January. Nobody objected Exh. R
to Abdul Kadar Shaikh being given the 2nd and 3rd doses of glycerol on 27th January. Till 28th January Abdul Kadar Shaikh was given glycerol as prescribed. When a drug is ordered to be stopped by the doctor from a particular date, it is not administered thereafter until such stoppage is revoked in writing.

110. Sister Jadhav admitted that the nurses' order book (Exh. 97), which would be the only correct record of the administration of drugs, was maintained by herself and the staff nurses. The record is made in this book contemporaneously with the administration of the drug. A mistake in making an entry is rectified by making a fresh entry and never by erasing the erroneous entry.

111. On 4th February 1986 between 9 and 10 a.m. sister Jadhav's staff nurses Bhalerao and Chikane told her that the nurses' order book had been taken away by the head of the department, i.e. Dr. (Miss) Kamble, to her room on 3rd February. These two staff nurses told sister Jadhav that Dr. (Miss) Kamble had told them to scratch out in the nurses' order book entries pertaining to glycerol and diamox in respect of four or five patients and that against the timings of the administration of these two drugs to make a circle after rubbing out the vertical lines. A vertical line across the timing indicates that the drug was administered at the time mentioned; a circle round the time indicates that the drug has not been administered. Nurses

Bhalerao and Chikane told sister Jadhav that in the nurses' order book (Exh. 97) they had at the behest of Dr. (Miss) Kamble erased the stroke marks against the timings and put a circle in the case of diamox and glycerol. Why Dr. (Miss) Kamble had them to do this, they did not know. Sister Jadhav thereupon instructed Bhalerao and Chikane to restore the *status quo ante* in the nurses' order book. They did so from memory in the presence of sister Jadhav. Till today the restoration has never been checked from the case papers.

112. Sister Jadhav did not make any enquiry from Dr. (Miss) Kamble. She was frightened to do so as Dr. (Miss) Kamble was the head of the department. Later however she admitted that she could give no reason why she did not make any enquiry from Dr. (Miss) Kamble or even try to verify from Dr. (Miss) Kamble the correctness of the version of nurses Bhalerao and Chikane. Even after Dr. (Miss) Kamble was transferred on 14th February 1986 to Nagpur, sister Jadhav did not bring this to the notice of her successor viz. Dr. (Miss) Dekate. It was only a fortnight after Dr. (Mrs.) P. G. Hingorani took over from Dr. (Miss) Dekate on 25th May 1986 that sister Jadhav brought to the notice of Dr. (Mrs.) P. G. Hingorani what the two staff nurses Bhalerao and Chikane had told her. Sister Jadhav attempts to explain her silence by saying that Dr. (Miss) Dekate was aware of all this. And pray, why was Dr. (Miss) Dekate aware? Because, says sister Jadhav, everyone in the ward was aware. Even though sister Jadhav knew that 13 patients had died by reason of drug adulteration and even though she did feel that Dr. (Miss) Kamble had asked her two staff nurses Bhalerao and Chikane to tamper with the nurses' order books in connection with those deaths, she did not bring this to the notice of her immediate superior, viz. the Matron or the Dean or for that matter anyone. Sister Jadhav attributed her silence as her mistake. Till she started giving evidence before this Commission she did not bring to anybody's notice that the nurses' order books had been tampered with at the behest of Dr. (Miss) Kamble. She can give no reason why she did not or why she did not think it necessary to do so.

113. Sister Jadhav did not consider tampering with the nurses' order books to be a serious matter. She asked staff nurses Bhalerao and Chikane to restore the *status quo ante* in the nurses' order books as they were hers and nobody could tamper with them.

114. Sister Jadhav continues that after 4th February 1986 she was apprehensive that the nurses' order books would again be tampered with by Dr. (Miss) Kamble. Hence she kept them with her under lock and key and kept the key until they were produced in this Inquiry.

115. In the nurses' order book, in addition to the over-writing and erasures in the case of Abdul Kadar, there is over-writing/double-writing of drugs in the case of Rajendrakumar Mishra under dates 18th to 21st January 1986. The entries under dates 18th and 19th January have been horizontally scored off in red ink. The entries under dates 25th and 26th January 1986 have been diagonally struck off in red ink in addition to other delineations in red ink. The entries under date 27th January have been vertically scored off in red ink. She did not know who had done all this, and saw it all for the first time on 4th February 1986 whereupon she confronted her staff nurses Bhalerao and Chikane who said they had done all this at the instance of Dr. (Miss) Kamble.

116. Sister Jadhav admitted that the corrections done by the two staff nurses Bhalerao and Chikane were only in the case of Abdul Kadar Shaikh.

117. As will presently appear, sister Jadhav is not supported by her staff nurses Bhalerao or Chikane.

118. Staff nurse Bhalerao of Ophthalmology, Ward No. 26 deposed that on 3rd February 1986 her hours of duty were from 1-00 p.m. till 8-00 p.m. At about 4-00 or 4-30 p.m. Dr. (Miss) Kamble came to Ward No. 26; the operation theatre staff nurse Chikane was present. Dr. (Miss) Kamble told nurse Bhalerao to bring the nurses' order books. She did so. Dr. (Miss) Kamble thereupon told her to look up and take out the names of the patients Abdul Kadar Shaikh, one Shivaji and one Bhairu. These were the only names Dr. (Miss) Kamble gave her. Dr. (Miss) Kamble ordered and forced her to rub out the entries pertaining to the administration of glycerol to Abdul Kadar Shaikh on 26th and 27th January. Nurse Bhalerao did so then and there in Dr. (Miss) Kamble's presence because Dr. (Miss) Kamble was the head of her department and she was under her pressure.

119. Immediately after Dr. (Miss) Kamble's departure from the ward, nurse Bhalerao reported the incident to staff nurse Chikane. Before she could do so, Chikane asked her why Dr. (Miss) Kamble wanted to see her with the nurses' order book, because at that time staff nurse Chikane was present. She told her what had happened and what she had done. Nurse Chikane told her that one was not supposed to tamper with the nurses' order book, that the nurses' order books should be retained as they were and that the following morning they should give this information to sister Jadhav, she being the head of the ward.

120. Nurse Bhalerao continues that the following day, viz. 4th February 1986, she and nurse Chikane were on duty from 7-30 a.m. till 2-30 p.m. At about 7-45 sister Jadhav came to the ward. They told her what Dr. (Miss) Kamble had asked Bhalerao to do with the nurses' order books the previous day, and that the tampering had been done in the case of 3 patients viz. Abdul Kadar Shaikh, Shivaji and Bhairu. Nurse Bhalerao did not tell sister Jadhav that Dr. (Miss) Kamble had asked her to put circles round the timings or that Dr. (Miss) Kamble had asked her to take the nurses' order book to Dr. (Miss) Kamble's room or that Dr. (Miss) Kamble had asked her to tamper with the entries of four or five patients. Sister Jadhav got angry with her and told her to correct the nurses' order books as they originally were. Bhalerao did so in Jadhav's presence from the tracings which were still visible on the pages and without reference to any record.

121. When Dr. (Miss) Kamble asked Bhalerao to bring the nurses, order book the case papers of the three patients named by Dr. (Miss) Kamble viz. Abdul Kadar Shaikh, Shivaji and Bhairu were not lying on the table. Dr. (Miss) Kamble did not ask for the case papers. She took the nurses' order book to the table in the centre of the ward, turned over the pages and found out the page where the entries of patient Abdul Kadar Shaikh were. Before Bhalerao rubbed out the entries at the instance of Dr. (Miss) Kamble, glycerol was shown to have been 'administered to Abdul Kadar Shaikh on 26th January 1986 (3 doses) and also on 27th January 1986 (2 doses, namely at 6-00 a.m. and 2-00 p.m.). The dosage appearing as of 28th January had not been rubbed out by her. She only rubbed out the entries pertaining to the dosages of 26th and 27th January. In the case of Abdul Kadar Shaikh all that Dr. (Miss) Kamble told her was to rub off the entries under dates 26th and 27th January showing the administration of glycerol to him. Dr. (Miss) Kamble asked her to use an eraser. As she did not have one she used a cork from a bottle for making the erasures. Along with the lines she also rubbed off the timings. While operation tampering was in process openly in the centre of the ward, nobody was present except staff nurse Chikane.

122. According to nurse Bhalerao, Dr. (Miss) Kamble shouted at her to make the corrections. Nurse Chikane heard this shouting; no one else did as Dr. (Miss) Kamble was not shouting loudly. Staff nurse Chikane asked Bhalerao why madam [i.e. Dr. (Miss) Kamble] was shouting at her. That was how she knew that staff nurse Chikane heard Dr. (Miss) Kamble's shouting. When Dr. (Miss) Kamble shouted at her, nurse Chikane was about 4 or 5 feet away.. That day, i.e. on 3rd February 1986 sister Jadhav's duty hours were in the morning. Nurse Chikane looked why Dr. (Miss) Kamble was shouting at Bhalerao. Chikane actually saw Bhalerao rubbing the entries. Bhalerao dis not ask Dr. (Miss) Kamble as to why she was shouting at her, as Dr. (Miss) Kamble used to shout at everyone. Bhalerao took this as Dr. (Miss) Kamble's normal behaviour. Bhalerao was however, afraid because the manner in which Dr. (Miss) Kamble shouted at her at that time was different from the manner in which she normally used to shout.

123. After drawing the fine and subtle distinction between the different kinds of shouting indulged in by Dr. (Miss) Kamble, nurse Bhalerao goes on that beyond telling her to get the nurses' order book and to do the rubbing, Dr. (Miss) Kamble did not tell her anything else. She felt pressurised because Dr. (Miss) Kamble told her that she should do the erasures immediately then and there and that until then she would not move from the table. Bhalerao did not utter a single word because Dr. (Miss) Kamble was her superior.

124. Nurse Bhalerao has one believe that when Dr. (Miss) Kamble asked her to rub out the entries pertaining to glycerol, she did not realise that they pertained to the deaths which had taken place in the J. J. Hospital. This is absurd because by 3rd February it was common knowledge that glycerol was the most likely suspect drug.

125. Almost immediately after Dr. (Miss) Kamble left, staff nurse Chikane asked Bhalerao why she was shouting at her and what she had done to provoke Dr. (Miss) Kamble. Bhalerao told Chikane that Dr. (Miss) Kamble had asked her to make the erasures in the nurses' order book. That is all she told her.

126. After she made the erasures and until her duty hours were over, nurse Bhalerao cannot say how many doctors or huosemen came to her ward. When nurse Chikane told her that she had done something wrong, Bhalerao was afraid that sister Jadhav would also shout at her. When Bhalerao realised that she had done something wrong, she was upset. She discussed the matter with Chikane who told her not to do anything at the moment. Bhalerao thereupon went to do her other work.

127. According to nurse Bhalerao, immediately after she narrated this incident to sister Jadhav on 4th February 1986, she also narrated it to the entire staff in her ward. No one suggested that she should complain to the Matron or the Dean. At that time she was not afraid that Dr. (Miss) Kamble would shout at her. She did not narrate this incident to any houseman or the Registrar.

128. Nurse Bhalerao knew that Dr. (Miss) Kamble was transferred from the J. J. Hospital on 14th February 1986. It was rumoured that she was transferred because of the glycerol episode. Even so it did not strike nurse Bhalerao to narrate the interpolation and erasure incident to any higher authority because according to her, she had already narrated it to her immediate superior sister Jadhav. She did not ask sister Jadhav whether she had narrated the incident to anyone superior to her.

129. Nurse Bhalerao goes on to say that Dr. (Mrs.) Hingorani never asked her about the interpolations and erasures though she was the head of her department. Sister Jadhav never told nurse Bhalerao that she had informed Dr. (Mrs.) Hingorani about what Bhalerao had told her.

130. Nurse Bhalerao admitted that the entry of 28th January 1986 in nurses' order book does not show that any glycerol was administered to Abdul Kadar Shaikh that day. She did not know who had drawn these circles round the timings of that day. She did not know whether on 28th January Abdul Kadar Shaikh had been given the first dose of glycerol at 6-00 a.m.

131. Contrary of sister Jadhav's evidence, nurse Bhalerao deposed that after 4th February the nurses' order books continued to remain as usual on the table in the centre of the ward and was not kept under lock and key by sister Jadhav or anybody else. She denied sister Jadhav's version (at page 476, para 9) that she *i.e.* Bhalerao and Chikane did not tell sister Jadhav the names of the patients except that of Abdul Kadar Shaikh. Bhalerao maintained that she gave Chikane the dates viz. 26th and 27th January in respect of which the entries were tampered with and that it was at the instance of sister Jadhav that she made corrections in the entries of these three patients. She admitted that she did not tell sister Jadhav that Dr. (Miss) Kamble had asked her to make changes in respect of these 5 patients. Nurse Bhalerao stated that she had not made any corrections in respect of the entries pertaining to 28th January and was unable to say what the position was on 28th January.

Such is the evidence of staff nurse Bhalerao.

132. And now to staff nurse Chikane.

132A. Staff nurse Chikane is attached to Ward No. 26 Ophthalmology since January 1985. She deposed that on 3rd February between 4-00 and 4-30 p.m. Dr. (Miss) Kamble came to Ward No. 26. Chikane was in the adjacent room dressing a patient. She overheard Dr. (Miss) Kamble ordering staff nurse Bhalerao to change the patients' orders in the order books which were lying on a table in the room, where Chikane was dressing the patient. Staff nurse Bhalerao took the order books to Dr. (Miss) Kamble. At that time Dr. (Miss) Kamble was in the sister's room in the ward. Staff nurse Bhalerao and Dr. (Miss) Kamble were in the sister's room for about 5-10 minutes. Dr. (Miss) Kamble came out of the sister's room first. As Chikane was going towards the sister's room, staff nurse Bhalerao came out. Staff nurse Bhalerao showed her the nurses' order book. Bhalerao opened the page concerning Abdul Kadar Shaikh and showed Chikane the erasure marks. Chikane

told her that nurses' order books should not be tampered with. Bhalerao asked Chikane whether she had acted correctly. She said so. Bhalerao asked her what she should do. Chikane told her to leave the books in their present from and not to make any correction. Staff nurse Bhalerao told Chikane that the following day she would bring the incident to the notice of sister Jadhav.

132B. On 4th February Chikane was on duty in the operation theatre from 7.30 a.m. till 2.30 p.m. When Chikane came on duty that day, staff nurse Bhalerao was on duty. Both of them went to sister Jadhav at about 7.45 a.m. Staff nurse Bhalerao told sister Jadhav what had transpired the earlier day with Dr.(Miss)Kamble. Chikane told sister Jadhav what Bhalerao had told her the earlier day.

133. On 3rd February Chikane had no talk with Dr. (Miss) Kamble. She cannot say whether she had seen her in the ward that day. Chikane could not overhear everything that transpired between nurse Bhalerao and Dr. (Miss) Kamble that day. From the room where Chikane was dressing the patient, she could see nurse Bhalerao and Dr. (Miss) Kamble. But Chikane could not see what Bhalerao was doing. The distance between them and Chikane was about 6 to 8 feet. All that, Chikane overheard was Dr. (Miss) Kamble telling Bhalerao to bring the order books and to make the changes in the order books.

134. Chikane was with the patient for about 3 minutes. Thereafter she took the patient to his cot in the ward. After Chikane reached the patient to his cot, she asked staff nurse Bhalerao what Dr. (Miss) Kamble was telling her. When Dr. (Miss) Kamble told staff nurse Bhalerao to bring the books and to change the entires Chikane was changing the dressing of the patient and was concentrating on her patient. Chikane was not looking in the direction of Dr. (Miss) Kamble and nurse Bhalerao. She only overheard what Dr. (Miss) Kamble told nurse Bhalerao. Chikane did not hear anything else beyond what she deposed. She herself did not see what was being done with the nurses' order books.

135. According to staff nurse Chikane, Dr. (Miss) Kamble shouted to staff nurse Bhalerao to fetch the nurses' order books. She overheard Dr. (Miss) Kamble telling Bhalerao to change the order of the patients. Chikane did not think that Dr. (Miss) Kamble was doing anything wrong. However, she did admit that it was wrong and a malpractice to tamper with entries in the Nurses' order books, as also that a person who would want to do so would do it secretly, as also what Dr. (Miss) Kamble was telling staff nurse Bhalerao to do was something wrong and illegal. Even so nurse Chikane insists, Dr. (Miss) Kamble told nurse Bhalerao loudly to change the entries in the nurses' order books.

136. Even so she did not think that there was anything improper or unusual. If nurse Bhalerao had not told Chikane anything, she would not have asked her because Chikane was accustomed to Dr. (Miss) Kamble's tone of voice and temper.

137. After Dr. (Miss) Kamble left, staff nurse Bhalerao told Chikane that madam Kamble had directed her to make changes regarding glycerol entries in the nurses' order book. Chikane told Bhalerao that the nurses' order books cannot be changed that way. Staff nurse Bhalerao also told Chikane that Dr. (Miss) Kamble had also directed her to change the orders in respect of two or three other patients. Bhalerao did not tell Chikane whether Dr. (Miss) Kamble had told her the drugs she desired to be altered in the case of other patients. Bhalerao told Chikane that alterations had been made under dates 26th and 27th January in the case of Abdul Kadar Shaikh by erasing the strokes over the timings and putting a red-inked circle round the timings. The timings had also been slightly rubbed out. Staff nurse Bhalerao told Chikane that she had erased the strokes and put the circles round the timings. When chikane saw the order book on 3rd February the circles round the timings in the entry of 28th January were not there, but the timings were there. Chikane does not know when these two circles were put under the date 28th January.

138. Nurse Chikane did not agree with the evidence of sister Jadhav (at page 472) that sister Jadhav had told Chikane and Bhalerao to restore original position in the nurses' order books and that this was done by Chikane and staff nurse Bhalerao. She maintained that she was not asked to restore anything, nor did she do so. After 4th February, the nurses' order books remained in the ward on the same table as before.

139. The version of these 3 witnesses is denied by Dr. (Miss) Kamble who says she had nothing to do with the tampering of the nurses' order books.

139A. To start with, the version of sister Jadhav is purely hearsay, based as it is on what was allegedly told to her by staff nurses Bhalerao and Chikane. If no reliance can be placed upon evidence of last two, the evidence of sister Jadhav must also fall to the ground apart from the deficiencies in her own evidence and her inexplicable secrecy in not bringing this serious incident to the notice of any one.

140. A bare reading of the evidence of nurses Bhalerao and Chikane discloses that it is replete with absurdities, inconsistencies and contradictions. To illustrate: sister Jadhav's version that she did not make enquiries of Dr. (Miss) Kamble, why the order books should be changed because she was afraid of Dr. (Miss) Kamble, is a myth. If indeed she had been afraid of Dr. (Miss) Kamble, she would even have been more afraid to order the restoration of the entries to what they were. However, it is not merely because of such, that the improbabilities come to light. They do from certain indisputable circumstances which cannot lie, while witnesses may. These circumstances are:

(1) It is inconceivable that Dr. (Miss) Kamble would have ordered any delineations or erasures regarding the entries pertaining to Abdul Kadar Shaikh for the simple reason that Abdul Kadar Shaikh was not her patient and she was not concerned with him.

(2) The erasures and interpolations are not only in respect of glycerol, but also in respect of diamox. There was no reason why diamox should have been included in the erasures and interpolations because by 3rd February diamox was almost in the clear and suspicion had been crystalised against glycerol as the killer drug.

(3) The case papers were not in the wards which would have shown the stoppage date of glycerol.

(4) Dr. (Miss) Kamble had only 2 patients in her care who received glycerol and had died. Vithal Bhokare died on 25th January 1986. To Rajendrakumar Mishra glycerol was ordered to be stopped on 25th January.

(5) Dawood Haji Dholakia was a patient of Dr. Dastoor; his case papers show that Dr. Dastoor had ordered stoppage of glycerol on 25th January. No patient of Dr. (Miss) Kamble was given glycerol after 25th January. In these circumstances, it is inconceivable that Dr. (Miss) Kamble should even think of tampering with the order books when she was not responsible for the stoppage of the drugs.

(6) There is no evidence that Dr. (Miss) Kamble had ever examined Abdul Kadar Shaikh or had even handled or seen his case papers.

(7) None of Dr. (Miss) Kamble's patients in Unit No. I were given glycerol after 25th January.

(8) There is no reason why Dr. (Miss) Kamble should order changes in the nurses' order books regarding Shivaji and Bhairu who did not die. In Shivaji's case erasures pertained not only to glycerol, but also to septron on 26th, 27th and 28th January. In Bhairu's case erasures pertained to the administration of glycerol on 26th and 27th January.

(9) One Dhyandeo Pote [patient in Dr. (Miss) Kamble's Unit I] was given glycerol till 20th January, one Mohamed Akhtar (Unit I) till 27th January and one Parshuram Surve (Unit II) till 27th January, one Jokim D'Costa (Dr. Hingorani's patient) till 27th January and one Guptadevi R. Singh (Unit I) till 27th January. None of them died. Yet no changes appeared in the nurses' order books pertaining to these patients including Dr. (Miss) Kamble's patient, viz. Pote, Mohamed Akhtar and Guptadevi R. Singh. If Dr. (Miss) Kamble was indeed involved in effecting erasures and alterations in the nurses' order books. It is inexplicable why the 5 patients should have been left out from that exercise and particularly Dr. (Miss) Kamble's own patient, viz. Dhyandeo Pote, Mohamed Akhtar and Guptadevi R. Singh.

141. Thus apart from the absurdities, inconsistencies and contradictions in the evidence of sister Jadhav and nurses Bhalerao and Chikane, circumstantial evidence must exonerate Dr. (Miss) Kamble from the charge of tampering with the nurses' order books.

142. From the version given by sister Jadhav and nurses Bhalerao and Chikane and the circumstantial evidence, it is impossible to come to the conclusion that Dr. (Miss) Kamble was instrumental for the tampering with the nurses' order books.

143. On the other hand, there is positive evidence which completely exonerates Dr. (Miss) Kamble of the wrong doing alleged against her by sister Jadhav and nurses Bhalerao and Chikane.

144. That positive evidence is that on 3rd February 1986, there was a Medical Board meeting attended by Dr. Nagori as Chairman, Dr. (Mrs.) Gupte (Medicine Dept.) and Dr. (Miss) Kamble (Ophthalmology Dept.). Medical Board meetings are usually convened at 2-00 p.m. and so it was on 3rd February. On an average Dr. Nagori would take about 2-1/2 hours to 3 hours to examine about 60 candidates. On 3rd February 1986 there were about 59 to 60 candidates for examination. The time taken by Dr. (Miss) Kamble to examine 60 candidates would be about 4 to 5 hours. All the 59 to 60 candidates were examined by Dr. (Miss) Kamble on 3rd February. This is established by the evidence of Dr. Nagori, an independent witness who had no axe to grind or reason to shield Dr. (Miss) Kamble. The indisputable presence of Dr. (Miss) Kamble at this meeting must put beyond the pale of controversy her alleged presence in Ward No. 26 and must demolish the entire version of sister Jadhav and nurses Bhalerao and Chikane.

145. The question that arises is: *Why should sister Jadhav and staff nurses Bhalerao and Chikane conspire against Dr. (Miss) Kamble?* This can be answered from the point of time when the erasures, alterations and interpolations first came to light. Did they come to light on 4th February as alleged by the staff nurses Bhalerao and Chikane or did they come to light after Dr. (Miss) Kamble's transfer from the J. J. Hospital on 14th February 1986? There is no doubt in favour of the latter. This is manifest from the fact that neither sister Jadhav nor nurses Bhalerao and Chikane brought this incident to the notice of their superiors, immediately, which a person of normal prudence would have done.

146. On this aspect there is the evidence of Dr. (Mrs.) Hingorani who took charge of the Ophthalmology Dept. from Dr. (Miss) Kamble after Dr. (Miss) Kamble's transfer on 14th February 1986. Dr. (Mrs.) Hingorani deposed with refreshing candour that when she inspected the nurses' order books after she took charge of the Ophthalmology Department, she found that the orders pertaining to glycerol had been deleted in several places and that the changes in the nurses' order books had not been made during her tenure as unit in-charge and Reader in Ophthalmology. Within a week of her taking charge of the Ophthalmology Department sister Jadhav told her that entries in the nurses' order books had been changed at the instance of Dr. (Miss) Kamble. That was all that sister Jadhav told her. Sister Jadhav never gave her the names of Bhalerao or Chikane or any member of the staff, nor did sister Jadhav even tell her that the entries had been changed by Bhalerao at the instance of Dr. (Miss) Kamble. Sister Jadhav never mentioned anything about staff nurses Bhalerao and Chikane to Dr. (Mrs.) Hingorani nor did sister Jadhav tell her why she was attributing to Dr. (Miss) Kamble the authorishp of the tampering of the nurses' order books. Thus from Dr. (Mrs.) Hingorani's evidence it is obvious that on her finding that the order books had been changed that sister Jadhav told her that it had been done at the instance of Dr. (Miss) Kamble. From this it is manifest that the first reaction of sister Jadhav was to save herself and found Dr. (Miss) Kamble a convenient scapegoat looking to the fact that the latter was not at the hospital any longer, having been transferred on 14th February 1986.

147. Further there was reason and motive for staff nurses Bhalerao and Chikane and sister Jadhav to tamper with the nurses' order book for their own protection. Administration of drugs fell within the duty of the sister in-charge and staff nurses. It is they who must also carry out the stoppage orders. Even though Ophthalmology units I and II are different, the staff is common with a common sister in-charge, viz. sister Jadhav. Admittedly the circular dated 27th January 1986 (Exhibit 8) was Exh. 8
received at 5-00 p.m. that day in the Ophthalmology Department. As it is there was negligence on the part of the sister in-charge and the staff nurses in not stopping administration of glycerol to Dawood Haji Dholakia on 24th. Despite the circular (Exhibit 8), the last dose of glycerol was given to Dawood Dholakia on 27th January Exh. 8
at 10-00 p.m. On the night of 27th January, Dr. Lele had put the stoppage order in the case of Rajendrakumar Mishra. The staff nurse in-charge was informed that the specific drug was not to be administered, even so glycerol was given to at least 2 patients on 28th, namely Abdul Kadar Shaikh [(Dr. Mrs.) Hingorani's patient]

and Pote [(Dr. (Miss) Kamble's patient]. Even so in Pote's case there is no tempering in the nurses' order books. This is a strong argument in favour of Dr. (Miss) Kamble and supports her denial of having had anything to do with the tempering of the nurses' order books. If she had wanted to temper with it there was no reason why she should not have ordered the tempering in the cases of 5 others, viz. Pote, Mohamed Akhtar, Parshuram Surve, Jokim D'Costs and Guptadevi R. Singh. Furthermore
Exh. 109 in her statement (Exhibit 109) on 7th February before the Choube Committee sister Jadhav had stated that Abdul Kadar was given glycerol till 28th January. In her
Exh. 120 statement before the Choube Committee (Exhibit 120) Dr. (Miss) Kamble has said the same. The statement of the glycerine given was prepared by sister Jadhav and Dr. Pargaonkar. Administration of drugs can only be found from the nurses' order books. Hence, there is no doubt that the erasures and tampering with the nurses' order books was intended to cover up the negligence of the nurses in administering the drug despite the circular dated 27th January (Exhibit 8). In order to cover up their negligence, sister Jadhav and nurses Bhalerao and Chikane had made a false accusation against Dr. (Miss) Kamble as the instigator who pressurised them into tampering with the order books. The attempt must fail. Their intention was obviously and essentially to discredit the nurses' order books because the sister in-charge would be held accountable. What better scape-goat than a person who would not be there to protest. The obvious choice was the unpopular Dr. (Miss) Kamble.

148. In the light of the above analysis the contention of the Government's, advocate Mr. Tulpule inviting me to hold Dr. (Miss) Kamble culpable for the tampering of the nurses' order books must stand negatived.

149. The next question that arises is—*Did Dr. (Miss) Kamble have any knowledge on 25th January about the stoppage of the suspect drugs ?*

150. According to Dr. (Miss) Kamble she had to no such knowledge. In order to examine the correctness or otherwise of Dr. (Miss) Kamble's version it is necessary to allude to the evidence of Dr. Pargaonkar, Dr. (Miss) Parul Shah, Dr. Kripalani, Dr. Asha Menon and Dr. Shaikh.

151. In January/February 1986,, Dr. Pargaonkar was the Registrar in the Nephrology Department. His verison is that while he was in the Ophthalmology Department on 25th January Dr. (Miss) Sirsat told him that he should contact any doctor in that department and inform that doctor that Nephrology had received several cases of renal failure in the past week and that suspicion had fallen on three drugs, namely diamox, mannitol and glycerol. Thereupon at about 12-00 noon Dr. Pargaonkar went to the Ophthalmology Department, Ward No. 26, on the 1st floor and enquired from the sister on duty which patient had been referred to Nephrology. Vithal Bhokare was pointed out to him in the main Ward No. 26.

152. While Dr. Pargaonkar was examining Vithal Bhokare, Dr. (Miss) Parul Shah came and introduced herself as the House Surgeon. Dr. Pargaonkar told her that Vithal Bhokare had gone into renal failure most probably because of drugs mannitol, diamox and glycdrol, that the patient needed urgent dialysis and should be transferred to Nephrology. Dr. Pargaonkar further told Dr. (Miss) Parul Shah that in the past week Nephrology had received 7 cases of renal failure from Neurology and Neurosurgery, out of which four had died and that all those seven patients had received mannitol and/or diamox and/or glycerol which were suspected to be contaminated. He further told Dr. (Miss) Parul Shah to stop the administration of these drugs in her Ophthalmology Department and to purchase these three drugs from outside. He further told Dr. (Miss) Parul Shah to bring this matter to the attention of her seniors. So sying he returned to AKD at 12-30 p.m.

153. After Dr. Pargaonkar returned from Ophthalmology Department that day, he had no discussion with his co-registrar Dr. Farhad Kapadia, but did discuss the matter with his house physician Dr. Tushar Vacharajani and told him that in Ophthalmology the had briefed Dr.(Miss)Parul Shah of the situation, namely drug contamination, and that he had given her specific instructions to stop the administration of the three suspect drugs. Beyond telling Dr. Vacharajani this Dr. Pargaonkar did not tell this to anyone on 25th January.

154. Dr. Pargaonkar continues that on 27th January he informed the head of his department, namely Dr. Kripalani during the morning round what he had done on 25th January in Ward No. 26.

155. In cross-examination he did deny the suggestion that Dr. (Miss) Parul Shah never informed Dr. (Miss) Kamble what he had told Dr. (Miss) Parul Shah that day, namely 25th January, in the Ophthalmology Department, because he believed Dr. (Miss) Parul Shah. He stated that he and Dr. (Miss) Kamble were not on talking terms. (This question was repeated before the witness gave his answer). Thereafter he stated that until 29th or 30th January he did not know who Dr. (Miss) Kamble was nor until 25th January did he know Dr. (Miss) Parul Shah until she introduced hereself as the House Surgeon that day.

156. On 25th January it is possible that Dr. (Miss) Kamble may have been in the ward that moring but even if she was, Dr. Pargaonkar would not know because he did not know her.

157. Dr. Pargaonkar admitted that after 25th January and prior to his second meeting with Dr. (Miss) Parul Shah about 4 months ago, he did not know whether she had in fact conveyed to Dr. (Miss) Kamble what he had told her on 25th January. It was on 29th January during the meeting in the Nephrology Department that to his surprise he came to know from an equally surprised Dr. (Mrs.) Sirsat of, Dr. (Miss) Kamble's grievance that nobody had informed her about the stoppage of the suspect drugs in Ward No. 26. At this meeting Dr. (Mrs) Sirsat ascertained from Dr. Pargaonkar what he had told Dr. (Miss) Parul Shah on 25th January. Dr. Pargaonkar admitted that on 29th January he did not know whether Dr. (Miss) Parul Shah had conveyed to Dr. (Miss) Kamble what he had told her on 25th January and that until his second meeting with Dr. (Miss) Parul Shah 4 months ago he did not know whether she had in fact informed Dr.(Miss) Kamble what he had told Dr. (Miss) Parul Shah on 25th January. About 4 months ago he accidentally met Dr. (Miss) Parul Shah who had come to inquire in the college office about some posts. She wanted zerox copies of the case papers from the Nephrology Department. On the way from the office to the Nephrology Department Dr. Pargaonkar asked her whether she had conveyed to Dr. (Miss) Kamble what he had told her on 25th January because Dr. Pargaonkar was doubtful whether she had in fact conveyed that message to Dr. (Miss) Kamble. Despite this Dr. Pargaonkar later stated that he was convinced that Dr. (Miss) Parul Shah had conveyed his message to Dr. (Miss) Kamble on 25th January. Dr. (Miss) Parul Shah told Dr. Pargaonkar that she had done so on the 25th January itself immediately after he had left Ward No. 26. Dr. Pargaonkar asked Dr. (Miss) Parul Shah why even so the suspect drugs had not been stopped in Ward No. 26 to which the latter retorted that Dr. (Miss) Kamble had neglected the matter and that even though Dr. (Miss) Kamble knew that mannitol and/or diamox and/or glycerol were contaminated she did not stop the administration of these drugs in Ward No. 26. During this time Dr. Kripalani was also present. Dr. Pargaonkar was surprised to hear all this from Dr. (Miss) Parul Shah. On Dr. Pargaonkar asking Dr. (Miss) Parul Shah why Dr. (Miss) Kamble should have neglected to stop the administration of the suspect drugs, Dr. (Miss) Parul Shah replied that Dr. (Miss) Kamble was not fully convinced that the three drugs were suspect drugs. Dr. Pargaonkar was also surprised that Dr. (Miss) Kamble should not be convinced that the three drugs were suspect drugs but did not convey his astonishment to anyone in the hospital. He admitted that he had only Dr. (Miss) Parul Shah's words that she had indeed conveyed his message to Dr. (Miss) Kamble on 25th January for it was very unlikely that Dr. (Miss) Parul Shah may have forgotten to do so. Dr. Pargaonkar continued that at this meeting 4 months ago Dr. Kripalani also asked Dr. (Miss) Parul Shah whether she had conveyed Dr. Pargaonkar's message to Dr. (Miss) Kamble on 25th as also whether Dr. Pargaonkar had conveyed his instructions to her that day. At this second meeting both Dr. Pargaonkar and, Dr. Kripalani told Dr. (Miss) Parul Shah that accrording to Dr. (Miss) Kamble no one had informed her about the stoppage of the suspect drugs, to which Dr. (Miss) Parul Shah retorted that she had done so.

158. Dr. Pargaonkar maintained that on 25th he had specifically asked Dr. (Miss) Parul Shah to convey this information to the head of her department and denied Dr. (Miss) Parul Shah's version in para 12 at page 568 to the contrary.

159. During Dr. Pargaonkar's second meeting with Dr. (Miss) Parul Shah, Dr. Kripalani was not present throughout. The college office where he met her that day is on the ground floor and the AKD is on the first floor. Dr. Kripalani joined them while he and Dr. (Miss) Parul Shah were having a discussion in the AKD, which he had started in the corridor prior to their coming to the AKD. According to Dr. Pargaonkar during this discussion he asked her many questions including whether she clearly remembered having conveyed his instructions to

Dr. (Miss) Kamble on 25th January and whether she remembered what those instructions were. Dr. Kripalani asked Dr. (Miss) Parul Shah and Dr. Pargaonkar whether Dr. Pargaonkar had told Dr. (Miss) Parul Shah regarding the stoppage of the drugs on the 25th and also whether Dr. (Miss) Parul Shah had also conveyed this to Dr. (Miss) Kamble.

160. This evidence of Dr. Pargaonkar must be read in the light of the evidence of Dr. (Miss) Parul Shah.

161. Dr. (Miss) Parul Shah was at the relevant time Resident House Surgeon in the Ophthalmology Department, Unit No. 1. Her evidence is that on 25th January 1986 between 11.00 a.m. and 12 noon she and Dr. (Miss) Kamble were taking round in the male ward of Unit No. 1. Dr. (Miss) Parul Shah and Dr. (Miss) Kamble were examining a patient when a staff nurse came over there and told them that Dr. Pargaonkar had come to examine Vithal Bhokare. Thereafter Dr. (Miss) Kamble told Dr. (Miss) Parul Shah to go with Dr. Pargaonkar and remain with him while he was examining Vithal Bhokare. Dr. (Miss) Parul Shah did so. There was no discussion between Dr. (Miss) Kamble and Dr. Pargaonkar. At that time the Nephrology Registrar Dr. Pargaonkar came there to examine Vithal Bhokare regarding whom they had written a nephro call over that morning. At Dr. (Miss) Kamble's behest Dr. (Miss) Parul Shah remained with Dr. Pargaonkar while he examined Vithal Bhokare. Dr. Pargaonkar told her that the patient had acute renal failure and required to be transferred to Nephrology for further management, that his Nephrology Department had already received 3 to 4 cases of renal failure from the Neurosurgery Department and that glycerol, mannitol and diamox had been the common drugs used on all these patients and that one of these three drugs was suspected to be the culprit drug which had caused renal failure in so many patients. Dr. (Miss) Parul Shah goes to say that she conveyed all this to Dr. (Miss) Kamble who, during the time that Dr. (Miss) Parul Shah was with Dr. Pargaonkar, was waiting for Dr. (Miss) Parul Shah to complete their round. Dr. (Miss) Parul Shah conveyed to Dr. (Miss) Kamble what Dr. Pargaonkar had told her immediately she rejoined Dr. (Miss) Kamble. On the reference paper Dr. (Miss) Parul Shah wrote what Dr. Pargaonkar had suggested regarding the transfer of Vithal Bhokare to Nephrology. She however did not write down the other things which Dr. Pargaonkar had told her. Dr. Pargaonkar did not have any talk with Dr. (Miss) Kamble.

162. During the course of their rounds, as instructed by Dr. (Miss) Kamble, Dr. (Miss) Parul Shah changed the orders in respect of various patients in the ward. She may have changed the orders regarding the administration of glycerol, mannitol or diamox. However she could not positively say whether she did or not.

163. In the morning of 29th January, a meeting was held in Dr. (Miss) Kamble's office in the Ophthalmology Department where all the resident doctors were present including Dr. (Miss) Parul Shah and Dr. (Miss) Kamble. At this meeting Dr. (Miss) Kamble informed them that she had received an official circular pertaining to the stoppage of the three drugs, namely, mannitol, diamox and glycerol, that these drugs were not to be administered to any patient whether indoor or outdoor, that the Patients who had received these drugs should be kept under observation and that the daily blood, urea and serum creatinine should be done from the Pathology Department, that a strict intake-output chart should be maintained pertaining to the urine and that certain drugs recommended by Nephrology like sodamint should be administered to those patients and that they should be given plenty of fluids.

164. However at this meeting Dr. (Miss) Parul Shah did not state that Dr. Pargaonkar had already told her on 25th January about these three drugs and that she had given this information to Dr. (Miss) Kamble in the morning of 25th itself. The reason given by Dr. (Miss) Parul Shah was that it was not necessary for her to say all this at that meeting of 29th because she had already conveyed this information to Dr. (Miss) Kamble on 25th January itself.

165. On 26th January (Sunday), Dr. (Miss) Parul Shah and Dr. (Miss) Kamble took a round in the ward after the flag salutation ceremony. She does not remember whether she took a round in the ward on Monday the 27th January. On Tuesday the 28th January she did not take a round in the ward because that was the one-day strike of the resident doctors.

166. During the course of her round with Dr. (Miss) Kamble on 26th January, Dr. (Miss) Parul Shah noticed from the treatment sheets that the patients were still being given the three suspect drugs. However Dr. (Miss) Parul Shah did not do anything about it nor did she draw the attention of Dr. (Miss) Kamble to this fact.

167. In her cross-examination Dr. (Miss) Parul Shah watered down to a great extent her version of what had transpired between herself and Dr. Pargaonkar in the morning of 25th January. After being so very categorical earlier about what Dr. Pargaonkar had told her, in her cross-examination she said that Dr. Pargaonkar had told her that since these three drugs were under suspicion, it would be better if they got them from outside. She did think what Dr. Pargaonkar had told her that morning was important for him to tell Dr. (Miss) Kamble herself, but she did not take Dr. Pargaonkar to Dr. (Miss) Kamble because it was for Dr. Pargaonkar to have brought this to the notice of Dr. (Miss) Kamble. To this day Dr. (Miss) Parul Shah is surprised why Dr. Pargaonkar should have conveyed this information to her and not directly to Dr. (Miss) Kamble. She could not say whether they were on talking terms. After being vociferous earlier that Dr. Pargaonkar had instructed her to give the information to Dr. (Miss) Kamble, *Dr. (Miss) Parul Shah admitted that Dr. Pargaonkar had not asked her to tell Dr. (Miss) Kamble what he had told her.*

168. Dr. (Miss) Parul Shah insisted that immediately after Dr. Pargaonkar left the ward on 25th morning she went to where Dr. (Miss) Kamble was standing and narrated to her what Dr. Pargaonkar had told her. She did not remember if anyone was with her or with Dr. (Miss) Kamble at that time.

169. *Dr. (Miss) Parul Shah admitted that except to Dr. (Miss) Kamble she had never spoken to anyone else about what Dr. Pargaonkar had told her that morning. She thereafter resiled from her categorical statement* by saying that she may have talked to any of her seniors about what Dr. Pargaonkar had told her in the morning of 25th January but she did not recollect their names except Dr. (Miss) Kamble. After stating that on her conveying to Dr.(Miss) Kamble what Dr. Pargaonkar had told her, Dr. (Miss) Kamble did not give her any specific instructions, she stated that if she had changed orders regarding the administtation of glycerol, mannitol or diamox in the course of her round in the morning it was under the instructions of Dr. (Miss) Kamble. She thereafter admitted that since Vithal Bhokare was transferred to Nepharology in the morning of 25th itself there was no question of changing his orders pertaining to glycerol, mannitol and diamox.

170. According to Dr. (Miss) Parul Shah it was after she told Dr. (Miss) Kamble about what Dr. Pargaonkar had informed her a little earlier that Dr. (Miss) Kamble asked her to discontinue mannitol, glycerol and diamox in the case of Rajendrakumar Mishra. *She gave a go-by to this version a little later* by saying that when she discovered on 26th January that the three suspect drugs were still being administered in Ward No. 26 she was not shocked because on 25th January Dr. (Miss) Kamble had not given any specific instructions for the stoppage of these three suspect drugs.

171. Dr. (Miss) Parul Shah noticed from the treatment sheets that enven after she narrated to Dr. (Miss) Kamble what Dr. Pargaonkar had told her about diamox. mannitol and glycerol they were continued to be given to some of Dr. (Miss) Kamble's patients after 25th January Dr. (Miss) Kamble must also have noticed this because when they took their round on 26th January she asked her about the condtions of her patients and the treatment given to them as per the normal paretice. Dr. (Miss) Parul Shah handled the case papers and gave Dr. (Miss) Kamble the requisite infrormation from those case papers. On 26th January she had handled the case papers of about 6-7 patients who had been given the suspect drugs, but could not *give the exact numbr. She however* did not remind Dr. (Miss) Kamble about what Dr. Pargaonkar had told Dr. (Miss) Parul Shah the perevious day. She did not specifically draw Dr. (Miss) Kamble's attention to the fact that six to seven patients were still being administered glycerol because they had a detailed round just the day before.

172. On being asked whether she was satisfied with the action taken by Dr. (Miss) Kamble on the information given by her to Dr. (Miss) Kamble, Dr. (Miss) Parul Shah admitted that *at that time she was far too junior to understand the drug toxicity* and therefore the best thing she did was to tell her senior Dr. (Miss) Kamble what Dr. Pargaonkar had told her. On 26th January she did not see any point in telling Dr. (Miss) Kamble what she had already told her on 25th. She did not remember if she mentioned to anyone in the department her feeling that Dr. (Miss) Kamble should have taken some stronger action pertaining to those three drugs in Ward No. 26.

173. Dr. (Miss) Parul Shah admitted that on 25th January she did not tell Dr. (Mrs.) Asha Menon (House Surgeon, Ophthalmology) what the Nephrology Registrar Dr. Pargaonkar had told her on the 25th, but she did not remember if she did so later. Dr. (Miss) Parul Shah admitted that she did not tell Dr. (Mrs.) Asha Menon " See, I told her about this " by ' her ' meaning Dr. (Miss) Kamble.

174. Dr. (Miss) Parul Shah finally admitted that on 25th January all that Dr. Pargaonkar had informed her was that the suspect drugs should be stopped in Ward No. 26 *and that he had not told her to inform Dr. (Miss) Kamble accordingly.* She denied Dr. Pargaonkar's evidence at page 780 in para 31 to the contrary. She also admitted that since Dr. Pargaonkar did not tell her specifically to convey his message to Dr. (Miss) Kamble she did not tell him that he should do so himself. She did feel it strange that Dr. Pargaonkar should convey this information to her the Junior-most and not directly to the head of the Department, namely Dr. (Miss) Kamble, even though Dr. (Miss) Kamble herself was present at that time. Prior to this incident she had never come across any incident of contaminated drugs or their effect. *All that Dr. Pargaonkar told her was that the three drugs were suspected to be contaminated and the patients were going into renal failure. Dr. Pargaonkar did not give her any details about the suspected contamination nor did she ask him.* Dr. Pargaonkar made *a casual remark to her* that these three drugs were suspected to be contaminated and should be stopped and should be purchased from outside. She did not specifically tell Dr. Pargaonkar that as House Surgeon she did not have any authority to stop any drug on her own. Then she felt it somewhat strange that he should not tell this to the head of the department, namely Dr. (Miss) Kamble, though she was present in the ward at that time. She denied the version of Dr. (Miss) Kamble in paras 68 and 70 at pages 642–643 that she had not told Dr. (Miss) Kamble anything about the suspect drugs or that they were not to be administered to any patients or that she and Dr. (Miss) Kamble were not together on 25th when Dr. Pargaonkar came to the ward.

175. This brings me to the evidence of Dr. A. L. Kripalani, Head of Nephrology. His part in this episode only extends to his asking Dr. (Miss) Parul Shah whether Dr. Pargaonkar had given her the information on 25th January and whether she in turn had conveyed it to Dr. (Miss) Kamble. To both these Dr. (Miss) Parul Shah replied to Dr. Kripalani in the affirmative during the second meeting of Dr. (Miss) Parul Shah and Dr. Pargaonkar about 4 months earlier prior to the evidence. Dr. Kripalani fairly admitted that he did consider it unusual that if Dr. (Miss) Parul Shah had given this information to Dr. (Miss) Kamble the latter should not have stopped the administration of the suspect drugs and that he had only the word of Dr. (Miss) Parul Shah that she had in fact conveyed this information to Dr. (Miss) Kamble. Dr. Kripalani added it could have been a serious matter for Dr. (Miss) Parul Shah not to have conveyed to Dr. (Miss) Kamble this information given to her by Dr. Pargaonkar. He however accepted Dr. (Miss) Parul Shah's version that she had given this information to Dr. (Miss) Kamble because it was not for Dr. Kripalani to pass judgment on anyone.

176. Dr. Kripalani also admitted that in the morning of 28th January in Nephrology meeting Dr. (Miss) Kamble was in complete agreement with the rest of them that the suspect drugs should be immediately stopped. Nor did she give the impression that the suspect drugs were being continued to be administered in her deparrtment till 28th January. Dr. Kripalani finally admitted that it did strike him that the fault may lie either with Dr. (Miss) Parul Shah or with Dr. Pargaonkar, adding that he was satisfied that Dr. Pargaonkar was not at fault. But he could not say about Dr. (Miss) Parul Shah or Dr. (Miss) Kamble.

177. In this episode Dr. (Mrs.) Asha Menon, House Surgeon, Ophthalmology, also plays a part. She admitted that on 25th January while Rajendrakumar Mishra was being examined, there was no talk in her presence between Dr. (Miss) Kamble and Dr. (Miss) Parul Shah regarding the stoppage of the drugs administered to that patient. On 25th January there was some discussion between Dr. (Mrs.) Asha Menon and Dr. (Miss) Parul Shah regarding Vithal Bhokare but not regarding Rajendrakumar Mishra. In the course of this discussion Dr. (Miss) Parul Shah mentioned what the Nephrologist (meaning thereby Dr. Pargaonkar) had informed her, namely, that something was wrong with some drug somewhere, the drugs being to the best of her recollection diamox, mannitol and glycerol. Dr. (Mrs.) Asha Menon however did not personally inform Dr. (Miss) Kamble about what Dr. (Miss) Parul Shah

had told her. She believed that Dr. (Miss) Kamble knew about it either from Dr. (Miss) Parul Shah or from the Nephrology Registrar. Dr. (Mrs.) Asha Menon did not remember if she had told anyone on 25th what Dr. (Miss) Parul Shah had told her regarding what the Nephrology registrar had told her. But to the best of her recollection she had mentioned this to Dr. (Miss) Nita Shah on Sunday the 26th. Later she stated that she did not remember whether she dad mentioned this to Dr. (Miss) Nita Shah.

178. Dr. (Mrs.) Asha Menon admitted that it was on 27th January that the existence of the suspect drugs came to be known for the first time by anyone in her Ward No. 26, adding that it was in the evening of that day that she came to know of the existence of the suspect drugs when Dr. Kapadia told her about them. Dr. (Mrs.) Asha Menon admitted that if Dr. (Miss) Kamble had been told by Dr. (Miss) Parul Shah on the 25th about the contaminated drugs, Dr. (Miss) Kamble would certainly Know about them, adding her surmise that she was not certain whether Dr. (Miss) Parul Shah had told Dr. (Miss) Kamble about what she had learnt about the suspect drugs from Dr. Pargaonkar. Dr. (Mrs.) Asha Menon also stated that on 27th January Dr. (Miss) Parul Shah had told her what the Nephrology Registrar Dr. Pargaonkar had told Dr. (Miss) Parul Shah about the suspect drugs on 25th and that she *i.e.* Dr. (Miss) Parul Shah, had conveyed this information to Dr. (Miss) Kamble. Dr. (Mrs.) Asha Menon admitted that when she came to know about the contaminated drugs and the patients affected thereby and also the death of some patients on 27th January, she considered it to be a very serious matter and the problem regarding the stoppage of the drugs to be an urgent problem. She however took no steps to stop the administration of the suspect drugs because Dr. Lele, her senior, was with her. She did not inform the doctor in-charge of what she had learnt from Dr. Kapadia on the night of 27th January. On 28th January she did not attend the work by reason of the one day strike though she was in the campus.

179. Dr. (Mrs.) Asha Menon did not remember whether she had brought to the notice of Dr. (Miss) Kamble what Dr. Kapadia had told her. She was not certain whether Dr. (Miss) Kamble knew about the drug contamination prior to 28th January.

180. Dr. Shaikh Saukat Ali, Lecturer-Ophthalmology, also plays a part, though a small one, in this episode. He says that on 28th January when he told Dr. (Miss) Kamble what the staff nurse had told him a little earlier (regarding contamination), Dr. (Miss) Kamble was shocked. From her facial expression he felt that it was for the first time Dr. (Miss) Kamble knew about the drug contamination from him. Dr. Shaikh stated that on 25th January nobody informed him about the three suspect drugs including Dr. (Miss) Parul Shah whom he had met that day.

181. The gut question is : *Did Dr. Pargaonkar tell Dr. (Miss) Parul Shah about the contaminated drugs and to convey this information to Dr. (Miss) Kamble.* Though initially Dr. (Miss) Parul Shah vociferously maintained that this information was indeed given to her by Dr. Pargaonkar which in turn she conveyed to Dr. (Miss) Kamble, later in her evidence Dr. (Miss) Parul Shah stated that what Dr. Pargaonkar had told her casually that the suspect drugs should be stopped as patients were going into renal failure and that Dr. Pargaonkar had not told her to inform Dr. (Miss) Kamble accordingly. From the evidence of Dr. Pargaonkar read in conjunction with that of Dr. (Miss) Parul Shah and the other evidence, it appears that while Dr. Pargaonkar did mention to Dr. (Miss) Parul Shah about the suspect drugs, it is doubtful whether he specifically asked her to convey this information to Dr. (Miss) Kamble, in the expectation that she would. It is also doubtful whether Dr. (Miss) Parul Shah appreciated or realised the gravity of the situation from what, according to Dr. (Miss) Parul Shah, Dr. Pargaonkar casually told her, looking to the fact that on her own admissions she had no knowledge or experience about toxicity and contamination of drugs. This would be more inexperience and a bona fide error on the part of Dr. (Miss) Parul Shah rather than negligence or dereliction of duty. At the same time, it was a mistake on the part of Dr. Pargaonkar not to have conveyed this serious information to somebody higher in authority than Dr. (Miss) Parul Shah, namely Dr. (Miss) Kamble herself, instead of conveying it to the junior-most doctor, namely Dr. (Miss) Parul Shah. Even if Dr. Pargaonka and Dr. (Miss) Kamble were not on talking terms or even if they had not known each other or had not met each other before, Dr. Pargaonkar should have made it his duty to contact her instead of leaving so serious a matter in the fragile hands of the junior-most doctor in the department, namely Dr. (Miss) Parul Shah and that too without making certain she understood the gravity of the situation and the

urgency of the message. It is obvious that finding herself in the predicament, perhaps not deliberately of her own making, Dr. (Miss) Parul Shah now wants to take cover up action by saying that she had conveyed Dr. Pargaonkar's information to her senior, namely Dr. (Miss) Kamble. Whosoever is responsible be it Dr. (Miss) Parul Shah or Dr. Pargaonkar it is manifest that Dr. Pargaonkar's message conveyed by him through Dr. (Miss) Parul Shah did not reach Dr. (Miss) Kamble who came to know of the contaminated drugs for the first time on 28th January, with the result that the failure to stop them in her ward cannot be laid at her door.

182. At this stage, the behaviour and conduct of Dr. (Miss) Kamble are pertinent, It struck her as unusual on Tuesday, the 28th January at 9-00 a.m. during her round of Ward No. 26 when she was told by Dr. Shaikh that Rajendrakumar Mishra had developed anuria and was transferred to Nephrology the previous night, he being the second patient to be transferred to Nephrology, the first being Vithal Bhokare. There is nothing to suggest that Dr. (Miss) Kamble's astonishment was feigned. Dr. (Miss) Kamble would have had no cause for this astonishment if indeed Dr. (Miss) Parul Shah had conveyed to her Dr. Pargaonkar's message of the 25th regarding the suspect drugs.

183. That is not all. On coming to know of Rajendrakumar Mishra developing anuria, Dr. (Miss) Kamble immediately contacted Dr. Shanbhag, in-charge of Unit 2 and enquired of him if any patient from that Unit had been transferred to Nephrology. He told Dr. (Miss) Kamble that Bittal Kevat was transferred from Unit No. 2 to surgical ward and thence to Nephrology and that another patient in Unit 2, namely Abdul Kadar was having urinary problem and the treatment given to him and Bittal Kevat. On this Dr. (Miss) Kamble remembered the treatment which had been given to her patients, namely Vithal Bhokare and Rajendrakumar Mishra and realised that the common drugs administered to all these four patients were mannitol, diamox and glycerol and hence thought that these four patients might have suffered adverse drug reaction due to drug contamination of any of these three drugs.

184. Thereupon she promptly told sister Jadhav to stop the administration of these drugs and also informed all the staff members of Ophthalmology, namely Dr. Shanbhag, Dr. (Mrs.) Gaikwad, Dr. Shaikh, Dr. (Miss) Dekate and Dr. Dastoor to discontinue the administration of these 3 drugs and that she would be holding a meeting in her room that day at 10:30 a.m., which she did. The same day, she also
Exh. 28 wrote a letter (Exh. 28) to the Dean setting out all the facts which had come to her knowledge.

185. The above conduct of Dr. (Miss) Kamble which was most natural, casts a grave shadow of doubt whether Dr. (Miss) Parul Shah did convey to her Dr. Pargaonkar's message of 25th January about the contaminated drugs, perhaps little realising its seriousness or its urgency.

Exh. 8 186. The next question that arises is : *Did Dr. Miss Kamble have knowledge of the 27th January circular (Exh. 8) ?*

187. From the evidence on record it appears that until 28th January she did not. This is brought to the fore by the evidence of certain staff nurse.

188. Staff nurse Mahamulkar attached to the Ophthalmology Ward No. 26 deposed that on 27th January her hours of duty were from 1-00 p.m. to 8-00 p.m. On that day between 5-00 p.m. and 5-30 p.m. she received the circular dated 27th
Exh. 8 January 1986 (Exh. 8). She was not given a copy of the circular. On a piece of paper she made a note of the drugs mentioned in the circular to be stopped as also the batch numbers. She kept this piece of paper with other papers in a pad on her table. After she received the circular she was not required to give any dose of those three drugs to any patient in her ward.

189. At 8-00 p.m. that day she handed over charge to staff nurse Ravi Varma and orally told her of the contents of the circular. She also showed her the piece of paper on which she had made a note of the contents of the circular. That day, namely 27th January, staff nurse Manjrekar was also on duty with nurse Mahamulkar. When
Exh. 8 nurse Mahamulkar received the circular (Exh. 8), nurse Manjrekar was not in the ward but was in the cabin of Dr. (Miss) Kamble. She however told nurse Manjrekar about the receipt of the circular when she returned to the ward. When nurse Mahamulkar received the circular in the ward, Dr. (Miss) Kamble was in her office, but

nurse Mahamulkar did not inform Dr. (Miss) Kamble about the receipt of this circular, nor did she tell nurse Manjrekar to inform Dr. (Miss) Kamble about this circular (Exh. 8). Dr. (Miss) Kamble's room is on the ground floor whereas nurse Exh. 8
Mahamulkar was on the first floor when she received the circular. She orally informed nurse Manjrekar about the circular and also gave her the noting she had made on a slip of paper. At that time there was no conversation between herself and staff nurse Manjrekar as to which patient had to receive or which patient had received any of the three drugs.

190. Nurse Mahamulkar admitted that when circulars are received they must inform the head of the department. She however admitted that she did not bring the circular dated 27th January (Exh. 8) to the notice of Dr. (Miss) Kamble, nor did she Exh. 8
tell staff nurse manjrekar to inform Dr. (Miss) Kamble about it. She knew that the administration of drugs cannot be stopped without doctor's orders. She admitted that when a stoppage circular is received the doctor concerned is asked by the staff nurse whether the drug should be stopped or not. She could not say from which day administration of glycerol was stopped in Ward No. 26. There were several patients in her ward to whom administration of glycerol had been prescribed on 27th and 28th January. Nurse Mahamulkar admitted that though Dr. (Mrs.) Asha Menon had come to Ward No. 26 on 27th January at about 7-30 p.m. and that doctors from her ward were attending on Rajendrakumar Mishra as his condition was serious, and even though she knew that Rajendrakumar Mishra was to be administered glycerol, she did not inform Dr. (Mrs.) Asha Menon about the circular dated 27th January 1986 (Exh. 8). The reason given by her was that she was alone in the ward Exh. 8
and had to attend a number of patients. The record discloses that the staff nurse has to handle as many as 100 patients almost single handed.

191. Staff nurse Ravi Varma attached to Ophthalmology Ward No. 26 was on 27th January 1986 on night duty from 8-00 p.m. to 8-00 a.m. the following day. She was the only staff nurse on duty. She took over charge from nurse Mahamulkar. Nurse Ravi Varma says that while giving charge to her nurse Mahamulkar did not inform her of any circular received by her nor did she tell her anything pertaining to the stoppage of any drug nor did she show her any paper on which she had made any noting nor did she give her any such paper. That night at 10-00 p.m. in ignorance of the circular (Exh. 8) nurse Ravi Varma administered glycerol to the patients according to the nurses' order book.

192. Nurse Ravi Varma deposed that she did not administer glycerol to Abdul Kadar Shaikh at 6-00 a.m. on 28th January. Sister Jadhav did not ask her whether she had administered glycerol to Abdul Kadar Shaikh at 10-00 p.m. on 27th or at 6-00 a.m. on 28th but she herself told sister Jadhav that she had not administered the 6-00 a.m. dose to Abdul Kadar Shaikh on 28th because of what Dr. Lele had told her the previous night. This information was given by nurse Ravi Varma to sister Jadhav while handing over charge to her at 7-30 a.m. the following morning, namely on 28th January.

193. Nurse Ravi Varma deposed that at 10-00 p.m. on 27th January she had given glycerol and diamox to Dnyandeo Pote. By the time Dr. Lele told her at 11-00 p.m. on 27th not be administer glycerol, patients to whom glycerol had been prescribed had already been given their doses at 10-00 p.m. as usual.

194. From the evidence of nurse Ravi Varma it is extremely doubtful whether the relieving nurse Mahamulkar had informed her about the circular (Ex. 8). No Ex. 8
stigma of negligence or dereliction of duty can be laid at the door of Mahamulkar looking into the fact that almost single-handed she had to look after as many as 100 patients and handle more than what a single human being could possibly do. Moreover looking to the fact that there was nothing in the circular to pointedly or otherwise draw attention to the fact that the three drugs mentioned therein were suspected to be contaminated, there was nothing whereby the person receiving such circular would be put on his or her guard. In these circumstances, despite the fact that nurse Mahamulkar says that she conveyed the contents of this circular and gave her note to the relieving nurse Ravi Varma, it is probable that she did not, as she had no means of realising the gravity of the situation. The fault for this defect must lie with the writer of such circular, namely Dr. (Mrs.) Worlikar as stated earlier.

195. The version of nurse Ravi Varma of glycerol not having been administered to any patient including Abdul Kadar Shaikh loses much of its probability in view of the overwhelming oral and documentary evidence discussed above.

196. This brings me to the evidence of staff nurse Manjrekar. She was staff nurse in ophthalmology, ward No. 26. Nurse Manjrekar was on duty on 27th January from 1-00 p.m. to 8-00 p.m. along with nurse Mahamulkar. Nurse Manjrekar did not receive any circular pertaining to the stoppage of mannitol, glycerol and diamox, but came to know about it from staff nurse Mahamulkar who received it in the ward on the 1st floor while nurse Manjrekar was in the office of Dr. (Miss) Kamble on the ground floor. Nurse Manjrekar was in Dr. (Miss) Kamble's office that day about from 2-30 p.m. When nurse Manjrekar returned to the ward at about 5-00 to 5-15 p.m. that day staff nurse Mahamulkar told her about the receipt of the circular of 27th
Exh. 8 January (Ex. 8). Nurse Manjrekar does not remember whether she mentioned to Dr. (Miss) Kamble what nurse Mahamulkar told her about the circular. During the time nurse Manjrekar was with Dr. (Miss) Kamble she did not mention to her anything about any circular. However Dr. (Miss) Kamble asked nurse Manjrekar the names of all the patients in Ward No. 26 who had received all the three drugs. Dr. (Miss) Kamble took down the treatment given to Vithal Bhokare and Bittal Kevat. Beyond telling nurse Manjrekar that there was a circular pertaining to the stoppage of glycerol, mannitol and diamox, nurse Mahamulkar did not tell nurse Manjrekar anything. Nurse Manjrekar admits that she did not tell Dr. (Miss) Kamble what staff nurse Mahamulkar had told her, nor did she tell anyone else. It did strike nurse Manjrekar that this was an important circular and that she should take some action after coming to know it from staff nurse Mahamulkar. The action which Manjrekar thought proper was to inform Dr. (Miss) Kamble about the circular. It did strike nurse Manjrekar that administration of these three drugs should be discontinued. She did not remember whether she had informed Dr. (Miss) Kamble about the circular. She thought Dr. (Miss) Kamble was aware of it because she had asked her to fetch certain bottles to her office of these three drugs. Staff nurse Mahamulkar knew that nurse Manjrekar was taking three bottles to Dr. (Miss) Kamble whereupon Mahamulkar told Manjrekar about the circular. (Ex. 8.) She did not remember if she told Dr. (Miss) Kamble anything about the circular after bringing these three bottles to her. After giving the bottles to Dr. (Miss) Kamble, nurse Manjrekar returned to Ward No. 26.

197. Nurse Manjrekar admitted that she came to know on 27th January that three suspect drugs were not to be administered, but she did not do anything as the second dose had already been given and the third dose was not to be given during her duty hours. Nurse Manjrekar admitted that she however did not give any instructions to the relieving nurse, namely nurse Ravi Varma, on the ground that it was for nurse Mahamulkar to do. She did not know if Mahamulkar did so. Nurse Manjrekar did not tell nurse Mahamulkar to do so, nor did she ensure that Mahamulkar did so.

198. There is also Dr. (Miss) Kamble's astonishment when during the Nephrology meeting. Dr. Palande told her about the circular sent to Ward No. 26 and that she did not know anything about it, which is a fact borne out by the evidence of of sister Jadhav and the staff nurses of Ward No. 26.

199. From this evidence it is clear that Dr. (Miss) Kamble had no knowledge of the 27th January circular (Ex. 8) nor did she have the means of knowing about it.

200. The question that next arises is, *Did Dr. (Miss) Kamble make any enquiries between 2-30 and 5-30 p.m. on 27th January about the 3 suspect drugs and the patients to whom they were administered ?*

201. The answer must be in the negative. On this aspect the evidence of staff nurse Manjrekar (Ward 26) and Dr. (Miss) Kamble herself is pertinent.

202. Staff nurse Manjrekar says that on 27th January she was in Dr. (Miss) Kamble's office at about 2-30 p.m. at her behest. The nurses' order book was lying of on Dr. (Miss) Kamble's table. She asked nurse Manjrekar to take out the order of Vithal Bhokare and Bittal Kevat which nurse Manjrekar did. Dr. (Miss) Kamble asked nurse Manjrekar what their full names were because that was not shown in the order book. Nurse Manjrekar thereupon went upstairs to ward No. 26, looked up the admission book, came down again to Dr. (Miss) Kamble's office and gave her their full names. Thereafter Dr. (Miss) Kamble asked Miss Manjrekar to get her the bottles of diamox, mannitol and glycerol from Ward No. 26. Before telling her to do so Dr. (Miss) Kamble went through the treatment given to these patients 2 months earlier, i.e. from their dates of admission and recorded this treatment on a sheet of paper. All this took about two and half hours during which time nurse Manjrekar was with Dr. (Miss) Kamble.

203. There is an inherent defect in this evidence of nurse Manjrekar. She is obviously not telling the truth when she says that Dr. (Miss) Kamble went through the treatment given to Bittal Kevat and Vithal Bhokare two months earlier. The falsity of such an assertion must be borne out from the fact that these patients were not in Ward No. 26 for two months. In Order to go through the treatment of Vithal Bhokare and Bittal Kevat. Dr. (Miss) Kamble must necessarily consult the case paper. Vithal Bhokare had died on 25th with the result that his case papers would be with Pathology for the purpose of postmortem and not in Ward No. 26. Similarly Bittal Kevat died on 27th at 5–45 p.m. in Nephrology where he had been transferred on 22nd January and his case papers would be in Nephorology and not in Ward No. 26. These factors denote the falsity of nurse Manjrekar's version about what Dr. (Miss) Kamble did at that time in her room, and thereby bring to the forefront Dr. (Miss) Kamble could not possibly have asked nurse Manjrekar to do the things stated by her. This would cast a grave shadow of doubt upon the veracity of nurse Manjrekar's assertaion that she was with Dr. (Miss) Kamble in her room on the ground floor between 2–30 and 5.30 p.m.

204. As against this there is Dr. (Miss) Kamble's version that on 27th January she took her morning round and thereafter went to the Surgery Department to scrutinise applications for Resident Doctors' posts. She was in the Surgery Department from 10–00 a. m. to 12–00 noon, scrutinising those applications. Thereafter till about 1–30 p. m. she was busy making arrangements in her Ophthalmology Department to meet the strike of the Resident Doctors the following day. At about 2–00 p.m. she returned to the Surgery Department for scrutinising the remaining applications. She was in the Surgery Department till 6–30 to 7–00 p.m. that evening. With her in the Surgery Department were Dr. K. K. Deshmukh (Professor and Head of the Gynecology Department), Dr. Shirodkar (Head of Anaesthesia Department) Dr. (Mrs.) Gaikwad (Reader in medicine and Dr. Nagori (Professor and Head of the Surgery Department). She and these persons comprised the scrutiny Committee which had been set up by the Dean's circular of 27th January 1985 [Part of Ex. 116 (colly.)] with Dr. Nagori as the Chairman. Dr Nagori had issued a Memo [part of Ex. 116 (colly.)] to all the Committee members for a meeting in his office on 27th January at 10.00 a.m. for scrutinising the applications. A number of applications had to be considered at this meeting. This meeting commenced on 27th January at 1.00 a.m. and got over at 7.00 p.m. It was essential thatall the application had to be discussed and dealt with on the 27th itself because the interviews had been fixed on the 29th or 30th January and the posts had to be filled on 1st February. Hence it was absolutely imperative that all the applications had to be dealt with on 27th January itself.

205. In the light of the fact that this meeting commenced at 10-00 a. m. and got over at 7–00 p. m. on the 27th January as stated by Dr. (Miss) Kamble, it is inconceivable that nurse Manjrekar would have been called by Dr. (Miss) Kamble to her room between 2–30 and 5–30 p.m. as deposed to by nurse Manjrekar. Dr. (Miss) Kamble's version of this meeting and her presence there-at from 10.00 a.m. till 7–00 p. m. on 27th January is corroborated by none other than Dr. Nagori himself who was the Chairman and Member of the Scrutinisation Committee for the selection of Registrars, Housemen and registration. Dr. Nagori deposed to the presence at this meeting of all the persons referred to by Dr. (Miss) Kamble with himself as the Chairman. The meeting commenced at about 10–00 a. m. and went on till 12–30 p.m. and thereafter from 2–00 p.m. till 6–30 to 6–45 p.m. During both the sessions, all the members of the Committee including Dr. (Miss) Kamble were present throughout.

206. There is no reason and none was suggested why Dr. Nagori, an independent witness, should go out of his way to tell a lie for the sake of Dr. (Miss) Kamble and with whom he had no connection other than strictly professional. Dr. Nagori's evidence corroborates that of Dr. (Miss) Kamble and reveals the falsity of nurse Manjrekar's version about Dr. (Miss) Kamble being present in her room between 2–30 p. m. and 5–30 p. m. on 27th Whereas she was actually at the meeting from 2–00 to 6–30 or 6–45 p.m. without a break.

207. While Dr. (Miss) Kamble is falsely sought to be inculpated in acts she did not do, it may also be stated that she has attempted to take false credit for having discovered the killer drug on 28th January. According t her, even before the discovery by the Nephrology Department that day at 11-30 a.m. she had already issued the stop order (Ex. 108) and circular (Ex. 107) and had written (Ex. 23) to the Dean between 9–30 and 10–00 a.m. that day. According to Dr. (Miss) Kamble it was her independent decision on 28th during her morning riound to stop further administration of the suspect drugs. Though her decision might well have been independent, Ex. 108 Ex. 107

it was not through her own endeavours that she came to know on 28th morning of the deaths but as the result of what was told to her by Dr. Shaikh. If she cannot be allowed to take credit for what she did not do, likewise she also cannot be blamed for what she did not do. Apparently she would not have won a popularity poll in the Hospital, much less in her own department. Obviously she knew that and her fear that she might be falsely inclupated is borne out by the fact that she took the precaution of having the original minutes of the meetings singed by all the participants and even took them away with her on her transfer from Bombay on 14th February.

208. This brings me to the next question.—*Was Dr. Kulkarni (Professor of Pharmacology) responsible for not withdrawing the suspect drugs* ?

209. On the evidence of Dr. Kulkarni himself, the answer must be in the affirmative. Untill 13th February 1986, Dr. R. D. Kulkarni was Professor of Pharmacology in the J. J. Hospital. From 1973 till 13th February 1986 (except for one year when he was posted at Poona), he was in charge of Medical Store at J. J. Hospital. In 1973, the post of Associate Professor was created to assist the Professor of Pharmacology In the afternoon of 27th the January, Dr. Kulkarni met Dr. (Mrs.) Worlikar on her way to Medical Store. She told him that she had received Dr.Kripalani's letter reporting the adverse drug reaction and that she was on her way to Medical Store to issue circulars to the sisters of various wards to stop use of the drugs mentioned in Dr. Kripalani's letter, namely mannitol, diamox and glycerol, and that she would have the stocks checked. That evening at 5.00 p.m. Dr. (Mrs.) Mujumdar reported to Dr. Kulkarni that glycerine had been administered to all patients in Neurology, Neuro-surgery and Ophthalmology Departments, but that the other suspect drugs had not been administered to all the patients affected with drug reaction, that several patients in the surgery ward had received gentamycin but had not suffered any drug reaction, that in the surgery department mannitol had been given only to one patient but she could not meet him as he had been discharged and that in the surgery department several patients had been administered gentamycin without any adverse drug reaction. In the evening of 28 th January, Dr. (Mrs.) Worlikar told Dr. Kulkarni that the FDA had been informed and that the Inspectors had collected the samples of the suspect drugs. At the meeting of the College Committee on 29th January, Dr. (Mrs.) Renu Patel (Head of Paediatrics) complained that neither she nor her department had received the stoppage circular. Dr. Kulkarni explained to her that the circular had been sent to the ward sisters as that was the surest way of stopping drug administration because the ward sisters store the drugs and nurses administer them. He admitted that there was some general lack of communication between the sisters-in-charge and the heads of many departments.

210. Dr. Kulkarni's culpability in his failure to stop and promptly withdraw the suspect drugs is brought to light by his own admissions, namely that though he was in charge of Medical Store he himself did not go to Medical Store on 27th to stop supply of the three suspect drugs, that he himself did not take any steps for stoppage of the suspect drugs, never told Medical Store to stop supply of the suspect drugs to the various wards and took no action to that end. It is futile for Dr. Kulkarni to attempt a mitigation of these lapses on the ground that Dr. (Mrs.) Worlikar was doing all this. As in charge of Medical Store it was primarily and essentially Dr. Kulkarni's duty to stop further dissemination of the suspect drugs and to oversee their recall from the various wards which he failed to do so despite his admission that he was the right and proper person to instruct Medical Store not to supply the 3 suspect drugs to the various wards. This answer Dr. Kulkarni gave with reluctance after the question was repeated to him twice. He also agreed that as Head and in charge of Medical Store it was his responsibility of instruct Medical Store not to supply the 3 suspect drugs to the various departments and that he abdicated this responsibility of his in favour of Dr. (Mrs.) Worlikar. This answer was also given by Dr. Kulkarni with reluctance after the question was repeated to him twice. It is futile for him to volunteer that Medical Store automatically discontinued supply whenever a circular to do so reaches it. He agreed that it would have been quicker for him as Head of Medical Store to instruct Medical Store not to issue the three suspect drugs rather than wait for Dr. (Mrs.) Worlikar to tell Medical Store what he should have done himself. (And to which I can legitimately add : Rather than wait for the circular to take its own sweet time to reach Medical Store.)

211. There is also Dr. Kulkarni's admission that it was in the first week of February 1986 that for the first time he saw the stoppage circular of 27th (Exh. 8) and the recall circular of 29th (Exh. 9). He did not even know if Dr. (Mrs.) Worlikar or anyone else

had given instructions to Pharmacist Jamadagni regarding the stoppage of the 3 suspect drugs or the recall of glycerine Batch No. 27. Till he gave evidence before this Commission he had not even seen the Dean's circular of 29th January (Ex. 12), adding that he might have mentioned to the Dean on 29th January that the main suspect drug was glycerol. Even so, as head and in-charge of Medical Store, Dr. Kulkarni himself did not do anything by way of stoppage or recall of the suspect drugs. He has also no personal knowledge that the supply of the suspect drugs was stopped from 27th January or that the alternate supply of Chem Pack's glycerol was made. There is his further admission that until he was transferred on 14th February, he made no enquiries nor did he come to know how many bottles of Batch No. 27 had remained unutilised nor did he make any enquiries whether all the wards had returned to Medical Store the glycerol from Batch No. 27 lying with them.

212. These admissions coming from the lips of Dr. Kulkarni himself must place beyond any pale of controversy, his responsibility in not stopping the dissemination of the drugs and his failure to promptly withdraw them.

213. The only thing that can be said in favour of Dr. Kulkarni on this aspect is that on 28th January in Medical Store he found that glycerine Batch No. 27 was in Section D where medicines are kept unlocked. He thereupon told Pharmacist Jamadagni to remove those, gycerol bottles from Section D and keep them under lock and key in Section C where medicines intended to be kept under lock and key are placed. However even then, he did not ask Jamadagni whether any bottle of glycerine had been delivered to any ward on 27th January or how many bottles from Batch No. 27 had been returned to Medical Store or were lying in Medical Store. It is futile for Dr. Kulkarni to shrug away his blatant acts of negligence by a bare assertion that in the matter of recall of drugs the duty of Medical Store comes to an end as soon as the recall circular is sent by the Pharmacist to the various departments, adding that if a suspect drug is reported to him, he would issue instructions to the Pharmacist to issue a recall circular. Pray, then, why did he not himself in this case, instead of abdicating his responsibility to Dr. (Mrs.) Worlikar? There is no answer.

214. It will becomes Dr. Kulkarni to philosophise that the present system of recall of drugs leaves much to be desired, and which should be done on an emergency footing. Pray, then, why did Dr. Kulkarni himself not resort to this measure on an emergency footing? There is no answer.

215. According to Dr. Kulkarni if sufficient manpower is placed at the disposal of Medical Store, Medical Store itself would visit each and every ward and take charge of the suspect drugs. Dr. Kulkarni himself does not suggest that he had made any such recommendation for " sufficient manpower " to anyone at any time before.

216. From the entire conduct of Dr. Kulkarni and his own admissions, for him escape from the charge of negligence and dereliction of duty in not stopping and not promptly withdrawing the suspect drugs, is impossible.

CHAPTER IX

QUESTION (d) : " Whether adequate, curative and preventive measures in respect of affected patients were taken by the concerned doctors/para-medical/other ancillary staff who were connected with the care of the patients? If not, who were responsible?"

1. The answer to this question is in the affirmative in so far as it pertains to taking of adequate, curative and preventive measures taken by doctors attending to the affected patients.

2. However as discussed in he earlier Chapter pertaining to question(c), no adequate preventive measures were taken by the Dean and the Superintendent and by the doctors of the Pharmacology Department, viz. Dr. R. D. Kulkarni, Dr. S. V. Shaligram, Dr. (Mrs.) P. S. Worlikar and Pharmacist Jamadagni.

3. On the aspect of the adequacy of taking preventive measures, the Ophthalmology Department cannot escape unscathed on the ground that even if adequate preventive measures had been taken, it would have made no difference to the end result.

4. Ophthalmology Department did not discontinue the killer glycerol till 28th January. It is true that deaths did not occur because of this unfortunate lapse because even assuming that the administration of the killer drug had been stopped in the Ophthalmology Department on the 25th, the afflicted patients had by then received enough as not to make any difference to the fatality which had to result. The patients would have died anyway even prior to suspicion falling on glycerol on the 25th. To illustrate, Dawood Haji Dholakia was given glycerol on ounce 3 times a day from 20th January 1986. Even if administration had been stopped on 24th January as ordered by Dr. Dastur, and not continued till 27th January, this patient had received already 8 ounces. Another patient Abdul Kadar Shaikh was administered glycerol one ounce 3 times a day from 23rd January 1986 till the first dose on 28th January. By 25th January he had received 9 ounces. According to Dr. Wagholikar, one ounce is sufficient to cause death and according to Dr. Kripalani one ounce 3 times a day is sufficient to cause death. Thus by 25th January these two and the other patients had received enough glycerol to end in fatality.

5. This is what Dr. Wagholikar has to say :

" The lethal dose of diethylene glycol has been estimated on the basis of the two previous episodes namely one in U.S.A. and one in South Africa. On this basis the lethal dose would be 2 to 3 ounces divided into multiple doses. The cases of diethylene glycol poisoning in the U.S.A. and South Africa were not confined to hospitals alone. They were spread over to hospitals as also treatment taken at home. In the present episode in the J. J. Hospital all the deaths that took place as a result of diethylene glycol poisoning were due to glycerol administered under medical supervision which normally would not have caused death had the glycerol been pure. Taking the statistics from the deaths in the present episode and looking to the fact that one patient, Bapu Thombre, had received glycerol one ounce 3 times a day for only two days and looking to the fact that even so he succumbed to diethylene glycol poisoning, my estimate would be that *even a total dosage of one ounce would be sufficient to cause death.*" (The italics is mine.)

6. From the case study, Dr. Wagholikar has opined that even one ounce diethylene glycol would be sufficient to cause death, the lethal doses of 2-3 ounces divided into multiple doses. Bapu Thombre received one ounce 3 times a day for only two days and even so he succumbed to diethylene glycol poisoning. Dr. Wagholikar's estimation is that even a total dosage of one ounce, would be sufficient to cause death. The question is total dosage of what-diethylene glycol or glycerol containing diethylene glycol? To that end, Jethalal Soni (proprietor of Ganesh Chemicals) has described the manner in which he manufactures industiral glycerine. For the manufacture of 250 kg. he mixes—

" Sorbitol	187 kg.
Diethylene glycol	40 kg.
Pure glycerine	25 kg."

On the basis of this proportion, the percentage of diethylene glycol would come to 16. Hence if patients are given doses of such glycerine containing diethylene glycol one ounce 3 times a day or one ounce 6 times a day, the total dosage of diethylene glycol consumed would be 96 per cent.

7. Can all this be a mitigating factor for negligence of the Ophthalmology Department in not stopping the killer drug on 25th? Certainly not. I am not exactly enamoured by the thought that this would be a mitigating factor for negligence or obliterates negligence in not stopping the administration of such drug. No doctor or nurse can be heard to say : Even if I had stopped the lethal doze, the patient would have died anyway. I fear in so far as the Ophthalmology Department is concerned, it is not the result that matters but what matters is the negligence itself in not stopping the doses from 25th January regardless of the fact that the patients would have died anyway.

CHAPTER X

QUESTION (*e*) : *" If certain deaths have occurred due to administration of any adulterated, sub-standard, contaminated or defective drugs, the causes and circumstances which resulted in administration of such drugs to the patients."*

This question answers itself covered as it is partly by questions (*a*), (*b*) and (*c*) which have been answered earlier in this Report. In view thereof, no separate answer to question (*e*) is called for.

CHAPTER XI

QUESTION (f).—"Whether the prescribed procedure for procurement, storage, as well as inspection of quality of these drugs at the J. J. Hospital was followed ? If not, the reasons therefore and the persons responsible for it."

1. Even looking to the limited space available in the J. J. Hospital, the manner in which the drugs are stored is by far and large unsatisfactory. Even Dr. Kulkarni has also expressed that the storage conditions " are not entirely satisfactory ". The conditions of storage in Medical Store is far from satisfactory. Drugs and medicines, gauzes, cotton etc. must be stored in an area which is spotlessly clean which the area of Medical Store is not. There must be no leakage of rain water from which Medical Store suffers. The storage space is inadequate and some drugs have to be kept on the floor. This is unhygenic apart from the heavy rain water accumulation on the floor of Medical Store. Gauze and bandages are soiled by reason of rain water. The areas of the Medical Store and floor pharmacy need expansion. For storage there does not appear to be any procedure prescribed by the Government. Until that is done a proper procedure in writing should be devised must be strictly adhered to and enforced. The Dean and/or the Superintendent and/or the Professor of Pharmacology in-charge of Medical Store should take periodic rounds and pay surprise visits. At the moment nothing of the kind is done.

2. Regarding inspection, while the FDA is empowered to inspect licenced premises and take action against erring licensees, for breach of licence conditions, there is no provision in the Act or Rules which enables the FDA to take action against hospitals as they are not licenced by the FDA. Hence even the annual inspection by the FDA of the J. J. Hospital once a year, when random samples are taken, is by far and large ineffectual for want of power in the FDA to take action when need arises. Further, in the J. J. Hospital there are no facilities for inspection of the quality of the drugs. The Dean and/or the Superintendent and/or the Professor of Pharmacology must carry out an inspection of the quality of the drugs, which is not done for the simple reason that the J. J. Hospital does not have any facilities to that end.

PROCUREMENT

3. In the J. J. Hospital the prescribed procedure for procurement was followed except that Alpana Pharma's order was not restricted to 11 per cent as it should have been. The procurement by Government for the J. J. Hospital was not proper, legal or valid and to that extent the prescribed procedure was not followed. Hereunder my reasons :—

4. The J. J. Hospital can place orders only from rate contracted suppliers. In the present case, Chem Pack was given the original contract and Alpana Pharma was given the alternate contract. Later Alpana Pharma's alternate contract was cancelled and transferred to the backward area reservation of 33 per cent. On 16th March 1985 preferential purchase (Ex. 55) was granted to Alpana Pharma, Universal Pharmacy and Deepti Pharmacy at the rate of 11 per cent each and to Chem Pack at the rate of 37 per cent. 2,900 bottles of glycerol were purchased, out of which— Ex. 55

1,400 bottles were from Chem Pack,

1,300 bottles were from Alpana Pharma, and

200 bottles were from Universal Pharmacy.

No purchase was ordered from Deepti Pharmacy.

Calculating 33 per cent out of 2,900 bottles, the number of bottles would be 880. 11 per cent of 880 bottles would be in the vicinity of 293 bottles. Hence while Universal Pharmacy was within the 11 per cent limit, the purchase from Alpana Pharma was 1,300 bottles, whereas it should have been 293 bottles.

5. On 28th May 1985 an order was placed with all the three suppliers, namely :

200 bottles on Alpana Pharma which were delivered on 27th June 1985.
200 bottles on Universal Pharmacy which were delivered on 9th July 1985.
800 bottles on Chem Pack which were delivered on 22nd July 1985.

On 4th July 1985 a second order was placed on Alpana Pharma for 700 bottles which were delivered on 16th August 1985.

On 5th December 1985 a third order was placed on Alpana Pharma for 400 bottles. 270 bottles were delivered on 27th December 1985.

On Chem Pack second order was placed on 18th December 1985 for 600 bottles which were delivered on 21st January 1986.

Thus in the case of Alpana Pharma the orders placed by J. J. Hospital exceeded 11 per cent.

6. Who is responsible for this? To that end, before alluding to the evidence of Pharmacist Jamadagni, I may state that the procedure for placing the order is for the pharmacist to prepare a proposal which he puts up to the Associate Professor of Pharmacology. However, in the instant case, this procedure was departed from as appears from the evidence of Pharmacist Jamadagni.

7. He says orders were prepared by the Senior Clerk Indulkar under his supervi-
Ex. 56 sion. The orders are Ex. 56 which do not show the total number of bottles ordered from any suppliers; this would be shown in the proposal form which Jamadagni prepared and signed. At the time Jamadagni prepared the proposal form for the purchase of glycerol he was aware of the proportion in which orders could be placed with various suppliers. He admitted that an order on Alpana Pharma could not have been placed for more than 11 per cent of the requirement. He admitted that the order placed with Chem Pack was for 1,400 bottles of glycerol and with Alpana Pharma for 1,300 bottles and that the orders placed with Alpana Pharma exceeded the 11 per cent quota for which an order could be placed. Pharmacist Jamadagni admitted that this was done pursuant to his proposal which was sanctioned by the Associate Professor of Pharmacology, namely Dr. (Mrs.) Worlikar or Dr. (Mrs.) Kelkar. Jamadagni's excuse for not restricting the order to Alpana Pharma to the permissible quota of 11 per cent was that the supply of the other two suppliers, namely Universal Pharmacy and Deepti Pharmacy was unpredictable, because those two suppliers were at Nagpur and sent their supplies to Dadar resulting in the J. J. Hospital to having incur an extra expenditure at the rate of Rs. 1·50 per bottle for lifting the consignment from Dadar. He admitted that both Deepti and Universal Pharmacy had been assigned 11 per cent each under the rate contract, but it was decided (though the decision according to him was not his) not to place an order with Deepti and Universal and instead place it with Alpana Pharma. He says that he placed all these facts before Dr. R. D. Kulkarni. According to Jamadagni, there were also many problems in getting the money from the accounts section for lifting the bottles from Dadar to J. J. Hospital. He admitted that it did occur to him that in not placing an order with Deepti Pharmacy and Universal Pharmacy they were contravening Government directions pertaining to reservation of backward areas in the rate contract. He admitted that he did not bring this to the notice of Dr. R. D. Kulkarni.

8. Jamadagni goes on to say that the proposals must be made according to the Government directions in the rate contract. He however adds a rider that local situation regarding supply is also given importance, namely the requirement of the J. J. Hospital and availability from other sources. He admitted that he did not point out to Dr. R. D. Kulkarni what the reservations were for Deepti, Universal and Alpana Pharma.

9. Jamadagni admitted that the total order for glycerol placed with Chem Pack was 1,400 bottles, with Alpana Pharma 1,300 bottles and with Universal Pharmacy 200 bottles; with Deepti Pharmacy not a single order was placed. The excuse given by Jamadagni was that Deepti Pharmacy had been on rate contract for some other drugs, namely, cough expectorant, that they also sent their consignment to Dadar and that their packing was the worst as the expectorant bottles received at Dadar Railway Station were found to be scattered.

10. Jamadagni goes on to say that he placed those facts before Dr. R. D. Kulkarni who decided not to place any order with Deepti Pharmacy. The order for 200 bottles placed with Universal was the first contract after finalisation of the 33 per cent of the rate contract. Acceptance of the contract by Deepti was received very late. The supply position of both these concerns was not proper, namely that they made late supplies. Jamadagni also placed before Dr. Kulkarni his difficulties about Universal.

Dr. Kulkarni did not tell Jamadagni to place the entire order of 33 per cent of glycerol with Alpana Pharma. Jamadagni however did so. The entire order of 33 per cent was placed with Alpana Pharma, because there was no other supplier except Alpana Pharma, Universal Pharmacy and Deepti Pharmacy.

11. Jamadagni admitted that he had exceeded the 33 per cent reservation in the case of Alpana Pharma, because the order for 700 bottles placed with Alpana Pharma was "due to the situation prevailing at that time". Initailly the order was placed with Chem Pack, Alpana Pharma and Universal Pharmacy for 800 bottles, 200 bottles and 200 bottles respectively. Alpana Pharma delivered 200 bottles, Chem Pack and Universal made a late delivery. At that time namely on 24th June 1985 the stock position of glycerol became nill when the stock-in-hand was only 700 bottles of glycerol. On 27th June 1985 Jamadagni received 200 bottles of glycerol from Alpana Pharma. On 9th July 1985 he received 200 bottles of glycerol from Universal Pharmacy. When asked why in the light thereof he placed an order for 700 bottles with Alpana Pharma on 4th July 1985, his reply was that it was done because of the approval taken on 2nd July 1985. He admitted that no reminder was sent to Chem Pack for non-supply as normally reminders are not sent by the Hospital. Chem Pack supplied 800 bottles on 22nd July 1985,. He did not tell anyone that as there was sufficient stock by 4th July 1985 the order with Alpana Pharma should be with-drawn.

12. A further order for 400 bottles of glycerol was placed with Alpana Pharma on 5th December 1985. Simultaneously an order had already been sent to Chem Pack for the supply of 600 bottles of glycerol. He admitted that when the order was placed on Alpana Pharma on 5th December 1985, he knew that the quota of Alpana Pharma had already been exceeded, but he did not bring this to the notice of anyone.

13. On 18th December 1985 his stock of glycerol bottles was 138. When shown evidence of Compounder Soudi in para 6 at page 239, Jamadagni says that this stock of 96 bottles was over and above the stock-in-hand on 18th December 1985. He had verified the stock on 24th December 1985; the stock tallied on that day. This was the stock physically counted by Compounder Soudi in his presence. Jamadagni says that the physical verification taken by him was meticulous. During the course of physical verification sometimes he comes across shortages or surpluses but not to an appreciable extent. The mistake is rectified in the bin-card after cross checking with the ward indents. The verification is done by the concerned compounder. Jamadagni himself does not do it. The Associate Professor of Pharmacology supervises his verification. Jamadagni has direct contact with the Associate Professor of Pharmacology. He has no direct contact with Dr. R. D. Kulkarni. If Dr. Kulkarni calls him he goes to him. In the case of Universal Pharmacy and Deepti Pharmacy, Dr. Kulkarni did not call him. He himself went to him because the case was unusual.

14. Jamadagni denied that it is on his recommendation that all the orders were placed on Alpana Pharma. He only prepared the proposal which was approved by the Associate Professor of Pharmacology after scrutiny. Thereafter the orders were placed.

15. On being shown the proposal from dated 16th December 1985 (Ex. 41), Jamadagni stated that when the approval for 1000 bottles of glycerol was given, it was not stated how this figure was to be divided between Chem Pack and Alpana Pharma. He admitted that when Dr. (Mrs.) Worlikar signed the proposal the proportion of 600 bottles to Chem Pack and 400 bottles to Alpana Pharma was not mentioned in the proposal form. This he filled up later as per the percentage and thereby the order for 400 bottles (33 per cent) was placed with Alpana Pharma. There is no written record that the entire 33 per cent should be given to Alpana Pharma. There is alsotnot written record of the difficulties pointed out by him to Dr. Kulkarni pertaining to Universal Pharmacy and Deepti Pharmacy. Jamadagni says that it was not necessary to bring to the notice of the Industries Department any of difficulties. In any event he was not required to do so. Jamadagni does not know whether any one pointed out these difficulties to the Industries Department. These difficulties should have been pointed out to the Industries Department. Ex. 41

16. Jamadagni was shown the amendment dated 16th March 1985 (Ex. 55). He admitted that he had not acted in accordance with this amendment. He added that by not acting on this amendment no loss was caused to Government. As in charge of Medical Store his duty was to procure the drugs. He made his proposal according to the rae contract sating that the rest was upto the Associate Professor. Ex. 55

Ex. 41 17. Jamadagni admitted that in the proposal form (Ex. 41) he had made no proposal regarding the proportion of orders to be placed with Alpana Pharma and Chem Pack. That proportion was fixed by him on his own within the total quantity of 1000 bottles to be ordered. He never pointed out except orally the undersir ability of placing orders with Universal Pharmacy and Deepti Phamacy. In the proposal he had written that supply was not effected by these two concerns. That proposal was dated 24th June 1985. Pursuant thereto the order was placed on 4th July 1985 with Alpana Pharma.

18. From Jamadagni's evidence it is manifest that no satisfactory explanation is forth-coming from him for exceeding the 33 per cent quota in case of Alpana Pharma. It is not out of place to mention that Alpana Pharma made its purchases at Rs. 54 per kg. and it sold to J. J. Hospital at Rs. 74·80 per kg. and thereby made a profit of Rs. 19·20 per kg. equivalent to Rs. 9·60 per bottle of 500 gms. No doubt if Alpana Pharma could get more orders and for larger quantities it would have been to its benefit and perhaps to the benefits of others. The placing of the order on Alpana Pharma was done by Pharmacist Jamadagni. It would have been better for Dr.(Mrs.) Worlikar, Associate Professor of Pharmacology to have persued the proposal order put before her by Jamadagni before signing it. If she had done so, she would have noticed that the proportion was not stated in the proposal order. She would have also noticed that in the proposal prepared by Jamadagni, the name of the supplier and the quantity were not mentioned. To the extent that Dr. (Mrs.) Worlikar signed such a proposal form where the name of the supplier and the proportion were not stated, she was negligent. Having thus obtained her signature, Jamadagni makes virtue out of necessity by foisting approval on the Associate Professor of Pharmacology and thereby liability and responsibility on her.

19. In substance Jamadagni's evidence reveals that :—

(*i*) there was a restriction on the J. J. Hospital not to exceed 11 per cent in placing an order to the supplier ;

(*ii*) the 11 per cent restriction was breached ;

Ex. 55 (*iii*) Jamadagni did not act on the amendment (Ex. 55) ;

(*iv*) he kept the Associate Professor of Pharmacology in the dark ;

(*v*) he took advantage of the innocence of the Associate Professor of Pharmaco-
Ex. 41 logy by not filling in proportion in the proposal form (Ex. 41) ;

(*vi*) he advanced untenable excuses for not placing orders with Universal Pharmacy and Deepti Pharmacy which he did not report to anyone, not even to the Industries Department ;

(*vii*) he did not bring to the notice of anyone, not even to the Industries Department, why he did not restrict himself to the 11 per cent proportion and why he did not place orders with Universal Pharmacy and Deepti Pharmacy.

20. Thus out of the 33 per cent quota reserved for backward areas, Universal and Deepti were side-tracked by Jamadagni for reasons he had brought to no one's notice and Alpana Pharma was given the order far in excess of the requisite 11 per cent. If this had not been done, perhaps Batch 27 would not have been ordered by J. J. and lives in the Hospital might have been saved, albeit lost elsewhere were Batch 27 woud have had the misfortune to be supplied.

21. *Why this warm-heartedness on the part of Jamadagni towards Alpana Pharma? Was it love?* No. *Was it friendship?* No. *Was it ignorance* ? No. *Was it a mistake?* No. *Was it stupidity?* No. *Was it the old adage—you tickle me, Toby, I tickle thee?* Perhaps the question best answers itself.

22. *This brings me to the procedure for procurement, storage and inspection insofar as Government is concerned.*

23. Regarding procurement, there is a prescribed procedure but it was not followed by Government. Regarding storage and inspection of drugs at the J. J. Hospital, there does not appear to be any procedure prescribed by Government, except that once a year the FDA visits Medical Store to ascertain whether the drugs are properly stored and whether the pharmacist is a qualified person.

24. I shall first recapitualte *the procedure for procurement of drugs by Government for the J. J. Hospital.* Drugs are and can only be procured from rate contracted manufacturers or repackers. This procurement is made by the Director of Industries for which purpose he constitutes various committees. Prior to 1st February 1975, there was a Committee for the selection of medicines and drugs. By Government Resolution dated 1st February 1975 the Committee set up for selection of drugs and medicines comprised of (*i*) the Director of Industries, (*ii*) the FDA Commissioner or his representative, (*iii*) Professor of Pharmacology, Grant Medical College, (*iv*) Professor of Medicine, Grant Medical College, (*v*) Director of Health Services and (*vi*) Superintendent of St. George's Hospital.

G. R. 1-2-75– Composition of Committee for selection of medicines and drugs.

25. By Government Resolution of 9th August 1977, preferential purchase treatment was given to units holding SICOM eligibility certificates; a reservation of 33 per cent was made for purchase at the lowest acceptable price to be obtained by open competitive tenders.

G. R. of 9-8-77 Preferential purchase treatment— 33 per cent reservation.

26. In 1984, the Director of Industries was represented by S. B. Satalkar, the FDA by Commissioner Bhirud or his representative Assistant Commissioner Raykar, Professor of Pharmacology by Dr. R. D. Kulkarni, Professor of Medicine by Dr. C. J. Mistry, Director of Health Services by Dr. (Mrs.) Chandrikapure and the Superintendent of St. George's Hospital by Dr. Phalke.

Representatives on the Selection Committee in 1984.

27. In March 1984, an indent was placed by Professor of Pharmacology Dr. R. D. Kulkarni with the Industries Department for the requirement of drugs and medicines at the J. J. Hosptial. Pursuant thereto on 29th March 1984, Tender Notification (Ex. 31) was published for invitation of tenders by 27th April 1984. This tender notification was in 10 parts with glycerol being in the last, i.e. 10th part, as a a miscellaneous item. As a result, the Industries Department received in all 900 quotations from various parties for various items.

Dr. Kulkarni places indent

Tender Notification dated 29-3-84 (Ex. 31).

900 quotations received.

28. Eighteen tenderers had quoted for glycerine. Out of them, on 25th April 1984 Alpana Pharma Pack of Nanded filled in its tender (Ex. 37) for 11 items including glycerine which was the last item. The rate quoted by them for glycerine was Rs. 21.50 per bottle of 500 ml. coupled with a condition that the minimum order placed with them should be of Rs. 1,000 else they would charge packing and forwarding charges. This tender was submitted by Alpana Pharma to the Industries Department on 27th April 1984.

Alpana Pharma's tender— Rs. 21.50 for 500 ml. (Ex. 37)

29. Chem Pack had also submitted their tender for glycerine at Rs. 18 for 500 gms. (equivalent to 450 ml.).

Chem Pack's tender

30. In June 1984, Alpana Pharma submitted their income tax clearnace and small scale industries certificates to the Central Stores Purchase Organisation (CSPO).

Alpana Pharma submits IT clearance and SSI Certificate.

31. Between 11th July 1984 and 25th July 1984 meetings of the Drugs Selection Committee took place. On 25th July 1984, the 10th and last part of the tenders was taken up for consideration. That day there were in all 50 items for the Committee's consideration; glycerine was the last item.

Drugs Selction Committee meetings.

32. In respect of glycerine, a Comparative Statement (Ex. 38) had been prepared in ascending order, namely the lowest tenderer shown first to be followed by the second lowest and ending with the highest. In this Comparative statement Chem Pack was shown at serial No. 1, Deen Pharmaceuticals at serial No. 2, P. M. Medicals at serial No. 3, Tridal Chemicals at serial No. 4 and Alpana Pharma at serial No. 5, followed by others.

Comparative Statement (Ex. 38)

33. At the meeting of the Drugs Selection Committee on 25th July 1984, serial Nos. 2, 3 and 4 of the Comparative statement, namely Deen Pharmaceuticals, P. M. Medicals and Tridal Chemicals were rejected; Chem Pack was selected as the original supplier and Alpana Pharma as the alternate supplier.

Chem Pack selected as orginal supplier and Alpana Pharma as alternate suppleir.

34. On 14th August 1984, CSPO wrote a letter to Chem Pack asking them to extend the validity period of their contract. Chem Pack did so.

Validity period of Chem Pack's contract extended.

35. In September 1984, CSPO wrote a letter to Alpana Pharma that their tender for castor oil, glycerol and salicylic acid was accepted.

Alpana Paharma's glycerol tender accepted.

Chem Pack asks for rate escalation from Rs. 18 to Rs. 37.40.

36. On 2nd September 1984, Chem Pack wrote a letter to the Director of Industries asking for a rate escalation from Rs. 18 to Rs. 37.40. (Here it may be mentioned that though this letter has been referred to in Chem Pack's subsequent letter dated 11th December 1984, no such letter is to be found in any of the files produced by Government or the FDA before this Commission as will appear later. Apparently no such letter was actually written by Chem Pack).

Contract with Chem Pack Rs. 18 for 500 gms. Chem Pack's file Ex. 491.

37. On 21st September 1984 a contract was entered into with Chem Pack for the supply of glycerine at Rs. 18 for 500 gms.

38. Till December 1984, no supply of glycerine was made by any party. On 11th December 1984, Chem Pack wrote a letter to the Director of Industries which purported to be in continuation of its earlier letter dated 2nd September 1984 (which as stated earlier is not to be found in any of the files produced by Government or the FDA before this Commission). By Chem Pack's letter dated 11th December 1984 it asked for a price escalation to Rs. 37.40 for 500 gms. on the ground of difficulty in making supplies of glycerine at Rs. 18 for 500 gms. and *change in Government policy*.

Chem Pack's letter of 11-12-84 for price escalation from Rs. 18 to Rs. 37.40 for 500 gms.

Note of Officer Torvi recommending price escalation.

39. That letter went to an officer in the office of Director of Industries one Torvi. He prepared a note supporting the price escalation from Rs. 18 to Rs. 37.40 as demanded by Chem Pack. Torvi's justification for doing so was that it was a a statutory increase.

Dharap's differing note

40. Torvi's note went to the Jt. Director of Industries *Dharap*. He differed *from Torvi* and made his note that Chem Pack's was not a case of statutory increase but that a note may be prepared for consideration by the Drugs Selection Committee. The latter Dharap did on the basis of Chem Pack's letter dated 11th December 1984.

Chem Pack's rate escalation accepted by the Committee.

41. On 23rd January 1985, a meeting of the Drugs Selection Committee was held; present were Professor of Pharmacology Dr. R. D. Kulkarni, Professor of Medicine Dr. C. J. Mistry, Joint Director of Industries Dharap and Commissnor Bhirud. Dharap's note was placed before the *Committee members*. They accepted Chem *Pack's* request for price escalation by the following endorsement at the foot of Dharap's note :—

> "The request of Chem Pack may be accepted until fresh decision is made in supplementary tender. If Alpana Pharma approach for price revision, they may be given parallel status at the same price of M/s. Chem Pack." (Sic.)

This endorsement was signed by all the Committee Members.

Revised contract with Chem Pack.

42. On 29th January 1985, a revised contract was entered into with Chem Pack.

Alpana Pharma selected for preferential purchase.

43. On 20th February 1985, a meeting of the Drugs Selection Committee was held to examine the units in developing areas. (In this meeting Chem Pack did not figure as it was at Pune, a developed area). Four units from the developing areas were selected for giving the 33 per cent preferential purchase contracts; they were Cherub Pharmaceuticals, Universal Pharmacy, *Deepti Pharmaceuticals* and Alpana Pharma at *Nanded*. Cherub's sample was found to be not satisfactory. Hence the selection for the 33 per cent preferential purchase went to the remaining three, namely Universal Pharmacy, Deepti Pharmaceuticals and Alpana Pharma.

Alpana Pharma asks for rate revision, cancellation of original contract and placement in reserved category.

44. Within 3 days, i.e. on 23rd February 1985, Alpana Pharma asked for a rate revision with a request that its contract as alternate supplier to be cancelled and that it be placed in the reserved category.

Fresh tenders invited

45. On 28th *February* 1985, fresh tenders for 17 items including glycerine were invited. As it turned out as appears hereafter, this was merely a ruse to create an impression that the earlier escalation given to Chem Pack was only a temporary expedient. The same day, without putting the matter before the Committee, it was ordered that Alpana Pharma would be placed under the 33 per cent reservation and would share equally with the other two suppliers, namely Universal Pharmacy and Deepti Pharmaceuticals.

Alpana Pharma rate revised and placed in 33 per cent reservation.

Amendment to Alpana Pharma (Ex. 55)

46. On 16th March 1985, an amendment (Ex. 55) was issued to Alpana Pharma cancelling the earlier rate contract given to it and giving it an increase in the rate and placing it in the reserved preferential list. This amendment stated that the revised rate would become null and void from the date of the fixation of the fresh rate contract.

47. At the Committee's meeting on 15th April 1985, the members decided to accept to the very paise the price escalation of Rs. 37·40 for 500 ml. for glycerine, with the result that the rate contracts of Chem Pack, Alpana Pharma, Universal Pharmacy and Deepti Pharmaceuticals were extended to the full period at the escalated price of Rs. 37·40. Thus this increased rate which originally was sought to be made out to be merely a temporary measure, now became a fait accompli.

Price escalated to Rs. 37·4 for 500 ml.–a fait accompli.

48. On 10th February 1986 Commr. Bhirud informed the Industries Department over the telephone about the J. J. Hospital deaths and Alpana Pharma's involvement. Commr. Bhirud followed this up by his confirmatory letter of 14th February to the Industries Department.

Bhirud's telephone call to Industries Dept. and his confirmatory letter.

49. On 11th February 1986, Industries Department informed the Direct Demanding Officer (DDO), namely Professor of Pharmacology Dr. Kulkarni, that Alpana Pharma's contract was suspended. On 21st February 1986 Alpana Pharma returned its licence to the FDA stating that it wanted to close down its business. On 1st April 1986 the Industsies Department cancelled Alpana Pharma's contract on the ground that its licence was cancelled.

Alpana Pharma's contract suspended.

Alpana Pharma returns licence.

Industries Dept. cancels Alpana Pharma's contract.

50. The above resume depicts that the procedure prescribed for procurement of glycerol was not followed and that despite several drawbacks which should have invalidated Alpana Pharma's tender it was not only considered but was also given the contract despite all odds. More on this later.

51. This brings me to the *procedure followed by the Industries Department for selection of drugs*. The procedure can be sub-divided into (A) the procedure followed until the tender is placed before the Committee and (B) the procedure followed at the Committee meetings.

52. Under head (A), tenders are received by the tenders clerk whereafter they come to the Industries Department. Thereafter Industries Department Officer Torvi prepares a scrutiny sheet which contains all facts and details. He thereafter prepares comparative statements in ascending order of tenders, the tenderer's terms and conditions, if any, and whether he is a trader or a small scale unit. He shows them to the Recovery Officers and submits them to the Committee. All facts and details mentioned in the scrutiny sheets are not mentioned in the comparative statements.

53. Now Chem Pack's tender was in the form of a letter dated 20th April 1984 addressed to the *Director of Industries*. In this letter, Chem Pack had imposed not less than 14 conditions. Even so, surprisingly neither in the scrutiny sheet nor the comparative statement prepared by Torvi was a single condition mentioned.

File 37 pertaining to Chem Pack.

Chem Pack's tender by letter—14 conditions—not mentioned in scrutiny sheet or comparative statement.

54. As far as Alpana Pharma is concerned, two conditions are mentioned in the scrutiny sheet, namely (*i*) that Alpana Pharma had not produced the SSI Registation Certificate and (*ii*) it had commenced from 26th April 1984. In the comparative statement (Ex. 38), it is mentioned that Alpana Pharma's order was conditional on an order being placed with it for not less than Rs. 1,000.

Alpana Pharma's scrutiny sheet

Alpana Pharma's comparative statement.

(Ex. 38)

55. In the comparative statement, Chem Pack was wrongly put first at Sr. No. 1 on the ground that its tender was the lowest, when actually it was not. The rate quoted by Chem Pack was Rs. 18 for 500 gms. whereas quotations were invited for 500 ml. Thus on conversion to 500 ml. Chem Pack's rate would work out to Rs. 20 for 500 ml. However the comparative statement (Ex. 38) was prepared by Torvi to give the impression that Chem Pack's rate was Rs. 18 for 500 ml. It showed that the sample bottle given as of 500 gms.

56. In addition there are several apparent defects in giving the contract to Chem Pack, to wit—

(*i*) Chem Pack made its offer by its letter dated 20th April 1984 and not in the prescribed form; thereby Chem Pack committed a breach of Clauses (1) and (16) of the Tender Conditions. Clause (1) provided—

" *Sealed tender in duplicate will* be received *on prescribed form* by the Director of Industries and Central Purchasing Officer ..... "

General Condition (16) provided—

" Priced Tender Form should be returned *duly filled* in failing which quotation will not be considered. "

Even so despite these two conditions patently having been breached by Chem Pack, its offer contained in a mere letter dated 20th April 1984 was not only considered but Chem Pack was also given the contract

(*ii*) Cham Pack laid down not less than 14 conditions which virtually amounted to Chem Pack not entering into any firm commitment either as to rate or the delivery period. Even so Chem Pack was considered and given the contract.

(*iii*) Chem Pack quoted its rate not for 500 ml. as required, but for 500 gms. This was in breach of the condition at Serial No. 496 at page 419 of the Tender
Ex. 31 Conditions (Ex. 31).

(*iv*) Chem Pack's sample was not according to specification of 500 gms. This was in breach of Condition 16(7) of Ex. 31 also violative of General Instructions 7 of Ex. 31 which provided—

> " Tenderer should indicate the rates in Metric System of Weight and Measures or in any equivalent Weights and Measures before showing conversion rates."

Hence, Chem Pack's failure to observe these Tender Conditions should have resulted in summary rejection of its so-called tender. Yet none of these obvious defects were even remotely reflected either in the scrutiny sheet or the comparative statement prepared by Officer Torvi. Thus, the procedure followed by Officer Torvi of the Industries Department was totally unwarranted.

57. Coming to head (B) of para 51 above, the procedure followed by the Committee Members at the meetings was also far from satisfactory.

58. At the Committee Meetings held between 11th and 25th July 1984 the Members present were Professor of Pharmacology Dr. R. D. Kulkarni, the Addl. Director of Industries S. B. Satalkar, Member of the Drugs Slection Committee Dr. C. J. Mistry and Assistant Commissioner Raykar representing Commissioner Bhirud. From then evidence of these witnesses, emerges the following :—

(*a*) 10 meetings were held between 11th and 25th July 1984. However nobody is certain of the date on which the 10th part of the tender was considered except Assistant Commissioner Raykar who says it was on 25th July.

(*b*) Decisions taken by the Committee Members were not contemporaneously reduced to writing. That was done later and never signed on the same day they were taken or written.

(*c*) No minutes of the meetings were kept, hence there is no written record to show what actually transpired.

(*d*) The comparative statements do not bear the dates of the decisions taken or even the dates the decisions were signed.

(*e*) Meetings went on from 11-00 a.m. to 5-00 to 6-00 p.m. daily with the conventional breaks. 50 items were discussed at each meeting, making an average of 8-10 minutes per item. By the time the last item came, everyone was not unnaturally in a hurry to depart.

(*f*) The procedure was that the items were called out serially, but only one comparative sta ement was placed before all the members; no copies made available for their benefit. The comparative statement remained with the Director of Industries and was not circulated amongst the Committee Members, with the result that they had no means or manner of knowing or recalling beforehand the names of the tenderers or the viability or otherwise of the drug concerned. However files of the tenderers were kept ready for perusal of the Members, in case they desired to see them. From the record it does not appear that any member expressed a desire in that direction.

(*g*) From the comparative statement, the Director of Industries read out the names of the tenderers serially starting with the lowest as also any conditions mentioned in the comparative statement.

(*h*) Everything hinged on a mere visual observation of the sample, the container and the label.

(*i*) All decisions have always been unanimous.

(*j*) In the remarks column, a brief noting was made if a tender was rejected; that nothing, whatever be the reason for rejection, was a mere "NTS"—an abbreviation of Not To Specification (which might mean anyting)—but the actual reasons for rejection were never stated.

(*k*) Decisions taken were not written down there and then—that was done the follwoing day or a few days later.

(*l*) These decisions were thereafter sent in bulk to the Members for their signatures. It is difficult to envisage how after a space of time, all the members would remember all the decisions taken. More so in view of the fact that not a single Member has produced before this Commission any of his private notes allegedly kept by him except Assistant Commissioner Raykar whose private notes are at page 585 of Ex. 546 of the meeting of 25th July 1984 and his notes pertaining to glycerine at page 592 of Ex. 546. It is even more significant that not a single member has ever complained that an inaccurate decision had been written down. Ex. 546 Ex. 546.

59. The above aspects emerging from the evidence of these witnesses indicate the slap-happy and totally unsatisfactory procedure adopted at the Committee Meetings where medicines and drugs including life saving drugs were selected for being administered in Government-run hospitals.

60. This is not all. Normally conditional tenders are not accepted. However Alpana Pharma's tender was the first instance of its kind where a conditional tender was accepted subject to the withdrawal of the conditions imposed by the tenderer, namely Alpana Pharma. This was in direct violation of Condition 11 (at page 420 of Ex. 31) which provided that the offer of the tenderers must be firm with italicised emphasis on the succeeding sentence, namely " Conditional offers will not be considered ". Yet in the teeth of this mandatory clause Alpana Pharma's conditional offer was not only considered but it was given the contract.

61. On the face of it, this was not an oversight but a calculated move to give the contract to Alpana Pharma, come what may. In the comparative Statement (Ex.38), Serial Nos. 2, 3 and 4 vis. Deen Pharmaceuticals, P. M. Medicals and Tridal Chemicals respectively were rejected. Serial No. 2 (Deen Pharmaceuticals) was rejected as " N. T. S. ". Serial No. 3 (P. M. Medicals) was rejected as " tender does not have inquiry packing and had also imposed a condition that the supply would be F.O.R. Nagpur and the bulk order would be of Rs. 1,500 ". For that matter in the Comparative Statement, none of this finds place. Serial No. 4 (Tridal Chemicals) has two remarks, namely that the tender does not have inquiry packing and NTS. The remark against Serial No. 1 (Chem Pack) to whom the contract was given is " original". The remark against Serial No. 5 (Alpana Pharma) is " alternate subject to withdrawal of condition." Evidence discloses that Alpana Pharma's case was the first of its kind where a tenderer was given a contract " subject to withdrawal of condition". The later serial numbers were thereafter not considered. Somebody was very certain that Alpana Pharma would indeed withdraw its condition, making unnecessary the consideration of the serial numbers after Alpana Pharma's serial No. 5. Alpana Pharma had a guardian angel in the Industries Department. If not, why this affinity towards Alpana Pharma ? The answer is obvious : You tickle me Toby, I tickle thee mutual aggrandisement. Ex. 38

62. No one has been able to explain why such preferential treatment was given to Alpana Pharma at Serial No. 5 at the cost of comparatively stepmotherly treatment given to Serial Nos. 2, 3 and 4 so that Serial No. 5 (Alpana Pharma) should bag the contract, which indeed it did.

63. According to the witnesses only the first five entries in the Comparative Statement (Ex. 38) were considered at the meeting. However surprisingly in the very same Comparitive Statement (Ex. 38) against Serial No. 9 pertaining to Shreephal Lab is mentioned the decision taken against it by the profound observation " NTS " in the remarks column. This is sought to be passed off as a mistake, The question which then arises is, pray, how could this ' mistake' arise if the Committee Members did not go beyond Alpana Pharma at Serial No. 5 ? No explanation is forthcoming. Apart from the fact that this ' mistake ' indicates that the decisions noted in the remarks column were written subsequently and not contemporaneously, it also indicates that Alpana Pharma at Serial No. 5 was not the last tenderer whose tender was considered but that it was Shreephal Lab at Serial No. 9 which was fobbed off and put in the shade with the remark 'NTS'. While needless to say a Comparative Statement such as this can inspire no confidence, it is manifest that with Serial No. 6 out of the way, the path was made clear for Alpana Pharma at Serial No. 5.

64. In addition to the general conditions of tender applicable to all the tenders (which are to be found from pages 396 to 419 of Ex. 31), there are conditions of

tender which apply specifically to drugs and medicines. These latter conditions are general conditions and special conditions; the former are to be found at pages 420 to 422 and the latter at page 423 of Ex. 31.

65. Apart from the fact that Alpana Pharma committed several breaches of the general conditions of the tender applicable to all tenders, it also committed a number of breaches of the general conditions of tender applicable to drugs and medicines. Condition 6 (*ii*) (at page 420 of Ex. 31) provides that tenders should be accompanied by certified copies of the latest income-tax clearance certificate. Even so, the income-tax clearance certificate submitted by Alpana Pharma did not accompany its tender on 27th April 1984. The income-tax clearance certificate was submitted to the CSPO in June 1984 along with small scale industries certificates. According to Condition 6(*iii*) the tender should be accompanied *inter alia* by copies of literature in a separate cover pertaining to the samples and the sample should be affixed with printed label showing (*a*) the name and address of the manufacturer, (*b*) the date of manufacture, (*c*) manufacturing licence number, (*d*) date of expiry, if applicable, (*e*) composition and (*f*) batch number. None of these requirements were met or could be complied with by Alpana Pharma for the simple reason that it had not even started its repacking business and had purchased its sample form the open market without even mentioning the source except to say " open market source". At that time Alpana Pharma had not even received the repacking licence from the FDA. All this by itself should have been an eye-opener and should have put the Industries Department on its guard including the fact that even if Alpana Pharma's sample was of standard quality, there was no guarantee that the bulk would be likewise. Further in the scrutiny sheet it was stated that Alpana Pharma had produced a letter that the licence would be issued to them shortly and that their production had commenced from April 1984. The latter was not correct even if Asstt. Commissioner Raykar's version that he had pointed out at the Committee meeting that Alpana Pharma had not been in the market for two years, is ignored.

66. Condition 18 provided that the tenderers who are not manufacturers must quote the name and address of the manufacturer of the *product* with the proviso that this condition *would not* apply in case of firms who are authorised distributors, agents or manufacturers.

67. Indisputably Alpana Pharma was never the authorised distributor or agent of any manufacturer. Indisputably Alpana Pharma was not a manufacturer but a repacker. Hence by virtue of condition 18 they were bound to quote the name and address of the manufacturer which Alpana Pharma never did.

68. Condition 20 provided that a product which has been in the market for more than 2 years may be preferred to that of other tenders.

69. Alpana Pharma had not been in the market at all, and yet was not only
Ex 38 considered but was even given the contract, as against Franco Italian at serial No. 6 in the Comparative Statement which was not even considered though it was in the market for more than 6 years.

70. Special conditions 9 and 12 (at page 423 of Ex. 31) provided that the tenderer should give the latest income-tax certificate along with the quotations and that conditional offers and incomplete quotations are liable for rejection. Even so, despite Alpana Pharma committed breaches of these two conditions its tender was considered and it was given the contract.

71. Under the general conditions applicable to tenders for drugs and medicines, condition 10 provides that the quotation should be submitted strictly according to specifications and packing mentioned against each item offered giving full details in the *pro forma* 'A' attached. This *pro forma* is to be found at page 424 of Ex. 31. Column 4 of that *pro forma* pertains to " Year of first marketing of the product", column 7 pertains to "Name of manufacturer" and column 9 pertains to "In case of dealer/repacker name of the manufacturer must be mentioned."

72. In all these three columns the information given by Alpana Pharma was false and misleading. Under column 4 Alpana Pharma made a false statement by giving the year 1984 as the year of its first marketing the product, when to its knowledge it had not even started its repacking business. Under column 7, namely, name of the manufacturer, Alpana Pharma falsely wrote its own name despite the fact that it was not the manufacturer and that on its own admission it had purchased the tender

sample from " open market source ". This was also a breach of condition 21 of the general conditions of tender for drugs and medicines. Against column 9 Alpana Pharma wrote " Not applicable ".

73. All these breaches were ignored in the case of Alpana Pharma, no doubt, in an anxiety to give it the contract, come what may.

74. It is correct that along with its tender Alpana Pharma had annexed FDA's letter dated 25th April 1984 which stated that a licence is granted to Alpana Pharma "on the condition that you provide quality control laboratory within 2 months ". In all fairness, this letter can be construed in two ways. To my mind, the strict legal construction would be that the licence is granted to Alpana Pharma provided they first have a quality control laboratory installed within two months. A looser construction can be that the FDA granted the licence to Alpana Pharma with an injunction that it must provide a quality control laboratory within two months in default the licence would stand revoked. Even assuming that the latter construction was placed by the Industries Department on this letter, the fact does remain that in the teeth of the conditions of tender, Alpana Pharma did not, as indeed it could not, enclose the licence along with the tender for the simple reason that the licence was not issued by the FDA. This fact would more be in support of the legal interpretation that Alpana Pharma would get the licence on the condition it provided a quality control laboratory within 2 months, which Alpana Pharma never did and in the words of its own partner Om Prakash Ladda had no intention of doing for paucity of funds. It is not without its own significance that this was the first instance of its kind when a contract has been given on the strength of such a letter and without actual production of the licence.

75. These were therefore the obvious and glaring deficiencies which were overlooked while even entertaining Alpana Pharma's tender which on the face of it warranted disqualification at the very threshold.

76. This is not all. Unasked Alpana Pharma was even given a price escalation on the pretext that such an expedient was followed in the case of Chem Pack. This price escalation was a direct violation of condition 23 of the general conditions of tender for drugs and medicines (page 421 of Ex. 31). Condition 23 entitles the Director of Industries and the Central Purchasing Officer to exercise his discretionary power to do one of three things in the event of a contractor failing to deliver the goods in part or in full. Now when Chem Pack expressed its inability to make delivery, the Director of Industries and the Central Purchasing Officer had under condition 23 the discretion either (*a*) to recover from the contractor liquidated damages or penalty, or (*b*) to make the purchase elsewhere at the risk of the contractor, or (*c*) to cancel the contract. None of these three mandatory powers were sought to be exercised in the case of Chem Pack which was given the price escalation to the very naye paise demanded by it and under the cloak whereof Alpana Pharma was also given an identical price increase unasked and without the Committee members sanctioning it. All this at a loss to Government.

77. In such cases there can never be direct evidence of corruption. However circumstantial evidence does indicate that Alpana Pharma had, as stated earlier, some protective and interested guardian angel in the Industries Department to look after the well-being of Alpana Pharma. There is no reason why obvious deficiencies should have been allowed to pass muster or why they should have been allowed to be " cured " at a later stage, to wit, the lack of income-tax clearance certificate. There is on record a certificate dated 1st August 1984 from the General Manager, District Industries Centre, Nanded. It is a strange certificate. It says that Alpana Pharma " has gone into initial repacking of pharmaceutical products w.e.f. 26th April 1984 ". Apart from the fact that Alpana Pharma had not done anyting of the kind, it is a matter of bewilderment how this certificate given in August 1984 should have found a place on the record of the Committee during its meeting in July 1984 when Alpana Pharma had already been selected for the contract. No explanation has been forthcoming for this amazing who-done-it.

78. In Ladda's books of accounts under date 19th May 1984 (i.e. after Alpana Pharma submitted its tender on 27th April 1984) there is an entry of Rs. 500 as " tender expenses CSPO". According to Om Prakash Ladda through oversight this entry remained to be made in April 1984, hence it was made on 19th May 1984. Be that as it may, Ladda has been unable to explain the nature of the tender expenses which culminated in a round figure of Rs. 500. It is true that this is a small amount.

However the smallness of the figure cannot militate from the mystery under which such an entry was made.

79. No doubt Alpana Pharma was a favoured " customer " in the Industries Department. Why should this be so unless there was a strong motivation for someone in the Industries Department ? Corruption is manifest.

80. To that end the strongest motivation was on the part of the Industries Officer Torvi as is clear from his evidence. Torvi scrutinised the tenders. Thereafter Torvi prepared the scrutiny sheet. The documents remained with Torvi. It was he who belatedly accepted in June 1984 Alpana Pharma's income-tax clearance and SSI registration certificates which Alpana Pharma was bound to file with the tender on 27th April 1984. No doubt, this was done by Torvi in order to make sure that Alpana Pharma's tender should not be invalidated at the threshold for the lack of these documents. Torvi also knew that a conditional tender had to be rejected. Even so he allowed Alpana Pharma's conditional tender to pass muster. In the Comparative Statement prepared by him he did say that the tender was conditional. That by itself does not indicate honesty of purpose on Torvi's part. He did so obviously to safeguard his own position, as a conditional tender was bound to come to light sooner or latter.

81. Torvi's course of conduct is highly suspect and more. To start with, he first asserted that Chem Pack's tender was unconditional. When it was brought to his attention that Chem Pack had laid down not less than 14 conditions, he admitted it was a conditional tender. Yet the scrutiny sheet prepared by him does not even remotely convey any such impression. He had to agree that the impression created by the scrutiny sheet prepared by him that Chem Pack's tender was unconditional, was erroneous as Chem Pack had laid down as many as 14 conditions in its letter dated 20th April 1984, which under the tender conditions, could not even be regarded as a valid tender. His explanation that a mere letter dated 20th April 1984 of Chem Pack was itself a quotation, is puerile, coming as it does from an officer of experience like Torvi. It is obvious that he took special interest in preparing the scrutiny sheet of Chem Pack and was anxious that Chem Pack's so-called tender should not be invalidated at the outset either on the ground that it was not a tender as mandatorily prescribed by terms and conditions of tender or was a conditional offer. Torvi cannot be allowed the luxury of passing off all this as an unintentional clerical error. It was all deliberate on his part. He ultimately had to admit that this was not a clerical error on his part. He maintained that it was not a deliberate error but a " general error "(whatever that means) and after seeing the Comparative Statement, scrutiny sheet and the files of other tenderers (Ex. 491), finally admitted that he could cite no other instance of such an error. Thus it was not a clerical error nor a " general error " but an error which conveniently took place only in Chem Pack's case. Bravo.

82. Further, in placing Chem Pack at Sr. No. 1 in the Comparative Statement as the lowest tenderer, Torvi played a fraud on other tenderers whose tenders were lower than Chem Pack's.

83. Reverting to Alpana Pharma, Officer Torvi's involvement is exposed. Pray, why would Torvi go out of his way to do all this. It is here that the entry for Rs. 500 shown as " tender expenses C.S.P.O." in Alpana Pharma's account book assumes significance. On the showing of Alpana Pharma's partner O. P. Ladda, this entry though made under date 19th May 1984 should have been made in April. That was the month when Alpana Pharma filed the tender. The " tender expenses C.S.P.O " appears to be an euphemistic way of denoting a bribe. In April who could have been bribed ? Some one who would not scuttle Alpana Pharma's tender at the very outset for its obvious and patent defect. Who could that someone be ? Who other than the one person in whose hands lay the power to invalidate that tender ? That person was officer Torvi.

84. Industries Officer Torvi is guilty of grave dereliction of duty. To that end corruption on his part cannot be ruled out.

85. This brings me to the involvement of the Additional Director of Industries, Satalkar.

86. Satalkar deposed that invitations for tenders for drugs are published in the Government Gazette whereafter they are received by the Store Purchase Department and are scrutinised by the Industries Officer (in this case Torvi) working in that Department. The Industries Officer must ascertain whether the Priced Tender Form

has actually been purchased by the tenderer. He admitted that Alpana Pharma's scrutiny sheet bore two adverse remarks, namely that it had produced a letter that the licence would be issued to it shortly by the FDA and that it had started production from April 1984. He also admitted that Alpana Pharma had not produced the licence along with the tender form as actually required. He also admitted that in the Comparative Statement (Ex. 38), the two adverse remarks appearing in the scrutiny sheet are not reflected. Ex. 38

87. Coming to the committee meetings, Addl. Director Satalkar deposed that there was no Chairman as such, but R. D. Kulkarni being the indenting officer was treated as the senior member of the Committee. According to Satalkar, the lowest offer for glycerine was Chem Pack's. It is inconceivable that Satalkar, himself the Addl. Director, should not have realised to the contrary as Chem Pack's offer was at the rate of Rs. 18 for 500 gms. whereas the requirement of the tender was a quotation for 500 ml. Satalkar however on plain arithmetic had to admit that at the rate of Rs. 18 for 500 gms. quoted by Chem Pack, the price for 500 ml. would be Rs. 22·50 with the result that Chem Pack's could not possibly be the lowest quotation and hence could not have been placed at Serial No. 1 in the Comparative Statement (Ex. 38). To that end Torvi's involvement is also exposed, for it was he who was responsible for the Comparative Statement (Ex. 38).

88. Satalkar's assertion that the rate quoted by Alpana Pharma was the least of the first 5 tenderers, is incorrect because while Alpana Pharma's quotation was for Rs. 21·50 p. that of Deen Pharmaceuticals was at Rs. 18. According to Satalkar, Deen Pharmaceuticals' sample was not approved as it was not according to the tender specification. The next lowest was P. M. Medicals, a trading unit at Nagpur. Their tender was rejected on the ground that it was restricted to Nagpur, hence was a conditional tender not in accordance with the tender inquiry. The next was Tridal Chemicals whose tender was rejected on the ground that the sample was not according to the tender inquiry, namely that the packing did not conform to the tender inquiry. This is not to be found in the remarks coloum in the Comparative Statement (Ex. 38). Thereafter, Alpana Pharma at Serial No. 5 was considered. However even though Alpana Pharma's tender was, like P. M. Medicals, also conditional and hence not in accordance with the tender, it was unlike P.M. Medicals, not only not rejected but was given the contract. Its sample of glycerine was approved by the members. According to Satalkar, he brought to the notice of the Committee members two deviations shown in Alpana Pharma's scrutiny sheet, namely that it did not hold a licence from the FDA and that it had gone into production only in April 1984. According to Satalkar, Alpana Pharma's file was also given to the members for examination. Satalkar admitted that Alpana Pharma's tender was not in accordance with the specification of the terms and conditions of tender because Alpana Pharma did not have the requisite licence under the Act and Alpana Pharma did not have a standing in the market for more than 2 years and also because Alpana Pharma's tender was a conditional tender, that these defects were NTS and were contrary to the terms and conditions of the tender. He goes on to say that a discussion took place between the Committee members whereat the first defect, namely Alpana Pharma not holding a licence, was overcome on the strength of the Joint Commissioner's letter that a licence had been granted to Alpana Pharma and that the same was under preparation. The second defect of Alpana Pharma not being in the market for more than two years was overcome by the fact that Alpana Pharma was not a manufacturing unit but a repacker. The defect regarding Alpana Pharma's tender being a conditional one was overcome by the decision that Alpana Pharma should be asked to withdraw that condition and that if Alpana Pharma did not, the matter would be reconsidered by the Committee.

89. Apart from the fact that there is nothing in the tender conditions which exampts a repacking unit from the two year limiting period, this entire version trotted out by Satalkar appears to be an inspiration on the spur of the moment not corroborated by any other member and positively denied by Dr. Mistry.

90. Satalkar goes on to say that in respect of all contracts including glycerine I.P., an alternate supplier is chosen in the event of the main supplier committing default in making supplies or not making supplies as stipluated in the tender. It is true that an alternate supplier is always chosen, but not necessarily for the reason given by Satalkar, because an alternate supplier can be required to make deliveries without the main supplier being called upon to do so.

91. Satalkar admitted that out of the 18 tenderers shown in the Comparative Statement (Ex. 38), Alpana Pharma at Serial No. 5 was the last to be considered and that the tenders of the remaining at Serial Nos. 6 to 18 were not considered because Chem Pack at Serial No. 1 had been chosen as the main supplier and Alpana Pharma at Serial No. 5 as the alternate supplier and because the rates of the remaining supplier were higher than those of Chem Pack and Alpana Pharma. These bland assertions by Satalkar cannot hide the truth that it was pre-determined that Chem Pack and Alpana Pharma be given the contracts.

92. Satalkar admitted that the tender conditions of 1982-84 required the production of a performance certificate and a no-conviction certificate under the Drugs Act but this provision was not included in the tender conditions of 1984-86, and has now again been included in the tender conditions of 1986-88 under the advice of the Indenting Officer, *viz.* Dr. R. D. Kulkarni. It need hardly be stated that if requirement of a performance certificate had not been sudednly and mysteriously discontinued for 1984-86, Alpana Pharma could never have bagged the contract as it had not even started its activities.

93. Satalkar admitted that there was no fool-proof system in the Industries Department to ensure that tenders are not received after the last date of submission. This is an indication that documents can be removed or introduced after the tenders are submitted just as Alpana Pharma's income-tax clearance certificate and the SSI registration certificate were surreptitiously introduced into the tender by Torvi long after Alpana Pharma's tender had been submitted.

94. Satalkar deposed that the meetings took place from 11-00 a.m. to 5-00 p.m. and sometimes till 6-00 p.m. everyday, during which time 50 to 55 items were disposed of with an average of about 5 minutes to each item. Only one file of each tenderer is circulated amongst all the Committee members, but every member does not read the file. One or two members do so and inform the remaining members whether the tenderer has fulfilled the tender conditions or not and whether the offer is acceptable or not from the procedural point of view. He admitted that in the present case all the 18 files were not circulated amongst all the members but only the first five files pertaining to Serial Nos. 1 to 5, namely those of Chem Pack, Deen Pharmaceuticals, P. M. Medicals, Tridal Chemicals and Alpana Pharma. All the members did not go through these 5 files. He admitted that members would have to rely upon the officers who prepared the Comparative Statement (in this case Industries Officer Torvi) regarding the order in which the tenders were placed in the Comparative Statement. It took about 2-3 minutes to go through each of these 5 files.

95. Sometimes the members examined as many as 50 offers for a single item, sometimes as few as two and sometimes even one. Sometimes there are no offers at all. He admitted that examination of the items offered is but cursory including the visual examination of the sample.

96. Satalkar admitted that no minutes of the meeting are kept and that everything transpired at the meetings is to be found only in the remakrs column and decisions are recorded in the Comparative Statement (Ex. 38). There is also no record maintained regarding the dates on which meetings are held. His assertion that the dates of the meetings would only be found in the Comparative statement, is incorrect. His version that it was on 17th July 1984 that meeting was held pertaining to the glycerine contract awarded to Chem Pack and Alpana Pharma, is based purely from memory and without any indication as to why he should remember that date and none other and is at variance with the contemporaneous personal note of Asstt. Commr. Raykar that this meeting took place on 25th July. Satalkar had finally to admit that he had not been able to ascertain from any record the exact date on which this meeting had taken place that even the Comparative Statement (Ex. 38) does not bear any date, it not being the practice to do so nor even to indicate the date on which decisions were arrived at for awarding rate contracts. At the time of the meeting, signatures of the members attending the meeting were taken on a loose sheet of paper which was missing. Nor was there any practice of maintaining any attendance register.

97. Satalkar admitted that the Comparative Statement (Ex. 38) was not signed on the day of the meeting, but was signed by the members subsequently, that it might be that the Committee members may not have signed it on the same subsequent

date, but on different dates, that none of the members signed the Comparative statement on the date of the meeting because the decisions at the foot of the Comparative Statement were written subsequently and not on the date of the meeting itself. He further volunteered that this was because there was no time to write the decisions on the same day, but assailed that in the remarks column the names of the original and alternate supplier were written during the meeting itself. It is not the practice of the Committee members to put the dates in the remarks column. He admitted that there was no contemporaneous record to corroborate the contents of the remarks column. However the other members made their own notes for their own record. But those personal notes did not form the part of the record. He admitted that all the Comparative statements are not sent to the Committee members at one time for their signatures, but they are sent in parts and sometimes their signature are taken at the next Committee meeting.

98. According to Satalkar in the present case, the signatures on the Comparative Statement of the Committee members were in some cases taken before 25th July 1984. It is perplexing why after so many lapses of memory Satalkar should remember the date 25th July—presumably because later that night Dr. R. D. Kulkarni left to go abroad. He admitted that signatures on the Comparative statement may be taken any time between the day following the meeting and 10-15 days thereafter.

99. Satalkar admitted that notes or minutes of the meetings are not maintained either by the staff present or by any Committee member. The decisions are written down by the Industries Officer (in this case Torvi) at the foot of the Comparative Statements, that the Industries Officer does not do so there and then for paucity of time but does so at the conclusion of the meetings. Even so there may not be any mistake in the notation. However there may be mistakes in the Comparative Statements because 900 quotations have to be scrutinised and arranged in ascending order and the rates have to be calculated after adding the various taxes. All this work is done by a team of people from the Store Purchase Section.

100. Satalkar continues that whenever the technical members say that a particular sample is not according to specifications, it is so stated in the Comparative Statements by the letter 'NTS'. However, he was not in a position to amplify what was not according to specifications (NTS) in the Comparative Statement (Ex. 38) pertaining to Deen Pharmaceuticals. He admitted that in the case of Deen Pharmaceuticals the quantity and the rates were according to the tender conditions and was unable to say why Deen's tender was rejected on the ground that it was NTS. He then assailed a reason from memory that it was found to be NTS on technical grounds, without being able to say what the technical grounds were even after going through Dean's file [Part of Ex. 492 (colly.)]. He was a party to the unanimous decision of NTS in the case of Deen. He volunteered that all decisions are unanimous. He could not say why a decision of NTS on technical grounds would not appear in the file and that no reason was noted why Deen's tender was discarded as NTS. He admitted that there was no contemporaneous document noting the reason why Deen's tender was rejected as NTS. Satalkar admitted that there was no system of furnishing any reason to any tenderer for rejection of his tender even though such tenderer may ask for the reason; to such a request no reply is sent by the department except an acknowledgement. Thereafter nothing happens.

101. Satalkar admitted that Alpana Pharma's tender was not in accordance with the specifications and the terms and conditions of the tender. (This answer was given by Satalkar with utmost reluctance and after the question was repeated three times.)

102. Satalkar admitted that there were 13 other quotations which could have been examined, but were not as there was no practice to go further once the original and the alternate suppliers had been chosen. He also admitted that he had decided to give the alternate contract to Alpana Pharma even though its tender had at least one term which was NTS, namely the Rs. 1,000 -minimum order limit. He admitted that no offer of a tenderer is ever considered unless he first has an actual drug licence, and further that if a tenderer's offer is not according to specifications or is against or is not in accordance with the tender condition, such tender is not considered. He however sought a path of retreat from this damning admission by volunteering that an exception is made if there are no other suitable offers. Even that could avail him nothing in the light of his admission that before accepting Alpana Pharma's tender he and the

Committee members did not ascertain whether the remaining 13 tenderers were suitable or not. On being questioned :

" Then it was only in the case of Alpana Pharma that you and your Committee resorted to the exceptional procedure which you deposed to just now ? ".

He replied :

"The contract to Alpana Pharma was given in chronological order.

Que. : Even though Alpana Pharma's tender was not according to specifications and against the conditions of the tender ?

Ans. : Yes.

Que. : And without even considering the cases of the remaining other 13 tenderers ?

Ans. : Yes. "

103. When asked why he did not refuse to consider Alpana Pharma's tender when admittendly it did not comply with the terms and conditions of the tender, Satalkar replied that they, i.e. the Industries Department were not authorised to reject such tenders which only the Committee members could do. When asked whether he was no the Committee, he replied in the affirmative and admitted that the Committee did not invalidate Alpana Pharma's tender because the Committee relaxed the conditions in the case of Alpana Pharma on some grounds, namely the Joint Committioner's letter, which was the ground he distinctly remembered. He admitted that his understanding of the Joint Commissioner's letter was that a conditional licence was under preparation and would be released shortly to Alpana Pharma and that the licence had already been granted to Alpana Pharma. He did not remember what the FDA representative said or did at this meeting.

104. Satalkar even attampted an escape route by suddenly remembering that during the 5 to 10 minutes that were devoted to Alpana Pharma, he might have gone out for a few minutes, but later admitted that he was present throughout.

105. Satalkar's evidence exposes him as a witness who, to say the least, abdicated his responsibilities. His evidence discloses that though he is the Addl. Director of Industries he treated the entire matter of Alpana Pharma very lightly, or allowed himself to be dominated, particularly by Dr. Kulkarni, who was regarded as the senior-most. To say the least he allowed himself to be made a tool of in the manoeuvring hands of Dr. Kulkarni, (more on him later) and worse still of officer Torvi.

106. While on this aspect there is overwhelming evidence which points to indifference, negligence and dereliction of duty, (though not corruption), there is evidence of Satalkar's involvement in positively favouring Bombay Chemicals from which it would be reasonable to conclude that he was not unamenable to extraneous considerations.

107. In March 1984 a letter was written by Bombay Chemicals to the Industries Department asking for extension of the contract period from 1984 to 1986. According to Satalkar, the Industries Department was entitled to give such an extension even without inviting tenders. However tenders were invited as Bombay Chemical's latter of March 1984 was not traceable and an indent for the drug items for 1984-86 had been received from the Professor of Pharmacology. Thereafter a representative of Bombay Chemicals, whose name Satalkar says he does not remember, made enquiries of Satalkar. Satalkar's enquiries in his section revealed that no letter of March 1984 had been received from Bombay Chemicals. The representative of Bombay Chemicals thereupon produced a copy of that letter. Satalkar says he asked the representative of Bombay Chemicals why they had not filled in the regular tender, to which the reply was that the had not done so because of their representation of March 1984 for extension of the contract. Satalkar says he brought all this to the notice of the Committee members. Thereupon the alternate contract was given to Bombay Chemicals as the other tenderers were not found suitable. Satalkar says he treated Bombay Chemicals as if they were tenderers.

108. This was strange behaviour on Satalkar's part. When asked whether there was a practice that if someone makes a representation, tenders are not invited, he replied :—

"There is no such practice—

Que. : Then why did you go out of your way in asking the party to give you a copy of the letter ?

Ans. : Because they approached me and requested me to do so.

Que. : Do you agree that thereby you did injustice to the other tenderers ?

Ans. : No. Because if any other tenderer had been found suitable the rate contract would have been given to him and not to Bombay Chemicals.

Que. : In the case of Bombay Chemicals there was nothing before the Committee either by way of a tender or earnest money or sample, etc. Then how is it that you preferred Bombay Chemicals ?

Ans. : These formalities can be dispensed with in the case of repeat order."

Satalkar admitted that in the drug section Bombay Chemicals was the only instance where a party was given the contract even though he had not filled in a tender form or complied with the tender conditions. He also admitted that the other tenderers were not informed that Bombay Chemicals had been given the contract even though they had not filled in the tender or otherwise complied with the tender conditions. According to him, in the Manual there is a provision whereby a repeat order can be placed with a party even though such a party had not filled in a tender or complied with the tender conditions. Unfortunately for Satalkar no such Manual or any such provision was sought to be produced by him.

109. Renewing a contract as done in the case of Bombay Chemicals was something unprecedented. Why should Satalkar go out of his way to do so ? And worse still suppress this fact from the other tenderers. He acted with reckless abandon in an obvious gesture to favour Bombay Chemicals. To that end, an appropriate enquiry should be held against him by Government. I fear in Bombay Chemicals' case, Satalkar can be accused of more than mere dereliction of duty.

110. This brings me to Professor of Medicine Dr. Chandrashekar J. Mistry.

111. Dr. Mistry was one of the members of the Drugs Selection Committee. His role was to see that suitable drugs were selected and made available to various Government hospitals in Maharashtra. As a member of the Drugs Selection Committee, Dr. Mistry had gone through the terms and conditions of the tender but admitted that he was not well acquainted with them. While selecting a drug the Committee considered all factors such as price, quality, packing and so forth. They proceeded on assumption that the quality of a drug was what was actually stated on the label of the sample. They also considered the price structure, the opinion of the FDA representative and the opinion of the Pharmacologist, in this case Dr. R. D. Kulkarni. Dr. Mistry's function differed from those of Dr. Kulkarni inasmuch as Dr. Kulkarni knew precisely the formulae and the method of visual testing of the drugs and admitted that as far as these aspects were concerned he and the other members were guided by Dr. R. D. Kulkarni. The FDA representative would know whether a tenderer held a valid licence, whether he had a quality control laboratory, whether any random samples drawn were found to be faulty and whether there had been criminal proceedings against him. Most of the questions of maintaining the quality came within the sphere of the FDA. The Director of Industries was basically concerned with the invitation of tenders, scrutiny and putting before the Committee such of the tenders which had satisfied the tender conditions. He was also expected to collect the samples submitted, preserve them for 3 months and present the samples to the Committee for inspection. The Director of Industries and his staff were expected to see that the tenderers were complied with all the tender conditions.

112. Dr. Mistry goes on to say that as Professor of Pharmacology Dr. Kulkarni's function and duties were to submit a list to the Director of Industries of the drugs for which the tenders were to be called for, that Dr. Kulkarni would also know the formulae of the drugs and their assessment by visual inspection and, if required, by chemical analysis and that as far as these aspects were concerned it was the voice of Dr. Kulkarni which would prevail.

113. Dr. Mistry continues that regarding drugs which were labelled according to I.P., they had nothing much to say, that most of the labels on the drugs indicated whether they were in accordance with I.P. or B.P. or U.S.P. In those cases they would only see the label and base their decision on what was stated on the label. Quality was never checked except by visual observation, which he admitted was only superficial and, with the limited time at their disposal, cursory. In every case they did not scan the original tender form and most of the time they never saw the files. They went by the Comparative Statement (Ex. 38), naturally assuming that it had been correctly prepared. Dr. Mistry admitted that in the present case, the very first item, namely Chem Pack's glycerine was selected. In the Comparative Statement (Ex. 38) there were in all 18 tenderers whose offers were listed. However even after seeing the Comparative Statement Dr. Mistry was not in a position to state whether the case of all these 18 tenderers had been discussed or not, and if not, the number of tenderers whose items were discussed. Committee members made their own private notes reflecting the items selected and names of the suppliers (namely, original, parallel or alternate). These personal notes were made in order to subsequently verify any information that would be required.

114. After seeing the Comparative Statement (Ex. 38), Dr. Mistry was unable to say why or when 'NTS' was written against any of the items in the remarks column. According to him 'NTS' probably means "not to specifications". He could not say whether NTS in any of the items in Ex. 38 was written contemporaneously or before or after the meeting of that day. The Comparative Statement was not seen by the members but was merely read over to them tender-wise by the representative of the Director of Industries. They could not see what was being written in the remarks column but they did so at the time of signing Ex. 38.

115. Dr. Mistry admitted that NTS is capable of signifying many defects, one of them being that the label was not according to specification or that the quality or quantity or container may not be according to specification or that it may not pass visual observation. He admitted that while rejecting Serial Nos. 2, 3 and 4 in the Comparative Statement (Ex. 38), the exact reason for rejection had not been noted. He admitted that only in case where the drug is not easily available, does the Committee have the power to relax the terms and conditions of the tender, otherwise no relaxation of the terms and conditions of the tender is permissible. He further admitted that the Committee never accepted conditional tenders, namely tenders subject to any condition. He also admitted that Alpana Pharma's tender being a conditional tender would be NTS and have been passed over to the next tenderer at Serial No. 6, namely Franco Italian. He admitted that even so Alpana Pharma at Serial No. 5 was selected despite its tender being a conditional tender. He could not say why even after seeing Alpana Pharma's file (Ex. 37) which he had not seen before. He had no recollection in what circumstances Alpana Pharma's tender was accepted even though it was a conditional tender.

116. Nobody pointed out to him at that meeting that Alpana Pharma did not have actually a licence, but was merely flourishing a letter from the FDA that a licence would be granted subject to the establishment of a quality control laboratory within 2 months. Dr. Mistry admitted that when Alpana Pharma's tender was under discussion, he was under the impression that Alpana Pharma held a regular valid licence and that they were in the market for two years. His attention was not drawn to office note at page 13 of Alpana Pharma's file (Ex. 37) at the time of the discussion of Alpana Pharma's tender. This note was not read over to any of the members. He did not remember whether in the Comparative Statement (Ex. 38), the statement in the remarks column pertaining to Alpana Pharma was read over to them. He admitted that if all this had been brought to his notice he would never have concurred in Alpana Pharma being accepted as alternate supplier.

117. After seeing Chem Pack's letter dated 20th April 1984 he admitted that Chem Pack's tender was a conditional tender and if this had been brought to his notice he would not have cast his vote in favour of Chem Pack.

118. Dr. Mistry agreed that in the Comparative Statement (Ex. 38) there is nothing to indicate why Deen Pharmaceuticals at Serial No. 2 was disqualified as NTS. Committee members can verify only the labelling and can visually observe the sample insofar as NTS is concerned. He agreed that from a mere visual observation it would not be possible to gauge whether a sample of glycerine is of standard quality or not.

119. He did not remember if anyone mentioned at this meeting that he would persuade Alpana Pharma to withdraw their condition. The very fact that no other tender after Alpana Pharma was considered showed that Alpana Pharma had agreed to withdraw their condition. It is bewildering how Dr. Mistry could come to any such conclusion in the light of his own admission that no tenderers were present at that meeting and further that none of the Committee members had stated at this meeting that Alpana Pharma should be persuaded to withdraw their conditional tender.

120. Dr. Mistry did not preserve the private notes kept by him during the discussion. The only time he saw his private notes after the meeting was when he signed the Comparative Statement (Ex. 38). He did not remember whether he did so the same day of the meeting or the following day or how many days thereafter.

121. Dr. Mistry also did not remember if any of the defects in Alpana Pharma's tender were discussed at the meeting. He did not remember the discussion deposed to by Satalkar, but admitted that if these defects in Alpana Pharma's tender had been brought to his notice he would not have waived them, and it is because these defects were not brought to his notice that he voted in favour of Alpana Pharma. He admitted that he was surprised that these defects should not have been brought to his notice and that he came to learn of these defects for the first time in Alpana Pharma's tender from the newspaper reports. It was the duty of the Director of Industries Satalkar and the representative of the FDA to have brought these defects to his notice but he does not remember whether Satalkar was throughout present when the glycerine item was being discussed. He did not remember whether it was pointed out to the members whether the grant of licence to Alpana Pharma was conditional or unconditional or whether such a licence could be treated as a licence or not, namely whether it was a valid or invalid licence, or whether it could be treated as a licence at all. He admitted that if these aspects had been brought to his notice then, he would not have voted in favour of Alpana Pharma. He also admitted that if it had been pointed out to him then that Alpana Pharma had not been in the market for two years he would not have voted in favour of Alpana Pharma. Even after seeing the Comparative Statement (Ex. 38), Dr. Mistry could not say which condition pertaining to Alpana Pharma was allowed to be withdrawn by the committee.

122. This evidence coming from the lips of Dr. Mistry himself can but lead to one conclusion, namely that Dr. Mistry was either inattentive or indifferent, guided as he was by Dr. Kulkarni who, on Dr. Mistry's showing, knew every thing about these things. It is futile for Dr. Mistry to keep on repeating a dnauseum that he would not have voted in favour of Alpana Pharma if all the facts had been brought to his notice. Assuming that they were not, it was for Dr. Mistry as a responsible member of the Committee to have asked for the facts, sought them out and asserted himself, instead of being a silent spectator and virtually doing noting. To that end while the evidence of Dr. Mistry does not indicate him to be a person who had any interest in Alpana Pharma (or for that matter in anything else going around him,) it does indicate that he abdicated his duties and responsibilities, and to that extent was guilty of negligence and dereliction of duty.

123. The macabre role played by the Professor of Pharmacology Dr. R. D. Kulkarni can best be seen from his own evidence.

124. From 1972 until 13th February 1986 Dr. Kulkarni was attached to the J. J. Hospital as Professor of Pharmacology except for a period of one year in 1976-77. From 1972 he was a member of the Drugs Selection Committee except in 1976-77 when he held an identical post at the B. J. Medical College, Poona. He was a full time Government employee. His last drawn monthly salary was Rs. 4,800 inclusive of non-practice allowance of Rs. 600. According to him, this was his only source of income coupled with remuneration for examining papers of Ph.D., post graduate and other students.

125. While he was Professor of Pharmacology, he started two units for doing research work in the J. J. Hospital, namely Unit I (Clinical Pharmacological Unit) in 1969 and Unit II (Dr. R. D. Kulkarni Research Unit) in 1972-73. Dr. Kulkarni was the Director of both units. The patron of Unit I was Hoechst Pharmaceuticals with an annual grant of Rs. 1,00,000 to Rs. 1,50,000 to cover expenses. The patron of Unit II was Himalaya Drug Company with an annual grant of Rs. 1,00,000 to

cover expenses. The expenditure of these Units was budgeted. Unit I had an account with the Syndicate Bank in the name of " Clinical Pharmacological Unit, Grant Medical ". This bank account was operated jointly by Dr. Pinto Pereira of Hoechst Pharmaceuticals and Dr. R. D. Kulkarni. Unit II had a savings account with the Maharashtra State Co-operative Bank, Opp. J. J. Hospital in the name of "R. D. Kulkarni Research Account". This savings account was opened on 22nd July 1977 (the introducer being Dr. S. V. Shaligram, J. J. Hospital) and was closed on 25th April 1986. This account was operated by Dr. R. D. Kulkarni alone. In Unit II there was no doctor connected with Himalaya Drug Co. assisting Dr. Kulkarni. Indisputably these units were controlled by Dr. Kulkarni as is manifest from the fact that after he left the J. J. Hospital in February 1986, both Hoechst and Himalaya terminated their agreements on 21st March 1986 and 21st August 1986 respectively.

126. For the purpose of the present inquiry, we are concerned with Dr. Kulkarni's manipulations in the savings account of Unit II which was operated by him alone. As will appear presently, from this account large amounts aggregating to about Rs. 2,00,000 were received every year and large withdrawals in cash or by cheque were made including certain withdrawals which on Dr. Kulkarni's own admission were his personal withdrawals, having nothing to do with Unit II. No account books were maintained and no income-tax returns were filed.

127. In 1982, bio-availability data study work was done in Unit II by Dr. Kulkarni for Artichem Laboratories, Pune. Since then he knows Artichem's partner Ramanlal Karwa. On 30th May 1985 Artichem issued a cheque for Rs. 18,000 in favour of R. D. Kulkarni Research Account. This amount was deposited by Dr. Kulkarni in the savings account with the Maharashtra State Co-operative Bank. This amount is said to have been legal payment for certain bio-availability data study work done by Dr. Kulkarni for Artichem in 1984. However as will be shown presently, it was nothing but a consideration given to Dr. Kulkarni by Ramanlal Karwa to ensure the passing of Alpana Pharma's tender by the Drugs Selection Committee of which Dr. Kulkarni was a member. That is how Unit II's savings account in the name of "R. D. Kulkarni Research Account" solely operated and controlled by Dr. Kulkarni comes into the picture.

128. Dr. Kulkarni pontificated that this savings account in the Maharashtra State Co-operative Bank was not his personal account and no personal expenses were met by him from that account. This will presently be shown to be utterly false. He knows a person by the name of Karwa, but initially sought to distance himself from him by professing not to know his first name. He professed not to have remembered Artichem's name that morning when he gave his evidence or even that it is situate at Pune, even though specifically asked, but suddenly remembered it when Artichem was mentioned in connection with Karwa. Thus after such and similar calculated and pathetic attempts to distance himself from Ramanlal Karwa and Artichem, Dr. Kulkarni ultimately admitted that Ramanlal Karwa is the same person connected with Artichem Laboratories for whom Dr. Kulkarni had done bio-availability data study work in 1982 and who had met him in 1984 for the same purpose and that it was the same Ramanlal Karwa and the same Artichem from whom in the past he had received payments in the vicinity of Rs. 30,000. Initially Dr. Kulkarni was categorical that receipts were always given to parties making payments for the bio-availability data work done by Units I and II, that such payments would be recorded in the account books maintained by the Unit concerned and that a regular account project-wise was maintained. He soon had to swallow these sanctimonious sentiments when he had to admit to the contrary, namely that he did not prepare yearly account so as to tally it with the bank account, nor was any account maintained in the form of a ledger, cash book or journal and that the accounts allegedly maintained have not been shown by him to anyone.

129. Dr. Kulkarni says that in 1983-84 the boi-availability data work done by him for Artichem Laboratories pertained to Tetracyclin.

130. Dr. Kulkarni admitted that having received a cheque dated 30th May 1984 for Rs. 18,000 from Artichem in favour of R. D. Kulkarni Research Account drawn on the Bank of Maharashtra, Tilak Road, Pune but professed that it was in payment for boi-availability data study done by Unit II immediately before or immediately after the receipt of the cheque. Dr. Kulkarni put this cheque in the saving account of Unit II, namely R. D. Kulkarni Research Account. The meeting of the Drugs Selection Committee was after this cheque which Dr. Kulkarni received.

Dr. Kulkarni professed that receipt was sent to Artichem according to the usual practice, that copies of receipts were kept and this payment of Rs. 18,000 would be recorded in the account books of Unit II. All these protestations were belied by his admissions that no receipt for Rs. 18,000 was given to Artichem (This is also corroborated by Ramanlal Karwa), that no copy receipts were ever maintained neither were any books of accounts, nor were any income-tax returns ever filed even though Unit II received payments from various parties and made profit, which Dr. Kulkarni facetiously calls, surplus. He admitted that if two studies were simultaneously done, there would be a surplus and if three studies were simultaneously done, the surplus would be larger. He would recover the full amount from each party even if the studies were simultaneous. After endeavouring to make some distinction (to him, no doubt subtle, but otherwise unintelligible) between profit and saving, Dr. Kulkarni admitted that there was usually a surplus from the bio-availability studies and that such surplus was indeed recovered from the parties. He proclaimed his non-accountability to anyone by admitting that he had never accounted for any surplus to any party from whom the surplus was recovered and that on an average the annual surplus could be about Rs. 50,000 in respect of the studies done by Unit II and that bio-availability study was not the only study done by that Unit. Amongst several things Dr. Kulkarni was unable to explain that if no profits were made, how it was possible for the account to support activities such as alleged foreign travel of students attached to the Units.

131. He admitted that he alone could operate, the savings account opened in the Maharashtra State Co-operative Bank in the name of R. D. Kulkarni Research Account as in fact he did. At the time of the closing of account till April 1986 he withdrew the balance and utilised it for payments of bills pertaining to Unit II. For that there is only his *ipse dixit*.

132. Dr. Kulkarni's assertain that the savings account in the Maharashtra State Co-operative Bank was never treated by him as his personal account was demonstrably untrue from his own admissions that a number of withdrawals had been made by him for his personal expenses, to name a few, payments to the Diners Club, the C.C.I., to George Motors for repairs to his personal motor-car, Rs. 15,000 to a builder towards the construction of Dr. Kulkarni's bungalow at Pune and electricity bills.

133. Dr. Kulkarni admitted that he had dealings with Tri-Star Construction Co. They had constructed his house at Pune. On 17th May 1983 Dr. Kulkarni had given a cheque for Rs. 15,000 to Tri-Star Construction Co. from his account. He admitted that he had paid other amounts to Tri-Star Construction Co. from his personal account, but not from this account. On 14th January 1983 he paid George Motors from this account a sum of Rs. 875 for repairs to his motor-car. On 4th July 1983 from this account he paid the BEST electricity bill for his flat amounting to Rs. 147. On 25th April 1984 out of this account he paid Rs. 555·35 to the Mandvi Post Office for his telephone bill. On 9th July 1985 out of this account he paid to the Reserve Bank an amount of Rs. 804·50 for his telephone bill. None of these amounts and many more, did Dr. Kulkarni ever think of putting back into this account. And there was reasons for his not doing so; because he treated this account as his secret undisclosed personal account, which indeed it was.

134. Subject to making his calculations he admitted that the Bank's statement revealed (*i*) that between 1st January 1983 and 31st December 1983 the amounts deposited aggregated to Rs. 2,31,342 and the withdrawals aggregated to Rs. 2,21,530 leaving a credit balance of Rs. 50,968 as on 31st December 1983, (*ii*) that in 1983 he had paid Jadhav and Co. various amounts aggregating to Rs. 24,475 and to one Bane Rs. 26,000, (iii) that from 1st January 1984 till 31st December 1984 he had deposited in this account amounts aggregating to Rs. 3,94,381 and had withdrawn amounts aggregating to Rs. 3,98,807 leaving a balance of Rs. 39,375 as on 31st December 1984, (iv) that in 1984 he had paid Jadhav and Co., Rs. 91,125 and to Bane Rs. 31,500, (v) that from 1st January 1985 to 31st December 1985 he had deposited Rs. 1,55,268 and had withdrawn Rs. 2,04,325 leaving a balance of Rs. 5,258.44 as on 31st December 1985, (vi) that from 1st January 1986 to 25th April 1986 he had deposited a total amount of Rs. 66,318 and had withdrawn amounts aggregating to Rs. 81,371. He admitted that on 25th April 1986 when this account was closed, he withdrew the balance of Rs. 4,716.59 by a bearer cheque made out in the name of one Tawte, a clerk in his Unit to enable him to withdraw the amount and to pay it to Dr. Kulkarni which Tawte did. Despite an opportunity given to Dr. Kulkarni to the

extent of keeping his evidence in abeyance for several weeks, Dr. Kulkarni never ventured to give any explanation regarding the vast amounts withdrawn by him purportedly towards the expenses of Unit II or dispute the correctness of the Bank's statement which of course he could not. There is nothing beyond Dr. Kulkarni's *ipse dixit* that all withdrawals pertaining to this account were made for various research projects and that all receipts, namely credit entries, are supported by the copy bills, none of which is forthcoming. Dr. Kulkarni finally admitted that he was not in a position to explain all the debit and credit entries appearing in this account.

135. Dr. Kulkarni's affectation that he made disbursements for his personal requirements from his personal Bank account in Bombay and Pune, does not militate from the fact that from R. D. Kulkarni Research Account Dr. Kulkarni did likewise. He cannot be heard to say that though he was not supposed to utilise this account for his personal expenses, he did so by mistake or that he had not taken any steps to replace into this account the amounts which he had taken towards his personal expenses. Between November 1982 and 7th January 1986 he claimed payments towards research bills aggregating to Rs. 17,147 from his personal account. This seeming act of generosity however Dr. Kulkarni did not satisfactorily explain. He admitted that his residential telephone bills had been paid from R. D. Kulkarni Research Account. It was so because his residential telephone had been mainly used for arranging conferences, seminars and for other official purposes. Though this account was an official account, he unintentionally utilised it partly for his private purposes and he also used his personal account for official purposes. He admitted that he had never tried to replace what he took from the official account for his private purposes and *vice versa*. He claimed that a total of about Rs. 400 only was drawn by him from the official account in excess of what he had drawn from his private account for official purposes. Though as stated earlier ample opportunity was given to him to give an explanation, and though he was represented by an advocate, Dr. Kulkarni did nothing of the kind.

136. The relevance of this account is that it is into such an undisclosed and unaccounted for account operated solely by Dr. Kulkarni as his personal and private account, that Dr. Kulkarni sought from Artichem a cheque in the name of R. D. Kulkarni Research Account so that it could be put into that account and utilised by him without anyone being any the wiser. This was genius in its very simplicity.

137. For Artichem Laboratories, Dr. Kulkarni had done three simultaneous studies, each study comprising of different drug and for each drug there were two samples, thus for Artichem, he had done six studies. For the first two drugs, the Ex. 170 cost of analysis was higher than normal. The total cost of these six studies came to Rs. 18,000 as estimated. He does not remember if any estimate was given to Artichem in respect of these six studies. Here it may be stated that even according to Ramanlal Karwa no estimate was given. When Ramanlal Karwa met him in 1984, Dr. Kulkarni told him to get the bio-availability data studies done by Haffkine Institute and that he would do the studies if Haffkine did not do. Prior to his receiving Artichem's cheque dated 30th May 1984 for Rs. 18,000 (Ex. 170) Dr. Kulkarni had received Artichem's cheque for a lesser amount which he had returned. He does not remember in whose name that cheque was drawn, or its amount. Be that as it may, the record discloses that the earlier cheque was only for Rs. 12,000 made out in the name of Professor of Pharmacology. After Dr. Kulkarni's refusal to accept that cheque, Artichem sent their fresh cheque for Rs. 18,000 made out at Dr. Kulkarni's behest in the name of R. D. Kulkarni Research Account.

138. *Now was this Rs. 18,000 really in payment for bio-availability data reports? Evidence unmistakably shows to the contrary.*

139. Dr. Mistry, Professor of Medicine at Grant Medical College was attached to Unit I as Associate Director and alongwith Dr. Kulkarni was one of the members of the Drugs Selection Committee. Even so, Dr. Kulkarni admits he never brought to Dr. Mistry's notice or to any other Committee member that he, i.e. Dr. Kulkarni, was doing boi-availability data study for Artichem. This bespeaks Dr. Kulkarnis' guilty mind and a guilty conscience. His motive is suspect.

140. The glycerol tenders shown in the Comparative Statement (Ex. 38) were the last to be discussed at the meeting; the discussion of these items took about 10-15 minutes and the meeting got over at 6·00 p.m. Dr. Kulkarni denied that this item was disposed of in two or three minutes because of his impending departure for London that night.

141. Dr. Kulkarni admitted that the only thing in this handwriting in the comparative Statement (Ex. 38) is his signature. This was the only comparative statement between the four Committee members. The Comparative Statement was read over to the members by a staff of the Industries Department. Thereafter each sample was seen by the members for their opinion whether it was acceptable or not. The persons from the Industries Department would then inform them which was the lowest tender; thereafter if the unanimous opinion of the four members was that the sample was acceptable and the tenderer was reliable, his tender would be accepted. He admitted that no sample of glycerol was rejected on the ground that it was sub-standard and that a mere visual inspection of the sample would not indicate whether it was sub-standard or not.

142. He admitted that the exact reason for rejection of Deen's tender is not mentioned in the Comparative Statement except that it was ' NTS ', which would mean that either the quantity in the sample bottle was insufficient or the labelling requirements were not fulfilled. The Committee went strictly by specification and had no right to reduce the rate offered by a tenderer without his consent or to impose without the consent of the tenderer any condition which was not in the specification. He admitted that even so without the consent of Alpana Pharma, its tender was accepted subject to Alpana Pharma withdrawing the condition imposed in its tender. He admitted that there was no discussion about awarding the contract to Deen subject to their complying with the specification and further that virtually there was nothing objectionable about Deen's sample and that the rate quoted by Deen was the lowest along with the rate quoted by Chem Pack. He admitted that no reasons have been stated in the Comparative Statement (Ex. 38) why tenders were rejected, and conceded that the Committee was bound to have stated the reasons. He admitted that in respect of Deen Pharmaceuticals, the Industries Department had not stated any objection in the remarks column of the Comparative Statement (Ex. 38) and that the remarks ' NTS ' against Deen was written by the staff of the Industries Department after the discussion about Deen had taken place.

143. Dr. Kulkarni tried to lay the blame on the Industries Department that it was primarily the duty of that Department to inform the Committee members which specification had not been complied with by the tenderer and that in this duty the Industries Department had failed. According to Dr. Kulkarni, it was also the duty of the Industries Department to bring to the notice of the Committee members that a tenderer must be in the line for at least two years and that in this duty too the Industries Department failed. He professed ignorance that Alpana Pharma was not in the line for the requisite period of 2 years prior to their making the tender and that this specification in the case of Alpana Pharma was not considered by the Committee because it was not brought to the notice of the Committee members by the Industries Department. In the case of Deen, the Industries Department did not point out to the Committee that the quantity was not according to the specification; it is most likely that the only objection to the Deen's tender was to the labelling of the sample for which the FDA is the only competent authority. He remember that all the Committee members were unanimous that Deen's tender did not comply with the specification. He expressed his inability to state if there had been any objection regarding Deen because nothing was mentioned in the remarks column of the Comparative Statement (Ex. 38). He admitted to the possibility of NTS having been written by mistake in the remarks column of Ex. 38 against Deen (Serial No. 2), Tridal Chemicals (Serial No. 4) and Shreephal Lab (Serial No. 9), as also to the possibility that NTS may have been written against these three serial numbers subsequently and that this would also be applicable to all other remarks pertaining to other tenderers in the Comparative Statement (Ex. 38).

144. He admitted that one of the specifications required was that the tenderer must submit the literature along with the sample. He did not see any such literature and admitted that if Alpana Pharma did not supply the literature it had not complied with the conditions of tender. He did not remember if Alpana Pharma had satisfied all the conditions of tender, but it had satisfied all the conditions of labelling. Dr. Kulkarni was positive that the discussion on Alpana Pharma's item took about 5 minutes; other items if simple and straight forward took about a minute or a minute and half each. Dr. Kulkarni however did not remember why Alpana Pharma's item should have taken 5 minutes. The irresistible inference is that it must have taken some time for Dr. Kulkarni to prevail upon the other members of the Committee to extend their approval to the grant of the contract to Alpana Pharma in the teeth of the fact that its tender should have been rejected at the outset.

It is here that the payment of Rs. 18,000 by Artichem to Dr. Kulkarni assumes sinister dimensions.

145. *What are those sinister dimensions* ? In 1984 Artichem had filled in its tender for 40 items. Nine of them required bio-availability data reports to be filed along with the tender. Some reports of Haffkine Institute and some of the Pharmacology Department, Grant Medical College, were filed. The letter was certified by Dr. Kulkarni as Professor of Pharmacology, Grant Medical College. According to both Dr. Kulkarni and Ramanlal Karwa, the consideration for Artichem's cheque of Rs. 18,000 was the bio-availability study work done by Dr. Kulkarni. This version does not bear the light of scrutiny. Indisputably, Ramanlal Karwa was the guiding factor of Alpana Pharma. To start with, (*a*) the closing date of Alpana Pharma's tender was 27th April 1984. Artichem's cheque for Rs. 18,000 was made out on 30th May 1984; (*b*) Six bio-availability data reports produced by Ramanlal Karwa reveal that they are of June-July 1984, namely two of 30th June 1984 and four of 9th July 1984, i.e. over a month and more of Alpana Pharma's closing date of tender on 27th April 1984; (*c*) these reports are not on any letter-head but are mere cyclostyled forms signed by Prof. R. D. Kulkarni, Professor and Head of the Department of Pharmacology, Grant Medical College; (*d*) they do not indicate that this study work was done by Unit II and (*e*) even assuming it was, Dr. Kulkarni's Unit II was in any event not a laboratory or organisation authorised to give bio-availability study reports under tender condition 29-A. It is therefore manifest that if at all bio-availability data studies were done, they were done by Dr. Kulkarni in his personal capacity and also that the payment to Dr. Kulkarni of Rs. 18,000 was unconnected with these reports produced by Ramanlal Karwa. Ramanlal Karwa wanted the bio-availability data reports for filing them with the tender which closed on 27th April 1984. Hence these six reports prepared in June and July 1984 would be useless and could possibly have no relation to the tender already submitted over 2 months earlier. There is no documentary evidence whatever which connects this payment with the bio-availability data studies for the purpose of filing a tender with the C.S.P.O. It is not without its own significance that Dr. Kulkarni was unable to produce any proof that the bio-availability data studies had in fact been carried out.

146. In Artichem's books of accounts an account was opened in the name of Dr. R. D. Kulkarni Research Account. There is a debit entry of Rs. 18,000 in this account under date 31st May 1984. In Artichem's books of accounts there is also a Professional Fees Account. However, curiously enough even though this amount is shown as professional fees, it is not debited to that account. This shows that despite the protestations of Dr. Kulkarni and Ramanlal Karwa, this amount of Rs. 18,000 was not paid to Dr. Kulkarni by way of professional fees.

147. In September 1984 C.S.P.O. intimated to Alpana Pharma of its being awarded the rate contract for glycerine and 2 other items. It was only thereafter that in Artichem's books of accounts a credit entry for Rs. 18,000 in Dr. Kulkarni Research Account under date 30th September 1984 is made. This is an adjustment entry. No explanation is forthcoming why this adjustment entry should have been made only on 30th September 1984 or why initially on 31st May 1984 itself the amount was not debited to the Professional Fees Account in Artichem's books of accounts.

148. Further no receipt has been given for this amount of Rs. 18,000 received from Artichem. There is no documentary avidence to connect this payment of Rs. 18,000 with any bio-availability data work allegedly done for the purpose of its being filed with the tender on 27th April 1984. In any event, there is nothing to show that Rs. 18,000 was the cost of those six reports. How this figure of Rs. 18,000 was arrived at is a mystery for which no explanation has been forthcoming from the persons it should have, *viz.* Dr. Kulkarni or Ramanlal Karwa. However it would
Ex. 178 not be out of place to recapitulate that on 23rd May 1984 a blank cheque was issued by Artichem in favour of Professor of Pharmacology, in which Artichem's liaison man Parulekar filled in the figure of Rs. 12,000. This cheque was refused by Dr. Kulkarni as for obvious reasons he did not want it in the name of Professor of Pharmacology and was for an amount which did not meet his approval. Thereafter on 30th May 1984 was issued the cheque for a higher amount, namely Rs. 18,000 in the name of R. D. Kulkarni Research Account and which was promptly credited by Dr. Kulkarni in his secret undisclosed account without issuing a receipt.

149. It may legitimately be asked if Rs. 18,000 was given as an inducement to Dr. Kulkarni for passing Alpana Pharma's tender, surely the payment would have been made in cash and not by cheque.

150. The answer is as simple as it is obvious. Ramanlal Karwa, a shrewd businessman was not the one to take any chances. The cheque would be evidence of payment in case a refund had to be called for it the rate contract was not granted to Alpana Pharma. Moreover by making a cheque payment, Artichem would get deduction from the income-tax, whereas Dr. Kulkarni had nothing lose as his R. D. Kulkarni Research Account had never been disclosed by him to anybody and least of all to the income-tax authorities. Hence it would be completely safe for this amount of Rs. 18,000 to be received by Dr. Kulkarni by cheque and advantageous to Ramanlal Karwa to pay it by cheque.

151. Undoubtedly the rate contract awarded to Alpana Pharma was done, to say the least, in a highly irregular manner where obvious deficiencies were swept under the carpet. As the senior-most and most experienced member of the Drugs Selection Committee Dr. Kulkarni carried every member with him. This is admitted by Satalkar. Dr. Mistry was indifferent and left it all to Dr. Kulkarni and Asstt. Commr. Raykar himself being Dr. Kulkarni's research student would not dare to go counter to the opinion of his mentor Dr. Kulkarni. Dr. Kulkarni took advantage of his position, status, experience and the respect which he seems to have commanded from the other Committee members. To them he was the guiding light and his pronouncements infalliable. With the experience of over 10 years at his command in the Drugs Selection Committee, there is nothing that Dr. Kulkarni did out of ignorance or mistake. His action was calculated to give the contract to Alpana Pharma as a quid pro quo for the Rs. 18,000 which he had received.

152. Despite opportunities being given to Dr. Kulkarni to explain even in the witness-box why serial Nos. 2, 3 and 4 of the Comparative Statement (Exhibit 38) were rejected, he was unable to do so. The sole intention obviously was to disqualify these tenderers and after Chem Pack at serial No. 1 come straight to Alpana Pharma at Serial No. 5 and willy-nilly pass Alpana Pharma's tender. In an unprecedented move Alpana Pharma's tender, though a conditional one, was accepted subject to withdrawal of the condition. None of the Committee members have given any plausible reason why it should have been assumed that Alpana Pharma would withdrew its condition, as a result Serial No. 6 was not considered. Ex. 38

153. The only person who obviously knew this was Dr. Kulkarni, known as he was to Alpana Pharma's guiding hand Ramanlal Karwa whose cheque for Rs. 18,000 he had received and accepted on 31st May 1984. Quid pro quo. It is amply manifest that Rs. 18,000 was not paid by Ramanlal Karwa for bio-availability work.

154. The timing of this payment is also significant. The tenders were filled on the last date, viz. 27th April 1984. This cheque for Rs. 18,000 is dated 30th May 1984 and could never have been payment for bio-availability reports of 30th June and 9th July 1984. Hence by no stretch of imagination can either Dr. Kulkarni or Ramanlal Karwa maintain the legitimacy of this payment of Rs. 18,000 as for bio-availability reports of June and July 1984, that is over two months after the closing of the tender on 27th April, 1984. The books of accounts of Artichem also indicate that this amount of Rs. 18,000 was not intended to be a fee for research work an adjustment entry was made on 30th September 1984 after Dr. Kulkarni did the work for which he had been paid and Alpana Pharma got the contract.

155. Even in the witness-box, despite opportunities given to Dr. Kulkarni, he was unable to justify how Alpana Pharma's tender could possibly have been accepted in the teeth of the number of breaches from which it suffered. Dr. Kulkarni cannot be allowed the escape route he assails by throwing the blame on the Industries Department. Dr. Kulkarni favoured Alpana Pharma by shutting his eyes to the obvious and patent deficiencies in Alpana Pharma's tender and even to the extent of resorting to the unprecedented step of accepting Alpana Pharma's conditional contract on the unexplained assumption that Alpana Pharma would withdrew its condition. There was no reason for any such assumption unless Dr. Kulkarni was in league with Ramanlal Karwa who was interested in Alpana Pharma getting the contract.

156. From the evidence of Artichem's liaison officer Parulekar it is manifest that the original bio-availability data study reports did not accompany the tender in the teeth of tender condition 29-A, for the simple reason that while the tender was submitted in April, 1984, the bio-availabiility data study reports were of June and July 1984. Hence, if the tender was considered by Dr. Kulkarni without the bio-availa-

bility data study reports, it was a dereliction of duty on his part. If he considered the tender with the bio-availability data study reports (or even xerox copies thereof) he must know that the reports were his own reports subsequent to the filing of the tender. To have done so was equally a dereliction of duty on the part of Dr. Kulkarni. In considering his own reports and without disclosing to the other members his connection with Artichem and the preparation of those reports, Dr. Kulkarni was equally guilty of dereliction of duty. Therefore, looked at from any point of view in addition to corruption, dereliction of duty on the part of Dr. Kulkarni is also established.

157. Even if Dr. Kulkarni's evendence is read in conjunction with that of Ramanlal Karwa, it makes no better reading.

158. Ramanlal Karwa *is a partner of Artichem*, a Pune based pharmaceutical manufacturing concern. Ramanlal Karwa has a vital interest in Alpana Pharma. He admitted that for such items where bio-availability data is necessary, reports must be submitted to the C.S.P.O. along with the tender documents. Tender Condition 29-A sets out the names of the organisations or institutions authorised to give *bio-availability data* reports, viz. (i) the Drug Control Laboratory of the FDA, (*ii*) Haffkine Institute, (*iii*) Pharmacology Department of G. S. Medical College and (*iv*) Pharmacology Department of Grand Medical College. Ramanlal Karwa admits that these are the only recognised laboratories, organisations or institutions from whom bio-availability data can be obtained and none other. Hence *it is manifest*, as was also admitted by Ramanlal Karwa that R. D. Kulkarni Research Unit (*viz.* Unit-II) was not an organisation or laboratory recognised under tender condition 29-A for the purpose of giving bio-availability data reports to tenderers.

159. Ramanlal Karwa deposed that *in* 1982 also Artichem had wanted bio-availability study reports as it had applied for rate contracts. In 1982 the recognised institutions for giving these reports were the same as those named by him earlier. In respect of this bio-availability study the report had been certified by Dr. R. D. Kulkarni as Professor of Pharmacology, and the cheque was made out by Artichem in favour of Professor *of Pharmacology*, Grant Medical College and accepted by Dr. Kulkarni without demur.

160. In 1984 Artichem had applied for a rate contract for about 40 items, out of which bio-availability data was required for 9 items. Ramanlal Karwa *approached* Dr. R. D. Kulkarni *personally* for the preparation of the bio-availability study reports. He told him that he wanted to have that work done from the Greant Medical College where upon Dr. Kulkarni directed him to the Haffkine Institute. The follow-up work was done by Ramarlal Karwa's brother Rameshwar, and Artichem's Bombay liaison man Parulekar. Later Ramanlal Karwa returned to Dr. Kulkarni as Haffkine Institute was unable to carry out all the bio-availability
Ex. 203 (colly.) study reports. On record there is a letter dated 16th April 1984 [Ex. 203 (collectively)] from Artichem to Haffkine Institute wherein it is stated that the last date for submission of tenders is 19th April 1984, and the Artichem requried bio-availability data reports for submission along with the *tenders*. In replay Haffkine Institute
Ex. 203 (colly.) addressed a letter to Artichem on 24th April 1984 [Ex. 203 (collectively)], stating that they would take at least one month to prepare bio-availability data reports after submission of the samples to them and that their charges would be Rs. 2,000 and Rs. 850 respectively for Ampicilin and Refampicin capsules.

161. In respect of these 9 items Ramanlal Karwa says he obtained these reports from Haffkine Institute and the Pharmacology Department of the Grant Medical College. The letter were certified by Dr. R. D. Kulkarni as Professor of Pharmacology of the Grant Medical College. Ramanlal Karwa admitted that there was no agreement between him and Dr. Kulkarni regarding the payment of any fixed charge to Dr. Kulkarn, there was also no agreement for payment to Dr. Kulkarni only the costs actually incurred by him, and that Ramanlal Karwa paid to Dr. Kulkarni whatever he asked for. Ramanlal Karwa did not make any payment ot the Pharmacology Department of the Grant Medical College for the *bio-availability* data report. Initially the payment was *offered* by a blank cheque drawn by Artichem in favour of Professor of Pharmacology, Grant Medical College, and sent to Artichem's liaison man Parulekar in Bombay. Parulekar filled in the figure of Rs. 12,000 but that cheque was returned by Dr. Kulkarni as the amount was inadequate and for
Ex. 31 change of name, viz. to the name of R. D. Kulkarni Research Account. Thereupon at a fresh cheque was made out for Rs. 18,000 in the name of R. D. Kulkarni Research

Account which was accepted by Dr. Kulkarni. According to Ramanlal Karwa this amount of Rs. 18,000 was paid by Artichem as fee of Dr. Kulkarni which as such was to be appropriated in its entirety by Dr. Kulkarni for preparing the bio-availability study reports. This was Ramanlal Karwa's business expenses; it was his practice to debit such expenses to the Professional Fees Account in Artichem's books. Ramanlal Karwa's accountant Apte had standing instructions that whenever no amount was to be refunded, it must bedebited to the Professional Fees Account in Artichem's books.

162. Ramanlal Karwa continued that a copy of the 1984 report was sent to him by Dr. Kulkarni certified by him as Professor of Pharmacology. Initially Artichem had been awarded contract for one product only out of the nine for which he had obtained the bio-availability study reports. Later Artichem made a claim under the 33 per cent reservation scheme applicable to units in backward areas. Under that scheme, Artichem got a contract for about 7 to 8 other products.

163. Ramanlal Karwa admitted that in 1983-84 R. D. Kulkarni Research Account (Ex. 179) was opened in Artichem's books of accounts; that this was done for the payment of Dr. Kulkarni's fees and that this amount of Rs. 18,000 was debited to that account on 30th May 1984. This amount of Rs. 18,000 was not a loan given to Dr. R. D. Kulkarni nor was it an on-account payment and that he had told his accountant Apte that this amount was paid as Dr. Kulkarni's fees. Ramanlal Karwa knew that this amount was not debited to the Professional Fees Account in Artichem's books till 30th September 1984 which was the end of the accounting year and claiming it to be a practice followed in respect of all fees paid to professional persons. Ramanlal Karwa finally had to give a go-by to this so-called practice when his attention was drawn that out of 30 to 40 entries in that account, only the last four had been debited to the parties, one of them being Dr. R. D. Kulkarni for Rs. 18,000, on 30th September 1984. Ex. 179

164. Ramanlal Karwa admitted that he was aware that in the Drug Selection Committee of the CSPO in 1982 and 1984 Dr. R. D. Kulkarni was a member and as such would be in charge of awarding contracts in respect whereof Ramanlal Karwa had filled in the tenders. However according to him, that was not the reason why he got the bio-availability study work done by Dr. Kulkarni in 1982 and 1984. He admitted that when he approached Dr. Kulkarni in 1984 he had informed Dr. Kulkarni and Dr. Kulkarni knew that he, i.e. Ramanlal Karwa, was going to fill in tenders with the CSPO. Ramanlal Karwa admitted that before he contacted Dr. R. D. Kulkarni he was aware of tender condition 29-A as also the fact that only the four institutions named by him earlier were authorised to carry out bio-availability data studies. Except Haffkine Institute which had agreed to do only a few such studies, all the other institutions had declined to do so other than Grant Medical College. However Ramanlal Karwa had not addressed any letter either to G. S. Medical College or FDA Laboratories asking them to do any bio-availability data sutdy because Parulekar told him they were not doing bio-availability data studies.

165. When Ramanlal Karwa met Dr. Kulkarni in 1984 he did not inquire about his fees for preparing the reports. Ramanlal Karwa's assumption was that Parulekar had filled in the figure of Rs. 12,000 in the cheque he gave to Dr. R. D. Kulkarni on the basis of the rates of the Haffkine Institute. He however admitted :—

"..... I would have paid whatever amount Dr. R. D. Kulkarni had asked. That is why initially blank cheque had been sent for payment of his fees ....."

Ramanlal Karwa was not surprised when Parulekar told him that this cheque should be changed to R. D. Kulkarni Research Account. He knew that the report had to be signed by the Professor of Pharmacology, Grant Medical College. Dr. Kulkarni never sent any receipt for the payment of this amount of Rs. 18,000 nor did he send him any statement of account. No covering letter was sent by Dr. R. D. Kulkarni with the bio-availability study reports [Exhibit 176 (collectively)] which unlike the data study reports of Haffkine Institute, were not on the letter-heads of the Pharmacology Department or of the Grant Medical College, but were typed on plain sheets of paper. After asserting that the reports were signed by Dr. Kulkarni as Professor of Pharmacology, Grant Medical College, Ramanlal Karwa admitted that the reports only bore the initials of Dr. R. D. Kulkarni and were not signed by him as Professor of Pharmacology. He admitted that the reports [Exhibit 177 (collectively)] bore the signature of Dr. R. D. Kulkarni but not as Professor of Ex. 176 (colly.) Ex. 177 (colly.)

Pharmacology, Grant Medical College. He admitted that there was nothing in these reports of Dr. R. D. Kulkarni to suggest their having been made by an institution recognised and authorised to do so under tender condition 29-A. Ramanlal Karwa was not surprised to receive Dr. Kulkrani's study reports on plain sheets of paper instead of on the letter-heads of Professor of Pharmacology of the Grant Medical College; he says he did not think about it. Surprising answers coming from an astute businessman.

166. The original reports were collected by Parulekar from Dr. Kulkarni in Bombay and were sent to Ramanlal Karwa after Parulakar got them zeroxed for being submitted to the CSPO. Pausing here for a moment, this could only have been done in June and July 1984 after the closing data of the tenders becasues Dr. Kulkarni's reports are of June and July 1984. Thus contrary to the tender rules, the bio-availability sutdy reports were not even submitted with the tender in April 1984. This in terms is admitted by Ramanlal Karwa :

"..... These reports were sent to the CSPO after the tenders were filled in by Arti Chem."

167. Here it may be stated that for the purpose of the present Commission of Inquiry Dr. Kulkarni had engaged his own lawyer Mr. K. H. Joshi who was present when Ramanlal Karwa gave his evidence. Despite the fact that in order to test Ramanlal Karwa's evidence, positive suggestions were made to him that the amount of Rs. 18,000 given by him to Dr. R. D. Kulkarni was not for the purpose of bio-availability study reports but as an inducement to awarding the contract to Alpana Pharma, Dr. Kulkarni's learned Advocate Mr. Joshi contented himself by merely asking two questions to Ramanlal Karwa. The first was an innocuous question pertaining to the amount paid by Ramanlal Karwa to the Professor of Pharmacology for the bio-availability data study done in 1982, to which the answer was Rs. 3,000 for one product. The second question was :

"*Question*—Yesterday you stated in para 68 at page 1014 of your evidence that you would have paid whetever amount Dr. R. D. Kulkarni had asked. Thereby do you mean to suggest that you would have paid whatever would have been Dr. Kulkarni's costs, fee and expenses ?

Answer—Yes."

By giving this answer Ramanlal Karwa contradicted Dr. Kulkarni according to whom he charged no fees for giving his bio-availability study reports. Thus by confining himself to these two questions, Dr. Kulkarni's learned advocate Mr. Joshi did not make even the slightest attempt to assail any calrification from Ramanlal Karwa on the most vital aspect of quid pro quo repeatedly suggested to Ramanlal Karwa. No doubt, Dr. Kulkarni's learned advocate considered discretion to be the better part of valour.

168. At this stage it will be convenient to recapitulate Parulekar's evidence on this aspect.

169. L. S. Parulekar was Artichem's liasion man in Bombay from April 1984 to April 1985. He was pre-eminently fit to be so looking as from 1947 to 1983 he was a clerk in the Directorate of Industries, and no doubt familiar with the working and ramifications of that department.

170. As Artichem's Bombay liasion officer, Parulekar was always in Bombay and never went to Pune where Artichem is based. His duties were to take follow-up actions with the various departments (but not the FDA), to wit-taking follow-up action in the concerned department where Artichem had filled up forms charting Artichem's progress in that department and give the feed-back to Artichem.

171. In May or June 1984, Parulekar accompanied Ramanlal Karwa on the latter's visit to Dr. R. D. Kulkarni at the J. J. Hospital. The two were closetted together in Dr. Kulkarni's office for 15 minutes. Parulekar waited outside. When Ramanlal Karwa came out, he told Parulekar to go to the Haffkine Institute as Grant Medical College was not undertaking bio-availability data studies. Parulekar made no enquiries whether any of the 4 institutions mentioned in tender condition No. 29-A would carry out the bio-availability data sutdy work for Artichem, but according to him, came to know from representatives of other firms that they were not doing so. Pausing here for a moment, this negatives Ramanlal Karwa's evidence

that inquiries to that end had been made by Parulekar. Parulekar however admitted that unless those four institutions mentioned in tender condition No. 29-A did bio-availability data study, their names would not be found in tender condition No. 29-A.

172. Parulekar continues that at Ramanlal Karwa's behest he went to Haffkine Institute where the rate quoted was between Rs. 2,000 to Rs. 2,500 per study; however Haffkine Institute agreed to undertake studies in respect of 2 products and regarding the others directed him to Dr. Kulkarni at Grant Medical College. Regarding the latter, there is only Parulekar's bare word in which he is not even corroborated by his employer Ramanlal Karwa.

173. Thereupon Parulekar addressed a letter to the Professor of Pharmacology after making inquiries with Dr. Kulkarni's stenographer. Parulekar however did not make any inquiries as to what Dr. Kulkarni's charges would be; he assumed that they would be comparable with those of Haffkine Institute, and telephonically informed Ramanlal Karwa that the charges of the Grant Medical College would come to about Rs. 2,000 per study.

174. Regarding Artichem's blank cheque, Parulekar says that Ramanlal Karwa sent a cheque for Rs. 12,000 in the name of Professor of Pharmacology; Parulekar had never seen that cheque. In this regard, Parulekar is obviously mistaken because indisputably and even according to Ramanlal Karwa himself a blank cheque had been sent to Parulekar by Ramanlal Karwa and Parulekar had himself filled in the amount of Rs. 12,000. Parulekar continues that he went to Dr. Kulkarni's office where the cheque was not accepted on the ground that it was made out in the name of Professor of Pharmacology. Parulekar telephonically informed Ramanlal Karwa that he should send Parulekar a fresh cheque in the correct name. Ramanlal Karwa did so by Artichem's cheque dated 30th May 1984 for Rs. 18,000 in the name of R. D. Kulkarni, Research Account. Parulekar delivered this cheque (Ex. 170) at the office of Dr. Kulkarni. No receipt was given to him. However Parulekar took the clerk's signature on the copy of the covering letter (Ex. 175). Ex. 170 Ex. 175

175. Parulekar had xerox copies of the reports and took the original and xerox copies to the Industries Department. The originals were returned to him after verification and the xerox copies were retained by the Industries Department. Parulekar sent the originals to Ramanlal Karwa at Pune.

176. *With this evidence of Ramanlal Karwa and of the liaison man Parulekar in the forefront, what does it all boil down to* ? It is manifest that Ramanlal Karwa was aware that the bio-availability study required to be done under tender condition 29-A could only be by the four recognised institutions mentioned in condition 29-A and actually named by him. It is also manifest that Ramanlal Karwa was aware that Dr. R. D. Kulkarni Research Unit was not one of the four recognised and authorised institutions. It is not without its own significance that though Artichem's liaison man Parulekar was deputed to do the bio-availability data study work, yet it was Ramanlal Karwa based at Pune who in 1984 personally went and met Dr. Kulkarni and was willing to pay whatever charges Dr. Kulkarni wanted. This is of greater significance in the light of Ramanlal Karwa's admission that he knew that Dr. Kulkarni was on the Drugs Selection Committee. Who then could be better person to tackle than Dr. Kulkarni with the ostensible bait of getting bio-availability work done by him at any price demanded by him. Hence on Ramanlal Karwa's admission he did not even bother to enquire from Dr. Kulkarni what his charges would be.

177. Parulekar's evidence also shows that when Ramanlal Karwa met Dr. Kulkarni at the J. J. Hospital, Parulekar was kept waiting outside Dr. Kulkarni's room. Unless what Ramanlal Karwa wanted to tell Dr. Kulkarni was of a delicate nature, there was no reason why Parulekar should be asked to wait outside instead of being introduced to Dr. Kulkarni for follow-up action as Artichem's liaison man. Greater the reason is Ramanlal Karwa sent Parulekar to Haffkine Institute to make inquiries about bio-availability data study. This seemingly minor aspect has its reflection on the later events culminating with Artichem's cheque dated 30th May 1984 for Rs. 18,000 made out in the name of R. D. Kulkarni Research Account after Alpana Pharma bagged the rate contract.

178. It is also manifest that Rs. 18,000 paid to Dr. R. D. Kulkarni were not only to cover costs and expenses because on 30th September 1984 this amount was debited to Professional Fees Account.

179. I need not repeat what I have already said earlier while dealing with Ramanlal Karwa's evidence including his alleged practice to square up entries on 30th September.

180. The evidence of Ramanlal Karwa, read by itself or in conjunction with that of Dr. Kulkarni and Parulekar or either of them establishes quid pro quo between Ramanlal Karwa and Dr. Kulkarni beyond reasonable doubt.

181. The next question that arises is : *In passing Alpana Pharma's tender, what was the role played by Assistant Commissioner Raykar ?*

182. Whatever be the alleged sins of commission or omission of Assistant Commissioner Raykar concerning other aspects, negligence on this aspect can be the ultimate that can be said against him. Raykar attended a meeting of the Rate Contract Committee when Alpana Pharma's tender was passed. He did so representing Commissioner Bhirud who was hospitalised. Whatever be Raykar's alleged amenability to the Commissioner's or ministerial influence, at least on the aspect of the rate contract being granted to Alpana Pharma, there is no evidence that he was influenced in their favour.

183. Assistant Commissioner Raykar deposed that in the meeting of 25th July 1984 which lasted from 11-00 a.m. till 6-00 p.m. he was required to give his opinion on the samples submitted by the various parties and the status of the suppliers. About 5 items were selected in that meeting. Samples were seen by the members of the committee including himself; Alpana Pharma glycerine sample was the best. He opined it to be so, based as it was on the label, the glass bottle, the cap and the clarity of the sample which he tested with his finger. Raykar says he brought to the notice of other members that Alpana Pharma had not been in the market for two years. However, the others were of the view that since glycerine is a chemical and had merely been repacked by Alpana Pharma, the two years period could be waived in their case. Raykar had no information about the source from which Alpana Pharma had procured the glycerine nor did he make any inquiries regarding its source.

184. Raykar admitted that he was the only member of the Committee in a position to state whether Alpana Pharma held a valid licence on the date they submitted their tender, which according to Raykar, Alpana Pharma did by virtue of the Joint Commissioner's letter to Alpana Pharma. Raykar admitted that if all the breaches of the Tender Conditions had been known to him at the time of the meeting, he would not have agreed to the grant of the rate contract to Alpana Pharma. He explained that all these facts could not be within his own knowledge because the papers pertaining thereto were in the custody of the FDA, but in the custody of the Director of Industries.

185. Raykar admitted that at the time of the meeting those papers were indeed available for his persual and the perusal of the other members. However, they were not perused either by himself or the other members. The representative of the Directorate of Industries told them that in Alpana Pharm's case everything was in order except that it had not been in the market for 2 years. This fact he himself had brought to the notice of the other members and assumed that other requirements had been fulfilled by Alpana Pharma as represented to them by the representative of the Directorate of Industries. He conceded that well-established and reputed pharmaceutical concerns are reluctant to fill in tenders for rate contracts and that generally rate contracts are tendered by small pharmaceutical companies and persons not well established and may not even be reputable.

186. To start with, even assuming Raykar's version that he had brought to the notice of the other members that Alpana Pharma had not been in the market for two years is incorrect, this fact was stated both in the scrutiny sheet as also in the Comparative Statement (Ex. 38). There was no reason why Raykar should have taken as gospel truth the statement of the Directorate of Industries that everything was in order in the case of Alpana Pharma exept that it had not been in the market for two years. It is correct that at that time Raykar was a research student doing his M. Pharm. in the Pharmacology Department of which Dr. Kulkarni was the Professor. He may have looked up to Dr. Kulkarni and even respected. Yet he was not supposed to be a mere figure-head at the meeting. It is true Alpana Pharma's background was not known to Raykar because the FDA itself did not know about it for the simple reason that Alpana Pharma not having been in the market at all, had no background which could be revealed by Alpana Pharma except to say that Alpana Parma had not been in the market for two years which Raykar did, and even assuming, he did not, was stated in the scrutiny sheet and the Comparative

Ex. 38

Statement. It is also significant that it was only for this period of 1984-86 that the requirement of a performance certificate was dispensed with the result that Raykar could have had no knowledge of any performance of Alpana Pharma, which in any event he could not have had because Alpana Pharma had not been in the market at all.

187. In these circumstances, Raykar's negligence lay in that he allowed the Director and /or Dr. Kulkarni to lead him by the nose and in subjugating his better judgement in favour of theirs.

188. This brings me to *the rate escalation granted to Chem Pack and Alpana Pharma.*

189. To that end, a reference to certain conditions in the Conditions of Tender (Ex. 31) are pertient. Condition 6 (*a*) and (*b*) reads as under :— Ex. 31

" 6.(*a*) In the case of stores, subject to price fluctuation clause the details, *viz.* (*i*) manufacturer's price ex-works or ex-point of despatch whether on Rail or Sea, (*ii*) freight, (*iii*) dues, and (*iv*) other charges including firms margin should be clearly and separately stated.

(*b*) Basis of revision in price, if claimed, should be accompanied by details or variation. In no other case any revision of price admissible.

Condition 8-A reads as under :—

" In the event of the order being placed against any of the *tenderers and if* the tenderer fails to supply any stores according to the terms and conditions of acceptance of tender or fails to replace any stores rejected by the Directorate or by any person on his behalf within such time as may be stipulated, the Director of Industries and Central Purchasing Officer shall be entitled to purchase such store from any other source and at such price as the Director of Industries and Central Purchasing Officer shall in his sole discretion thinks fit. "

If action as *stipulated above is taken* :—

" (1) The offer of the defaulting contractor will not be considered.

(2) The defaulting contractor will be penalised to the extent of the difference in the rates or 10 per cent of the value of the earlier order, whichever is higher.

(3) If the defaulting contractor fails to pay the penalty he will be permanently delisted from the list of approved contractors of the C.S.P.O. and the registration deposit of the contractors will be *forfeited to Government.*"

Condition 9 reads as under :—

" In the case of non-delivery and/or delayed delivery against an order placed with you, the Director of Industries and Central Purchasing Officer, reserves to himself the right to impose such penalty in his sole discretion as he thinks fit."

Condition 16(3-A) and (3-B) reads as under :—

" 16. General Instructions:—

(1) Priced Tender Form should be returned duly filled in, failing which quotation will not be considered.

(3-A) Any statutory increase or decrease as an act of States or the Central Government relating to Sales and other taxes shall be to the account of the purchaser by a contractor.

(3-B) *Fall Clauses.*—It is a condition of the contract that all through the currency thereof, the price at which you will supply the stores should not exceed the lowest price charged by you to any customer during the currency of the rate contract and that in the event of the prices going down below the rate contract prices you shall promptly furnish such information to us to enable to amend the contract rates for subsequent supplies."

190. With these *tender conditions* in the forefront, I shall briefly recapitualte the events leading to the rate escalation given to Chem Pack and Alpana Pharma. It is alleged that by a letter dated 2nd September 1984 Chem Pack asked for a rate revision. The exact contents of this letter are shrounded in mystery as this letter is not in any of the files produced before this Commission. Four days after this alleged letter, on 6th September 1984 the Industries Department wrote to Chem Pack accepting Chem Pack's tender for glycerine. On 21st September 1984 Chem Pack entered into the rate contract. However, before that on 11th December 1984 Chem Pack

addressed a letter to the Industries Department containing a reference to Chem Pack's alleged earlier letter of 2nd September 1984 and asking for a price escalation from Rs. 18 to Rs. 37·40 for 500 gms. This letter gave a break-up of Rs. 37·40 asked for as under :—

	Rs.
Cost of glycerine 500 gms. (landed cost Rs. 62 + 4% S.T.) ..	32·50
Cost of bottle, packing, labour, interest, etc.	01·50
Total cost of production	34·00
Profit at the rate of 10%	03·40
Sale value of each unit	37·40

with this letter Chem Pack enclosed a Government Notification and a quotation from the Chemical Weekly of the prevailing market rates of glycerine in 1984, *viz.* Rs. 62 per kg.

191. Here it may be stated that in this letter the figure ' 12 ' denoting the month December is in ink and has been written over a typed figure which has been erased and is illegible. This letter was not inwarded but was received directly by Dharap on 20th December 1984 just a few days after his taking over charge as Superintending Industries Officer-in-Charge of Store Purchase Section in the Directorate of Industries on 13th December 1984. From the fact that this letter does not bear any fold marks, it seems that it had not been put into any envelope but was delivered as it was to Dharap. On this letter Dharap made an endorsement " please inward and return ".

192. It is the admitted position that such an application for price escalation was the first of its kind where a rate escalation was actually granted. On 23rd January 1985 a meeting of the Committee members was held, it also being the admitted position that such a meeting was the first ever to be called for such a purpose, namely to grant the rate escalation asked for by Chem Pack.

193. Before this meeting was called, Industries Officer Torvi prepared his note on 27th December 1984 justifying the price escalation on the ground of statutory increase merely by summarising Chem Pack's case as contained in its letter dated 11th December 1984. When this note came to Dharap, he made an endorsement—

" This is not a case of statutory increase. We may however prepare a note for D.C. "

194. What transpired at this meeting can be seen from the evidence of Industries Officer Torvi, Dr. R. D. Kulkarni, Dr. Mistry and the then Superintending Industries Officer, Dharap (at present Assistant Director of Industries).

195. Torvi says that he attended this meeting in order to write down the decisions and remarks as Dharap's hand was shaking. He admitted having based his recommendation for price escalation on the basis of Chem Pack's letter dated 11th December 1984. According to him, Chem Pack was entitled to the price escalation asked for from Rs. 18 to Rs. 37·40. He claims to have read the Government of India Notification enclosed with Chem Pack's letter before making his recommendatory note. Pausing here for a moment, merely an excuse on Torvi's part because this Government Notification was irrelevant as it admittedly pertained to imported goods and as also admitted by Torvi there was nothing in Chem Pack's letter of offer dated 20th April 1984 that they would be supplying imported glycerine. He compounded absurdity with mendacity by posing that when he prepared his note he did not know that Chem Pack had not agreed to supply imported glycerine and that even so he did not consider it necessary to go through Chem Pack's offer-letter dated 20th April 1984 in order to ascertain what type of glycerine they had contracted to supply. He attempted to justify his recommendatory note on the ground that he thought that the increase asked for by Chem Pack was a statutory increase because Chem Pack had written that the price of raw material had gone up. He admitted that within 10 days of Chem Pack entering into the contract on 21st August 1984 they asked for a price increase by their letter dated 2nd September 1984. These answers were recorded as given. However the admitted position is that Chem Pack's contract was entered into not on 1st August 1984 but on 21st September 1984. Curiously enough even so Torvi's suspicions were not roused and he coolly wrote his

recommendatory note. Torvi however does not remember if he drew Dharap's attention to Chem Pack's quotation letter of 20th April 1984. Torvi admitted that he does not know of any other occasion when rates have been escalated as done in the case of Chem Pack.

196. Torvi admitted knowing the meaning of " risk purchase ", which he elaborated that Direct Demanding Officers are authorised to make risk purchases in which cases the difference of price is recoverable from the defaulting contractor. Torvi admitted that there was no discussion between him and Dharap that risk purchase should be resorted to even though he knew that Chem Pack was asking for more than double the price it had originally quoted. Torvi volunteered that the discussion between him and Dharap was that if the price escalation was not given to Chem Pack, purchases have to be made at a higher rate from the market and therefore even if the price rise was not statutory, the matter should be placed before the Drugs Selection Committee. However, no explanation was forthcoming why purchases would have to be made from the market at a higher rate. He admitted that there were no conditions of tender under which the matter could be placed before the Drugs Selection Committee, nor did he consider that a loss would be caused to Government if the price escalation was given to Chem Pack.

197. In this meeting of 23rd January 1985 which lasted about 20 minutes Torvi says that he did not take part or consider it necessary to draw attention of the Committee members to Chem Pack's offier-letter of 20th April 1984 because the contract had been given to them on the terms and conditions which had been accepted by Chem Pack. He says he was not attentive at the meeting as he attended it merely to hand over such papers as may be required by the Committee members.

198. Torvi admitted that before making his note supporting the increase asked for by Chem Pack, he did not make any enquiries whatsoever. The reason he assailed was that Chem Pack's letter dated 11th December 1984 was accompanied by the Government of India Notification (which as stated earlier was on his own admission irrelevant as it dealt with imported goods) and two sheets of a journal showing the current market price of glycerine. According to Torvi he went through those enclosures and noticed that the market price of glycerine in Bombay was Rs. 62 per kg.

199. Torvi admitted that in his note of 27th December 1984 he had also written about Alpana Pharma as under:—

" Further the same firm had asked for R/C for this item under 33% purchase reservation selection. "

But this passage was deleted by him as neither Alpana Pharma nor anyone else on their behalf had come to see him. After trying to blame the head-clerk as being the author of Torvi's note and realising his failure in the attempt, Torvi finally admitted that Chem Pack could not be given a rate escalation unless there was a statutory increase and that is why he added in the note that there was a statutory increase in the case of Chem Pack. He admitted that this was erroneous.

200. In the matter of the price escalation to Chem Pack and Alpana Pharma, Dr. R. D. Kulkarni was one of the Committee members. He says he had gone through the terms and conditions of the tender. According to him, in the past 5 years, there were several occasions for rate escalation. This is palpably false, contradicted as it is by Torvi and Dharap who were categorical. Chem Pack's case was the only one where the Committee had granted a price escalation.

201. Dr. Kulkarni admitted that rate escalation could only be given in cases of statutory increase adding that this aspect was looked after by the Industries Department. He however agreed that a price increase is dependent on statutory increase. However surprisingly, despite his being an experienced and senior member of the Committee and functioning as such from 1972 and who had gone through the terms and conditions of tender, he affected not to know what constitutes a statutory increase. He admitted that he was aware of Tender Conditions 6(3-A), 23-A and B and 24, but has one believe these conditions have never been implemented for several years because of the opinion expressed by the Director of Industries of legal difficulties in implementing them.

202. Dr. Kulkarni admitted that whenever a contractor tenders his price he should take into account market fluctuations, and if he does not, the Committee cannot

come to his rescue. Attempting to blame the Director of Industries, Dr. Kulkarni deposed that the price escalation given to Chem Pack from Rs. 18 to Rs. 37·40 for 500 gms. was done on the opinion expressed by the Director of Industries that this would be a statutory increase. Dr. Kulkarni however admitted that it would always be wiser to fall-back on the alternate supplier if the original supplier asks for a price increase. Dr. Kulkarni further admitted that it was improper on the part of Chem Pack to have asked for an upward price revision within 3 months of the order being placed with them on 21st September 1984. He admitted that glycerine was all along available indigenously, that prior to December 1984 he never pointed out to any member of the Drugs Selection Committee that Chem Pack or Alpana Pharma had not made any supplies of glycerine and that in December 1984 there was no shortage of glycerine in the J. J. Hospital. These vital admissions were made by Dr. Kulkarni at the end of the day's evidence. However when his evidence was resumed the fo following morning, Dr. Kulkarni went back on his earlier admissions by saying that at the discussion in the Committee meeting he had stated that J. J. Hospital was finding it difficult to get glycerine. Dr. Kulkarni tried to shift the responsibility on the Associate Professor of Pharmacology and the Pharmacist of the J. J. Hospital as having told him that there was difficulty in the J. J. Hospital in getting glycerine. He had to admit that there was no record about this. While according to Dr.Kulkarni the Director of Industries had stated that there was a shortage of glycerine in the market, he admitted that no documentary evidence was produced by anyone to suggest that there was any shortage in any of the government hospitals. No rate contract had been given to Chem Pack for imported glycerine and that the increase asked for by Chem pack was by reason of increase of import duty. Dr. Kulkarni admitted that there is noting in the note of 23rd January 1985 to justify the price increase given to Chem Pack which was more than double the original agreed price, that he himself did not ask for any break-up of the increased price from Rs. 18 to Rs. 37·40 and blamed the Director of Industries for justifying the increase by saying that glycerine was not freely available in the market and that there had been an increase in the import duty.

203. In the witness-box Dr. Kulkarni affected surprise that the price revision should have been given to Chem Pack to the exact paise asked. He was however not surprised then, because according to him the quantum of increase was calculated by some formula by the Director of Industries which came to the very paise asked for by Chem Pack. He had to admit that it was too much of a coincidence that that formula which he did not know should coincide exactly to the paise with the increase asked for by Chem Pack, that the coincidence did not occur to him then but which occurred to him now in the witness-box. He then stated that he did not think it was a coincidence then, though he does think it to be so now, and that he should have realised it then which for some inexplicable reason he did not, that the price increase coincided exactly to the paisa asked for by Chem Pack. He admitted that he did not apply his mind to the justification or otherwise of the price increase demanded by Chem Pack. He claimed that though he was not anxious to give this price increase, he did not apply his mind because that was done by the Director of Industries according to the existing Rules and Formulae. He admitted that in granting this price increase to Chem Pack to the very paise, the Committee members did not act in a responsible manner. He finally admitted that the only thing that occurred to him was that Chem Pack should be given price escalation demanded to the very paise.

204. Dr. C. J. Mistry was one of the members of the Drugs Selection Committee. He was not present at the meeting when the rate escalation was given to Chem Pack and Alpana Pharma. However he was present at the earlier meeting on 23rd January 1985, when a temporary escalation of rates was given to Chem Pack from Rs. 18 to Rs. 37.40 for 500 gms. This Dr. Mistry says was a temporary measure as a fresh tender was decided to be floated for glycerine. At that meeting the Director of Industries Dharap who was Well-conversant with this matter was also present. Dr. Mistry candidly expressed his difficulty to justify the financial aspect of the price escalation. He admitted that this was the only purpose for which the meeting had been called that day, there being no other item on the agenda.

205. As Dr. Kulkarni was in-charge of the drugs stores at the J. J. Hospital he was aware of the demand and supply position of glycerine; hence Dr. Mistry assumed that Dr. Kulkarni must have brought to the notice of the other members that glycerine was required urgently and that he must have purchased glycerine in the open market at a higher price. That in Dr. Mistry's assumption was why

Dr. Kulkarni must have recommended a price escalation to Chem Pack from Rs. 18 to Rs. 37·40 for 500 gms. as an interim arrangement. To the best of Dr. Mistry's recollection he accepted what Dr. Kulkarni must have told the meeting and on the basis thereof, he, i.e. Dr. Mistry, acquiesced to the price escalation to Chem Pack at the rate asked for.

206. Dr. Mistry continued that as a member of the Drugs Selection Committee he had gone through the terms and conditions of the tender but was not very well acquainted with them.

207. Dr. Mistry did not know whether the Drugs Selection Committee was empowered to revise the rates after they had been fixed and admitted that it was only from newspaper reports during the course of the present inquiry that he came to know that Chem Pack had been given price escalation from Rs. 18 to Rs. 37·40 for 500 gms. To the best of his recollection, this was the only meeting of its kind which he had ever attended. Dr. Mistry was not informed the reason for calling the meeting and came to know of its purpose at the meeting itself. Neither at nor before nor after the meeting did Dr. Mistry to ascertain from the terms and conditions of the tender or otherwise whether they had any power or jurisdiction to grant a price rise. He had read the terms and conditions of the tender when they were published but was not aware that price escalation could not be granted except in cases of statutory increases. Dr. Mistry proceeded on the basis that they had the power and jurisdiction because the proposal was mooted by the Director of Industries himself at this meeting.

208. On being shown the conditions of tender, Dr. Mistry admitted that the Committee had no power or jurisdiction to grant a price escalation except in the case of statutory increases. He did not make any independent inquiry as this meeting whether the price rise asked for by Chem Pack was statutory or not, but from Dharap's note which Dr. Mistry read, he did come to know that it was not a statutory increase. Even so at that time he did not realise and it did not occur to him that the Committee had no power to grant a price rise as the increase asked for by Chem Pack was not a statutory increase. To the best of his recollection the meeting had been called for grant of the increased rate to Chem Pack, that the price increase was mooted at this meeting by the Director of Industries who was supported by the FDA's representative (namely, Commr. Bhirud) and by Dr. Kulkarni.

209. Dr. Mistry was unable to say whether other members of the Committee had read Dharap's note; the question of the Committee's right and jurisdiction to grant a price rise was never discussed as no one doubted that the Committee indeed had such power and jurisdiction. He did not remember what the Committee members saw at this meeting other than Dharap's note and admitted that for himself he had not seen any paper other than Dharap's note. He participated in the discussion to the extent that he asked Dr. Kulkarni whether glycerine was in short supply and whether the market price was high and whether a tender should be refloated or not; to which Dr. Kulkarni replied that there was a short supply of glycerine in the market and that local purchases would have to be made, by which Dr. Mistry understood that Medical Store would make purchases from the open market. Dr. Mistry maintained that Dr. Kulkarni and the FDA representative (namely, Commr. Bhirud) stated that there was a shortage of glycerine in the market and that they had to make purchases from the open market and that a tender would be refloated. Dharap informed the members the reason why Chem Pack wanted a price rise. To the best of Dr. Mistry's recollection this was the entire discussion that took place at that meeting. He admitted that neither he nor any member raised any objection to giving the price rise to Chem Pack as demanded, that neither he nor any other member tried to examine in detail the justification for giving such price rise or whether a contract had already been entered into with Chem Pack after the acceptance of its tender and that he did not inquire whether any order had been placed with Chem Pack, adding that Dr. Kulkarni may have as he was the indenting officer.

210. Dr. Mistry admitted that Dharap's note mentioned that Chem Pack wanted a price rise as there was an increase in the price of raw material. But he did not ask to see Chem Pack's letter. He did not remember whether there was an alternate supplier about whom there was no discussion at the meeting. Nobody told him that glycerine was freely available in the market. Dharap told the members that

the revision of rate as asked for by Chem Pack was justified. But Dharap did not bring to the notice of the Committee any journal or literature pertaining to glycerine or its rates or its availability.

211. Dr. Mistry stated that at this time he was attached to the J. J. Hospital and admitted that as far as his medical ward was concerned there was no short supply of glycerine, however he did not bring this to the notice of the other members as the consumption of glycerine in his ward was very small. He admitted that neither he nor any member of the Committee made any effort to find out from the J. J. Hospital or any other hospital whether glycerine was in short supply and that he relied on Dr. Kulkarni who stated that it was. He admitted that regarding the price escalation and the quantum he relied on Dharap and Dr. Kulkarni and the FDA representative and that he, i.e. Dr. Mistry, did not independently apply his mind whether Chem Pack should or could be given the exorbitant price escalation asked for at more than double the contract rate. He was however lulled by the explanation of the Director of Industries that the duty had gone up from 100 per cent to 200 per cent and of Dr. Kulkarni and the FDA representative that the revised price of Rs. 37·40 demanded by Chem Pack was the price at which glycerine was available in the market and also by reason that the Director of Industries stated that the increased rate to Chem Pack was merely a temporary measure as a fresh tender would be floated.

212. Dr. Mistry admitted that he was aware that tenders are invited for a two-year supply period and that the tenderer whose tender is accepted must supply for two years at the contracted rate irrespective of the rise or fall in the market price. He further admitted that if a tenderer defaulted in making supplies, purchases could be made from the open market and the difference in price could be realised from the tenderer. However Dr. Mistry did not then realise the anxiety of the others was to confer a benefit on Chem Pack and he accepted as true and took for granted that what the others told him at the meeting was correct. Dr. Mistry admitted that if he had realised that what had been represented to him and the impressions given to him at this meeting were not correct, then the decision to give price rise to Chem Pack was not correct. He admitted that in the light of what he learnt later, he felt that he was misled by the other members into voting for a price increase in favour of Chem Pack.

213. The other Committee member N. D. Dharap, now Assistant Director of Industries, was from 13th December 1984 till 6th January 1986 the Superintending Industries Officer in-charge of Store Purchase Section in the Directorate of Industries. He deposed to the meeting held by the Drugs Selection Committee on 23rd January 1985 which was the sequel to Chem Pack's letter dated 11th December 1984 asking for price revision from Rs. 18 to Rs. 37·40 for 500 gms. At this meeting Dr. Kulkarni pointed out that the supply position of glycerine in all Government Hospitals was very bad and that it was difficult both for Chem Pack and Alpana Pharma to make supplies. According to the normal procedure a fresh rate contract inquiry had to be issued; since however that procedure took about 3 to 4 months it was decided to accept Chem Pack's proposal because there was some basis in Chem Pack asking for a price increase from Rs. 18 to Rs. 37·40 for 500 gms. Accordingly on 29th January 1985 a rate contract was granted to Chem Pack at the revised rate asked for. On 28th February 1985 a fresh tender inquiry was issued which was published in the Gazette for all told 17 items including glycerine.

214. As to what transpired at the Committee meeting on 20th February 1985, Dharap deposed that he, Dr. Kulkarni, the FDA representative and Dr. Mistry were present. At this meeting the units of the developing areas were examined as Chem Pack was already situate in a developed area, namely Pune. In the present case 33 per cent contract for glycerine had to be awarded to units in the developing areas. For that purpose 4 units were considered, namely Cherub, Deepti Pharmaceuticals, Universal Pharmaceuticals and Alpana Pharma, the last being the one to whom rate contract had earlier been given on the basis of alternate supplier. Alpana Pharma's sample was not examined by the Committee on 20th February 1985 as their sample had already been examined and found to be satisfactory when it was awarded the alternate contract.

215. On 28th February 1985 Alpana Pharma wrote a letter to the Director of Industries stating that as the glycerine rate in the market had stabilised they were willing to supply glycerine at the same revised rate as Chem Pack and that Alpana Pharma should be given the contract under the 33 per cent purchase preference. This

33 per cent would have to be shared between Deepti, Universal and Alpana Pharma with the result that each of them would be entitled to 11 per cent. Accordingly on 16th March 1985 an amendment was issued to the earlier rate contract in the case of Alpana Pharma giving them an increased rate and purchase preference at 11 per cent. This amendment also mentioned that the alternate contract which had been given to Alpana Pharma stood cancelled and the revised rate contract in the case of Alpana Pharma would become null and void on the fixation of the fresh rate contract.

216. On 15th April 1985, it was found that the price of Rs. 37·40 quoted by Chem Pack was acceptable with the result that the rate contract was further extended till the end of the two-year period of the basic rate contract.

217. Dharap admitted that there is a provisions for revision of rates for statutory increases under clause 16(3)(A) of the tender conditions which are general conditions applicable to all tenderers. The tender conditions at page 420 are in addition to these general conditions. He agreed that under the conditions of tender the obligation on the part of the supplier to make supplies would remain and he could not refuse to make supplies on the ground that the prices have been statutorily increased.

218. Dharap admitted that his understanding of Chem Pack's letter dated 11th December 1984 was that Chem Pack was finding it uneconomical to make further supplies; he however did not understand that Chem Pack was refusing to make supplies even though they were finding it uneconomical to do so. He admitted that he did not enquire from the alternate supplier (namely Alpana Pharma) whether they would be in a position to make supplies at the contracted rate on the ground that this had to be done by the Direct Demanding Officer and that they did not make enquiries from the Direct Demanding Officer whether supplies were being made either by the main supplier or the alternate supplier or whether the alternate supplier was willing to make supplies at the contract rate or whether glycerine was freely available or was in short supply or what its rates were. He however, denied any assumption or justification for increasing Chem Pack's rate on the ground that Chem Pack's letter dated 11th December 1984 would be placed by him before the Committee before which would put forth his point of view.

219. According to Dharap he would go through the tender to ascertain how a party would be making supplies and from what sources. At that time he knew that glycerine was available in India. He agreed that when a tenderer offers his goods he does so at the rate accepted by Government subject to statutory increases. In Chem Pack's case in the strict sense no statutory increase was involved and that in the strict sense Chem Pack was not entitled to ask for a rate revision nor was the Committee entitled to grant it. However, his excuse was that he granted the price escalation because Government of India had banned the import of mutton tallow on account of which there was an extreme shortage of glycerine in the market and also because glycerine was placed on the open general licence list (OGL). These two factors, according to Dharap, accounted for the shortage of glycerine in the market and were beyond the control of Chem Pack and Alpana Pharma. He admitted that if Government had relaxed import restrictions and if more glycerine had been available in the market, a supplier would not have been justified in asking for a price reduction. According to Dharap he was not willing to apply his mind unless a problem was posed before him.

220. When asked under what provision of law or rules he had power to entertain Chem Pack's application or to place it before the Committee or to grant it, he admitted that there was no such rule or regulation. He volunteered that this was a peculiar situation, the like of which he had not come across before.

221. Even though, according to Dharap, glycerine was expensive in the market, he did not have any enquiries made to that end, but came to know this from the chemical weekly and other journals circulated to them which spoke of short supply of glycerine. He admitted that, according to him, if Chem Pack had to supply glycerine at the revised rate it would have been able to do so despite the shortage and if the rate had not been increased Chem Pack would have suffered a heavy financial loss. He admitted that with his past experience he could say that tenderers took into consideration the normal price fluctuations in the market and that statutory increases are not provided in normal price fluctuations. He did not agree that in order to cover abnormal price fluctuations a provision is already made in cases of statutory increases. All fluctuations which are not normal have been statutorily provided. for. According to the rules there is no other category in which a price increase can be asked. He admitted that whether a tenderer made a profit or loss he must be held to his bargain

and it is not Government's duty to protect the tenderer from losses if he is held to his bargain. According to Dharap what impelled him to consider Chem Pack's letter of 11th December 1984 and to place it before the Committee was that if the price increase was not granted to Chem Pack and if Chem Pack committed a default in making supplies, the purchasing officer would have to purchase the glycerine at a higher price from the open market and its quality could not be assured. He admitted that he was aware that the difference in the price could be recovered from Chem Pack by making risk purchase. In giving a price increase to Chem Pack at double the rate originally contracted for he took shelter by saying that it was not he who gave such an escalation but the Committe.

222. He admitted that during his tenure no price revision had been granted much less at double the originally contracted rate, to anyone except Chem Pack. He admitted that this was statutorily not justified nor was it permitted by the general terms of the contract nor by any statute, rules or regulations, but assailed an excuse that it was done as some solution had to be found out as Chem Pack's basis was justified and if the purchasing officer had to make local purchase he would have done so at a much higher rate. In so deciding, Dharap affected to take Government's interest into consideration on the ground that Government would not have been able to recover the difference from Chem Pack as risk purchase procedure is very elaborate. He admitted that is was his duty to follow risk purchase procedure in order to save loss to Government and this duty he failed to perform on the ground that risk purchase procedure would have taken considerable time and something had to be done immediately; hence the problem was solved by giving Chem Pack more than double the rate which they had originally been given.

223. Regarding Chem Pack's earlier alleged letter of 2nd September 1984, Dharap stated that he was unable to find it and from enquiries from his subordinates he learnt that no such letter had been received. He admitted that no communication had been addressed to Chem Pack that their earlier letter of 2nd September 1984 had not been received or Chem Pack should send a copy of that letter. He further admitted that simultaneously with Chem Pack entering into the contract, they had started asking for an upward revision of the rates, even though Chem Pack's tender was unconditional as to price, and that the conditions of tender did not permit any upward revision of rates to Chem Pack.

224. Dharap admitted that he gave oral directions to his subordinates to put them Pack's letter of 11th December 1984 before the Committee at the next Committee meeting. He also admitted that the Committee meetings were not called on oral directions and that at no time before were matters placed on the agenda of the Committee meetings on oral directions. He also admitted that no agenda had been circulated and that for the purpose of this meeting all members were asked telephonically to name a convenient date for holding the meeting. He also admitted that the Committee members did not know the topic for which this meeting was being convened and that the agenda was given to the Committee members at the meeting itself and not before.

225. According to Dharap at the meeting of 23rd January 1985 when Chem Pack's rate revision letter of 11th December 1984 was discussed there were 7 or 8 items on the agenda and the meeting lasted about 3 to 4 hours. Pausing here for a moment, this is a false statement made by Dharap which has been contradicted by the other witnesses, namely Torvi, Dr. Kulkarni and Dr. Mistry, according to whom, Chem Pack's letter was the only matter which was discussed at this meeting and for which. the meeting had been specifically called. Dharap admitted that an upward revision was also given by the Committee at this meeting to Alpana Pharma even though there was no practice to grant any such upward revision without a request first coming from the party concerned.

226. Dharap admitted that if Chem Pack refused to make supply and the Directorate of Industries and CSPO were not without a remedy as by virtue of condition 23 of the general conditions of tender they could (*a*) recover from the contractor liquidated damages or penalty, (*b*) make a risk purchase without cancelling the contract or (*c*) to cancel the contract. (This answer the witness gave after the question was repeated to him thrice and after a great deal of prevarification). He admitted that neither he nor the committee had any authority or even the discretion to award a contractor an upward revision of price and that the rate revision grantd to Chem Pack was without authority.

227. After making the above admissions, Dharap attempted a self-justification by saying that he personally thought resorting to the remedies provided by clause 23 would not solve the problem. Even though he did not think that either he or the Government would be at the mercy of Chem Pack, he did not think that he had gone out of his way in considering and granting Chem Pack's upward rate revision. He admitted that there was nothing in the Rules or any provision or in the conditions of tender which gave him any authority to refer such matter to the Committee. He however denied that in doing so he had gone out of his way because he wanted to ascertain in the Committee meeting whether the alternate supplier had supplied the material. After a great deal of prevarication Dharap finally admitted that in placing Chem Pack's letter of 11th December 1984 before the Committee, he did go out of his way.

228. Dharap admitted that when he considered his office note of 27th December 1984 he found that the office's contention that there was statutory increase was not justified. According to him, it was only on the basis of Chem Pack's letter dated 11th December 1984 and his office note that he decided to put the matter before the Drugs Selection Committee. He however had to admit that when he made his endorsement on the office note he know that legally or contractually Chem Pack was not entitled to a price escalation and that he was convinced that statutorily and contractually Chem Pack was not entitled to any price escalation. He also admitted that even so he made an endorsement that the matter be placed before the Committee but could not say why he did not give any reasons in his endorsement to justify the matter being put up before the Committee. He admitted that no one had the power to grant a price escalation and admitted to the impropriety of his endorsement in placing the matter before the Committee. He could give no reason why he did not write his opinion in the endorsement and close the file.

229. Dharap admitted that he did not know that in March 1985 imported glycerol was available at Rs. 44 per kg. and that he did not make any inquiry to ascertain the price, that he granted the increase to the very paise asked for by Chem Pack only on the basis of Chem Pack's letter dated 11th December 1984 and the prices in the journal enclosed by Chem Pack which were for August 1984, namely even before Chem Pack entered into the contract with the Industries Department.

230. Dharap admitted that when he referred the matter to the Committee during the discussion in the meeting of 23rd January 1985, he knew that Chem Pack had entered into a contract in September 1984 and that the higher glycerol rates were in the journal sent by Chem Pack of August 1984. He admitted that even so he did not bring these factors to the notice of the Committee members because strangely enough it did not strike him to do so, nor did it strike him why Chem Pack should be asking for an upward revision even though it had entered into a contract in September 1984 on the basis of the price pravailing in August 1984.

231. Dharap admitted that on 14th August 1984 his department had addressed a letter to Chem Pack asking them to extend the validity period of their offer made in the tender and that it was only after Chem Pack signified their assent to enter into a contract on the terms and conditions tendered by them, that the contract was entered into with them on 21st September 1984. He also admitted that Chem Pack had no monopoly in the supply of glycerin and that there was no dearth of glycerine in the market. He however maintained that by reading the chamical weekly and other journals he got the impression that there was a scarcity of glycerine in the market. He had to agree that the issue of August 1984 did not say that glycerine was scarce in the market.

232. According to Dharap though at that time it did not occur to him that after signing the contract Chem Pack was raising an unjust demand, it occurs to him now. He further admitted that he should have obtained more details and should have exercised more care, which it did not occur to him to do then but which occurs to him today. He admitted that there has been no other case where he has acted in a manner which was as unwarranted as he did in the case of Chem Pack, because it did not then occur to him what he was doing was unwarranted.

233. Dharap admitted that he did realise that by granting the price escalation to Chem Pack, Government would have to pay Rs. 37.40 instead of Rs. 18 contracted for and thereby he, i.e. Dharap, secured to Chem Pack a benefit and to Government

a loss. These admissions were made by Dharap after the question was repeated to him thrice and after a great deal of reluctance. Dharap admitted that the sum and substance was that Chem Pack wanted over double the price escalation and which it was given irrespective of loss to Government. He admitted his negligence in giving price escalation to Chem Pack at more than double the contracted rate.

234. He also admitted that he now realised that Chem Pack was asking for escalation in the amount of profit. He also admitted that along with Chem Pack's letter of 11th December 1984 Chem Pack had sent some literature showing the availability of glycerine in Bombay at Rs. 62 per kg. and that on that basis Chem Pack's profit would be Rs. 12.80 per kg. and not Rs. 6.80 as mentioned by Chem Pack in its letter of 11th December 1984. He also admitted that by reason of the price escalation asked for and given to Chem Pack, they would be getting double the profit mentioned in their letter of 11th December 1984.

235. Dharap admitted that it occurs to him now that what he did was not legal and was improper. Dharap admitted that Chem Pack's rate revision was found to be justifiable by the Committee only on going through the contents of Dharap's agenda note and Chem Pack's letter of 11th December 1984 and that no query was raised by any of the Committee members. He also admitted that his only justification in his agenda note was the demand made by Chem Pack in their letter of 11th December 1984.

236. Dharap admitted that on 28th February 1985 a supplementary tender was invited for the supply of glycerine. Thirteen tenders were received. The price quoted by Chem Pack was Rs. 43 for 500 ml. bottle. Chem Pack did not mention that they would supply imported glycerine. Sahakar Medical Stores quoted Rs. 31.85 for 500 ml. Sahakar's tender was however rejected because it was a conditional tender as the packing and forwarding charges had not been specified, and one of the conditions was that the minimum order should be for Rs. 1,000, which was a condition similar to that of Alpana Pharma. No one pointed out to Dharap at that meeting that a similar condition made by Alpana Pharma had been waived. They did not ascertain the packing and forwarding charges of Sahakar or any other party. Thereupon having rejected the tender of Sahakar Medical Stores they proceeded to consider the next tender of Alpana Pharma at Rs. 38.48. Alpana Pharma's tender was a conditional tender, hence it was rejected. All the 13 tenders were rejected as the rates of these 13 tenderers were found not to be comparable to the rate of Chem Pack at Rs. 37.40; hence the contract given to Chem Pack at the interim rate of Rs. 37.40 was perpetuated.

237. Dharap admitted that in practice conditional tenders are not accepted. The tender of Sahakar Medical Stores, even though at a lesser rate than Rs. 37.40 and therefore beneficial to Government, was rejected merely because it was conditional. Sahakar Medical Stores was a trader and had not quoted the name of the supplier, nor had Sahakar furnished a guarantee letter from the supplier. At this Committee meeting was present Dharap himself, Satalkar, Dr. R. D. Kulkarni and Raykar representing the FDA. At the earlier meeting Satalkar was not there but the others were. Torvi was present at both the meetings as staff member.

238. The partner of H. M. Chemicals, Mahendra Doshi has stated that at the relevant time the price of pure glycerine I.W. in the market was in the vicinity of Rs. 50 per kg. He has further stated that it is possible that in July 1984 the manufacturing price of refined and industrial white glycerine of Companies like Hindustan Lever, Godrej and Tatas was around Rs. 41 and Rs. 39 per kg. respectively.

239. Girdhar Kasat, a partner of Kailash and Co. stated that between March and November 1985 the original price of Tatas' glycerine was Rs. 40 to Rs. 42 per kg. and that the same glycerine was sold by the dealers in the market at Rs. 44 to Rs. 45 per kg. He goes on to say that in December 1985 the market price had increased from Rs. 44-45 to Rs. 52-55 per kg. On 6th December 1984 Godrej Co. had written a letter to Alpana Pharma giving the price at Rs. 47,637.60 per metric ton inclusive of excise duty and new M.S. drums. This would work out to Rs. 47 per kg.

240. The evidence of these Committee members brings to the forefront that (despite Dr. Kulkarni's protestations to the contrary which are fales) glycerine

was freely available in the market. For that matter between 1st March 1985 and 12th June 1986 Bakewell had sold 98 drums of glycerine. It is also manifest that at the price revision granted to Chem Pack and Alpana Pharma, the rate works out at Rs. 74·80 per kg. whereas evidence indicates that at no time was the rate higher than Rs. 50 per kg.

241. The evidence of these Committee members brings out in stark manifestation that each and every one of them knew that no rate revision could be considered much less granted, unless there was statutory increase in sales and other taxes. They also knew that no meeting was necessary for the purpose of rate escalation because on the plain reading of Rule 16(3-A), the price increase should be automatic once there was a rise in the sales and other taxes. These Committee members knew or in Ex. 31
any event ought to have known that there was no provision in the tender or elsewhere to enable the Industries Department to make any recommendation for a price increase or for that matter for the Committee members to consider it, much less grant it. The Committee members were also well aware that the consideration of the price escalation in favour of Chem Pack and unasked for, in favour of Alpana Pharma had no precedent and was an exercise indulged in for the first time. They knew or in any event it was their duty to know that Chem Pack's case was not one of statutory increase and that in any event they had no power, authority or jurisdiction to grant price escalation, much less to the very paise asked for by Chem Pack as a result whereof the rate actually worked out to Rs. 74·80 per kg. as against Rs. 50 per kg. available in the market at its highest. It is also manifest that this price escalation granted to Chem Pack was without due application of mind, or rather that the application of mind was in one direction only, namely willy-nilly to grant the escalation to the paise demanded by Chem Pack. This is borne out by the fact that no inquiries were made by any one regarding the merits of Chem Pack's application for increase and the fact that they all quietly and no doubt conveniently took as gospel truth whatever Chem Pack had stated in its letter dated 11th December 1984. The evidence clearly shows that they wanted to benefit Chem Pack and Alpana Pharma at the cost of Government and at a loss to Government. It was a fraud on Government. The evidence brings to the fore a conspiracy between Dharap, the present Joint Director, then the Superintending Industries Officer and Dr. Kulkarni, aimed to benefit Chem Pack and Alpana Pharma.

242. The ostensible granting of a temporary price escalation to Chem Pack and Alpana Pharma was merely a hoax and a ruse and a fraud on Government to perpetuate what was supposed to be temporary. After the price escalation was granted to Chem Pack supposedly as a temporary measure, a tender was refloated. All the tenders were rejected including Sahakar Medical Stores which offered Rs. 31·85 for 500 ml. which was certainy less than Rs. 37·40 given to Chem Pack and Alpana Pharma. Sahakar's tender was rejected on the ground that it was a conditional tender. This was unlike the reaction to Alpana Pharma's tender which was also a conditional tender. Thus, on some ground or other, all the refloated tenders were rejected and thereby the escalated price of Rs. 37·40, supposedly a temporary expedient, was made permanent.

243. From Dharap's evidence there emerges the startling fact that Chem Pack's letter dated 11th December 1984 was received by him personally on 29th December 1984 i.e. within a week of his taking charge as Industries Officer on 13th December 1984. By normal channals, this letter would have come in an envelope be it by post or hand delivery, and would in the normal way have been inwarded. However it is obvious that Chem Pack's letter dated 11th December 1984 did not come in an envelope, as it is apparent from the fact that it has no folds. It was also not inwarded before Dharap received it. It came to him deirectly and he made an endorsement on it that it should be inwarded.

244. Further the reference in Chem Pack's letter dated 11th December 1984 to Chem Pack's earlier alleged letter dated 2nd September 1984 is not above suspicion. To start with, no such letter of 2nd September 1984 written by Chem Pack to be found in the files. For that matter, Torvi says no such letter was received by the Department. It is also highly doubtful and most improbable that Chem Pack could have written any such letter dated 2nd September 1984 because 4 days later i.e. on 6th September 1984, the Industries Department wrote to Chem Pack accepting its offer and on 21st September 1984 Chem Pack willingly signed the contract. Further, according to the tender form the offer was to remain valid till 31st August 1984. Chem Pack also agreed to extend this period of validity and entered into Ex. 31

a contract on 21st September 1984 though not bound to. On 14th August 1984 Chem Pack extended its period of validity. Surely, all this is not the normal conduct of a party who finds it difficult to make a supply at the contracted rate.

245. It is not without its own significance that Dharap made not the slightest movement to ask Chem Pack to supply a copy of the letter dated 2nd September 1984, which should have been the normal reaction of any reasonable person and more so of an experienced government officer. The reason for this curious omission seems to be that no such letter was received by the Department. For that matter it is admitted by Torvi that no letter dated 2nd September 1984 was ever received.

246. In these circumstances, the only purpose of referring to Chem Pack's alleged letter of 2nd September 1984 in their subsequent letter dated 11th December 1984 was to prepense Chem Pack's demand for escalation in an attempt to show that this demand was not made for the first time on 11th December 1984 when Dharap was about to take charge, which he did on 13th December 1984 and himself received the letter on 20th December 1984. This apparent manipulation indicates a pattern and could not have been woven without the active consent, co-operation and participation of Dharap himself.

247. Dharap's evidence reveals in stark measure that he was conscious that Chem Pack's was not a case of statutory increase. He had said so in his own note. Then why should he have added that it should be placed before the Committee ? The very fact that he did so in his note indicates that he wanted to divert suspicion from himself for an act which he knew was illegal, without jurisdiction, unwarranted and improper as he himself had to admit. Obviously he wanted to protect himself and yet to make sure that Chem Pack got to the paisa the price escalation it wanted.

248. Coming to the meeting itself, it was not one of the regular meetings normally held by the Committee members. This was an unusual meeting where no agenda had been circulated to the members earlier. They were summoned to the meeting by telephone and Dr. Mistry says that he knew of the purpose of the meeting only at the meeting itself. Only one item was discussed namely the unprecedented granting of price escalation. It is only Dharap who says that 7-8 items were discussed and that the meeting lasted for 3 to 4 hours. The evidence of the other members is that only this solitary item of increase was discussed at this meeting for a duration ranging from 10-30 minutes.

249. At this meeting there were two active participants, namely Dharap and Dr. Kulkarni. The others were either indifferent or inattentive. The only thing taken into consideration was Torvi's recommendatory note, bassd as it was solely on the contents of Chem Pack's letter dated 11th December 1984. No inquiry was made by Torvi or Dharap before placing the matter before the Committee. Since Dharap's endorsement was that this was not a case of statutory increase it need not have gone to the Committee; but Dharap wanted it to go before the Committee ; to clear himself in advance of suspicion. Obviously Dharap wanted the protection of a Committee decision. In the meeting itself Dharap supported the contentions of Chem Pack's letter dated 11th December 1984 and did not utter a single word that this was not a case of statutory increase. This is yet another factor which indicates that his note was intended for his protection and to divert suspicion from himself.

250. It was nobody's case that Chem Pack had any monopoly or that glycerine was not available in the market. At this meeting, the sole anxiety of Dharap and Dr. Kulkarni, who were the only spokesmen, was that the Direct Demanding Officer should not make purchases in the market but should do so only from Chem Pack or Alpana Pharma, hence unasked even Alpana Pharma was given a price escalation at the same rate as Chem Pack.

251. Looking to all these circumstances and the behaviour of Dharap, one may legitimately ask : *What would an honest and upright officer do in these circumstances* ? The answer is clear. He would have caused all necessary inquiries to be made, more so when *prima f cie* his first reaction would have been to reject such an application because of his intimate knowledge of the terms and conditions of the tender. He would have called upon the tenderer to justify his application for price escalation *inter alia* by asking him the simplest of questions, namely the market price prevailing when the tenderer made his offer. He would have made inquiries about the missing letter dated 2nd September 1984; he would have asked Chem Pack to furnish a copy of that letter and above all he would never have been a party to give such a tenderer escalation to the very paise asked

for and thereby giving him not only double the price, but also double the profit. In all this and more, Dharap failed. It cannot be attributed the mere innocence or even ignorance but to a calculated course of conduct in order to favour Chem Pack contrary to and in dereliction of his duties. Dharap's admissions are legion. They put him beyond the pale of suspicion into the sphere of certainty. He stands self-condemned. You tickle me Toby, I tickle thee.

252. As 'partner' in this nefarious exercise was Dr. R. D. Kulkarni, withouts whose active help Dharap could never have succeeded. Dr. Kulkarni was undoubtedly an experienced member who had served on such Committees since 1972. It too was well aware that this was the first time where price escalation was being granted. He raised no query why it should be so. He did not even bother to post himself with the particulars of the supply position. While at first he admitted that in December 1984 there was no shortage of glycerine in the J. J Hospital and that all along glycerine was available indigenously, the next day no doubt realising the consequences of his earlier statement, he recanted and yet admitted that the record did not show that there was any shortage of glycerine in the J. J. Hospital. Further more, on Dr. Kulkarni's own showing the J. J. Hospital was paying Rs. 25 per 500 ml. Pray, why did he agree to give Chem Pack escalation at Rs. 37·40 ? No reason was forthcoming. Undoubtedly, Dr. Kulkarni was anxious that purchase should only be made from Chem Pack or Alpana Pharma. This is borne out from his admission that glycerine could not be continued to be purchased from the local market. Pray, why not, if it was cheaper than the escalated price of Rs. 37·40 given to Chem Pack ? Even though an opportunity was given to Dr. Kulkarni in the witness box, he was unable to give any facts or figures regarding the supply position in the J. J. Hospital to justify the price increase to Chem Pack. He cannot shrug this off merely by saying that the supply position at the J. J. Hospital would be known to the Associate Professor of Pharmacology and thereby unworthily throwing the responsibility on her.

253. Further, as an experienced Committee member Dr. Kulkarni would know that no rate revision could be granted to a tenderer without his applying for it, yet Alpana Pharma was given the same rate revision at Rs. 37·40 even without any application. It is not improbable that Dr. Kulkarni had told O. P. Ladda of the price increase given to Chem Pack because Ladda has admitted that he came to know this from the J. J. Hospital. From who would he come to know about this but Dr. Kulkarni, the Head of the Pharmacology Department. Dr. Kulkarni's conduct is on a par with that of Dharap. Dr. Kulkarni's admissions from his own lips are like Dharap's legion. He too, like Dharap, stands self-condemned by his own lips. Dr. Kulkarni was guilty of dereliction of duty and more. Circumstances and his own admissions establish beyond reasonable doubt that he favoured Chem Pack and Alpana Pharma. You tickle me Toby. I tickle thee.

254. Less however can be said about Dr. C. J. Mistry. He did not even know the purpose of the meeting and hence came totally unprepared. His evidence indicates that he was totally indifferent to what was going on. He relied solely on Dr. Kulkarni and Dharap. Regarding power, jurisdiction and legality of the Committee to grant the rate escalation, he relied on the Industries Department and on requirement, on Dr. Kulkarni. That was his mistake. In fact in the witness-box he showed his deep resentment at being duped by them. Thus while the charge of negligence and dereliction of duty can be brought to him, albeit in a technical sense, it cannot be said that he did anything (for that matter he did not do anything) to favour anyone.

255. Industries Officer Torvi cannot get off as lightly as Dr. Mistry. Torvi made no inquiry whatsoever regarding the price escalation asked for by Chem Pack. In his note he supported Chem Pack's claim to price escalation and merely paraphrased Chem Pack's submission in its letter of 11th December 1984, whereas a presumably responsible officer in the Industries Department acquinted with the terms and conditions of the tender as Torvi was or should have been, he should have set out that Chem Pack's was not a case of statutory increase and should have said so in his note. He even admitted that in his note he had to say that Chem Pack's was a case for statutory increase otherwise it would have not been given a rate escalation. This, coupled with his other admissions place Torvi beyond the pale of suspicion and into the sphere of certainty beyond reasonable doubt. Torvi is guilty of not mere negligence but also of dereliction of duty and worse. You tickle me Toby, I tickle thee. He cleared the way for Dharap and Dr. Kulkarni.

CHAPTER XII

1. That brings me to Questions (*g*) and (*h*) as under :—

" (*g*) Whether any breach of provisions of Drugs and Cosmetics Act, 1940. was committed by manufacturer/distributor/supplier of these drugs and if so, who are responsible ?

(*h*) Whether statutory and effective control was exercised by the authorities responsible for implementing the provisions of Drugs and Cosmetics Act, 1940 and if not who are responsible ? "

2. They can conveniently be disposed of together. For the purpose I shall set out the various concerns and those constituting them.

(*a*) Jethalal Chaturbhuj Soni is the sole proprietor of Ganesh Chemicals Corporation carrying on business as manufacturer of so-called glycerine intended and used for commercial purposes.

(*b*) Mahendra Doshi and his brothers Girish and Mahesh are the partners of H. M. Chemicals carrying on business of supplying chemicals which are available in the market including glycerine I.W. Since the past 4-5 years they have been selling sub-standard glycerine made by local manufacturers which is not according to I.S.I. standards. Since 1984 they purchased their glycerine from Jethalal Soni of Ganesh Chemicals.

(*c*) (*i*) Haresh Kumar and Co. and Haresh Chemicals purchase and sell pharmaceutical raw materials and chemicals. They hold drugs selling licences. They are situate in the same building but carry on business from different rooms. The partners of Haresh Kumar and Co. are Girdhar Kasat and other members of his family. The partners of Haresh Chemicals are Girdhar Kasat, his brother Bharat Kasat and other members of the family.

(*ii*) Kailash and Co., only purchases and sells chemicals. It does not deal in drugs, hence does not have any drugs selling licence. The partners of Kailash and Co. are Girdhar Kasat and members of his family.

(Hereafter transactions of these 3 concerns will be referred to either by their names or simply as being of Kasats.)

(*d*) At the relevant time, Alpana Pharma Pack carried on business of repacking drugs at Nanded. The partners were Om Prakash Ladda, his mother Basantidevi, Nirmaladevi, Rameshwar Karwa and Sarla Ashok Kumar Karwa, sister-in-law of Rameshwar Karwa.

(*e*) Arti Chem Laboratories carries on business of manufacturing pharmaceuticals at Pune under its own manufacturing licence. The partners are Ramanlal Karwa, Sarala Karwa (who was also a partner of Alpana Pharma) and other members of the Karwa family.

(*f*) Deepali Enterprises carries on business in pharmaceuticals in Bombay since 1983 and acts as the distributor of Arti Chem Laboratories, of which Ramanlal Karwa is a partner. His brother Rameshwar and his wife Nirmala are the partners in the Deepali Enterprises.

3. I shall set out the orders placed by Alpana Pharma for glycerine I.P. They were 4 in all; three with Haresh Chemicals and one (Batch No. 21) with Indian Drugs Co. For the purpose of this Inquiry, the last is unnecessary.

(*a*) The first order placed by Alpana Pharma was an oral order with Haresh Chemicals on 29th March 1985 for 500 kgs. glycerine I.P. The supply was made partly by Haresh Chemicals and partly by Kailash and Co. No sample had been asked for nor given. This glycerine had been purchased by Kasats from Bakewell (India) at Rs. 46·50 per kg. and sold to Alpana Pharma at Rs. 49·50 per kg. Thus Kasats made a profit of Rs. 1,475.

(*b*) The second order was placed by Alpana Pharma with Haresh Chemicals on 13th August 1985 for 500 kgs. through Arti Chem of Pune. The supply was made by Kailash and Co., by making purchase from Maks International at Rs. 49·50 per kg. and selling it to Alpana Pharma at Rs. 52·80 per kg. Kailash and Co., thus made a profit of Rs. 1,650.

(c) The third order was placed by Alpana Pharma with Haresh Chemicals on 18th November 1985 for 500 kgs. through Arti Chem of Pune. The supply was made by Kailash and Co., by making the purchase from H. M. Chemicals at Rs. 40 per kg. and selling it to Alpana Pharma at Rs. 54 per kg. Thus Kasats made a profit of Rs. 7,000.

H. M. Chemicals had made the purchase at Rs. 30 per kg. from Jethalal Soni of Ganesh Chemicals and thereby made a profit of Rs. 5,000. From this, batch No. 27 was repacked by Alpana Pharma and supplied to the J. J. Hospital.

4. This brings me to the orders placed by the J. J. Hospital with Alpana Pharma. They were 3 in number as tabulated hereunder:—

Orders placed by J. J. Hospital with Alpana Pharma

Orders	Bottles	Delivery to J. J. Hospital
I 28th May 1985	200	27th June 1985.
II 4th July 1985	700 (Bottles of 500 ml. each)	16th August 1985.
III 5th December 1985	400	27th December 1985 (270 bottles, Batch No. 27)

5. As far as glycerine batch No 27 repacked by Alpana Pharma is concerned, the chronology is as under :—

Ganesh Chemicals sold the so-called glycerine to H. M. Chemicals (Mahendra and Girish Doshi). They in turn sold it to Kasats who in turn sold it to Alpana Pharma. Alpana Pharma repacked it and sold it to J. J. Hospital as batch No. 27.

6. Regarding the dates on which the supply was made to Alpana Pharma, the version of Girdhar Kasat and Alpana Pharma's partner O. P. Ladda differ. I shall therefore, set out hereunder their respective versions:—

VERSION OF O. P. LADDA

24th September 1985 .. Om Prakash Ladda came to Bombay and met Girdhar Kasat. Ladda wanted to oplace an order for 500 kgs. glycerine. Kasat quoted Rs. 52 per kg. O. P. Ladda expressed his willingness to purchase at that rate provided Girdhar Kasat gave him a sample and the sample passed the I. P. test.

28th September 1985 ... Some person from the office of Deepali Enterprises went to Kasats' office and collected a sample which was sent for analysis to Chem Med Laboratories with a covering letter dated 24th September 1985 (Ex. 442) on the letter-head of Alpana Pharma wherein it was stated that Alpana Pharma was sending samples of glycerine I. P. batch No. 26, 500 kgs. supplied by Kailash and Co. Ex. 442

9th October 1985 ... (*i*) Chem Med made its report (Ex. 444) certifying the sample to be of standard quality and complying with the prescribed I. P. standards. In this report the name of the supplier was mentioned as Kailash & Co. and the number of the batch as 26. This report was received by O. P. Ladda in the 2nd or 3rd week of October 1985. Ex. 444

(*ii*) In the last week of October 1985, O. P. Ladda came to Bombay and contacted Girdhar Kasat over the telephone and informed him that the sample had passed the I. P. test and requested Girdhar Kasat to supply two drums from the same stock as the sample. Girdhar Kasat told O. P. Ladda that that stock was not available and offered to give another sample to O. P. Ladda and asked him to send someone after 3–4 days to collect it. O. P. Ladda told Girdhar Kasat to give particulars to the person who came to collect the sample, as also the batch number of the sample.

5th November 1985 .. (*i*) Chavan, a clerk in Deepali Enterprises collected a sample from Kasat's office at Haresh Kumar & Co. and also one empty sample bottle. From the sample, Chavan prepared two samples by pouring a part of the contents into the empty sample bottle for the purpose of sending them for analysis.

Ex. 212 (colly.) (*ii*) Chavan prepared a letter dated 5th November 1985 [part of Exhibit 212 (collectively)] addressed to Chem Med forwarding the sample for analysis. In this letter the samples were described as glycerine I. P. batch No. 27, the manufacturing date as October 1985 and the supplier's name as Haresh Kumar & Co., Bombay. This letter was signed by Chavan for Alpana Pharma. This letter and sample were delivered to Chem Med on 6th November 1985.

18th November 1985 .. (*i*) O. P. Ladda was at Pune. He saw Chem Med's passing-slip for batch No. 27 in Ramanlal Karwas' office in Artichem. Just then Ramanlal Karwa was about to place an order on behalf of Artichem with Haresh Kumar & Co. for certain items. In this order at O. P. Ladda's request Ramanlal Karwa incluced O. P. Ladda's order for glycerine I. P., 2 barrels (500 kgs.) at Rs. 52 per kg. inclusive of tax, to be sent directly to Alpana Pharma at Nanded.

Ex. 632 (*ii*) Accordingly Ramanlal Karwa prepared an order dated 18th November 1985 (Ex. 632) on Haresh Kumar & Co. in which was included Alpana Pharma's order for glycerine I. P. (500 kgs.) at Rs. 52 per kg. including tax for immediate delivery to Alpana Pharma at Nanded and to be billed to Alpana Pharma as usual.

21st November 1985 .. Haresh Kumar and Co. addressed a letter to Artichem
Ex. 633 (Ex. 633) seeking an amendment of rate of glycerine I. P. from Rs. 52 to Rs. 54 per kg. inclusive of tax, pursuant to a telephonic conversation which had taken place with Ramanlal Karwa. In this letter Haresh Kumar and Co. expressed its inability to execute Artichem's order if this rate of Rs. 54 per kg. was not accepted.

22nd November 1985 .. O. P. Ladda was in Pune. Ramanlal Karwa told him that Girdhar Kasat of Haresh Kumar and Co. wanted Rs. 54 per kg. Thereupon from Pune O. P. Ladda telephoned Girdhar Kasat at Bombay. Ultimately the price agreed was Rs. 54 per kg.

23rd November 1985 .. Two drums were despatched to Alpana Pharma by Girdhar Kasat in the name of Kailash and Co. under invoice No. 007 dated 23rd November 1985 for
Ex. 392 Rs. 27,000 (Ex. 392). These drums were forwarded through Batco Road Lines under lorry receipt dated
Ex. 392-B 23rd November 1985 (Ex. 392-B).

4th December 1985 .. These two drums were received by Alpana Pharma at its factory at Nanded.

8th December 1985 .. Alpana Pharma started its repacking operation.

9th December 1985 .. Alpana Pharma repacked 15 bottles of 50 gms. each.

10th December 1985 .. Alpana Pharma sent samples of this glycerine with other samples to Chem Med for a complete analysis. The batch number given by Alpana Pharma to the glycerine sample was 29. This sample was sent to
Ex. 213 (colly.) Chem Med by Alpana Pharma's covering letter dated 10th December 1985 [part of Ex. 213 (collectively)]

14th December 1985	.. Chem Med received Alpana Pharma's letter of 10th December 1985 and the sample.	
16th December 1985	.. O. P. Ladda telephoned Deepali Enterprises and was informed by their clerk Chavan that he had made a telephonic inquiry from Chem Med and had learnt from them that the sample had passed.	
18th December 1985	.. Alpana Pharma received Chem Med's acknowledgement of having received Alpana Pharma's letter dated 10th December 1985 and the sample. While O. P. Ladda was filing this letter from Chem Med he noticed that he had made a mistake in mentioning the batch number as 29 instead of 27. Thereupon O. P. Ladda addressed a letter to Chem Med requesting them to correct that mistake. This letter was sent to Chem Med under certificate of posting [Ex. 393 (collectively).].	Ex. 393 (colly.)
27th December 1985	.. (*i*) O. P. Ladda came to Bombay and handed over to Deepali's clerk Chavan the lorry receipt pertaining to the consignment of 270 bottles of glycerine for delivery to the J. J. Hospital. These 270 bottles were delivered to J. J. Hospital against their order for 400 bottles.	
	(*ii*) O. P. Ladda went to Deepali's office and collected Chem Med's report dated 23rd December 1985 [part of Ex. 213 (collectively)] regarding batch No. 29.	Ex. 213 (colly.)
14th January 1986	.. A cheque for Rs. 27,000, *viz.* the amount of invoice No. 007 dated 23rd November 1985 (Ex. 393) was prepared by Artichem in favour of Haresh Chemicals.	Ex. 393
17th January 1986	.. However as the amount of Rs. 27,000 was to be paid to Kailash and Co., Girdhar Kasat wrote a letter to Artichem that he had made adjustment entires in the books of Haresh Chemicals and Kailash and Co.	

VERSION OF GIRDHAR KASAT

3rd week of October 1985	Ramanlal Karwa made an inquiry from Girdhar Kasat who quoted Rs. 54 per kg. Ramanlal Karwa asked for sample. Girdhar Kasat requested Mahendra Doshi of H. M. Chemicals to give Ramanlal Karwa a sample.	
28th October 1985	.. H. M. Chemicals wrote a letter (Ex. 575) to Edgar Handley to allow samples to be taken from two drums of glycerine.	Ex. 575
31st October 1985	.. On the strength of this letter (Ex. 575) at 3-00 p.m. Chetan Thakkar, an employee of Haresh Kumar and Co. collected the sample from Girdhar Kasat's office in a bottle similar to the plastic bottle (Ex. 239). As Chavan wanted to collect another sample he was called again for the purpose by Girdahr Kasat. However later be was told by Girdhar Kasat that another sample was not available and Chavan was given an empty sample bottle and told by Girdhar Kasat to make two samples from one. Girdhar Kasat gave no instructions to Chavan about the labelling of the sample bottles.	Ex. 239
17th or 18th November 1985.	Ramanlal Karwa told Girdhar Kasat that the sample had passed and that he should supply two drums.	
18th or 19th November 1985.	Girdhar Kasat placed an oral order with Mahendra Doshi of H. M. Chemicals for supply of glycerine.	

Ex. 632	21st November 1985 ..	Girdhar Kasat received Artichem's order dated 18th November 1985 (Ex. 632) and thereafter telephoned Ramanlal Karwa that the rate should be Rs. 54 and not Rs. 52 per kg. as stated in Artichem's order. This telephone call by Girdhar Kasat was followed by a letter dated 21st November 1985 (Ex. 633) from Haresh Kumar and Co. to Artichem.
Ex. 633		
Ex. 579 (colly.)	22nd November 1985 ..	Girdhar Kasat received H. M. Chemicals' delivery memo dated 21st November 1985 [part of Ex. 579 (collectively)] addressed to Edgar Handley for delivery to the bearer of two drums of glycerine.
Ex. 579	23rd November 1985 ..	Edgar Handley delivered two drums to H. M. Chemicals *vide* its memo (part of Ex. 579).
Ex. 392		Girdhar Kasat prepared a *pro forma* (Ex. 392) of invoice No. 007 dated 23rd November 1985 for Rs. 27,000.
Ex. 392-A	24th November 1985 ..	Girdhar Kasat prepared invoice No. 007 (Ex. 392-A) as of 23rd November 1985. In both the *proforma* and the invoice the description of the goods is glycerine.
Ex. 589	26th or 27th November 1985.	(*i*) Girdhar Kasat received from H. M. Chemicals invoice dated 23rd November 1985 (Ex. 589) where the goods were described as glycerine I. W.
Ex. 392-A Ex. 392-B		(*ii*) In the meanwhile Girdhar Kasat had already sent to Alpana Pharma the original invoice (Ex. 392-A) and the lorry receipt (Ex. 392-B). Therefore when Girdhar Kasat received the invoice from H. M. Chemicals, he corrected his office copy of the invoice by inserting the letters " I. W. " in ink after the word " glycerine ".
	25th or 26th December 1985.	O. P. Ladda came to Girdhar Kasat's office complaining that the glycerine contained " kachra ". Thereupon Girdhar Kasat stopped payment of the cheque for Rs. 20.000.
	12th December 1985 ..	Girdhar Kasat received another order from Artichem for 250 kgs. glycerine.
	31st December 1985 ..	Girdhar Kasat supplied this quantity of 250 kgs. glycerine to Artichem, but is yet to receive payment.
	9th January 1986 ..	Girdhar Kasat sent another cheque for Rs. 20,000 to H. M. Chemicals.
	14th January 1986 ..	Girdhar Kasat received payment of Rs. 27,000 from Alpana Pharma.

7. With these two versions of O. P. Ladda and Girdhar Kasat the following points of controversy arise :—

(1) Whether in September 1985 the sample of glycerine which was analysed as Batch 26 was given by Girdhar Kasat to Alpana Pharma ?

(2) Whether according to Girdhar Kasat the sample was given by him to Chavan on 31st October 1985 or whether according to O. P. Ladda it was given on 5th November 1985 ?

(3) Whether Girdhar Kasat gave the particulars for getting the sample which was numbered as Batch 27 ?

(4) Whether O. P. Ladda came to Bombay on 25th or 26th December 1985 and complained to Girdhar Kasat about Kachra in the glycerine ?

(5) Whether the words " I. W. " were added in the copy invoice 007 dated
Ex. 392-A 23rd November 1985 (Ex. 392-A) ?

8. As between Alpana Pharma and Chem Med an additional point of contro-
Ex. 393 versy : Whether the letter dated 18th December 1985 (Ex. 393) was sent by Alpana Pharma to Chem Med ?

9. At this stage, I shall set out the rival versions of Jethalal Soni (proprietor of Ganesh Chemicals) and Mahendra Doshi (partner of H. M. Chemicals).

VERSION OF JETHALAL SONI

(Proprietor of Ganesh Chemicals)

17th October 1985	Mahendra Doshi of H. M. Chemicals approached Jethalal Soni and wanted to purchase 500 gms. of glycerine on approval basis which should be stored in the godown of Edgar Handley. Thereupon Mahendra Doshi gave Jethalal Soni his note dated 17th October 1985 [part of Ex. 574 (collectively)] addressed to Edgar Handley to store two drums of glycerine in the name of H. M. Chemicals.	Ex. 574 (colly.)
26th October 1985	Two drums were accordingly stored with Edgar Handley. However for a week no reply was received from Mahendra Doshi. As a result, Jethalal Soni told Mahendra Doshi to return those two drums as Jethalal Soni had a ready customer.	
4th November 1985	One leaking drum left the godown of Edgar Handley [part of Ex. 576 (collectively)].	Ex. 576 (colly.)
6th November 1985	One drum was received by Jethalal Soni.	
14th November 1985	The other drum was received by Jethalal Soni.	
18th or 19th November 1985.	Girdhar Kasat placed an order with Mahendra Doshi for 500 kgs.	
19th November 1985	H. M. Chemicals placed an order for 500 kgs. with Jethalal Soni (Ex. 578).	Ex. 578
21st November 1985	Jethalal Soni sent two drums to Edgar Handley(Exs. 590-A and 590-B).	Exs. 590-A, 590-B

VERSION OF MAHENDRA DOSHI

(Partner of H. M. Chemicals)

1st week of October 1985	(*i*) Girish Doshi (partner of H. M. Chemiclas) had gone to the office of Kailash and Co. and told Bharat Kasat (partner of Kailash and Co.) that H. M. Chemicals was in a position to supply local glycerine. Bharat Kasat asked for a sample. Hence Girish Doshi went to Jethalal Soni, took a sample from him and gave it to Kailash and Co. (*ii*) Two or three days later on enquiry from Mahendra Doshi, Bharat Kasat informed him that there was no reply from the customer. Seven to eight days later Mahendra Doshi again telephoned Bharat Kasat who told him that he would like a sample from the drum itself.	
17th October 1985	Mahendra Doshi went to the office of Jethalal Soni (Ganesh Chemicals) and placed an order with him for two drums of glycerine ' I. W. ' on approval basis.	
16th November 1985	Mahendra Doshi telephoned Bharat Kasat and enquired whether any reply had been received from the customer. Bharat Kasat told him that he required two drums. Mahendra Doshi informed him that the drum from which the sample had been taken was sold away. Even so Bharat Kasat wanted two drums.	
21st November 1985	Jethalal Soni (Ganesh Chemicals) sent his bill for Rs. 16,500 (Ex. 590) to H. M. Chemicals. This amount was paid by H. M. Chemicals to Jethalal Soni by instalments, namely :—	Ex. 590

	Rs.
31st January 1986	10,000
28th March 1986	3,000
April 1986	3,500

10. The first question that arises is : *Was there any negligence, malfeasance or misfeasance on the part of Alpana Pharma insofar as placement of the orders was concerned* ? None of this can be brought home to Alpana Pharma for the following reasons :—

(*a*) In all Alpana Pharma had placed 4 orders for glycerine. Three of them were with Kasat on 29th March, 13th August and 18th November 1985. They were all for glycerine I.P. To that end, there is the admission of Girdhar Kasat himself that with regard to the first transaction of March 1985, O.P. Ladda had asked him to supply Alpana Pharma glycerine which may pass the I.P. test. Regarding the second order of August 1985, Girdhar Kasat admits that it was for glycerine which would pass the I. P. test. Regarding the third order of November 1985 (which is the crucial order) Ramanlal Karwa also admitted that the glycerine required by Alpana Pharma was glycerine I.P. and that in the Purchase Order Ramanlal Karwa had described it as such.

(*b*) The evidence of Mahendra Doshi (H. M. Chemicals) discloses that in the first week of October 1985 his brother Girish went to Kailash and Co., at that time Girish told Girdhar and Bharat Kasat that if Kailash and Co. required any chemicals, H. M. Chemicals would be glad to do so. Bharat asked Grish for a sample of H. M. Chemicals' glycerine I. W. Thereupon Mahendra Doshi took a sample from Jethalal Soni (Ganesh Chemicals) and sent it to Kailash and Co.

(*c*) (*i*) Girdhar Kasat admitted that Haresh Kumar and Co. had by its letter dated 21st November 1985 to Artichem (Ex. 633) informed Artichem that the
Ex. 633 supply to Alpana Pharma would be of glycerine I.P. He further admitted that when the order for glycerine I. P. was placed, he understood that it was required for the purpose of drugs. He knew that only a wholesaler could sell pharmaceutical material in bulk if he held a licence from the FDA, that Kailash and Co. never held a licence and hence could not sell wholesale the drug ordered by Alpana Pharma, and that even so Kailash and Co. did sell Alpana Pharma glycerine which was ordered as I. P. glycerine. After attempting prevarications which took him nowhere, Girdhar Kasat finally admitted that the glycerine sold by Kailash and Co. to Alpana Pharma was not according to the description ordered, by Alpana Pharma (namely I. P.), that at the time of the execution of the order, he (i.e. Girdhar Kasat) knew that the glycerine which was supplied by Kailash and Co. to Alpana Pharma was not of the quality or nature ordered by Alpana Pharma and that he (i.e. Girdhar Kasat) did give an impression to Alpana Pharma that what Kailash and Co. would supply and had supplied to Alpana Pharma was of the nature, quality and description of the glycerine ordered by Alpana Pharma (viz. I. P.), that at no time did he (i. e. Girdhar Kasat) directly or indirectly tell Alpana Pharma that what he had supplied to them was not glycerine I. P. and that if a party ordered glycerine I.P. he would supply him either glycerine I.W., glycerine C.P. or glycerine P. Girdhar Kasat's attempts to overcome these vital admissions by feigning ignorance of the various grades of glycerine can only be attributed to ludicrity.

(*ii*) It is also not without its own significance that O.P. Ladda had asked for samples twice and had also sent them for analysis to Chem Med as glycerine I.P. samples.

(*d*) Regarding the order placed by Alpana Pharma with Indian Drugs Co. (Batch No. 21), Alpana Pharma's requirement was also glycerine I. P. This
Ex. 653 is brought to the forefront by the delivery challan (Ex. 653) of Indian Drugs Co. which describes the glycerine as I.P.

Ex. 655 (*e*) There is also on record a letter dated 6th December 1984 (Ex. 655) from Godrej Soaps Ltd., to Alpana Pharma which is in reply to Alpana Pharma's inquiry for glycerine I.P. Thus it is manifest from the earliest point of time Alpana Pharma wanted to purchase glycerine I.P. grade.

11. All these circumstances and in particular Girdhar Kasat's own admissions clearly establish that the orders placed by Alpana Pharma, including the crucial order of 18th November 1985 was for glycerine of I.P. grade. Thus, Kasats were put to notice and knew that what Alpana Pharma required was glycerine I.P. and none other and that it was such glycerine and none other that they had agreed and were bound to supply.

12. The question that next arises is : *Did Kasat ever inform Alpana Pharma directly or indirectly orally or in writing, that the glycerine supplied to them was of I.W. grade and not I.P. grade* ?

The evidence on record unmistakably discloses that Kasat did nothing of the kind or even gave a hint to Alpana Pharma that the supply made to them was not in conformity with the order. Hereunder my reasons :—

(*a*) Kailash and Co.'s invoice No. 007 dated 23rd November 1985 (Ex. 392) does not describe what was sent as glycerine I.P., but merely glycerine. There is also Girdhar Kasat's admission that the *proforma* invoice which was sent to Batco Road Lines also mentions the goods as glycerine simpliciter and so also it is mentioned in the lorry receipt. Ex. 392

(*b*) However, in Girdhar Kasat's office copy of invoice No. 007 the words 'I. W. ' have been inserted by him in ink after ' glycerine '. Girdhar Kasat says he did so 2-3 days after 23rd November 1985 when he received Chem Med's report. This is a lie and has been exposed as such for the following reasons:—

(*i*) To start with, Girdhar Kasat never informed Alpana Pharma or Rameshwar Karwa orally or in writing that he had amended his office copy of invoice 007 by adding the words ' I.W. ' after ' glycerine '.

(*ii*) Even when according to Girdhar Kasat when O.P. Ladda met him in Bombay on 25th or 26th December 1985 and complained to him that the glycerine contained 'kachara', Girdhar Kasat kept quiet about the amendment made by him in his office copy of invoice No. 007. That was because he had then not made any such amendment in his office copy. It was done much later, after the police investigation started into the J. J. Hospital deaths.

(*iii*) At first Girdhar Kasat disclaimed all knowledge before the police as to who had added the words ' I.W. ' in the office copy of invoice 007. This is borne out by the evidence of Police Inspector N. S. Nikam, one of the Supervising Officers appointed for the investigation of J. J. Hospital tragedy. Police Inspector Nikam denied the suggestion that Girdhar Kasat had told him that he himself had added the words ' I.W. ' in his office copy of invoice 007. There is no reason why the Investigating Officer should go out of his way to tell a falsehood or why he should not be believed that Girdhar Kasat told him that he did not know who added the words ' I.W.' in the office copy of invoice 007.

(*iv*) Until 21st March 1986 when Girdhar Kasat gave his statement to the police, he mentioned to absolutely nobody that a few days after 23rd November 1985 he had inserted the words ' I. W. ' in his office copy of invoice 007. This was not his first statement to the police. Before that he had given one statement to the FDA and 5 statements to the police. This unaccountable amnesia on the part of Girdhar Kasat till 21st March 1986 in not remembering that he had inserted the words ' I.W.' in his office copy of the invoice 007 in December 1985 establishes in abundant measure that he did so not in December 1985 but just prior to 21st March 1986 in order to save his skin after the police investigation had started. This is also borne out from his conduct prior to 21st March 1986.

(*v*) On 19th March 1986 Girdhar Kasat gave his first statement to the police. In that he stated that Alpana Pharma's order was for glycerine ' I.W.' which he supplied. Curiously enough, he did not tell the police that Alpana Pharma's order was a written order or that it was for glycerine I.P., nor did he tell the police from where he obtained the sample. On the contrary, he told the police that he would make inquiries and would find out if Alpana Pharma's order was an oral or a written order. At that time he did not produce his copy invoice 007, nor did he even refer to it in the statement made by him that day to the police.

(*vi*) On 21st March 1986 for the first time Girdhar Kasat produced his office copy of invoice 007 along with other documents, but significantly did not produce either Artichem's order dated 18th November 1985 (Ex. 632) where I.P. is mentioned, nor Haresh Kumar and Co.'s letter dated 21sr November 1983 (Ex. 633) where I.P. is also mentioned. At this time, he told the police that he had informed O.P. Ladda that what he would be supplying him would be glycerine I.W. and that Ladda had no objection. This is palpably a false statement in the light of the admissions made by him in his evidence, to wit, that though it would be good business practice to inform the customer, namely Alpana Pharma, of the addition of ' I.W. ' made by him in his copy invoice, he did not think it necessary to do so, and that even though there were enough opportunities Ex. 632 Ex. 633

for him to ask Alpana Pharma to correct the invoice 007 in the manner done by him in his office copy he did not do so as he did not think it necessary.

(*vii*) It was only when he gave his statement to the DCB CID on 24th March 1986 that Girdhar Kasat produced Ex. 632 and 633.

(*c*) All these machinations of Girdhar Kasat must come to naught in the light of Bharat Kasat's admission that the supply of Alpana Pharma was not in accordance with the requirements and description given by Alpana Pharma.

13. The next question that arises is : *Did Kasats inform Alpana Pharma that the two drums from which the sample was given had been disposed off* ? The answer must be in the negative for the following reasons :

14. Girdhar Kasat's version is that on 17th or 18th November 1985 he received a telephone call from Ramanlal Karwa who told him that his sample had passed and that he, i.e. Girdhar Kasat, should arrange to supply two drums of glycerine to Alpana Pharma at Nanded. According to Girdhar Kasat he told Ramanlal Karwa that the drums from which the sample had been drawn had been sold by the party, but Girdhar Kasat would be able to supply two fresh drums in due course of time, to which Ramanlal Karwa agreed.

15. This version of Girdhar Kasat has nothing to commend it except his *ipse Dixit*. This telephonic conversation finds a place for the first time in Girdhar Kasat's evidence. If any such telephone conversation had taken place on 17th or 18th November, the rate of Rs. 52 would not have been mentioned by Artichem in its Ex. 632 order dated 18th November 1985 (Ex. 632) but instead the rate of Rs. 54 would have been mentioned.

16. If these drums had been sold off it would have been stated by Haresh Kumar Ex. 633 and Co. in its letter dated 21st November 1985 to Artichem (Ex. 633). It has not been.

17. Though Girdhar Kasat made in all 6 statements (namely one to the FDA and 5 to the police) and though Bharat Kasat made 3 statements (namely 2 to the police and one to the FDA), in not a single statement has either of them even faintly alluded to the disposal of the drums from which the sample had been drawn. On the contrary, in Girdhar Kasat's first statement to the police on 19th March 1986 he stated that after the sample was given, the two drums were delivered, thereby suggesting that they were the very drums from which the sample had been drawn.

18. Girdhar Kasat's version about the drums having been sold off is obviously an expedient at saving himself as is borne out by his evidence that he would draw a sample merely because his purchaser wants it and giving the purchaser a sample is merely a formality from the point of view of Girdhar Kasat.

19. All these circumstances establish that Alpana Pharma had never been informed that the two drums from which the sample was drawn had been sold, if indeed they were.

20. The question that next arises is : *What is the validity of Kasat's version that they informed Alpana pharma and/or Ramanlal Karwa that they would purchase glycerine from a new manufacturer* ?

21. This version cannot be accepted because on his own admission Girdhar Kasat was under the impression that he would be supplied by H. M. Chemicals glycerine available in the market which was manufactured by reputed concerns like Tatas, Hindustan Lever or Godrej and that he did not even know that industrial glycerine was available in the market.

22. The question that next arises is : *Did Kasats know that Alpana Pharma was a pharmaceutical repacking units* ?

23. This is best answered by Girdhar Kasat himself. He says that he understood that Alpana Pharma wanted glycerine which was commonly available in the market and which would be used by Alpana Pharma for pharmaceutical purposes *if it passed* the I. P. test. Thereafter he says that he was supplying glycerine as a chemical to pharmaceutical manufacturers through Kailash and Co., and thereby laid emphasis

on his supply to Alpana Pharma of glycerine not as a drug but a as chemical. This pose of his was exposed to be false by his admissions as under :—

"I know the meaning of I.P. A material complying with pharmacopoeia standards is described as I.P. material. All raw materials used for drugs must comply with pharmacopoeia standards. *If an article is specified as I.P.*, I would understand that it is *required for drugs* ....."
(The underlining is mine.)

Indisputably Alpana Pharma's order was for glycerine I.P. Hence on his own showing Girdhar Kasat understood that Alpana Pharma wanted the I.P. glycerine for being used as a drug. This is borne out by his admission :—

" *When the order for Glycerine I.P. was placed with me, I understood that it was required for the purpose of drugs*"
(The underlining is mine.)

These admissions clearly indicate knowledge on the part of Girdhar Kasat that as Alpana Pharma required the I.P. glycerine as a drug, it was a pharmaceutical repacking unit.

24. He further admitted that only a wholesaler can sell pharmaceutical material in bulk if he holds a licence from the FDA and that Kailash and Co. never held a wholesale licence and therefore had no right to sell wholesale drugs ordered by Alpana Pharma. Even so Kailash and Co. sold to Alpana Pharma glycerine which was ordered as I.P. glycerine, but not as I.P. He admitted that the glycerine sold by Kailash and Co. to Alpana Pharma was not according to the quality and description ordered by Alpana Pharma, and that at the time of the execution of the order he knew this to be so. Thus once again on Girdhar Kasat's own showing, sub-standard glycerine was passed off to Alpana Pharma with the knowledge that it was pharmaceutical repacking unit. This finds corroboration from his own admission that he did give an impression to Alpana Pharma that he (Kailash and Co.) could supply and had supplied to Alpana Pharma glycerine which was of the nature, quality and description of the glycerine ordered by Alpana Pharma, viz. I.P., when in fact it was not, coupled with his final admission that he did not at any time, directly or indirectly, tell Alpana Pharma that what he had supplied to them was not glycerine I.P.

25. Girdhar Kasat's own admission clearly establish that Kasat knew that Alpana Pharma was a pharmaceutical repacking unit and even so plamed off sub-standard glycerine in the place of I.P. glycerine ordered. Futher it is only pharmaceutical units that mention the word " Pharma " in their name. Hence from the very name, namely Alpana Pharma Pack, Girdhar Kasat was or should have been put to notice that Alpana Pharma was a pharmaceutical drug repacking unit.

26. The question that next arises is : *Did O. P. Ladda meet Girdhar Kasat on 25th or 26th December 1985 and talk to him about the "kachra" in glycerine Batch 27* ?

27. According to Girdhar Kasat on 25th or 26th December 1985 O. P. Ladda came to his office at about 5-00 p. m. and asked him (O. P. Ladda) for payment for the supply made to him. O. P. Ladda told him that there was some doubt about the quality of glycerine as it contained some foreign particles (kachara) and that he would be able to use the glycerine if he received the test report from the laboratory and that O. P. Ladda would inform Girdhar Kasat at a later stage.

28. Girdhar Kasat's version of this meeting and conversation is denied by O. P. Ladda. Probabilities indicate that Girdhar Kasat's version is not correct. My reasons :—

(*a*) This version of Girdhar Kasat finds a place for the first time in his evidence and not at any time before either orally or in writing despite opportunities available to him.

(*b*) This version of Girdhar Kasat is an afterthought as is manifest from the fact that even though he gave 5 statements to the police and one statement to the FDA, not in a single one of them did he allude to any such conversation.

(*c*) It is therefore obvious that Girdhar Kasat's motive in now alluding to this conversation is merely a self-protective measure in a desperate attempt to evade liability by now seeking to convey that as far back as 25th or 26th December 1985 Ladda knew that what had been supplied to him was not glycerine I. P.

(*d*) Even assuming Ladda did, it would make Ladda a co-conspirator, but could not absolve Girdhar Kasat from liability or mitigate his wrongful act in supplying O. P. Ladda glycerine which was not of the quality and description ordered by O. P. Ladda.

29. In the circumstances, Girdhar Kasat's version about this meeting and conversation with O. P. Ladda is highly improbable. In any event, Girdhar Kasat cannot be absolved for supplying glycerine I. W. instead of glycerine I. P. ordered by Alpana Pharma.

30. The next question that arises is : *Was the sample given by Girdhar Kasat to Chavan on 31st October 1985 as is his version or was it given on 5th November 1985* ?

31. Girdhar Kasat seeks support from the evidence of Chetan Thakkar and certain documents of Edgar Handley. On the other hand, there is the evidence of Chavan coupled with documentary evidence in the form of the letter dated 5th
Ex. 212 November 1985 (Ex. 212).

32. Chavan, a clerk in Deepali Enterprises deposed that in the end of October or the beginning of November 1985, Om Prakash Ladda had come to the office of Deepali Enterprises. He told Chavan to go to Haresh Kumar and Co. and bring the sample. Chavan did so four or five days later as he had to attend to his own work in Deepali Enterprises. Chavan did not receive this sample from Chetan Thakkar. This was the first time that O. P. Ladda had asked Chavan to get a sample of glycerine. Girdhar Kasat gave Chavan the particulars for labelling the sample bottle. Chavan's evidence therefore indicates that the sample was given sometime in the beginning of November 1985.

33. In support of Chavan's version, there is documentary evidence in the form of the letter dated 5th November 1985 on the letterhead of Alpana Pharma signed
Ex. 212 (colly) by Chavan addressed to Chem Med [part of Ex. 212 (collectively)] enclosing samples for analysis. It would have been most unnatural for such a letter to have been addressed to Chem Med on 5th November 1985 if the sample had in fact been drawn on 31st October 1985. This letter is therefore an independent piece of corroboration that after the sample was drawn on 5th November 1985 it was immediately sent for analysis the same day to Chem Med along with the covering letter dated 5th November 1985.

34. Girdhar Kasat's version that this sample had been given on 31st October 1985 is negatived by his own statement to the police on 20th March 1986 that the sample was given to Chavan on 5th November 1985. Having made that statement before the police and being confronted with it, Girdhar Kasat attempted to resile from it in his evidence by saying that after he made that statement to the police on 20th March 1986, his man, *i.e.* Chetan Thakkar, told him that the sample had been collected not on 5th November 1985 but on 31st October 1985. If that was so, there was no plausible reason why Girdhar Kasat did not have his earlier police statement corrected. According to him he did not do so because he was not called again by the police and because he did not consider a difference of 4-5 days to be important. This is a lie. After he gave his statement to the police on 20th March 1986, he gave another statement to the police on 24th March 1986 in which whether or not 4–5 days made any difference he could have set the record straight at the first available opportunity by telling the police on 24th March 1986 that his earlier statement on 20th March that the sample was taken on 5th November 1985 was a mistake and that the correct date was 31st October 1985. Girdhar Kasat did nothing of the kind as he knew that his earlier statement was correct.

35. In support of his version that the sample was drawn on 31st October 1985 Girdhar Kasat seeks corroboration from the evidence of the warehouse manager of Edgar Handley.

36. Suresh Daftary is the warehouse manager of Edgar Handley and Co. who had their godown at Lal Chimney Compound, near Nair Hospital, Bombay. His duties comprised of keeping the records of goods received in the warehouse and goods sent out of the warehouse for delivery to various parties. For this purpose, he maintains a stock register, a receipt book and a delivery book. He deposed that on 26th October 1985, 2 drums 500 kgs. each of glycerine I. W. grade were received in the godown from H. M. Chemicals with their covering letter dated 17th October 1985 addressed to Edgar Handley. One drum was leaking.

37. Daftary continued that on 31st October 1985 Chetan Thakkar came to him
Ex. 575 with a note (Ex. 575) from H. M. Chemicals for taking a sample from these two drums. Daftary sent his peon with Chetan Thakkar for the purpose who pointed out the drums to Chetan Thakkar. Chetan Thakkar drew one sample from one drum in

a white plastic bottle having a capacity of 50 to 100 gms. Daftary's servant told him later that Chatan Thakkar had taken a sample only from one drum. Daftary himself was not present when the sample was taken and admitted that he did not know whether Chetan Thakkar drew the sample from the leaking drum or from the other drum which was not leaking. *Daftary did not write the name and address* of Haresh Kumar and Co. on the reverse of H. M. Chemicals' note dated 28th October 1985 (Ex. 575) on 31st October 1985. Ex. 575

38. The question which may arise is : *From which two drums was the sample drawn by Chetan Thakkar* ? His evidence suggests that the sample was drawn from the drum which was not leaking. This was the drum which remained in the godown till 14th November 1985. The evidence however further suggests that when sample was drawn on 5th November 1985 both the drums were in the godown. Therefore, if one of the drums, whether leaking or not leaking, had left the godown on 4th November 1985, drawing of sample by Chetan Thakkar on 5th November 1985 becomes highly doubtful.

39. Chetan Thakkar deposed that in the evening of 30th October 1985 Girdhar Kasat told him to go to the godown of Edgar Handley and draw a sample the following day of glycerine and for the purpose gave him a letter dated 28th October 1985 (Ex. 575) addressed to Edgar Handley on the letter-head of H. M. Chemicals and Ex. 575 a white plastic bottle (Ex. 239) to draw the sample in. Accordingly on 31st October Ex. 239 1985 at about 11-00 a.m. Chetan Thakkar went to the godown of Eedgar Handley and met Daftary to whom he handed over the letter Exhibit 575. Dafatry showed Chetan Thakkar the two drums and told him to take the sample. Chetan Thakkar himself did not go near the drums, he told Daftary that as the drums were large, he alone would not be able to draw the sample. As Chetan Thakkar had no instruments to open the drum, Daftary told his servant to take out the sample from one of the drums and to give it to Chetan Thakkar. While the servant was drawing the sample from one drum, Chetan Thakkar was waiting outside Daftary's cabin at a distance of about 40-50 feet from the drum from which the sample was being drawn. Daftary's servant opened the lid of the barrel with a spanner and drew the sample in a white plastic bottle which Chetan Thakkar had given him for the purpose by dipping that white plastic bottle in the barrel and taking the sample. Thereafter the servant closed the lid of the barrel, capped the white plastic bottle and gave it to Daftary. Chetan Thakkar himself never went near the drums and did not verify for himself whether one drum was leaking nor could he from the distance from where he was standing notice whether one drum was leaking. Throughout this time Daftary was in his own cabin doing his own work. Chetan Thakkar entered Daftary's cabin. Chetan Thakkar gave the name of Haresh Kumar and Co. On the reverse of the letter Exhibit 575 Daftary wrote down the name of Haresh Kumar and Co. and the address. Daftary took Chetan Thakkar's signature on the face of the note (Ex. 575) in token of Chetan Thakkar having received the sample. Ex. 575

40. Chetan Thakkar did not know which drums belonged to H. M. Chemicals. He himself did not see any label on any drum and does not know from which drum sample was drawn. He has nothing to show that the sample which had been drawn was from the drum of H. M. Chemicals. However 500 drums were lying in the do-godown on that day. The drum from which the sample was drawn was red coloured with white coloured top. There were several other drums similarly coloured.

41. Chetan Thakkar returned to the office of Haresh Kumar and Co. with the sample and informed Girdhar Kasat what he had done. The same afternoon Chavan rang up the office of Haresh Kumar and Co. and spoke to Girdhar Kasat. Soon thereafter Chavan came to the office and had some conversation with Girdhar Kasat who told Chetan Thakkar to hand over the sample which he had brought that morning to Chavan.

42. It will be seen that the varsions of Suresh Daftary and Chetan Thakkar regarding what transpired at the godown are diametrically opposite, to wit. Chetan Thakkar deposed that in February or March 1986 he was called by the police to CID office where his statement was recorded on 2 occasions. To the best of his recollection, he had stated in his police statement that on 31 October 1985 Chavan had come to the office of Girdhar Kasat and had taken away the sample. While in his evidence Chetan Thakkar says that Daftary did not take his signature in any register, he had to admit that he had stated before the police that Daftary had taken his signature in the sample register. This statemen tmade to the police at the earliest

point of time cannot be washed away by his endeavour in the witness-box that he said this to the police by mistake. It is merely to cover up the suppression of this sample register.

43. Now why does Chetan Thakkar remember that Chavan had come in the afternoon of 31st October 1985 ? Because according to him it was raining that day as a result he did not go to the Vadgadi Chemical Market which he normally did. It is strange that because of the rains he did not go to the Chemical market, yet went to the godown of Edgar Handley. Naturally he did not remember if it rained on 5th November 1985. On that day he was on leave for which there is only his *ipse dixit.*

44. Chetan Thakkar stated that on the second occasion when he was called to the CID office on 22 nd March 1986 at 11-00 a.m. he didnot go there at 11-00 a.m. on the patently lame excuse that Sub-Inspector Aklujkar himself came at 12-30 p.m. S.I. Aklujkar asked Chetan Thakkar why he did not come at 11-00 a.m. to which Chetan Thakkar says he gave him no reply. Pausing here for a moment, there was another reason why Chetan Thakkar did not go to the CID office at 11-00 a.m. that day and why he gave no reply to S.I. Alkujkar over his tardiness. Daftary admitted that on 22nd March 1986 between 11-00 a.m. and 12-00 noon one person whom he did not know came to him asking to see the account of H. M. Chemicals. The same day CID officers had come to the warehouse at about 2-00 p.m. On both the occasions Daftary's co-worker Umesh Sheth was present. Umesh Sheth's statement was recorded by the CID. Daftary knows what was recorded by the CID, but did not remember if Sheth had mentioned before the CID officers that some person from Haresh Kumar and Co. had come to the godown earlier that day. Sheth did not show the record of H. M. Chemicals to that person. He does not know what transpired between that person and Umesh Sheth. Daftary denied that any entry in the stock register of Edgar Handley had been manipulated at the instance of that person.

45. *Now, who could this person be who wanted to see the account of H. M. Chemicals* ? This mysterious person goes to the warehouse of Edgar Handley at the same time and day that Chetan Thakkar fails to turn up at the CID office though called at that time that day. If it is a coincidence, it is a remarkable coincidence.

46. Apart from the inconsistencies in the evidence of Suresh Daftary and Chetan Thakkar regarding what transpired in the godown, it is manifest that a vital piece of evidence has been suppressed, namely the sample register of Edgar Handley. According to Edgar Handley's manager Daftary, no sample register was maintained. This is untrue, in the light of Chetan Thakkar's statement made to the police on 21st March 1986 that his signature was taken by Daftary in the sample register kept in the warehouse. This must necessarily show that Daftary's assertion to the contrary in the witness-box is false. He has been tutored to deny the existence of the sample register. The irresistible inference can only be that if this sample register had been produced it would not have supported Girdhar Kasat that the sample was drawn on 31st October 1985 and not on 5th November 1985 as stated by Girdhar Kasat at the earliest point of time before the police. Stratagems came later as the investigation progressed. *Suppressio veri.*

47. There is also *suggestio falsi,* as there is strong evidence that a number of documents were subsequently prepared. On H. M. Chemicals' note to Edgar Ex. 576 (colly.) Handley dated 4th November 1985 [part of Ex. 576 (collectively)] there is Edgar Handley's rubber stamp with the number written in ink of Edgar Handley's challan as 4257, which is also part of Exhibit 576 (collectively). The date on this rubber stamp is shown in ink as 5th November 1985. This rubber stamp is the clearest indication that these two documents, namely the challan bearing No. 4257 which is dated 4th November 1985 and H. M. Chemicals' letter also dated 4th November 1985, are not contemporaneous. When Daftary was shown H. M. Chemicals' note dated 4th November 1985 and the delivery challan dated 4th November 1985 Ex. 576 (colly.) [Ex. 576 (collectively)], he admitted that the date of the delivery challan shown as 5th November 1985 on the rubber stamps was a mistake for 4th November 1985. He continued that the posting also had been made in the ledger under 5th November 1985. All this, to say the least, casts a grave suspicion on the genuineness of such documents.

48. It would also be pertinent to ask why having said in his statement to the police that the sample was taken on 5th November 1985 Girdhar Kasat should now resort to 31st October 1985 as the date of the drawing of the sample. The only

answer is the one that Girdhar Kasat dared not give, namely that having created false evidence that one drum had gone out on 4th November 1985, there was no possibility of drawing a sample on 5th November 1985 from both the drums, with the result that he had to advance the date in order to show that the sample was drawn prior to 4th November 1985. Hence he fixed the date as 31st October 1985.

49. There has been a manifest conspiracy between Girdhar Kasat, Mahendra Doshi, Edgar Handley and Jethalal Soni to falsely suggest that two drums were not available. To that end, I shall advert to the evidence of Jethalal Soni presently. But before I do, it may be noted that if the evidence of Chetan Thakkar falls, he must carry with him the evidence of the others also. And the evidence of Chetan Thakkar must fall. My reasons :

(*a*) At the earliest opportunity he told the police that the sample had been drawn not on 31st October 1985 as he now seeks to make out but on 5th November 1985.

(*b*) At the earliest opportunity he disclosed to the police the existence of the sample register in Edgar Handley's warehouse and of Chetan Thakkar's signature having been taken in that register on 5th November 1985. Hence his evidence to the contrary is false and an afterthought coupled with the suppression of the sample register which would have disclosed the date of the drawing of the sample as 5th November 1985 and not 31st October 1985.

(*c*) His recollection in evidence that he went to take the sample on 31 st October 1985 is based solely on the fact that it was raining that day. Assuming that there was unseasonable rain on the last day of October 1985, it is strange that he should go out of his office to the godown of Edgar Handley and not go to the Vadgadi Chemical market on the ground that it was raining.

(*d*) There is nothing beyond his *ipse dixit* that he was on leave on 5th November 1985 for 1 months.

(*e*) There are several discrepancies in the evidence of Chetan Thakkar and Daftary regarding what transpired at the godown as set out earlier. There is nothing beyond Chetan Thakkar's *ipse dixit* that he was told that one drum was leaking. If Chetan Thakkar had gone, he would have been able to identify the drums of H. M. Chemicals in the godown which on his own showing he could not.

(*f*) Chetan Thakkar has been assigned a part merely to support the version of Girdhar Kasat that the sample was drawn prior to 4th November 1985, hence 31st October 1985 was hit upon.

(*g*) Chetan Thakkar's evidence shows that both the drums were in the godown of Edgar Handley when the sample was drawn. This falsifies the version of Girdhar Kasat that one drum had been sold.

50. In this conspiracy Jethalal Soni, proprietor of Ganesh Chemicals also has a part. He, as sole proprietor of Ganesh Chemicals, manufactures what he calls " chalu glycerine", which is a substitute for glycerine I.W. He deposed that on 17th October 1985 H. M. Chemicals' partner Mahendra Doshi told him that he wanted to purchase 500 kgs. glycerine on approval basis and gave Soni a letter addressed to Edgar Handley for storage of the two drums in the warehouse. Mahendra Doshi never told Soni that he required glycerine for medicinal purpose and Soni did not ask him for what purpose he required Soni's glycerine. Accordingly on 26th October 1985 Soni sent two drums 250 kgs. each containing industrial glycerine to Edgar Handley for storage. For about a week thereafter Soni did not hear from Mahendra Doshi. When Mahendra Doshi came to see Soni thereafter, Soni told him that he had not heard from him whether his glycerine lying in the godown of Edgar Handley had been approved or not and that Soni had a ready customer for those two drums which should be returned to him. Mehendra Doshi told Soni that he would arrange to have the two drums re-delivered to Soni.

51. However on 6th November 1985 Mahendra Doshi returned to Soni only one drum which had been given to the transport company the previous day for delivery to Soni. That drum he sold to Om Dye Chem Industries on 7th November 1985. Mahendra Doshi returned the other drum to Soni on 14th November 1985 after giving it to the transport company a day earlier. Out of that drum Soni sold 100 kgs. to K. A. M. Syndicate on 16th November 1985 and 150 kgs. to Om Dye Chem Industries on 21st November 1985.

52. On 21st November 1985 Jethalal Soni sold 500 kgs. of glycerine to H. M. Chemicals in the quantity of 250 kgs. each, pursuant to an order which Mahendra Doshi had placed with him on 19th November 1985 and which he had asked Soni to send to Edgar Handley for storage. Mahendra Doshi gave Jethalal Soni a letter to Edgar Handley on the letter-head of H. M. Chemicals requesting them to store these two drums on behalf of H. M. Chemicals. Accordingly on 21st November 1985 Soni sent these two drums to Edgar Handley for storage on behalf of H. M. Chemicals.

53. He came in contact with H.M. Chemicals in 1984. He had never given to Mahendra Doshi or any of his customers any sample of his product. He has no personal knowledge whether any sample was taken from any of his drums stored in the godown of Edgar Handley.

54. F. D. A. officers made enquiries from Soni on 19th February 1986 and recorded his statement. He was arrested on 3rd March 1986.

55. After the deaths in the J. J. Hospital, Mahendra Doshi told Soni that the two drums which he had sold to H. M. Chemicals had in turn been sold by H. M. Chemicals to Kailash and Co.

56. After stating that he never gave his sample of glycerine to Mahendra Doshi he later retracted this statement.

57. Mahendra Doshi had informed Soni that he had a sample drawn from the second drum of which Soni had taken delivery from Edgar Handley. Therefore, Soni's suspicions were not aroused when he found that the seal on the drum was missing.

58. The lorry charges for conveying these two drums from his factory to the godown of Edgar Handley were borne by Soni. Soni had not prepared any challan for those two drums but had obtained the signature of Mahendra Doshi on Soni's letter-head the same day or the next day; he got it written by Mahendra Doshi that he had received two drums from Soni. He produced a writing dated 26th October
Ex. 640 1985 (Ex. 640). He also produced two letters dated 5th November 1985 and 13th November 1985 from H. M. Chemicals to Soni returning the first and second drums respectively. Those letters dated 5th November 1985 and 13th November 1985 were Exhibit 641 (collectively). He admitted that until he gave his evidence he
Ex. 641 (colly.) never disclosed to anyone the existence of the writing (Ex. 640) or the letters [Ex. 641
Ex. 640 (collectively)]. He admitted that the details of the transactions and the particulars
Ex. 641 (colly.) of the drums were not stated in the writing dated 26th October 1985 (Ex. 640) because the details were known to him and Mahendra Doshi.

59. The drum which was returned by H. M. Chemicals on 5th November 1985 was received by Soni on 6th November 1985 and sold to Om Dye Chem Industries on 7th November 1985. When H. M. Chemicals returned only one drum which he received on 6th November 1985 Soni did not prepare the bill for the other drum in favour of H. M. Chemicals because a day or two later Mahendra Doshi told Soni that the sample had been drawn from the other drum and Soni should allow the other drum to remain with Edgar Handley and Mahendra Doshi would return it to Soni a few days later. Soni told Mahendra Doshi to return the second drum before Diwali if he was unable to sell to his own customer.

60. Soni was shown the account of H. M. Chemicals in his ledger. He admitted that at page 49 in the debit entry the original figure had been rubbed out and over which the figure "8,250" had been overwritten. He also admitted that even the overwritten figure was a mistake for Rs. 7,500 and that there must be a similar mistake in the corresponding cash book entry as also in the sales register.

61. On 19th February 1986 he knew that some people had died in the J. J. Hospital as a result of the glycerine supplied by him. Round about that time H. M. Chemicals also knew that something was wrong with Jethalal Soni's glycerine. Jethalal Soni admitted that H. M. Chemicals paid him the balance amount of his bill in April 1986 on demand being made by him in March 1986 and without raising any dispute.

62. Jethalal Soni's trade practices are not entirely beyond reproach. For example he admitted that the sales invoices maintained by him are not in a regularly bound book and neither are his delivery challans and that the sales register is written up once a month on the basis of the copy invoices.

63. On 20th November 1985 Soni had purchased 250 kgs. glycerine from Royal Corporation, Bombay. He agreed that in the delivery challan of Royal Corporation there was an overwriting on the date of the challan as also in the copy of the delivery challan, but he did not know who was responsible for this overwriting or when it was done. He admitted that there was a corresponding entry under date 20th November 1985 in his purchasing register (Ex. 635). He made payment to Royal Corporation by cheque. However he admitted that his version of not knowing who is responsible for the overwriting in the challan of Royal Corporation or when it was done, is not correct and that the alterations/overwriting in the date of the original challan was done by him through mistake sometime in February 1986. He admitted that he purchased 250 kgs. I. W. glycerine from the market without a bill round about 15th November 1985. Thereafter without purchasing any material from Royal Corporation he took a bill from them for Rs. 13,500 on 20th November 1985 for 250 kgs. of glycerine at the rate of Rs. 54 per kg. Thereafter he overwrote the date 20th on the delivery challan of Royal Corporation in order to give an impression that 250 kgs. of glycerine mentioned in the bill of Royal Corporation had been sent to him *vide* the delivery challan of Royal Corporation. He admitted that therefore both the delivery challan and the bill of Royal Corporation are bogus documents. He also admitted that there were a number of other bogus bills in his possession which had been entered in his purchase register and in his stock register even though the quantities of glycerine covered by those bills had not been actually purchased by him. He also admitted to several other bogus bills and entires. He also admitted that several sales are not reflected in his stock register and sales register. **Ex. 635**

64. The fact that on demand being made by Jethalal Soni on H. M. Chemicals in March 1986 he received in April 1986 the balance amount of his dues from H. M. Chemicals without the latter raising any dispute, shows that Kasat, Soni and Mahendra Doshi of H. M. Chemicals had joined hands with a view to extricate themselves from their involvement in the J. J. Hospital tragedy. The demand and payment were most unnatural under the circumstances. The payment by H. M. Chemicals to Soni was more in the nature of a bribe than a *bona fide* payment. Soni was bought over.

65. This brings me to the *nature of the product manufactured by Jethalal Soni.*

66. Jethalal Soni carries on business in the name and style of Ganesh Chemicals Corporation as the sole proprietor since the past 7 years. He is a B. Sc. in Chemistry from the Gujarat University. He manufactures and supplies only what he calls "chalu glycerine" which is a substitute for glycerine I. W.

67. Jethalal Soni manufactures glycerine industrial grade and glycerine textile grade. The former is used for manufacture of writing ink, stamp pad ink, typewriter ribbons and carbon papers and metal treatment chemicals. The latter is used for textile purposes.

68. Jethalal Soni manufactures industrial glycerine by mixing sorbitol, diethylene glycol and pure glycerine. For the manufacture of 250 kgs. of industrial glycerine, he mixes 187 kg. sorbitol, 40 kg. diethylene glycol and 25 kg. pure glycerine. For the manufacture of 200 kg. of textile glycerine, he mixes 120 kg. liquid glucose, 60 kg. diethylene glycol and 20 kg. water. In textile glycerine, no pure glycerine is used.

69. He admitted that his product, be it industrial glycerine or textile glycerine, is unfit for human consumption and would cause death if taken internally, because one of the ingredients is diethylene glycol.

70. The normal price of glycerine is Rs. 54. per kg. and of sorbitol and diethylene glycol between Rs. 18 to Rs. 20 each per kg. Jathalal Soni never sold his product for less than Rs. 30 per kg. All he did was to measure the quantities of the 3 components, namely sorbitol, diethylene glycol and glycerine, and mix them, the quantity of glycerine being the least used by him as it was the costliest component.

71. He does not hold a manufacturing licence from the FDA because his product does not fall within the purview of the Drugs and Cosmetics Act.

72. He purchases drums from hawkers or utilises the drums in which he received the raw material. His 250 kg. drums are painted in red and the lids in white. On the lids he stencils in red paint, one and half inch in length and 5 mm. in breadth,

the words "GLYCERINE NOT FOR MEDICINAL USE. NET WEIGHT 250 KG." He claim that his purpose in doing so was to make sure that even by mistake his product would not be used for medicinal purposes.

73. Jethalal Soni never sold his glycerine as per I.S.I. standards, but as substitute glycerine. The raw material which he purchased in the market was not I.P. glycerine; it was either I.W. glycerine or refined glycerine; he did not test the glycerine purchased by him from the market. He admitted that I.W. glycerine could not be used for pharmaceutical purposes. In the market all substitute glycerine is popularly know as glycerine. His final product would be equivalent to glycerine I.W. for industrial purpose by reason of the presence of sorbitol and diethylene glycol. He knew that by addition of diethylene glycol, his final product would be a deadly poison. He also knew that glycerine I.P. is used for medicinal purposes.

74. Jethalal Soni says that Mahendra Doshi never told him that he required glycerine for medicinal purposes. Jethalal Soni's glycerine always contained diethylene glycol or monoethylene glycol, as would any glycerine which is a substitute for I.W. glycerine. This according to Soni is know in the market.

75. He admitted that his product is the result of his own formula not be found in any recognised text book or Merck Index. He admitted that it was to make more money that he invented his own formula whereby his product would be identical to glycerine and yet not be glycerine, by which he meant that the properties of his product would be the same as those of industrial glycerine, namely industrial white. The weight per ml. of his product was about the same as that of pure glycerine, but his product was less viscous than pure glycerine.

76. He knows that I.P. means the standard prescribed by the Indian Pharmacopoeia. For industrial white glycerine, no standards are laid down except by I.S.I., provided the I.S.I. mark is used.

77. If he was given a mixture containing 70 per cent coconut oil and 30 per cent groundnut oil, he would call the product neither the one nor the other but would give a name to it depending upon the purpose for which it was used. If such a mixture was to be used edibly, he would call it coconut oil. He called his product glycerine because it was a substitute for glycerine. His product could not be used as a substitute for sorbitol or diethylene glycol. However he used sorbitol and diethylene glycol because they could be used for producing his substitute or ' chalu ' glycerine.

78. He admitted that his product is cheaper than standard I.S.I. glycerine by half the price and that he mixed sorbitol and diethylene glycol in glycerine and called his product glycerine because the price of glycerine by itself is more than that of diethylene glycol and sorbitol. He also admitted that therefore what he called glycerine manufactured by mixing diethylene glycol and sorbitol with pure glycerine would cost him less than if he were to sell pure glycerine. He also admitted that unless he called his product glycerine, he would not get the same price as he would get merely from the sale of sorbitol or diethylene glycol, and that if his purchasers knew that he was mixing sorbitol and diethylene glycol in pure glycerine, they would not pay him the same price as they would for pure glycerine. When asked why he used glycerine at all in his product, he replied that he did so because he wanted to sell his product as glycerine and that he wanted to sell diethylene glycol and sorbitol in the guise of glycerine. According to him, his product could be called adulterated glycerine.

79. He admitted that he never indicated either by any document or on the drums of his product that it was a substitute for glycerine; that he held out his product to be glycerine I.W. and that he did not display his name or address or identify the commodity though required to do so under the weights and Measures Act professedly out of ignorance of the rules framed under that Act.

80. He professed that all his customers knew what his product actually was, because he himself told them that it was not actually glycerine but equivalent to I.W. glycerine not for medicinal use and issued his invoices accordingly.

81. From Jethalal Soni's evidence and his own admissions, it stands out in bold relief that looking to the fact that he used an infinitesimal percentage of pure glycerine and a preponderantly large percentage of the lethal poisons like

diethylene glycol and sorbitol, it would be a misnomer to call Soni's concoction glycerine which to Soni's knowledge is a dual purpose item. His product was actually diethylene glycol, a deadly poison with a dash of glycerine and was sold by him in the guise of glycerine. Thereby Jethalal Soni was guilty of making representations which were false to his knowledge and of deceiving his purchasers into believing that his product was indeed the product which the name suggested, namely glycerine. He knew that glycerine is a dual purpose item, yet his intention was to pass off his product as glycerine because if he were to call it by any other name, the purchaser might not buy it or if he did, would not pay the price quoted by him. His own admissions reveal that his sole anxiety was to make a larger profit which he could never have done if he had disclosed to his purchasers that diethylene glycol and sorbitol were the components of his product. Being a Chemistry graduate himself, he knew or in any event is deemed to have known that glycerine is a dual purpose item. He knew that diethylene glycol and sorbitol are extremely hazardous to health and are deadly poisons, yet he failed to warn his purchasers of the dangers likely to raise by using his glycerine which he admitted was imitation of " chalu " glycerine. He knows the provisions of the Drugs and Cosmetics Act. It was not for altruistic reasons that he marked his invoices and drums " Not for Medical Use " but for a more mundane purpose, namely to take advantage of Schedule K of the Rules.

82. In this context the evidence of H. M. Chemical's partner Mahendra Doshi is also relevent. He now knows that I.S.I. standard for glycerine is 98 per cent; he came to know this from Jathalal Soni after the J. J. Hospital incident. According to I.S.I. standards, glycerine, whatever its grade be, must contain at least 98 per cent of glycerine.

83. He admitted that in none of his invoices had he ever described the sales of his glycerine as substandard glycerine or as " local glycerine", or " Not For Medicinal Purposes " but as glycerine I.W. and that I.W. glycerine as also " local glycerine " are used in the textile and carbon paper industries. He agreed that glycerine I.W. which he mentioned in his invoices contained ingredients other than glycerine. In the market sub-standard glycerine is sold as I.W. glycerine at a rate lower than I.W. glycerine as per I.S.I. standards. He admitted that the glycerine which he supplied to his customers did not contain minimum 98 per cent glycerine and that what he purchased from Jethalal Soni did not contain the nimimum requirement of 98 per cent glycerine and that there was some other chemical in that product.

84. Mahendra Doshi also admitted that when Jethalal Soni told him that he was manufacturing " local glycerine", he understood that he (Jethalal Soni) did so for industrial purposes, and that it was such glycerine which Mahendra Doshi purchased from Jethalal Soni and supplied to Kailash and Co.

85. Intitially Mahendra Doshi stated that Jethalal Soni had told him that he was preparing local glycerine (" chalu " or substandard glycerine) used as a substitute for a I.W. glycerine. However later Mahendra Doshi admitted that his earlier statement was not correct. He admitted that he knew that the product supplied to him by Jethalal Soni as glycerine was not glycerine according to I.S.I. standards, and that Jethalal Soni's product contained ingredients other than glycerine.

86. He attempted to absolve himself from responsibility by protesting that he never took upon himself of the responsibility of the glycerine sold by him to his purchasers and that every party made purchases form H. M. Chemicals at the party's risk.

87. It was on 1st March 1986 when C.B. Drugs (Control) Inspectors came to him that he learnt that this glycerine had been used for medicinal purposes. He admitted that he did not contact Kailash and Co. though he considered it necessary to give them the information that this glycerine was not intended for pharmaceutical purposes, as by then no useful purpose would have been served.

88. Mahendra Doshi admitted that at the relevant time the price of pure glycerine I.W. in the market was in the vicinity of Rs. 50 per kg. and never in the vicinity of Rs. 40 per kg. Thus it is clear that Mahendra Doshi knew that what he was purchasing at Rs. 30 from Jethalal Soni was substandard glycerine or a misbranded drug. This is borne out from his admission that because Jethalal Soni charged him only Rs. 30 per kg., he did realise that Jethalal Soni was mixing something in his glycerine but made no effort to know what; he did not know ti was some poison.

Mahendra Doshi warned his customers not to use it for medicinal purposes because Jethalal Soni had told him that it was not meant for such purpose. Pausing here for a moment, this is a false statement made by Mahendra Doshi; there is noting to commend it except his *ipse dixit* and particularly in view of the fact that, on his own admission, in none of his invoices had he ever stated that the product was not for medicinal use, even though he knew that glycerine is a dual purpose item also used for medicinal purposes.

89. From the evidence and admissions of Mahendra Doshi there emerges in bold relief that he was aware that glycerine is a dual purpose item also used for medicinal purpose; that Jethalal Soni manufactured ' chalu ' glycerine which H.M. Chemicals purchased from him at Rs. 30 per kg. as against the market rate prevailing of at least Rs. 40 for pure glycerine. Mahendra Doshi's admission that from the price which Jethalal Soni charged him he did realise that Soni was mixing something in his product should have been enough for Mahendra Doshi to put him on his guard, making it his bounden duty to disclose to his customers that Soni's product was not pure glycerine and could not be used for medicinal purposess. Mahendra Doshi cannot evade responsibility merely by his ipse dixit that whosoever purchased from him did so at his own risk. It is apparent that regardless of the nature of the product he purchased from Jethalal Soni, Mahendra Doshi's intention was merely to make an excessive profit, namely Rs. 10 per kg., by not disclosing to his own purchasers the real nature of the product because if he had done so, he would not have been paid the price he demanded.

90. It is also manifest that Mahendra Doshi sold Jethalal Soni's concoction as a drug, because he did not describe it in his invoice as " Not For Medicinal Purpose". Hence it is reasonable to come to the conclusion that he was selling mibranded drug within the meaning of Section 17 of the Drugs Act.

91. There is no doubt that in attempting to absolve themselves from liability, Mahendra Doshi, Girdhar Kasat, Bharat Kasat and Jethalal Soni have now jointed hands. This is brought to the force by the admissions both of Mahendra Doshi as also Jethalal Soni that the letter dated 26th October 1985 from Ganesh Chemicals
Ex. 640 to H. M. Chemicals (Ex. 640) and H. M. Chemicals' challans dated 5th November
Ex. 641 (colly.) 1985 and 13th November 1985 pertaining to the return of one drum each [Ex. 641 (collectively)] were disclosed for the first time in evidence before this Commission and never before to anyone including the police or the FDA. As stated earlier, these documents appear to be subsequently prepared in order to evade responsibility.

92. This brings me to the breach of the provisions of the Drugs and Cosmetics Act, 1940 (referred to hereafter as " the Act ").

93. The Act was enacted to regulate amongst other things the manufacture, distribution and sale of drugs and cosmetics. *'Drug' is defined in Section 3(b)* as uncer :

" (b) " drug " includes—

(*i*) all medicines for internal or external use or human beings .... and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings.... ;

(*ii*) such substances .... intended to affect the structure or any function of the human body .... as may be specified from time to time by the Central Government by notification in the Official Gazette ;

* * * * * * * * * ; and

(*iv*) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings .... as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board. "

Glycerine is indisputably a drug falling under Section 3(*b*).

94. Chapter IV of the Act pertains to " MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS " (" AND COSMETICS " with which we are not concerned). Section 17-A sets out what shall be deemed to be adulterated drugs, to wit,—

* * * * * * * * *

(*e*) if it contains any harmful or toxic substance which may render it injurious to health ; or

(*f*) if any substance has been mixed therewith so as to reduce its quality or strength. "

Section 17-B sets out what shall be deemed to be spurious drugs, to wit,—

"* * * * * * * * *

(*d*) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its lable or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or

* * * * * * * * *

(*d*) if it has been substituted wholly or in part by another drug or substance; or

* * * * * * * * * "

From Section 17-A and 17-B it is manifest that the "chalu glycerine" manufactured by Jethalal Soni, containing as it did a preponderance of diethylene glycol which is a lethal posion and the minimum of pure glycerine, which ultimately found its way to the J. J. Hospital, was both an adulterated drug and a spurious drug, and known to be so to Jethalal Soni, Girdhar Kasat, Bharat Kasat, Mahendra Doshi and Girish Doshi.

95. Part XI of the Act pertains to "EXEMPTIONS". Section 123 exempts the drugs specified in Schedule K from the provisions of Chapter IV of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule. The relevant excerpts from Schedule K are as under :—

"SCHEDULE K

(*See* Rule 123)

Class of Drugs	Extent and Conditions of Exemption
1. Drugs falling under clause (*b*)(*i*) of Section 3 of the Drugs and Cosmetics Act, not intended for medicinal use.	All the provisions of Chapter IV of the Act and the Rules thereunder, subject to the conditions that the drug is not sold for medicinal use or for use in the manufacture of medicines and that each container is labelled conspicuously with the words 'NOT FOR MEDICINAL USE'.
* * * * * * * * *	* * *

Thereby drugs falling under Section 3(*b*)(*i*) are exempted from all the provisions of Chapter IV of the Act and the Rules if such drug is not sold for medicinal use or for use in the manufacture of medicines, and each container is conspicuously labelled " NOT FOR MEDICINAL USE ".

96. It is true that Jethalal Soni did label his drums " Not for Medicinal Use " and that these 2 drums ultimately came to Alpana Pharma. However Soni labelled his drums thus not from altruistic motives but to attract the exemption given by Schedule K and in the teeth of his knowledge that what he manufactured was a concoction containing a lethal posion and which concoction he passed off as glycerine, a dual purpose item. Even though Kasat and Doshis were aware that glycerine is a dual purpose item, the invoice No. 007, dated 23rd November 1985 sent to Alpana Pharma was not marked, but the concoction was sold to Alpana Pharma as a drug. Hence the exemption provided by Schedule K will not apply to any of them and to each of them the penalty under Section 27 for breach of Sections 17-A and 17-B will be attracted.

97. Section 27 of the Act provides for penalty for manufacture, sale, etc., of drugs in contravention of Chapter IV. Section 27 reads as under :—

" Penalty for manufacture .... Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution or sells ....—

(*a*) any drug deemed to be adulterated under Section 17-A or spurious under Section 17-B or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause

his death .... solely on account of such drugs being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees ;

*** *** ***

98. In addition, Section 2 of the Act is also attracted to each and every one of them. Section 2 pertains to the application of other laws not barred. It reads as under :—

" The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 (2 of 1930), and any other law for the time being in force. "

99. Section 299 of the Indian Penal Code defines culpable homicide as under :—

" Whoever causes death by doing an act with the intention of causing death, or with the intention of causing such bodily injury as is likely to cause death, or with the knowledge that he is likely by such act to cause death, commits the offence of culpable homicide. "

While evidence does not disclose intention on the part of any of these persons to cause death, there is overwhelming evidence that the act of each one of them was "with the knowledge that he is likely by such act to cause death". Thus all these persons are guilty of culpable homicide.

100. *What is the nature of this culpable homicide* ? Is it culpable homicide amounting to murder under Section 300 or is it culpable homicide not amounting to murder punishable under Section 304 ?

101. Under Section 300 culpable homicide is murder if the act by which the death is caused is done with the intention of causing death; or secondly if it is done with the intention of causing such bodily injury as the offender knows to be likely to cause the death of the person to whom the harm is caused; or thirdly if it is done with the intention of causing bodily injury to any person and the bodily injury intended to be inflicted is sufficient in the ordinary course of nature to cause death ; or fourthly if the person committing the act knows that it is so imminently dangerous that it must, in all probability, cause death or such bodily injury as is likely to cause death, and commits such act without any excuse for incurring the risk of causing death or such injury as aforesaid.

102. Section 304 of the Indian Penal Code reads as under :—

" Whoever commits culpable homicide not amounting to murder, shall be punished with imprisonment for life, or imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine; if the act by which the death is caused is done with the intention of causing death, or of causing such bodily injury as is likely to cause death ;

" or with imprisonment of either description for a term which may extend to ten years, or with fine, or with both, if the act is done with the knowledge that it is likely to cause death, but without any intention to cause death, or to cause such bodily injury as is likely to cause death,— ".

103. Unfortunately in the facts and circumstances of this case and on the evidence on record, it is with great reluctance that I must perforce come to the conclusion that Sections 300 and 304 are not attracted because from the evidence on record Jethalal Soni cannot be imputed with the knowledge that his concoction would be used internally or as a drug and was therefore likely to cause death. While Doshi and Kasat and O. P. Ladda knew that Jethalal's concoction would be used as a drug, the evidence does not disclose that they had any knowledge that it contained the poisonous diethylene glycol or for that matter any poison at all. Further on the evidence on record it would be impossible to come to the conclusion that either Kasat or Doshi or O. P. Ladda had any intention to cause death.

104. It is in these circumstances, alive as I am to the fact that not less than 14 innocent lives were lost by reason of the ingestion of the contaminated glycerol, under the law as it stands I find myself unable to attract the provsions either of Section 300 or Section 304 of the Indian Penal Code to any of these persons.

105. However the section which can be applied to them all is Section 304-A of the Indian Penal Code. It runs as under :—

" Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine or with both. "

106. It is ironical that under Section 304-A of the Indian Penal Code, the maximum punishment in a case as heinous as this should only be two years. Unfortunately in the state of the law as it stands that cannot be helped. However a ray of sunshine is that under section 27(a) of the Drugs and Cosmetics Act, 1940, the penalty for manufacture for sale, distribution, etc. of drugs in contravention of Chapter IV is a minimum of 5 years which may extend to a term of life and fine which shall not be less than Rs. 10,000.

107. In my opinion, instead of resorting to prosecution against the abovementioned persons under section 304-A of the Indian Penal Code only, it would be in the fitness of things that prosecutions should also be launched under the Drugs and Cosmetics Act, 1940, against the following persons attracting the Penalty under section 27(a) of the Act. They are Mahendra Doshi Girish Doshi, Girdhar Kasat, Bharat Kasat and O. P. Ladda.

108. If after enquiry Government finds that as a result of the ingestion of this glycerol other deaths or injuries have been caused to other persons, the same provisions of the Drugs and Cosmetics Act, 1940, be resorted to as also to section 304-A I. P. C. where other deaths have resulted, or to Section 338 I. P. C. where grievous hurt has been caused.

CHAPTER XIII

PART I

1. This brings me to the FDA and its set-up.

(*a*) The set-up of the FDA is constituted under the Drugs and Cosmetics Act, 1940 to control *inter alia* manufacture, distribution and sale of drug (and cosmetics with which this Report is not concerned). The FDA is a controlling factor of the drugs industry in Maharashtra, which has an annual turnover of Rs. 2,000 crores.

(*b*) Under the Act only two posts are prescribed, namely Indpectors and the Licensing Authority. Various posts like Commissioner, Joint Commissioners and Assistant Commissioners are not to be found in the Act, but are created by Government Notifications, Rules and Regulations. From 1982 all Chief Inspectors have been designated as Assistant Commissioners.

(*c*) The set-up is the Commissioner and 6 posts of Joint Commissioner, out of which5 are attached to the Drugs Department and one to the Food Department. In hierarchy come the Commissioner, Jt. Commissioners, Asstt. Commissioners and Inspectors.

(*d*) There are 5 Divisions in Maharashtra, namely (*i*) Head Quarters, (*ii*) Nagpur Division, (*iii*) Aurangabad Division, (*iv*) Thane Division and (*v*) Bombay Division, which includes Greater Bombay. All these Divisions are controlled by Head Quarters. Each Division is headed by a Jt. Commissioner.

(*e*) At Head Quarters which has overall control, is the Commissioner and Jt. Commissioner who is appointed as the Licensing Authority. The Commissioner is the controlling authority. He supervises the work of all the Divisions. As Commissioner, he is ex-officio member of the CSPO and ESIS. Amongst his other powers, he is empowered to sanction prosecutions.

(*f*) In Head Quarters the powers and authority of the Jt. Commissioner are greater than those of the other Jt. Commissioners as the former is the only statutory Licensing Authority for the entire State of Maharashtra. As Jt. Commissioner and Licensing Authority (HQ) he receives applications for licences which he is empowered to grant or refuse. In addition, he approves the technical staff, the lay-out of the premises and grants various certificates including performance and non-conviction certificate under the Drugs and Cosmetics Act. He is empowered to take action by way of issuing show cause notices in respect of contraventions of conditions of licence.

(*g*) The FDA has 4 main branches, namely:—

(*i*) Administration and control of the quality of drugs,

(*ii*) Administration and control of the manufacture of drugs,

(*iii*) Analytical Laboratory (Drugs Control Laboratory),

(*iv*) Intelligence branch which investigates into spurious and sub-standard drugs.

(*h*) *Drugs Control Laboratory.*—(*i*) At an average 500 samples are tested mostly in this laboratory. Its personnel comprises of 4 Senior Scientific Officers (Class I), 15 Scientific Officers (Class II), Administrative Officer and Chemists (Junior Analysts).

(*ii*) Each Inspector is entitled to send to the Drugs Control Laboratory 6 samples at the highest. On the sample being analysed, reports are prepared in sextuple. There are sent to the Drugs Inspector concerned, one to the Commissioner, one to the Drug Controller of India and one is retained by the Government Analyst. Out of the three copies sent to the Drugs Inspector he must send one to the manufacturer, one to the person from whom the sample was drawn and one is retained by him. The Commissioner's copy goes to the Analytical Report Section (ARS) of the FDA. The ARS forwards it to the Jt. Commissioner and Licensing Authority who on such report is entitled to recommend action. Thereafter the report with the Licensing Authority's recommendation is returned to the ARS which will take the necessary action under the supervision of the Jt. Commissioner.

(*i*) (*I*) The Government Analyst Dr. R. D. Pilankar has under him 22 analysts. According to Dr. Pilankar the area of the Analytical Laboratory is 3000 to 4000 sq.ft. and 1500 sq. ft. more are required.

(2) Chemicals and glasses necessary for testing are regulated by rate contracts, hence there is often delay in testing because chemicals and glasses are not available in time.

(*j*) Under the Act the FDA does not control production of drugs except by way of granting licences which will regulate the manufacture of drugs.

(*k*) FDA Inspectors are required to inspect the premises of the licence-holders, namely manufacturers, repackers, shops, etc. at least twice a year. However, administratively it is ordered that an Inspector is required to make inspection visits at least 19 times in a month.

(*l*) In Maharashtra there are 3500 licensed manufacturing units. In addition, there are 4000 loan licence manufacturers, namely those who manufacture drugs in the premises of licensed owners using the staff of the latter. 10 per cent of these 3500 units in Maharashtra do not have in-house drugs testing laboratories in their own premises. However, contrary to the provisions of the Act, licences are granted to such manufacturers/repackers on their giving a written undertaking to have an in house laboratory installed within 2 months. A Nelson's eye was turned to breaches of such undertakings and they were never enforced.

(*m*) In Nanded (having an area of 10,000 sq. kms.) where Alpana Pharma was situate, there were two posts of Inspectors in 1984-85. However one post was vacant throught out and one Inspector who was functioning had to look after 306 drugs selling units and 16 manufacturing units.

Such is the set-up of the FDA.

PART II

2. From the evidence on record, the following facts emerge in grisly detail :—

(*i*) The entire structure of FDA, at one time a prestigious body famous in all Asia, has been corroded by rampant and unabashed corruption, deleterious indiscipline, naked favouritism, crude nepotism and gross ministerial interference at every stage and a sense of non-accountability all round.

(*ii*) As a result, there is hardly any control or supervision by superiors over their subordinates in the matter of carrying out their statutory obligations and strict compliance with the provisions of the Act and Rules which are deliberately breached and knowingly flouted.

(*iii*) Health Ministers who have given evidence have rarely shown any anxiety to control the unbridled power and authority of the FDA officers. On the contrary, such Health Ministers have encouraged corruption, favouritism, deliberate violation of the Act and Rules by their own acts of omission and commission intentionally and knowingly performed with a view to confer favours or ministerial largesse in the form of transfers and postings of choice, underserved promotions of FDA officers and concessions, cancellation of stringent orders or withdrawal or withholding of mandatory prosecutions in accordance with the provisions of the Act against the licencees, *viz.* manufacturers, repackers, etc.

(*iv*) From the evidence on record, it will by my duty to conclude that the respective Health Minister not only failed to discharge their duties in ensuring proper enforcement of the provisions of the Act and Rules but each of them was guilty of violating the provisions of the Act and Rules and of gross mis-use of their position, power and authority, knowingly done for extraneous considerations and for all considerations other than equity, justice and good conscience required of them in the discharge of their duties.

(*v*) Every Health Minister who has given evidence, has not allowed FDA to function as an independent organisation vested with certain power and authoriy and obligated to ensure public health and safety by properly regulating the manufacture, sale and distribution of drugs and preventing manufacture, sale and distribution of sub-standard, spurious and mis-branded drugs; and have thereby rendered FDA to be an important organisation, existing merely for collection of licence fees officially and vast sums of money unofficially.

(*vi*) Gross ministerial interference, mis-use of powers and failure to enforce the provisions of the Act and Rules in all matters have been done for the benefit of or to suit the convenience of licence holders with the knowledge of the same being against public interest, public health and public safety.

(*vii*) Most of the Health Ministers who gave evidence and FDA officers lack basic knowledge or understanding of the provisions of the Act and Rules and/or their respective duties and/or thier authority thereunder.

(*viii*) Attempts to improve the working and restore the image of the FDA and to root out corruption were deliberately thwarted by officers of the FDA with the active connivance of the Health Ministers concerned.

(*ix*) Large powers are vested in the Jt. Commissioner (Head Quarters) who is the Licensing Authority. He is not even amenable to the supervision and control of the Commissioner. Subject to an appeal to the Minister, the Licensing Authority is the final authority and last word in matters vitally concerning the licence holders. Such vast and untramelled powers in the hands of an unscrupulous Jt. Commissioner and Licensing Authority were an instrument of harassment and a device to make vast sums of money added to the inducement of the manufacture of sub-standard, spurious and mis-branded drugs and total lack of fear of the consequences provided by the Act and Rules.

(*x*) The procedure followed by the FDA for granting licences is faulty and contrary to the provisions of the Act and Rules and is deliberately moulded to suit the convenience of the licence holders instead of protecting the interest and health of the general public, for which the FDA is intended to function.

(*xi*) The procedure for inspection before and after grant of licence is not only defective and faulty, but is also grossly inadequate and contrary to the provisions of the Act and Rules.

(*xii*) FDA has formulated certain policies and procedures which are not only contrary to the provisions of the Act and Rules but are in violation of the stringent provisions therein and are highly dangerous from the point of view of public interest, public health and public safety.

(*xiii*) These policies are formulated and procedures followed only with a view to benefit the licence holders and to circumvent the stringent requirements of the law.

(*xiv*) There is hardly any machinery worth the name in the FDA to take up any follow-up action after grant of licence and/or receipt of complaints against manufacturers.

(*xv*) Records maintained by FDA in respect of receipt of complaints and/or follow-up action are faulty, inadequate, and misleading. Thereby recurring breaches are permitted to go unnoticed and/or unpunished.

(*xvi*) For the FDA, penal provisions of the Act and Rules, even though mandatory, do not exist. These penal provisions have deliberately not been enforced in almost all cases. Such actions, if taken, by the FDA against erring licence holders, are initiated after procrastination and reluctance, by which time the mischievous drug, be it a life saving drug continues to be sold to an unwary public and continues to be prescribed by unwary medical practitioners.

(*xvii*) The Analytical Laboratory of the FDA is ill-equipped and inadequate to meet the requirements of sampling. There is no guarantee that the samples are correctly analysed as records maintained of the analysis are not such as to inspire confidence as to their accuracy or veracity.

(*xviii*) Even though, subject to an appeal to the Central Drug Laboratory, the report of the Government Analyst is final and binding on all concerned including FDA, the FDA has omitted to abide by or follow such reports so as to favour licence holders for extraneous considerations.

PART III

3. In order to make good these assertions, I shall start with the investigation conducted by the FDA regarding the J. J. Hospital tragedy. To that end, the evidence on record also discloses in stark reality—

(*a*) The investigation was faulty, slipshod, leisurely and deliberately defective and misleading.

(*b*) Either the FDA did not know how to tackle the situation (which is difficult to believe) or it deliberately omitted to take steps for expeditious investigation or to file a legally sustainable complaint against Alpaha Pharma.

(c) The FDA investigation is barred by group rivalries, the desire to undermine the work of colleagues, casualness of approach, negligence and dereliction of duty resulting in faulty clues being pursued and the correct clues being ignored.

(d) The provisions of the Act and Rules with minor variations are adequate to serve the purpose for which they are enacted. However lack of integrity on the part of those in charge of the enforcement of the Act has resulted in the present situation. The improvements will have to include proper enforcement of the provisions of the Act and from time to time accountability to the general public in that behalf.

PART IV

4. The FDA investigation can be divided into two heads, namely investigation at Nanded and Investigation at Bombay.

5. On 28th January 1986, samples of glycerol Batch No. 27 were taken by the FDA from the J. J. Hospital. The following day, namely on 29th January 1986, a meeting was held in the chamber of Commissioner Bhirud where it was decided to inform the Nanded office about certain steps to be taken there. That day Asstt. Commr. Raykar tried to telephonically contact the FDA office at Nanded but was unable to get through. Thereupon at 1-30 p.m. he telephoned the FDA's Aurangabad office and told Jt. Commr. Rahim that 10 patients had died in the J. J. Hospital due to administration of Alpana Pharma glycerol Batch No. 27, that the Nanded office should seal the drums, take them into their custody, draw samples and prohibit the stock.

6. According to Jr. Commr. Rahim, Asstt. Commr. Raykar told him that Batch No. 27 may contain diethylene glycol and that he noted down this telephonic conversation on a piece of paper. This version is denied by Asstt. Commr. Raykar, according to whom he did not give any such information to Jt. Commr. Rahim nor could he have done so as the presence of diethylene glycol was not then known to Raykar himself.

INVESTIGATION AT NANDED

(a) *29th January 1986.*—(i) Pursuant to Raykar's tel phone call to Jt. Commr. Rahim that day, Rahim telephoned Inspector Babne at 2-00 p.m. and gave him the message as delivered by Raykar to Rahim. According to Rahim, he told Babne that it was likely that the glycerol contained diethylene glycol. This version is corroborated by Inspector Babne in his evidence.

(ii) At 3-00 p.m. Babne went to Alpana Pharma. O. P. Ladda who was there showed Babne the stock of Batch 27. Babne drew four samples, prohibited the stock and seized certain documents. He also saw the drum. Ladda told Inspector Babne that he, i.e. Ladda, had the requisite test reports, which Babne saw. He also saw the bill of Kailash and Co. Babne searched the premises for diethylene glycol but did not find any. Babne made his report (Ex. 410). Ex. 410

(iii) At that time the Asstt. Commr. at Nanded was S. D. Kamble. He was at Aurangabad. At 10-30 p.m. he returned to Nanded and contacted Babne the same night. Babne reported to him all that had transpired.

(iv) Asstt. Commr. Kamble thereupon telephoned Asstt. Commr. Bhange at Aurangabad and reported to him what Babne had told him and asked Bhange to pass on this report to Asstt. Commr. Kochar at Bombay.

(v) The same night, Asstt. Commr. Kamble sent phonograms to the Civil Surgeons of various hospitals not to use Alpana Pharma's glycerol Batch No. 27.

(b) *30th January 1986.*—(i) Asstt. Commr. Kamble telephoned Commr. Bhirud but Kamble's message was taken by Asstt. Commr. Kochar that Alpana Pharma's supplier was Kailash and Co.; Kamble gave Kochar the bill number of Kailash and Co.

(ii) Thereafter at 11-00 a.m., Asstt. Commr. Kamble received a call from Asstt. Commr. Bhange asking that samples should be drawn and that the drum should be seized. This was done by Kamble at 2-00 p.m. and he made his report (Ex. 411). Ex. 411
The panchanama of the seizure of the drum is Ex. 399 and the drum is Ex. 391. Exs. 399 and 391

(c) *31st January 1986.*—(i) Asstt. Commr. Kamble and Inspector Babne went to Nanded Police Station to logde an F.I.R. against Alpana Pharma and to get Ladda arrested. However this trip proved futile as the police officer was not present at the police station. Thereupon Kamble and Babne returned to the FDA office at 8-15 p.m.

Ex. 413 (*ii*) There Kamble prepared his Note (Ex. 413) to Asstt. Commr. Dolas at Bombay, stating that as Batch No. 27 repacked by Alpana Pharma was not tested for analysis by the repacker after it was repacked and was released for sale as such in the market without prior analysis, it was necessary to lodge an F.I.R. at Nanded and to arrest the partner of Alpana Pharma. Necessary orders were solicited by Asstt. Commr. Kamble by this note.

(*iii*) Asstt. Commr. Kamble received a telephone call from Asstt. Commr. Kochar in Bombay asking Kamble to draw samples of empty plastic bottles in the premises of Alpana Pharma. Accordingly Asstt. Commr. Kamble deputed Inspector Babne to do so. However Babne found Alpana Pharma's premises closed. Hence Babne posted a police constable and sealed the factory.

(*iv*) Asstt. Commr. Kamble sent letters and made telephone calls to Asstt. Commrs. in the various districts to prohibit the stock of Alpana Pharma Batch No. 27.

(*d*) *1st February 1986.*—(*i*) In the morning Babne accompanied by two panchas visited Alpana Pharma's factory and in the presence of O. P. Ladda's mother (also a partner in Alpana Pharma) after breaking open the seal took charge of the samples of the plastic bottles.

(*ii*) At 4-00 p.m. Kamble received a telephone call from the Bombay (HQ) asking him to remain present at a meeting fixed on 3rd February 1986 in Commr. Bhirud's chamber.

(*e*) *2nd February 1986.*—Kamble proceeded to Bombay carrying with him the relevant records which had been seized by the FDA from the premises of Alpana Pharma.

(*f*) *5th February 1986.*—Kamble returned to Nanded.

(*g*) *6th February 1986.*—(*i*) Kamble handed over to Babne a draft complaint against Alpana Pharma and told Babne to file it in the Court at Nanded by 8th February 1986.

(*ii*) Apparently Kamble found the evidence against Alpana Pharma not to be sufficient, hence he decided to look for more evidence. As a result, Kamble directed Inspector Babne to visit the premises of Alpana Pharma. Babne did so, but Ladda was not there. Hence Babne spent the night outside Alpana Pharma's premises.

(*h*) *7th February 1986.*—(*i*) At 6-00 a.m. Kamble went to Alpana Pharma and relieved Babne and posted another Inspector outside Alpana Pharma.

(*ii*) At 6-00 p.m. Kamble and Babne returned to Alpana Pharma where Kamble
Ex. 389 seized certain documents including Alpana Pharma's bin card (Ex. 389) under a
Ex. 415 panchanama (Ex. 415).

(*i*) *8th February 1986.*—At 2-00 p.m. Kamble and Babne went to Alpana Pharma
Ex. 416 and asked Ladda to produce certain documents. Ladda's statement (Ex. 416)
Ex. 417 was recorded and certain documents (Ex. 417) were seized included Chem Med's report.

(*j*) *9th February 1986.*—Kamble re-drafted the complaint against Alpana Pharma.

(*k*) *10th February 1986.*—Kamble filed the complaint against Alpana Pharma in the Court at Nanded.

(*l*) *11th February 1986.*—Kamble asked Babne to carry out further investigation in Bombay and to submit a search and seizure report. To that effect Babne's sub-
Exs. 418, 419 mission is Ex. 418 and the report is Ex. 419. In para 14 of his report Babne stated that investigation in Bombay is necessary. Presumably suspicion had already been formed in Kamble's mind that the prime source of supply, namely Bakewell (India) mentioned in the complaint may not be the correct source.

(*m*) *13th February 1986.*—Dolas went to Nanded carrying with him the show
Ex. 659 cause notice for cancellation of Alpana Pharma's licence (Ex. 659) for service on Alpana Pharma. Accordingly service was effected. This according to Dolas was the only reason why he went to Nanded, because on his own showing he did nothing there.

(*n*) *20th February 1986.*—Kamble wrote a letter (Ex. 420) to Commr. Bhirud
Ex. 420. pointing out that additional charges were required in the complaint against Alpana Pharma and requested the Commissioner to make investigation in Bombay and to see that Kailash and Co. was also joined as a co-accused in the complaint.

(o) *21st February 1986.*—Kamble was trnasferred to Buldana and Babne to Chandrapur. (As will appear hereafter, this was done at the instance of Health Minister Bhai Sawant.)

(p) *27th February 1986.*—Kamble wrote a letter to Commr. Bhirud setting out the details of the investigation done by him until his transfer. In the last para of that letter Kamble stated that it was necessary to lodge an F.I.R. in Bombay against Alpana Pharma and that this should be done by the Commissioner.

(q) *28th May 1986.*—Kamble was served with a show cause notice for certain discrepanices in his investigation. On merits no reply was sent by Kamble on the ground that the present Commission of Inquiry was in progress and that he would do so thereafter.

7. From the above it is more than manifest that no fault can be found with the investigation carried out at Nanded. At the earliest point of time, Kamble and Babne took charge of the relevant documents from Alpana Pharma including Chem Med's report, drew samples seized the drums and recorded O. P. Ladda's statement. From the very beginning, Kamble was not satisfied with the manner in which the complaint against Alpana Pharma was drafted and having formed the suspicion that Backwell (India) may not be the prime source of supply, had insisted that investigation should be carried out in Bombay and that additional charges should be framed in the complaint making Kailash and Co. as the co-accused. It is also manifest that because of the energy and independence shown by these two officers, as will appear presently, at the behest of *Health Minister Bhai Sawant* they were transferred to Buldana and Chandrapur respectively on 21st February 1986 while the investigation had not yet been completed, presumably to get these 2 "inconvenient" officers out of the way.

PART V

8. Since I have alluded to the fact that Kamble was not satisfied with the draft complaint prepared by Asstt. Commissioner Kochar, it is in the fitness of things that I should, at this stage, refer straight away to the draft complaint.

9. It may be recalled that in the Commissioner's meeting of 3rd February 1986 Asstt. Commissioner Kamble had reiterated that a prosecution must be filed against Alpana Pharma. Curiously enough, *none of the other officers present* at that, meeting, namely Commissioner Bhirud, Jt. Commissioner Dolas, Asstt. Commissioner Kochar, Raykar and Dani, seem to have been exactly enthusiastic about Kamble's proposal. If Raykar and Dani were not they may be excused looking to the fact that in hierarchy they were junior to Bhirud and Dolas. However for Commissioner Bhirud, Jt. Commissioner Dolas or Asstt. Commissioner Kochar, himself in the Intelligence Branch, there was no excuse for filing a defective complaint which could only result in the acquittal of Alpana Pharma as is obvious from what follows.

10. On 3rd February 1986 Mahendra Doshi, partner of H.M. Chemicals wrote a letter to the FDA (Ex. 397) stating that he was not in his office when FDA officers had come on 31st January 1986 and that he had visited the office of the FDA regarding the inquiry made by the FDA officers. Mahendra Doshi went on to say that his firm of H. M. Chemicals deals in chemicals such as glycerine I. W. and had supplied tow drums of 250 kgs. each of glycerine I.W. to M/s Kailash and Co. under invoice dated 23rd November 1985, that this glycerine had been purchased by H. M. Chemicals from Ganesh Chemical Corporation, Mulund, Bombay, and that Mahendra Doshi would produce a copy of the purchase invoice within two or three days. Ex. 397

11. H. M. Chemicals' letter dated 3rd February 1986 clearly indicates the original source of supply, viz. Ganesh Chemicals. By this letter the eyes of the FDA officers should have been opened wide enough to direct their investigation against Ganesh Chemicals as the prime supplier, ending with Alpana Pharma as the ultimate purchaser. No clue could have been more obvious. Even so, no inquiry was directed against Ganesh Chemicals for 16 days thereafter. Thus latest on 3rd February 1986 by virtue of H. M. Chemicals' letter dated 3rd February 1986 (Ex. 397), these three highranking FDA officers, namely Commissioner Bhirud, Jt. Commissioner Dolas and Asstt. Commissioner Kochar of Intelligence Branch, had enough material to detect the prime source of supply, namely Ganesh Chemicals. Yet it was on 19th February 1986 for the first time that inquiries were made with Ganesh Chemicals and until 12th February 1986 no inquiries were made with Chem Med despite the fact that by this time the test reports sent by Chem Med had been received by the FDA independently.

12. The further significance of this letter is that Kamble's suspicion regarding Bakewell as not being the prime supplier should have struck a responsive chord in the minds of Commissioner Bhirud, Jt. Commissioner Dolas and Asstt. Commissioner Kochar. Instead for some mysterious reason, instead of immediately directing inquiries againt the prime supplier, Ganesh Chemicals, inquiries were directed against Bakewell (India), despite Kochar's knowledge that Bakewell's glycerine could not be connected with Alpana Pharma's Batch No. 27 for which there was no documentary evidence. It was Kochar who did not immediately follow the obvious
Ex. 397 clue given by H. M. Chemicals' letter dated 3rd February 1986 (Ex. 397) indicating Ganesh Chemicals as the prime source of supply and instead indulged in futile and time consuming investigation against Bakewell in order to save Kailash and Co. because there was reasonable suspicion that there was something radically wrong in the glycerine supplied by Ganesh Chemicals which was known at least to Kochar who therefore prevented inquiries being made with Ganesh Chemicals and Kailash and Co. until 19th February 1986.

13. On 4th February 1986, Kamble again asked Dolas and Kochar for permission to file a complaint against AlpanaPharma. Dolas gave permission to Kamble to do so and Kochar was assigned the task of drafting it. However Kamble was refused permission to lodge an F.I.R. with the police.

14. *Why was attention deliberately diverted to Bakewell (India).*—So as to save the manufacturer, namely Ganesh Chemicals, who though himself had no clout with the FDA, got an indirect advantage because the persons primarily intended to be saved were Kasat. For that purpose H. M. Chemicals' letter dated 3rd February
Ex. 397 1986 (Ex. 397) pointing out the correct facts had to be ignored as long as possible and that was done till 19th February 1986. Ignoring such a vital clue and the information given by H. M. Chemicals in its letter dated 3rd February 1986 would be unthinkable unless an officer of the FDA wanted to favour Kasat because it was ultimately for the FDA either to ignore H.M. Chemicals' letter dated 3rd February 1986 or not.

15. I refuse to subscribe to the thought that nobody in the FDA applied his mind to the importance of H. M. Chemicals' letter dated 3rd February 1986 because positive steps were taken by Asstt. Commissioner Kochar but in exactly the opposite direction by ordering investigation against Bakewell (India) when he should have taken the obvious steps by directing investigation against the prime supplier Ganesh Chemicals under the clue provided by H. M. Chemicals' letter dated 3rd February 1986. If this had been done Kasat would have come into the picture and Kasat had to be protected.

16. Which FDA officer is the real and active culprit ? Commissioner Bhirud himself did not take part in the investigation but supervised it. Jt. Commissioner Dolas did not apply his mind except for the purpose of saving the analytical laboratories, namely Chem Med and Apex. To them can be attributed negligence and dereliction of duty and also to Asstt. Commissioner Dani and Raykar, though to a lesser degree as they were junior in hierarchy to speak up for themselves. The real and active culprit was Kochar who was virtually in charge as is also indicated by the fact that it was to Kochar that earlier Kamble and Bhange had spoken over the telephone from Nanded and Aurangabad. Kochar was in the Intelligence Branch and this investigation fell within Kochar's courtyard. He could advance it or impede it by not at once following up the vital information given in H. M. Chemicals' letter dated 3rd February 1986.

17. For these reasons it was important and in Kasat's interest to see that a defective complaint should be filed against Alpana Pharma at Nanded suppressing the fact that the prime supplier was Ganesh Chemicals and the other facts mentioned
Ex. 397 in H. M. Chemicals' letter dated 3rd February 1986 (Ex. 397).

Ex. 384-B 18. Kochar himself prepared the first draft of the complaint. It is Exhibit 384-B. In para 16 of that draft it is stated as under :—

> " 16. That the enquiries revealed that batch No. 27 of Glycerine was repacked from the drums received from M/s. Haresh Chemicals, Bombay-2 and who in turn had purchased from Back way India has imported the said glycerine from Italy. That the enquiries revealed that the plastic containers used to repack glycerine were purchased by the accused from M/s. . . . . " (sic).

The reference in para 16 to Bakewell India (erroneously spelt Back way India) as the supplier was a deliberately false and misleading statement in the teeth of H. M. Chemicals' letter dated 3rd February 1986 that the prime supplier was Ganesh

Chemicals. *Suggestio falsi.* There is also *suppresio veri*, namely, (*i*) that Ganesh Chemicals was the prime supplier; (*ii*) that Kailash and Co. was the immediate supplier to Alpana Pharma; (*iii*) that the sample was analysed by Chem Med; (*iv*) that the Government Analyst Dr. Pilankar had on 3rd February 1986 stated that the sample analysed by him was found to be substandard; and (*v*) that in the light thereof Chem Med's report to the contrary was incorrect. All this was suppressed.

19. Kochar knew that Alpana Pharma was only the repacker and alone could not be held responsible and that the prime supplier, viz. Ganesh Chemicals was also responsible. He also knew that if the prime supplier; namely Ganesh Chemicals, was to be made responsible, Kasat could not be saved. Thus in Kochar's anxiety to save Kasat he indirectly saved the prime supplier, namely Ganesh Chemicals, and made a false statement in para 16 of the draft complaint inculpating Bakewell (India) as the prime supplier, knowing full well that Bakewell (India)'s glycerine imported from Italy was not the killer glycerine of Batch No. 27. Kochar even tried to throw the blame indirectly upon the containers on the ground that they were plastic containers.

20. From the first draft Ex. 384-B, a fair draft Ex. 384-A was prepared. In para 16 of the latter the contents of para 16 of the former were reproduced. However in the margin of para 16 of the fair draft, are to be found the words in ink, "subject to change". This was written because of Kamble's insistence that the name of Kailash and Co. must be incorporated in para 16, which met with resistance from Kochar. Hence in para 17 of the complaint filed in the Court at Nanded, a compromise was reached whereby a change was effected by inserting the name of Kailash and Co. as Alpana Pharma's immediate supplier and retaining the rest of para 16 of the fair draft. Para 17 of the complaint as filed in the Nanded Court reads as under :—

> "17. That the enquiries also revealed that Batch No. 27 of Glycerine repacked by the accused firm was repacked from the drums received by it from M/s. Kailash and Co., Bombay-2 who in turn had purchased it from Back Way India, Deonar, Bombay and that M/s. Back Way India had imported the said Glycerine from Italy. That the enquiries revealed that the accused firm had purchased the plastic container used by it to repack that Glycerine from M/s. PRASAN UDYOG, BOMBAY-22."

The mischief of this was that though Kamble knew that Alpana Pharma's supplier was Kailash and Co., he did not know who the suppliers of Kailash and Co., were. This was know to Kochar as H. M. Chemicals had in their letter dated 3rd February 1986 Exihibit 397 stated that they, i.e. H.M. Chemicals had made the supply to Kailash and Co. Hence Kochar was perfectly safe in giving the name of Kailash and Co. as the purchaser from Bakewell (India). Thus Kochar ensured that the prosecution would fail as the prime source of supply was, to Kochar's knowledge not Bakewell (India). Ex. 397

21. The complaint authored by Asstt. Commissioner Kochar is also defective because :—

(1) Kailash and Co. has not been made a co-accused and

(2) Chem Med also has not been made a co-accused.

Thus all that Alpana Pharma need do is to produce Chem Med's report certifying the sample as of standard quality and ask for an acquittal.

22. None of this can be attributed either to mistake or negligence or ignorance on the part of Kochar. It was all a part of a deliberate pre-planned strategy to let Kasat off the hook.

23. This is brought to the forefront by the fact that Kochar's Inspectors had visited Kasat on 30th and 31st January and Kasat had given them the particulars of the supplies made. Now if the prime supplier was disclosed in the complaint as Ganesh Chemicals, the complaint would have been sustainable because Ganesh Chemicals (as the name itself indicated) could not supply drugs and neither could H. M. Chemicals as is indicated by the name and its letter dated 3rd February 1986 (Ex. 397). Hence the question would have arisen how these chemicals units could have supplied drugs to Alpana Pharma. This would not have suited Alpana Pharma's supplier, namely Kailash and Co. Ex. 397

24. That such was the thinking process of Asstt. Commissioner Kochar is clear by the subsequent addition of the letters 2 " I W " in Girdhar Kasat's office copy of Invoice No. 007 dated 23rd November 1985, not round about that time as professed by Girdhar Kasat but after the J. J. Hospital tragedy occurred. The letters " I W " were added in that office copy by way of abundant caution, namely that if ultimately and despite Kochar's best efforts to let Kasat off the hook, some how Batch No. 27 was connected with Ganesh Chemicals, the defence of Kasat would be that they had made the supply to Alpana Pharma as a chemical and not as a drug.

25. It was Kamble who persisted that complaint must be filed. And when this correct advice could not be ignored, the precaution taken was to file a defective complaint which could only result in an acquittal. Though Kamble was persistently requesting permission to lodge an F. I. R. with the police at Nanded, his request was turned down in the Commissoner's meeting of 3rd February 1986. The reason for doing so is obvious, namely that if permission had been granted and if an F. I. R. had been filed, the police would have made their own independent enquiries and Kasat would have found themselves in difficulties in the light of H. M. Chemicals' letter dated 3rd February 1986 (Ex. 397). Thus the best expedient that could be resorted to was to keep the police out of the picture, file a private complaint, make it defective by keeping the drafting away from Kamble and leaving it to Kochar to do the defective job himself and which no doubt he admirably did whereby Alpana Pharma's acquittal must be a foregone conclusion.

PART VI

26. This brings me to the investigation in Bombay.

No. FDA officer, be it Commissioner Bhirud, or Jt. Commissioner Dolas or Asstt. Commissioner Kochar or Raykar was willing to take responsibility of being in-charge of the investigation in Bombay. Bhirud himself took no interest, except on his own showing, giving advice when it was sought. He made reports to Government [Ex. 246 (colly.)], but actually they were prepared by Dolas and he (Bhirud) merely signed them. More on the Reports presently.

With this prelude I shall set out the various dates of investigation carried out in Bombay.

28th January 1986 .. Samples were drawn in the J. J. Hospital by Inspectors Vadnere and Dube who were followed later to the Hospital by Asstt. Commr. Raykar.

Ex. 206 & Ex. 207 — 29th January 1986 ..

(*i*) Samples were sent to the Government Analyst. A separate letter (Ex. 207) was written by Inspector Vadnere to the Government. Analyst for carrying out the toxicity test along with the other tests.

(*ii*) From Aurangabad Asstt. Commr. Bhange telephoned Asstt. Commr. Kochar at Bombay and gave him the name of Kailash and Co. Kochar passed on this message to Jt. Commr. Dolas and told him that Bhange had given the name of Haresh Chemicals. Under Dola's instructions Kochar deputed Inspectors Bankar (attached to Dolas) and Fadnavis (attached to Kochar) to H. M. Chemicals for investigation, which they did.

Ex. 210 — 31st January 1986 ..

(*i*) The Government Analyst made his report (Ex. 210) stating that the sample was not of standard quality as the sample had a faint odour like that of burnt sugar and did not comply with I. P. test for (1) Acral dehyed and Glucose, (2) certain reducing substances and (3) fatty acids and esters. This report was sent by the Government Analyst to Inspector Vadnere with his covering letter dated 3rd February 1986.

Ex. 382

(*ii*) Inspectors Bankar and Fadnavis made their report (Ex. 382). Dolas directed Kochar to depute a Drugs Inspector to Bakewell (India) and H. M. Chemicals. Accordingly Kochar deputed Drugs Inspectors Banker, Barde and Ransube to Bakewell (India) and H. M. Chemicals. They made an oral report to Kochar that their inquiries with Bakewell (India) were over and that H. M. Chemicals was found closed.

(*iii*) *9-30 p.m.*—Asstt. Commr. Kochar received a telephone call in Bombay from Asstt. Commr. Kamble from Nanded that he was unable to draw samples of the plastic bottles from the premises of Alpana Pharma as O. P. Ladda was out of station and his mother refused to come to the factory premises at night. Kamble told Kochar of his desire to file an F. I. R. with the police at Nanded. However Kochar told him not to do so as he wanted to consult Commr. Bhirud and told Kamble to telephone him later.

(*iv*) *11-15 p.m.*—Kamble telephoned Kochar. Kochar told him that Bhirud had said that samples should not be drawn at night and that no F. I. R. should be lodged at that juncture.

3rd February 1986 .. (*i*) Bankar, Darde and Ransube made their report (Ex. 383). Ex. 383

(*ii*) H. M. Chemicals addressed its letter to FDA that they had supplied two drums of 250 kg. each of Glycerine I. W. to Kailash and Co. after purchasing them from Ganesh Chemicals. This letter has been referred to earlier.

(*iii*) FDA received Xerox copies of Chem Med's test reports pertaining to Batch Nos. 27 and 29 (Ex. 212-B and Ex. 213-B). This indicates that on 3rd February 1986 FDA knew that Chem Med was the Analytical Laboratory which had carried out the tests.

(*iv*) At 9-00 a.m. Kamble went to FDA (HQ) and in the meeting handed over a copy of his interim report (Ex. 412) to the Commissioner. At this meeting were present Commr. Bhirud, Jt. Commr. Dolas and Asstt. Commr. Kochar, Raykar, Dani, Kamble and the Government Analyst Dr. Pilankar who was present to inform the meeting the result of the analysis carried out by him. Ex. 412

(*v*) What transpired at this meeting was—

(*a*) The Government Analyst Dr. Pilankar informed the members that the glycerol sample was found to be sub-standard ;

(*b*) Kamble's oral and written reports indicated that Alpana Pharma's supplier was Kailash and Co. ;

(*c*) That Chem Med was the Analytical Laboratory which had done the analysis certifying the sample as of standard quality ;

(*d*) Kamble reiterated that a prosecution must be launched against Alpana Pharma. This was again reiterated by Kamble to Kochar and Dolas on 4th February 1986.

4th February 1986 .. Kochar prepared draft complaint against Alpana Pharma (Ex. 384-A) to be filed at Nanded. Ex. 384-A

5th February 1986 .. (*i*) A show-cause notice (Ex. 235) was issued to Trans India Transfusion Pharmaceuticals for withdrawal of permission to manufacture mannitol on the ground that it failed in pyrogen test. Ex. 235

(*ii*) This show-cause notice was replied to by Trans India's letter dated 14th February 1986 (Ex. 236) that the sample complied with the pyrogen test conducted by them. Ex. 236

7th February 1986 .. Pursuant to Dolas's instructions, Kochar directed Inspectors Bankar, Apsingekar and Ransube to conduct an investigation against Bakewell (India).

10th February 1986 .. Inspectors Bankar, Apsingekar and Ransube made a report dated 10th February 1986 (Ex. 386) that no responsible person was present in the premises of Bakewell (India).

Ex. 386

11th February 1986 .. The Government Analyst made his toxicity report after experimentation on mice. The sample was not found to be toxic.

12th February 1986 .. (*i*) A meeting was held in Commr. Bhirud's chamber. Present were Commr. Bhirud, Jt. Commr. Dolas and Asstt. Commr. Kochar and Raykar. The matter of taking action against Bakewell (India), Haresh Chemicals and Kailash & Co. was discussed. The action contemplated was under the Drugs and Cosmetics Act for selling glycerine without a licence. It was decided that action be taken after obtaining the opinion of the Chief Police Prosecutor.

(*ii*) Kochar met the Chief Police Prosecutor who directed him to his Assistant Gujarati.

(*iii*) Inspectors Vadnere and Choudhari were deputed to Chem Med under Raykar's instructions who was directed to do so by Dolas on 11th February 1986.

(*iv*) Accordingly Vadnere and Choudhari went to Chem Med and obtained xerox copies of Chem Med's report of Batch Nos. 24, 27 and 29 and the following day made their report (Ex. 216).

Ex. 216

14th February 1986 .. According to Raykar, he told Kochar that there was another source of supply to Alpana Pharma (namely Ganesh Chemicals being the prime supplier named by H. M. Chemicals in its letter, dated 3rd February 1986 (Ex. 397) required to be investigated and Kochar replied that it was not necessary to do so.

19th February 1986 .. In view of Kochar declining to investigate into Ganesh Chemicals, the matter was taken to Commr. Bhirud. Commr. Bhirud gave instructions that investigation must be made with Ganesh Chemicals. Accordingly Inspectors Choudhari and Vadnere visited the office of Ganesh Chemicals and thence with Jethalal Soni the manufacturing premises of Ganesh Chemicals, recorded the statement of Jethalal Soni and made investigation. According to Kochar at page 1640 of his evidence, he saw H. M. Chemical's letter, dated 3rd February 1986 for the first time on 19th February 1986.

20th February 1986 .. (*i*) Police Prosecutor Gujarati gave his written opinion (Ex. 387) that complete investigation should be done.

Ex. 387

Ex. 388

(*ii*) Inspector Choudhari made his report (Ex. 388) regarding the investigation at Ganesh Chemicals. This is the only report which has been initialled by Commr. Bhirud, Jt. Commr. Dolas and Asstt. Commrs. Kochar and Raykar.

Ex. 222 21st February 1986 .. (*i*) The toxicity report (Ex. 222) was received in the FDA office.

(*ii*) A meeting was held in Commr. Bhirud's chamber. Present were Bhirud, Dolas, Kochar and Raykar. The last two are directed to go to Nanded to ascertain the source of supply of Batch No. 27 and to verify the condition of the drum which had been seized on 30th January 1986.

(*iii*) A show cause notice was issued to Chem Med (Ex. 237) for withdrawal or suspension of approval of its licence by reason of various deficiencies set out in the notice. To this, Chem Med sent its reply (Ex. 238) on 4th March 1986.

Ex. 237

Ex. 238

23rd February 1986	..	Asstt. Commrs. Kochar and Raykar left Bombay for Nanded where they inspected the drum and noted the cyclostyling and saw Alpana Pharma's Bin Card (Ex. 389). They made their joint report (Ex. 390).	Ex. 389 Ex. 390
24th February 1986	..	(*i*) Alpana Pharma wrote to the FDA disputing the Government Analyst's report [Ex. 218 (colly.)].	Ex. 218 (colly.)
		(*ii*) Inspector Vadnere wrote to Alpana Pharma asking them to adduce evidence to controvert the Government Analyst's report.	
27th February 1986	..	(*i*) Asstt. Commr. Bijamwar and the Government Analyst Dr. Pilankar and some others visited Apex Laboratories for inspection which lasted till 1st March 1986 whereafter they made their report dated 1st March 1986 (Ex. 285).	Ex. 285
		(*ii*) Inspector Vadnere filed an F. I. R. (C. R. No. 12/86) with C. B. Drug Control (Drugs C. I. D.) against Kailash & Co. for dealing in glycerine without a licence. The F. I. R. was recorded by S. I. Pimple.	
		(*iii*) S. I. Pimple and three Drugs Inspectors went to Kailash & Co. and seized certain documents.	
		(*iv*) C. R. No. 16/86 was filed against Haresh Chemicals and the Kasat brothers, namely Girdhar Kasat and Bharat Kasat were arrested. Documents were seized including the office copy of Invoice No. 007, dated 23rd November 1985 in which the letters "I.W." had been added in ink after the word 'glycerine'.	
28th February 1986	..	(*i*) Sixteen Assistant Chemists of Apex Laboratories made a written complaint to the FDA setting out certain malpractices which they were required to commit by Apex Laboratories. This complaint was a sequel to an earlier similar Complaint (Ex. 289).	Ex. 289
1st March 1986	..	H. M. Chemicals were searched by the C. B. Drug Control. Mahendra Doshi was arrested.	
3rd March 1986	..	Ganesh Chemicals were searched and documents were seized.	
5th March 1986	..	Ganesh Chemicals' proprietor Jethalal Soni was arrested.	
13th March 1986	..	A show cuase notice was issued to Apex Laboratories to which Apex sent its reply on 31st March 1986.	
5th May 1986	..	An order was passed suspending Apex's licence for 15 days. [The last three are Ex. 286 (colly.)].	Ex. 286 (colly.)

PART VII

27. With this chronology of events of the investigation in Bombay, I shall deal with the Reports made by the FDA to Government. In all they are nine, the first being of 31st January 1986 and the last of 23rd June 1986.

28. By way of introduction, all these reports though signed by Commissioner, Bhirud were on his own showing actually prepared by Jt. Commissioner Dolas and their contents accepted by Bhirud as gospel truth.

29. With this preliminary observation, I proceed to deal with the salient aspects of these 9 reports.

REPORTS

(*a*) *31st January 1986.*—(*i*) This was the first report made to Government. It sets out the strong doubt expressed by Dr. (Mrs.) Worlikar about the quality of glycerine leading to the deaths in the J. J. Hospital and that the Government Analyst was instructed to carry out the toxicity test in addition to pharmacopoeial chemical testing. File No. 533

(*ii*) The Report goes on to say that from the initial enquiry made with the Government Analyst it was learnt that the sample was not of standard quality as it failed in three chemical tests, namely—

" (1) Certain Reducing Substances.

(2) Acraldehyde + Glucose and

(3) Fatty acids and Esters. "

(*iii*) Curiously enough, despite (*i*) and (*ii*) above the Report says that the FDA does not consider that glycerine was responsible for the deaths and that it would be appropriate to obtain an opinion of a pharmacologist. This indicates that the stalling process, so manifest from the later Reports, had already begun.

(*iv*) It is also stated that further investigation revealed that M/s. Haresh Chemicals, Bombay 2, had purchased the stock from M/s. Bakewell Chemical, Deonar.

(*v*) The above was a deliberately vague, false and misleading statement in order to focus attention on Bakewell India as the price supplier, when it was not.

(*vi*) The Report goes on to say that all the three drugs, namely glycerine, mannitol and acetazolamide have known side effects as revealed from the available scientific literature.

(*vii*) This was yet another false statement deliberately made in order to divert Government's attention from glycerol about the genuineness of which Dr. (Mrs.) Worlikar had cast serious doubts as stated in this Report itself. Side-effects can be fever, diarrhoea, skin-irrigation, drowsiness, loss of appetite and the like. Death can never be a side-effect and no " available scientific literature " vaguely referred to in this Report classifies it as such.

File No. 533 (B) *3rd February 1986.*—The tiresome length of this Report is a camouflage for its lack of substance and total silence on certain material aspects for instance, in it there is not a word (or for that matter in any subsequent Report) as to what had transpired at the Commissioner's meeting that day, nor was Government informed of the name of the prime supplier, namely Ganesh Chemicals, though this was known to the FDA on 3rd February 1986 when this Report was made.

File No. 533 (C) *10th February, 1986.*—(*i*) In this Report the emphasis is still on Bakewell India as being the prime supplier, though it was already known to the FDA that it was not, and that the prime supplier was Ganesh Chemicals.

(*ii*) Though Bakewell India had mixed in its glycerine a chemical hexane, this fact was suppressed in this Report. On the contrary what was sought to be conveyed is that Bakewell's glycerine being imported from Italy was of standard quality.

(*iii*) Even though by 10th February 1986, Dr. Sane had reported the presence of diethylene glycol, there is no mention of this in this report.

File No. 533 (D) *17th February 1986.*—This Report is an innocuous Report pertaining to grant of licence to Alpana Pharma.

File No. 533 (E) *19th February 1986.*—This Report does not pertain to the J. J. Hospital episode.

File No. 533 (F) *21st February 1986.*—(*i*) In this Report once again the emphasis is non Bakewell India as being the prime supplier who had imported glycerine found to be of 98% purity.

(*ii*) This was known to the FDA to be false, because by then the trail had already led to Ganesh Chemicals as being the prime supplier.

(*iii*) The last four lines of this Report state that during investigation it was also revealed that Alpana Pharma had also received more supplies from other suppliers "and the same is being investigated ".

(*iv*) Once again this was a false statement intended to lull Government into the belief that vigorous investigation was in progress, when it was not as it had been completed on 20th February 1986 as is manifest from Inspector Chaudhari's Report
Ex. 388 (Ex. 388) of that day which was the only Report which had been initialled by all the officers, namely Commissioner Bhirud, Jt. Commissioner Dolas and Assistant Commissioners, Kochar and Raykar.

File No. 533 (*g*) *21st February 1986.*—This Report informs Government about the experiments on animals.?

(h) 4th March 1986.—(*i*) In apara 2(B) of this Report it is stated— File No. 533

" During investigation, it was found that M/s. Bakewell (I) Bombay or M/s. H. M. Chemicals, Bombay or both might have supplied the said Glycerine to M/s. Kailash and Co. Bombay. About the batch No. 27 of the Glycerine in question it cannot be firmly ascertained whether it has been repacked from the stocks supplied by any one of the suppliers. It is possible that the said Glycerine of Batch No. 27 has been repacked from the stocks supplied by both the suppliers."

This is patently an attempt to confuse and mislead Government by suggesting that the prime source cannot be found, despite the fact that it was already known to the FDA that the prime supplier was Ganesh Chemicals whose concoction that ultimately found its way to the J. J. Hospital was contaminated with the lethal diethylene glycol.

(*ii*) In this Report it is stated that according to the written statement of Ganesh Chemicals they had mixed different chemicals which they sold as glycerine of industrial grade. Though a copy of that statement was enclosed with the Report, there is not a whisper of a suggestion that Ganesh Chemicals had mixed diethylene glycol, a lethal product, in the concoction manufactured by them, or for that matter the nature of the chemicals mixed.

(*iii*) In para 7 of this Report reference is made to an item appearing in newspapers that the glycerine had been analysed in a private testing laboratory by Dr. Sane. The Report continues that officers of the FDA visited the approved laboratory of Ruia College on 24th February 1986 and found that there was no entry in the register about the date of the receipt of the glycerine sample, and that it was possible that Dr. Sane had analysed the sample in a purely personal capacity.

(*iv*) Except for the reference to the news item the rest of the above statements are mischievous calculated as they were to discredit Dr. Sane, an independent expert, and his discovery of the presence of diethylene glycol, corroborated as it was by the admission of the prime supplier, namely Jethalal Soni of Ganesh Chemicals that he indeed had mixed diethylene glycol in his concoction. Indisputably Dr. Sane had indeed discovered the presence of the lethal diethylene glycol which the FDA's Government Analyst should have done and which he still had not. Yet an attempt was made in this Report to be little and divert Government's attention from this important discovery, made by Dr. Sane by an attempt to cast a doubt on its genuineness and that it was possibly done by Dr. Sane in a purely personal capacity. It was and should have been a matter of no consequence whether Dr. Sane carried out the analysis in his official or personal capacity. The fact remained that he did carry it out and that he did make the discovery that the sample contained diethylene glycol. In its attempt to belittle Dr. Sane and his discovery, the FDA slapped a flimsy show cause notice against the laboratory as will appear immediately hereafter.

(*v*) On 4th March 1986 a show-cause notice was issued to Ruia College that certain requirements were not found in the laboratory during the time of inspection by two Inspectors and two Assistant Commissioners on 24th February 1986. Ruia College sent its reply dated 27th March 1986. The sequel was FDA's letter dated 25th April 1986 stating that the explanation given by Ruia College was found not to be satisfactory and a warning was given [Ex. 284 (colly.)] Ex. 284 (colly)

(*vi*) This show-cause notice was a piece of machiavellism on the part of FDA, apparently calculated to discredit the discovery made by Dr. Sane. None of the requisitions had the slightest connection with the test carried out by Dr. Sane or that Dr. Sane's analysis showing the presence of diethylene glycol was incorrect. This show-cause notice was manifestly a rear guard action to lay a foundation that Dr. Sane's finding about the presence of diethylene glycol should not be accepted or be looked askance with suspicion. The attempt was unworthy.

(*vii*) It may legitimately be asked : Why should the FDA stoop so low ? The answer stares one in the face. If the presence of diethylene glycol was accepted by the FDA, they would have to proceed against the prime supplier, namely Jethalal Soni of Ganesh Chemicals and thence against Kasat who had to be saved at any cost.

(*viii*) In para 5 of this Report, there is a reference to prosecution being launched against Trans India Transfusion and Pharmaceuticals on the ground that their mannitol was reported to be not of standard quality. However, the irony of this is that while prosecution was recommended (and launched on 2nd April 1986) against Trans India for the sub-standard mannitol which could not and did not result in any

deaths, the vital discovery made by Dr. Sane regarding the presence of diethylene glycol which caused the deaths, was sought to be shrugged away. I do not suggest for a moment that no action against Trans India should have been taken ; but in the circumstances it was merely a cover-up action by the FDA intended to mislead government by FDA's so-called activity in the so-called investigation by roping in Trans India and letting the real culprits off the hook which could only be done by denigrating Dr. Sane's discovery of the lethal presence of diethylene glycol which caused the havoc in the J. J. Hospital.

(*ix*) In para. 8 of this Report, reference was made to Trans India's mannitol having been analysed by Apex Laboratories, that it was inspected on 3 days and found that it had " recorded the performance of some tests in the Report even though some specific testing facilities are not available in their laboratory for carrying out these tests ", and that action was being taken against Apex by way of a show-cause notice for withdrawing " the approval or suspending the same for a particular period".

(*x*) While no grievance can possibly be made for issuing a show-cause notice against Apex, what is of importance is that FDA never intended to prosecute Apex and indeed till today has not, which it should have.

(*xi*) Significantly in this Report there is no reference to the written complaint given by Apex's 16 Assistant Chemists (Ex. 260) complaining of the malpractice they were compelled to resort to by Apex or to even the earlier similar complaint (Ex. 259). This omission is indefensible in the light of the fact that on 3rd March 1986 i.e. just one day prior to this Report two of Apex's Chemists had met Jt. Commissioner Dolas and had orally complained to him about what is set out in the complaint (Ex. 260). This is corroborated by Dolas' own endorsement in Ex. 260. All this was suppressed from Government.

(*xii*) In para 6 of this Report it was stated that the premises of Chem Med Laboratory which had analysed Batch No. 27 were inspected by drugs inspectors and on the basis of the defects observed by them " which were of a serious nature " a show-cause notice for withdrawal or approval or suspension of licence was issued and that their reply was awaited.

(*xiii*) Once against even though on the showing of the FDA itself, the lapses on the part of Chem Med were of a serious nature, there is not a whisper of a suggestion in the show-cause notice that why a prosecution should not be launched against Chem Med. Even in the show-cause notice annexed to this Report, curiously enought there is no mention that the glycerine analysed by Chem Med was in fact contaminated with diethylene glycol which fact was known to the FDA because Dr. Sane had on analysis found its presence as far back as 7th February 1986.

(*i*) *17th June 1986.*—(*i*) By this Report the FDA wanted to take false credit by seeking to convey to Government that it was the FDA that was responsible for the discovery of diethylene glycol, when in truth it was not, its discovery having already been made by Dr. Sane as far back as 7th February 1986.

(*ii*) The Government Analyst Dr. Pilankar whose duty it was to expeditiously and correctly analyse the sample of Batch No. 27 for toxicity, failed to do so. Initially Dr. Pilankar did not carry out all the toxicity tests.

(*iii*) By 11th February 1986 when Dr. Pilankar gave his first Report, Dr. Sane had already discovered the presence of diethylene glycol and this was known to Dr. Pilankar from newspaper reports. Even so, till June 1986 Dr. Pilankar did not carry out the toxicity tests.

(*iv*) All this was an attempt on the part of the FDA to cover its own tracks and misinform and mislead government about the dificiencies of the FDA in an endeavour to protect itself and Dr. Pilankar who is also part of FDA under the Commissioner.

(*v*) All this was suppressed from Government.

(*vi*) This otherwise unaccountable and mysterious spurt of activity on the part of Dr. Pilankar in carrying out the toxicity test in June, 1986 and making his report on 17th June 1986, namely after the present Commission of Inquiry was appointed and after it held its first sitting on 11th June 1986, is an obvious indication of the belated and unsuccessful endeavour by the FDA to put its house in order so as to cover-up its earlier mischief, deliberate lapses and its mysterious reasons for wanting itself to be convinced that the killer glycerine did not contain diethylene glycol.

(*vii*) The last para. of this Report says that in the prosecution launched in the Nanded Court against Alpana Pharma and its partners, instructions are being issued to incorporate the additional charges for the manufacture and sale of adulterated drugs under section 17-A(*c*) of the Drugs and Cosmetics Act.

(*viii*) This was yet another attempt on the part of the FDA to mislead and hoodwink Government. FDA knew or should have known that the additional charge against Alpana Pharma and its partners of manufacturing the drug was bound to fail as to the knowledge of the FDA Alpana Pharma was merely a repacker and not the manufacturer which to FDA's knowledge Jethalal Soni of Ganesh Chemicals was. In any event, the record does not disclose that any such instructions were in fact issued, and if not, why not, in the teeth of representation made to Government that they were being issued. If they at all were, they have not been carried out.

(*j*) *23rd June 1986.*—(*i*) In this Report once again Alpana Pharma is referred to as the party who had manufactured Batch No. 27 despite the fact that to FDA's knowledge it was Jethalal Soni of Ganesh Chemicals and not Alpana Pharma who was the manufacturer.

(*ii*) In this Report Credit is sought to be given by the FDA to the Government Analyst Dr. Pilankar (and thereby to itself) for " the exact percentages " of deithylene glycol found by Dr. Pilankar on analysis. This self-back patting was intended to mislead Government by not telling Government the truth that it was Dr. Sane who had discovered the presence of diethylene glycol as far back as 7th February 1986.

30. These Reports submitted by FDA to Government bring to the forefront that —

(*a*) FDA deliberately failed to reveal to Government the true facts of the investigation it was doing ;

(*b*) Vital information was suppressed in an attempt to misinform and mislead Government from knowing the true state of affairs ;

(*c*) Vital facts were deliberately not stated, for instance to name a few—

(*i*) the receipt by FDA of Chem Med's report which revealed or should have revealed to the FDA that Chem Med had falsely certified Batch No. 27 to be of standard quality.

(*ii*) H. M. Chemical's vital letter dated 3rd February 1986 clearly establishing the purchase by them from the original supplier Ganesh Chemicals (Jethalal Soni), sale thereafter to Kailash and Co. (Kasat brothers), whereby was revealed the link between Alpana Pharma and its prime and intermediary suppliers;

(*iii*) That Assistant Commissioner Kamble had given information as far back as 30th January 1986 identifying Kailash and Co., as the immediate supplier of Alpana Pharma. Instead diversionary tactics were used to focus attention on Bakewell India who had not supplied the killer glycerol to Alpana Pharma;

(*d*) an impression was sought to be created in Government's mind that a thorough inquiry by FDA revealed that glycerine was not the cause of the deaths in the J. J. Hospitals;

(*e*) Obvious steps in the investigation were deliberately ignored which if taken would for instance have led FDA straight to Kailash and Co., and other links would have been revealed;

(*f*) Government was misled as FDA deliberately took no steps against Chem Med by way of a prosecution;

(*g*) no mention was made that as early as 7th February 1986, Dr. Sane had discovered the presence of diethylene glycol. On the contrary, Dr. Sane's achievement was belittled and suspicion was sought to be cast on it to the extent of slapping a show-cause notice on the laboratory regarding matters which had nothing to do with the discovery by Dr. Sane of the presence of diethylene glycol;

(*h*) FDA tried to take credit for the discovery of diethylene glycol and shielded Dr. Pilankar's lethargy and lapse in not discovering its presence till June 1986 after the present Commission started its sittings;

(*i*) The Reports were merely a ruse to hide from Government the deliberate and premeditated scuttling of FDA investigation in the right channels and diverting it into wrong channels as FDA had decided who to protect (*viz.* Kasat) and who was to be made scapegoats (*viz.* Bakewell India and Dr. Sane).

(*j*) the Reports contradicted themselves. On the one hand FDA sought to implicate Alpana Pharma as having mixed a contaminant, yet at the same time advanced the proposition that there was no diethylene glycol in Batch No. 27 and all in a potent attempt to protect Kasats and their concern Kailash & Co., who were the immediate suppliers of Alpana Pharma;

(*k*) Instead of appreciating Dr. Sane's discovery of the presence of diethylene glycol, which should have been done by the FDA and not belatedly in June 1986 as a face saving device after the Commission started its sittings, FDA tried to shrug away Dr. Sane's discovery on the specious ground that it was not an official test and even slapped a show-cause notice on the laboratory.

31. These Reports do not project the correct picture of the situation, intended as they were under the genius of Jt. Commissioner Dolas to mislead and misguide Government not only regarding the investigation but also to lull Government into a sense of false security by playing down the gravity of the entire incident.

32. In the matter of these Reports, Commissioner Bhirud cuts a sorry figure. Out of inefficiency, indolence or fear of Jt. Commissioner Dolas or all three, Commissioner Bhirud allowed himself to be manipulated by him and merely signed on the dotted line. Thereby Commissioner Bhirud renounced his power, position and authority in favour of that unworthy man, Dolas.

PART VIII

33. This brings me to Alpana Pharma Pack and its patron Ramanlal Karwa of Artichem Laboratories, Pune.

(*a*) Ramanlal Karwa is an M. Pharm. of the Nagpur University. He obtained his M. Pharm. Degree in 1975. Several FDA officers were either his colleagues or his students. He started the business of manufacturing pharmaceutical formulations on loan licence at Pune in the name and style of Artichem Laboratories as sole proprietor. From 1980 Artichem started its manufacturing activities on its own licence. In 1981 he converted it into a partnership firm with himself and his two sisters-in-law as partners. He is the moving spirit in Artichem.

(*b*) In 1982 Artichem applied for and was given a rate contract for two years for the supply of certain medicines to Government. Thereafter in 1982 Artichem again applied for a rate contract under the 33 per cent reservation given to backward areas, Artichem's manufacturing unit being at Ahmednagar a backward area.

(*c*) Between 1982 and 1984 Artichem got certain bio-availability data work done by Dr. R. D. Kulkarni.

(*d*) Karwas have another family concern. It is Deepali Enterprises in Bombay. The partners are the Karwa family members. This firm was started in 1984 and acts as the Bombay distributors of Artichem in Pune, and prepares Artichem's bills at a commission of 10 per cent.

(*e*) Om Prakash Ladda is the cousin of Ramanlal Karwa's wife Nirmala. In 1973 O. P. Ladda obtained his B.Sc. Degree. Till 1982-83 he worked as the medical representative of Artichem and thereafter also as its travelling salesman. According to O. P. Ladda, between 1980 and 1982 he assisted the chemists in Artichem's factory in order to gain experience. In 1984 he was given the sales agency of Maharashtra region of Artichem on commission basis.

(*f*) In 1983 O.P. Ladda thought of starting a repacking business in the name of Alpana Pharma Pack. As a result on 1st December 1983 he entered into tenancy agreement for six rooms at a monthly rent of Rs. 400.

(*g*) On 10th January 1984 O. P. Ladda made an application to the FDA at Nanded for grant of a drug repacking licence. However on 15th January 1984 he withdrew his application as he could not afford the requisite machinery. In the meanwhile O.P. Ladda asked Chem Med if it would act as the quality control laboratory for Alpana Pharma and Chem Med agreed on 22nd January 1984.

(*h*) In February 1984, O. P. Ladda told Ramanlal Karwa that due to paucity of fund he was unable to start his repacking business. Two or three days later Ramanlal Karwa told O. P. Ladda that he, i.e. Ramanlal Karwa would provide the necessary finance. It was thereupon agreed that there would be a partnership between two groups, namely the Karwa group and the Ladda group, each group having a 50 per cent share and that finance would be provided by Ramanlal Karwa. As will appear

presently, Alpana Pharma was the creation and creature of Ramanlal Karwa and he was the moving spirit. Alpana Pharma was established at Nanded, a backward area, so that it would apply for rate contract with CSPO and ESIS.

(*i*) In March 1984, Ramanlal Karwa told O. P. Ladda that a CSPO tender was likely to be issued and that he should apply.

(*j*) On 6th March 1984, O. P. Ladda obtained certain machinery like pilferproof capping machine, etc. On 9th March 1984, a Deed of Partnership was executed between P. O. Ladda and his mother Basantidevi comprising of the Ladda group and Ramanlal Karwa's wife Nirmala and Ramanlal Karwa's sister-in-law Lalitha comprising the Karwa group.

(*k*) On 13th March 1984, Alpana Pharma applied to the FDA for a repacking licence for 212 drugs under Form 34-B to be granted under Form 25-B. The address given was Anand Nagar, Nanded.

(*l*) There days later on 16th March 1984, Drugs Inspector Giri of the Nanded office inspected Alpana Pharma's premises and 4 days later on 20th March 1984, the Asstt. Commissioner at Nanded recommended the grant of licence to Alpana Pharma.

(*m*) In the end of March 1984, Ramanlal Karwa told O.P. Ladda that an undertaking may have to be given to the FDA to have a quality control laboratory in the premises of Alpana Pharma (in-house laboratory) within two months.

(*n*) Sometime after 20th March 1984, the papers were given for scrutiny to Inspector Desai at Bombay.

(*o*) On 6th April 1984, on behalf of Alpana Pharma, Nirmala Karwa wrote a letter to the Commissioner, FDA giving an undertaking to establish an in-house laboratory and also to provide a qualified analytical chemist approved by the FDA within two months.

(*p*) On 9th April 1984 Ramanlal Karwa told O. P. Ladda that Asstt. Commissioner S. J. Jadhav had raised an objection that Alpana Pharma's area was insufficient for the simultaneous repacking of liquids and powders. As a result an undertaking was apparently given by Alpana Pharma that liquids and powders would not be repacked simultaneously.

(*q*) On 25th April 1984, Alpana Pharma addressed a letter (Ex. 37) to the Director of Industries wherein it was stated the Alpana Pharma was submitting its lowest quotation alongwith certain documents.

The same day, barely 2 days before the last date of the closing of the CSPO tenders, FDA issued a letter to Alpana Pharma that licence No. 116/B was granted to Alpana Pharma " on the condition that you will *provide quality control laboratory within two months* " (sic) and that the " abovesaid licence is under preparation and the same will be sent to you shortly " (sic). Ex. 37

(*r*) *7th June 1984.*—Alpana Pharma received the licence (Ex. 192) from the FDA with the list of products. This was handed over by the FDA to Krishnakumar Karwa in pursuance of a letter dated 7th June 1984 addressed by him on behalf of Alpana Pharma to the Commissioner, FDA (Ex. 193). Ex. 192 Ex. 193

(*s*) *17th July 1984.*—Alpana Pharma made an application to the FDA for permission to repack additional products. This application came up before Fadnavis. The permission sought for was granted.

(*t*) *September 1984.*—Alpana Pharma received an intimation from the CSPO that Alpana Pharma's quotation had been accepted for three items, one of them being for glycerine.

(*u*) *1st February 1985.*—There was a change in Alpana Pharma's partnership inasmuch as Lalitha Karwa went out and Rameshwar Karwa and Sarla Karwa became partners.

That day Alpana Pharma made an application to the FDA for grant of licence under the new partnership. A plan of the new premises was sent to the FDA.

(*v*) *15th April 1985.*—This application and plan were received in FDA (HQ) and were scrutinised by Drugs Inspector Vadnere.

(*w*) *31st May 1985.*—Vadnere made his endorsement that despite the undertaking given by Alpana Pharma to have an in-house laboratory, they had failed to do so and that Alpana Pharma should be asked to have an in-house laboratory.

(*x*) *1st June 1985.*—Vadnere's endorsement was endorsed by Asstt. Commissioner Raykar. Fadnavis passed an order that Alpana Pharma must be asked to set up an in-house laboratory.

(*y*) *5th June 1985.*—In reply to Alpana Pharma's letter dated 1st February 1985 FDA addressed a letter to Alpana Pharma asking them to establish an in-house laboratory and to return the old licence for cancellation.

(*z*) *1st August 1985.*—Alpana Pharma took on rent larger premises (900 sq. ft.) at Rs. 600 per month.

Ex. 195 (*aa*) *1st October 1985.*—Alpana Pharma addressed a letter to the Commisioner, FDA (*Ex. 195*) applying for licence in Form 24-B in its new premises. By this letter Alpana Pharma represented that as suggested by the FDA, Alpana Pharma had already provided for a Quality Control Section in the new premises for carrying out routine analysis in their laboratory and for the same had appointed R. R. Karwa, M. Pharm, an approved quality control chemist. (Here it may be stated that both O. P. Ladda and Ramanlal Karwa had admitted in the evidence that these statements in this letter are incorrect.).

After scrutiny of this application by Drugs Inspector Dube (HQ), he recommended the grant of licence to Alpana Pharma.

Ex. 196 (*bb*) *3rd October 1985.*—Alpana Pharma addressed a letter to the Commissioner, FDA enclosing certain documents, to *wit*, approved plan of the premises, list of equipment and machinery, list of equipment for routine chemical analysis and no objection certificate of the Nanded Municipal Council. (As admitted by Ramanlal Karwa in his evidence (p. 1006) the list of equipment was not sufficient to set up an in-house laboratory.). The same day Alpana Pharma's new premises were inspect-
Ex. 254 ed and Drugs Inspector Babne made his report (*Ex. 254*). The same day Asstt. Commissioner Kamble recommended the grant of licence to Alpana Pharma.

(*cc*) *8th November 1985.*—Fadnavis ordered the grant of licence to Alpana Pharma on the ground that it had a sufficient staff and that Ramanlal Karwa was a qualified chemist appointed by Alpana Pharma. That day licence was granted to Alpana Pharma.

(*dd*) *1st December 1985.*—(*i*) Alpana Pharma's new premises were inaugurated.

(*ii*) That the licence to Alpana Pharma was issued on 25th April 1984 just two days before the closing of the tender, cannot be dismissed as mere coincidence. For that matter, circumstances Indicate that it was issued sometime subsequently but was predated to 25th April 1984 so as to enable Alpana Pharma to apply for the tender as no tender would be valid without a valid licence. Those circumstances are :

34. On 12th April 1984 Inspector Desai at Bombay made his report stating that Alpana Pharma had given both the undertakings asked, for namely to have an in-house laboratory and a qualified analytical chemist approved by the FDA within two months and not to carry on repacking of liquids and powders simultaneously. At the foot of this report the Asstt. Commissioner made his endorsement and under his signature put the date " 26/4 ". This has subsequently been altered to " 24/4 ". V. D. Deshmukh who then was the Joint Commissioner and Licensing Authority (HQ) signed on the copy of Alpana Pharma's application in Form 24-B stating " licence in Form 25-B granted ". The visible date of this endorsement is " 24/4 " but has clearly been altered. The alteration not of one date but 2 dates must rule out any possibility of error. This dovetailing had to be done if FDA's letter granting the licence was to bear the date 25th April 1984. These dates were therefore subsequently altered by the FDA to show that Alpana Pharma had procured a licence at the time it gave its tender.

35. It is also manifest that in issuing the licence to Alpana Pharma obvious legal defects in the licence application were overlooked by the FDA and the correct procedure was not followed, to wit.

(*a*) Unless premises are approved a licence is never given. The token of approval is the signature on the plan of the premises given to the FDA. The plan of Alpana Pharma's premises is not signed in token of approval.

(*b*) The list of the drugs must be scrutinised by the technical officer before a licence is given. In the case of Alpana Pharma even though the licence was issued on 25th April 1984 the scrutiny of the drugs was done by technical officer Nehete one month and 11 days later, namely on 7th June 1984, when 62 items were granted out of the

212 applied for, that is nearly a whopping 30 per cent. Thus the licence (Ex. 279) which was prepared on 16th May 1984 does not, as indeed it cannot, indicate the items for which the licence was granted. Ex. 279

36. The then Jt. Commissioner and Licensing Authority V. D. Deshmukh admitted that despite Alpana Pharma's undertaking not to simultaneously repack powders and liquids (assuming such an undertaking was given) Alpana Pharma could not have been prevented from carrying on these activities in their premises simultaneously, that in the plan no separate rooms were shown for repacking of liquids and powders, that Alpana Pharma's premises were not adequate which was the reason why he did not sign the plan in token of his approval, that as Licensing Authority it was indeed his duty to refuse the grant of licence to Alpana Pharma on the ground that their premises were not adequate. He could assign no reason why he did not refuse his permission, adding that it was an error on his part in not refusing the grant of licence to Alpana Pharma which error he realised in the witness-box. He admitted that he had seen the papers and even though he did not approve of Alpana Pharma's premises, he did grant the licence, laying the blame on Asstt. Commr. Jadhav on whom he purportedly relied. According to Jt. Commr. Deshmukh he did not apply his mind to the inadequacy of the premises of Alpana Pharma nor to the undertaking given by Alpana Pharma. He admitted that there was no provision in the Act or Rule which empowered the FDA to take an undertaking from an applicant that repacking of powders and liquids will not be done simultaneously and that if Alpana Pharma had violated this undertaking, FDA would have been helpless.

37. The prompt inspection of Alpana Pharma's premises within 3 days of its application for grant of the licence is breath-taking looking to the vast area to be covered by just one Drugs Inspector. For that matter, Commr. Bhirud himself admitted this in the witness-box. For that matter, even the prompt inspection by the FDA of Alpana Pharma's new premises on 3rd October 1985 followed by Babne's report followed by Asstt. Commr. Kamble's recommendation, all on the same day and the actual grant of licence 5 days later, namely on 8th November 1985 is breathtaking.

38. FDA officers both at Nanded and Bombay were actively helping Alpana Pharma by the record breaking speed they acted. O. P. Ladda himself was small fry. He had no influence. The moving spirit and guiding hand was Ramanlal Karwa to whom FDA Officers were amenable. And no FDA Officer ever went out of his way gratis.

39. (*i*) Even in Alpana Pharma's letter dated 25th April 1984 addressed to the Director of Industries (Ex. 37), sharp practice has been indulged in by the former. In that letter Alpana Pharma had purported to enclose certain documents *inter alia* xerox copies of income-tax clearance certificate, list of samples, xerox copy of Alpana Pharma's SSI Registration and a xerox copy of the repacking licence issued by FDA. In the last para of that letter it was represented to the Directorate of Industries that Alpana Pharma is a registered SSI unit situate in the backward area of Nanded and hence was entitled to the 33 per cent purchase preference. As will appear immediately hereafter none of these documents could possibly have been enclosed by Alpana Pharma with its letter of 25th April 1984. Ex. 37

(*ii*) A xerox copy of the income-tax clearance certificate could never have been enclosed with the letter of 25th April 1984 because that certificate was issued on 30th April 1984 in respect of a firm constituted by partnership deed on 9th March 1984 which had never carried on business. A xerox copy of the SSI Registration could also not have been enclosed with Alpana Pharma's letter of 25th April 1984 because the SSI Registration Certificate was issued on 1st August 1984. A xerox copy of the repacking licence could also not have been enclosed with Alpana Pharma's letter dated 25th April 1984 as the licence was issued after 25th April 1984. Nor could the list of samples have been enclosed with Alpana Pharma's letter dated 25th April 1984 because the list was approved on 7th June 1984. Though in the last para of Alpana Pharma's letter dated 25th April 1984 it was stated that it is a registered SSI unit, significantly enough the number and date of the purported registration were left blank, which would not have been the case, if indeed the unit had been registered as claimed by Alpana Pharma. All this was ultimately admitted by O. P. Ladda in his evidence that it was in June 1984 that he submitted to the CSPO the income-tax clearance certificate and the SSI Registration Certificate and that it was in June 1984 that he had received from the FDA the certificate and the list of products which he was permitted to repack under the licence.

40. Thus, in Alpana Pharma's application dated 25th April 1984 positively
Ex. 37. p. 15 false statements were made and not having been accompanied by the mandatory documents, it was an incomplete and defective application which should have been rejected on the spot. Even so, it was accepted. This shows that it was not only with the FDA but also with the Directorate of Industries that Alpana Pharma wielded tremendous influence.

41. It cannot even be said that these obvious defects in Alpana Pharma's application dated 25th April 1984 could have escaped the notice of the Directorate of Industries because in the Comparative Statement (Ex. 38) it has been stated that Alpana Pharma's tender was conditional on an order being placed with it for Rs. 1,000 and above. This condition finds place in Alpana Pharma's application dated 25th April 1984 and has been incorporated in the Comparative Statement from Alpana Pharma's application itself. If this condition could be read at the time of scrutiny, as indeed it was, there is no reason why it could not have been detected that the documents purporting to be enclosed with that application had in fact been enclosed. The omission to do so was deliberate so that Alpana Pharma's application should not be rejected out of hand, as indeed it deserved to be.

Ex. 37. p. 15 42. It is not unlikely that Alpana Pharma's tender application dated 25th April 1984 and filed on 27th April 1984 was prepared in anticipated certainty that the licence would be granted by the FDA. The tender form had been purchased prior to 25th April 1984. The letter dated 25th April 1984 granting the licence to Alpana Pharma was delivered to Krishnakumar Karwa the same day at Bombay. O. P. Ladda was at Pune. According to O. P. Ladda on 25th April 1984 he filled in the tender form when he received FDA's letter dated 25th April 1984 granting the licence. The same day, *viz.* 25th April 1984, he purchased 11 different samples from the market. He also had got labels printed for the samples, which he received from the printers by 4-00 p.m. on 25th April 1984.

43. All this is most unnatural. O. P. Ladda could not have prepared the tender form on 25th April 1984. FDA's letter dated 25th April 1984 giving the licence was handed over by the FDA to Krishnakumar in Bombay during office hours. To send this licence even *posthaste* to Pune where O. P. Ladda was, would take at least 4 hours and another 4 hours would be required thereafter for preparing the tender. Even assuming that the licence was given to Krishnakumar Karwa by the FDA the earliest at 10-00 a.m. it would not reach Ladda that day before 2-00 p.m. It was therefore pyhsically impossible for O. P. Ladda to complete all the formalities that day prior to his departure for Nanded.

44. According to O. P. Ladda he had instructed Artichem's clerk Apte to forward the tender form and samples to CSPO. O. P. Ladda admitted that he had taken the help of Apte in preparing the tender form, that he had even forgotten to sign the tender which Apte signed for him even though he had not given any authority to Apte to do so. He had told Apte that the tender should be sent to Bombay for submission to the CSPO. Apte therefore signed the tender on his own.

45. According to Ladda on 25th April 1984 he purchased 100 kgs. of sodium bicarbonate by making a cash payment. To that end, there is only his *ipse dixit* which is contrary to documentary evidence, namely that in O. P. Ladda's own books of accounts, there is an entry under date 25th May 1984 which according to O. P. Ladda denoted payment for this purchase made on 25th April 1984. Obviously all this was in an endeavour to project before the FDA that before he submitted his tender on 27th April 1984 he had started his repacking activity because a certificate to that effect was required to be sent to the Industries Department. O. P. Ladda had sent a letter to the Industries Department after June 1984 stating that he had started his repacking activity with effect from 26th April 1984. However he admitted that he induced the Industries Department to give a certificate that he had started repacking work on 26th April 1984 when actually he had not and that his statement to the Industries Department that he had started his repacking work on 26th April 1984 was a false statement. O. P. Ladda made these admissions in his evidence with the greatest reluctance and after a great deal of prevarication and after the questions were repeated to him several times. Thus O. P. Ladda cheated the Insustries Department and the FDA.

46. This brings me to the role of Ramanlal Karwa. The evidence discloses that he was the moving spirit behind Alpana Pharma which for all practical

purposes was his enterprise financed by Ramanlal Karwa himself, with O. P. Ladda having neither the experience nor the qualifications to do repacking work, mereby being his dummy.

47. This is best disclosed by the evidence and admissions of Ramanlal Karwa and O. P. Ladda themselves.

48. Ramanlal Karwa admitted that initially O. P. Ladda had applied for a licence but as he was infinancial difficulties he approached Ramanlal Karwa's wife Nirmala. It was thereupon decided by Ramanlal Karwa's family members to start a partnership firm in the name of Alpana Pharma at Nanded for repacking of drugs and medicines. Ramanlal Karwa's family decided that Rameshwar Karwa and Sarla Karwa should join as partners. Initially Rameshwar's wife Lalitha was also a partner but she retired in November 1984 and Sarla and Rameshwar became partners. All contributions made to Alpana Pharma by the members of the Karwa family were out of the joint funds of that family. O. P. Ladda gave Ramanlal Karwa the impression that the Ladda group would not be able to make any contribution and that the entire contribution would have to be made by the Karwa group. Ramanlal Karwa further admitted that it was he who supervised and financed the affairs of Alpana Pharma on behalf of the Karwa group, that O. P. Ladda was to make purchases and payments were made from the accounts of Alpana Pharma or by Artichem.

49. Ramanlal Karwa admitted that he is very well acquainted with Girdharlal Kasat and his nephew Bharat Kasat who are connected with Haresh Kumar and Co., Haresh Chemicals and Kailash and Co. with whom Artichem had a running account. He introduced O. P. Ladda to Girdharlal and Bharat Kasat who gave glycerine to O. P. Ladda on credit basis and Artichem paid amounts to them for the supplies made by them to Alpana Pharma.

50. Artichem had an account of Alpana Pharma in its books of accounts and most of the purchases made by Alpana Pharma were paid by Artichem. Ramanlal Karwa further admitted that there is a large outstanding of Alpana Pharma in Artichem's books of accounts but Artichem never sent any debit note to Alpana Pharma nor did it ever claim any interest from Alpana Pharma on the outstanding amount nor has Artichem ever made any demand from Alpana Pharma either for principal or interest due.

51. Ramanlal Karwa admitted that O. P. Ladda had with his consent given his name as the qualified analytical chemist for Alpana Pharma and that an analytical chemist must be present in the laboratory during business hours. However the question of Ramanlal Karwa remaining present in the premises of Alpana Pharma did not arise as O. P. Ladda had not started his operation of Alpana Pharma nor had Ramanlal Karwa any intention of settling down in Nanded as the analytical chemist of Alpana Pharma. He admitted that without his name being shown as the chemical analyst in Alpana Pharma's application, no licence would have been granted by the FDA to Alpana Pharma and that his name was given as chemical analyst only with a view to induce the FDA to grant the licence to Alpana Pharma.

52. After a great deal of prevarication, Ramanlal Karwa stated that he did not remember any instance in his experience of the past 10 years of a party being informed the same day that the licence was granted. A good number of people in the FDA in Bombay know Ramanlal Karwa and he finally admitted that O. P. Ladda had successfully used his name with the FDA officials in order to expedite the grant of the licence.

53. He admitted that he personally knows Asstt. Commr. Jadhav at the Bombay Headquarters since the past 3 to 4 years, that the same S. G. Jadhav was to process the licence application and the recommendation of the Asstt. Commissioner, Nanded, that it was possible that as a result of Ramanlal Karwa's talking to Jadhav or Ladda talking to Jadhav, the grant of the licence was expedited, that Jadhav might have obliged him by expediting the grant of the licence to O. P. Ladda because Jadhav was known to Ramanlal Karwa personally. Ramanlal Karwa might consider Jadhav having conferred a favour on Alpana Pharma by expediting the grant of the licence.

54. Ramanlal Karwa admitted that he knew that ultimately it was for V. D. Deshmukh to grant or refuse the licence to Alpana Pharma ; he might have talked about it to V. D. Deshmukh and put in a word with him as it was in Deshmukh's

hand to expedite the grant of the licence. He admitted that Jadhav had told him that he had recommended the grant of licence to Alpana Pharma whereafter he had seen V. D. Deshmukh once or twice. He further admitted that V. D. Deshmukh was repeatedly requested to expedite the grant of the licence and that he might have told Deshmukh and Jadhav the reason for the expedition, namely that Alpana Pharma wanted to fill in the tender by 27th April 1984 which it could not do unless the licence was expedited. He admitted that he came to know of FDA's letter dated 25th April 1984 granting of the licence the same day which was one of the reasons for his specially coming to Bombay from Pune to accept this letter and that it was written by Jadhav at his request.

55. Ramanlal Karwa admitted that his wife Nirmala Karwa had given an undertaking on 6th April 1984 to establish a quality control laboratory within two months in Alpana Pharma but attempted to dissociate himself from it on the excuse that this letter was not prepared with his consent or knowldge. He however admitted that this letter had been typed in his office at Pune and that his office had Alpana Pharma's letter-heads. His wife Nirmala did not take an active interest in Alpana Pharma. That was done by him and O. P. Ladda. He admitted that he took an active interest in Alpana Pharma because of his financial involvement in Alpana Pharma in which his family had a 50 per cent stake. He advised O. P. Ladda.

56. Ramanlal Karwa admitted that the contents of the letter dated 6th April 1984 (Ex. 194) signed by his wife were based on the suggestion made to him by Asstt. Commissioner Jadhav on the ground that it would be easy to get the licence. He admitted that Asstt. Commissioner Jadhav may have told him about the objection having been raised regarding Alpana Pharma not having an in-house laboratory and that such a letter like Ex. 194 should be written and that S. G. Jadhav may have told him that he had recommended the grant of licence to Alpana Pharma.

57. Ramanlal Karwa admitted that the contents of the letter dated 1st October 1985 from O. P. Ladda to FDA that Alpana Pharma had already provided for quality control section in the new premises and had appointed R. R. Karwa as the quality control chemist was stated in that letter with his consent even though he had not been appointed by Alpana Pharma as its quality control chemist and had lent his name to Alpana Pharma as its qualified quality control chemist. He also admitted that the statements in that letter that he had been so appointed, as also that Alpana Pharma had already made a provision for carrying out routine tests in its laboratory, were incorrect and that Alpana Pharma had never appointed anyone else as its quality control chemist and had never established an in-house laboratory.

Ex. 195 58. Ramanlal Karwa admitted that the letter dated 1st October 1985 (Ex. 195) of Alpana Pharma might have been typed in his office and that probably it was written to obviate the complying with the undertaking given by his wife to the FDA x. 194 in the letter dated 6th April 1984 (Ex. 194).

59. He deposed that Artichem is still in business, that Arti Pharma is another partnership concern comprising of the members of the Karwa family, and that Arti Pharma made its bills for the supplies of glycerol made by Alpana Pharma to various parties and that for doing this work Arti Pharma got a 10 per cent deduction of the invoice value of Alpana Pharma's goods. In respect of the supplies of glycerol made to the J. J. Hospital the bills were sent by Alpana Pharma to J. J. Hospital; Arti Pharma had billed to many Government hospitals for goods supplied by Alpana Pharma and received 10 per cent commission from Alpana Pharma; that Arti Pharma's books would show 90 per cent of the bills as having been received on account of Alpana Pharma and credited to Alpana pharma and the balance 10 per cent would be shown in Arti Pharma's books as credited to Commission Account. He admitted to an adjustment where the amount credited to Alpana Pharma was with a view to off-set the amount due to Arti Chem.

60. This evidence of Ramanlal Karwa and the admissions made by him clearly go to show that it was he and not O. P. Ladda who was in the saddle as far as Alpana Pharma was concerned. To that end, there is also the evidence of O. P. Ladda.

61. According to O. P. Ladda the capital contribution of the Ladda family was Rs. 45,750. The fixed capital contribution of the Karwa group was Rs. 26,000 and Ramanlal Karwa was to make further contributions as and when required. He admitted that Ramanlal Karwa thereafter made further contributions with the result that at present Alpana Pharma has to pay Ramanlal Karwa over Rs. 1,00,000.

Alpana Pharma had to receive from Arti Pharma Rs. 1,66,901 in respect of the bills prepared by Alpana Pharma in the name of Arti Pharma. He admitted that supplies were made by Alpana Pharma and all that Arti Pharma did was to prepare the bills. O. P. Ladda admitted that Alpana Pharma has to pay Arti Chem a sum of Rs. 2 05,452 representing the purchases made and the bills paid by Arti Chem on behalf of Alpana Pharma. No interest was agreed to be paid by Alpana Pharma to Artichem or vice versa. However it had been agreed that Alpana Pharma would pay Ramanlal Karwa interest on his fixed contribution of Rs. 26,000 and that he i.e. O. P. Ladda would receive interest from Alpana Pharma on his fixed contribution aggregating to Rs. 45,750. There was no written agreement between Alpana Pharma and Arti Pharma for the payment by Alpana Pharma to Arti Pharma for the 10per cent commission for preparing the bills of Alpana Pharma. The understanding to pay 10 per cent commission to Arti Pharma was an inducement to Ramanlal Karwa to finance Alpana Pharma from time to time as and when required. O. P. Ladda admitted that the bills of Alpana Pharma were actually prepared by him in the name of Arti Pharma as if to show that these bills had been prepared by Arti Pharma.

62. O. P. Ladda admitted that he himself had no finance and had no resources and hence would not have been able to start Alpana Pharma and that everything he did pertaining to Alpana Pharma was under the advice of Ramanlal Karwa.

63. O. P. Ladda had never gone to the FDA office after making his application in March 1984. He admitted that Ramanlal Karwa had indeed made efforts to see that the licence to Alpana Pharma was granted expeditioulsy by the FDA and that Ramanlal Karwa knew several officers in the FDA and that he himself had not made any endeavours to get the licence by 27th April 1984.

64. O. P. Ladda finally admitted that it was Ramanlal Karwa who indeed had made efforts to see that the licence to Alpana Pharma was granted by the FDA and was obtained expeditiously, that O. P. Ladda himself had not made any endeavours to that end, and that Ramanlal Karwa knew and knows several officers in the FDA. He also admitted that the letter dated 6th April 1984 (Ex. 194) signed by Ramanlal Karwa's wife Nirmala had been prepared from a draft given by Ramanlal Karwa to O. P. Ladda and that Arti Chem had letter-heads of Alpana Pharma. Ex. 194

65. The evidence of Ramanlal Karwa and O. P. Ladda by itself is sufficient to show that it was the former and not the latter who was the moving force and spirit behind Aplana Pharma but for whose influence the FDA and the Directorate of Industries would never have bent the Rules or shut their eyes to obvious deficiencies or granted the licence to Alpana Pharma within the record time it was done for at all.

66. The fact that O. P. Ladda was merely a dummy is brought to the forefront by the fact that he himself had neither the experience nor the qualifications to do any repacking business. This was admitted by Ramanlal Karwa himself. O. P. Ladda's ignorance is apparent from his admission that though he was required to maintain a record of his repacking activities, he did not know if these records were required to be maintained under the Drugs and Cosmetics Rules and that he did not go through any such Rules before applying for his repacking licence, that he had only heard that the repacked material also required to be tested, that what he got tested were the raw materials and never the finished products except in the case of Batch No. 27. He did not even know the quantity of the sample which would be required for testing purposes. Even to the extent as to the minimum quantity required for analysis, Ladda was ignorant. Even the requisite sample which he sent to Chem Med was merely 50 ml. instead of the requisite minimum of 100 ml. He admitted that before he started his repacking operations he did not draw any samples from these two drums or send them for analysis. O. P. Ladda admitted that he had no previous experience of repacking until he started Alpana Pharma. Before he started Alpana Pharma he did not know any manufacturer and that it was Ramanlal Karwa who guided him from whom he should make the purchases.

67. Even for doing the simplest of things, O. P. Ladda relied on Ramanlal Karwa. To illustrate, on O. P. Ladda's own showing, even the letter dated 6th April 1984 from Alpana Pharma to the Commissioner, FDA (Ex. 194) was prepared from a draft given to him by Ramanlal Karwa and from that draft O. P. Ladda dictated the letter over the telephone to an employee of Arti Chem. There is further his own admission that when Alpana Pharma was started, he did not even know that samples had to be sent twice for testing which he came to know for the first time in December 1984 from other repackers. O. P. Ladda admitted his total ignorance of the provisions of the Drugs and Cosmetics Act and the Rules. Ex. 194

68. There is abundant evidence on record, *including admissions made by O. P.* Ladda himself, that Alpana Pharma had not the slightest intention of honouring the undertakings given to the FDA to set up a quality control laboratory in its premises and to have a *qualified chemist* in its premises. O. P. Ladda admitted that even though an undertaking was given by Alpana Pharma's letter dated 6th April 1984 Ex. 194 (Ex. 194) to set up a quality control laboratory in the factory within a period of two months, none had been set up nor had he any intention of doing anything of the kind, adding that such undertaking was given not because he wanted to keep it but because the FDA required it, knowing full well that the licence would not be given without this undertaking. He also admitted that when he gave Ramanlal Karwa's name as qualified chemist to the FDA both he and *Ramanlal Karwa knew that Ramanlal* Karwa would never come to Nanded and work as Alpana Pharma's qualified chemist. He did not advertise for a quality control chemist but made oral enquiries at Aurangabad *for one but without* offering any terms and conditions. Such was the rediculousness of his quest. According to O. P. Ladda after he shifted into the larger premises in December 1985, he equipped himself with some apparatus with which only certain tests could be carried out. He admitted that the quality control laboratory never functioned even for a single day and that out of 16 tests for glycerine only one or two tests could have been done, namely the colour test and the description test, which did not require any equipment at all. He also admitted that the items contained in the two *lists enclosed with Alpana Pharma's letter dated* 3rd October 1985 to the FDA were not sufficient to start a fully equipped functional quality control laboratory and that it was financially not possible for him to do so at one time. It would have taken him one or two years minimum to have started a fully functional laboratory in his premises and finally admitted that the undertaking given by him to do so was a false undertaking. He agreed that in the show-cause notice given to Alpana Pharma by the FDA the breach of this undertaking does not find a place. He ultimately admitted that the statement in the last para. of Alpana Pharma's *letter* Ex. 195 dated 1st October 1985 (Ex. 195) that all the necessary formalities had been complied with was not a correct statement and that it was on the basis of that letter that the FDA was *induced to give the licence to* Alpana Pharma.

69. These factors indicate that but for Ramanlal Karwa's financial interest in *Alpana Pharma and his tremendous influence with the FDA*, O. P. Ladda, left to himself, would not have dared either to give a false undertaking, much less fail to carry it out. O. P. Ladda's prop and pillar was Ramanlal Karwa whereby O. P. Ladda could give false undertakings unabashedly, commit breaches thereof with impunity and make false statements unabashedly, all with the knowledge that somebody influential was behind him; somebody who had much to gain and much to lose. That somebody was Ramanlal Karwa and the Karwa group.

70. The fact that these undertakings had been breached and that false statements had been made by Alpana Pharma was something not unknown to the FDA. Yet *no punitive steps were taken against Alpana Pharma. For that matter no* steps at all were taken against Alpana Pharma and objections taken by some officers were swept under the carpet by their superiors. It may be recalled that on 31st May 1985 an objection was raised by Drugs Inspector Vadnere that Alpana Pharma had not provided an in-house laboratory and must be asked to carry out its undertaking. Vadnere's objection was endorsed by Asstt. Commissioners, Phadnavis and Raykar on 1st June 1985. Despite this, on 5th June 1985 the FDA merely wrote a letter to Alpana Pharma requesting an in-house laboratory. Realising the futility of *merely* giving another undertaking, Alpana Pharma addressed its letter dated 1st October 1985 (Ex. 195) to the Commissioner that an in-house laboratory had already been *provided and was functioning.* This on O. P. Ladda's own admission in his evidence was a false statement made in that letter. Within two days of that letter, Drugs Inspector Babne at Nanded made his report dated 3rd October 1985 that Alpana Pharma had set up an in-house laboratory for routine chemical analysis, that it had equipment and apparatus necessary for the same, that testing not of a routine type could also be done in that in-house laboratory and that Ramanlal Karwa appears to have been appointed as a quality control chemist. This report of Drugs Inspector Babne was a *totally false report as is manifest from the admissions made by* O. P. Ladda himself in his evidence that only two tests could be carried out, namely the colour test and the description test and which, again on his own admission, do not require any apparatus at all, and that Ramanlal Karwa being appointed as the chemist was plain eye-wash. Inspector Babne's report was approved by Asstt. Commissioner Kamble perhaps under the *bona fide* belief that it was correct. However the sinister machinations of Inspector Babne's report are brought more to the forefront by the

fact that with its letter dated 1st October 1985, Alpana Pharma had annexed a plan showing an area of $15\frac{1}{2}' \times 11'$ as Quality Control. If Inspector Babne had made a correct report the false statements made by Alpana Pharma in its letter and the plan annexed would have been exposed. Thus even Babne at the Nanded Office was a pliable tool in the hands of Alpana Pharma and surely not for love.

71. All these circumstances indicate the complicity of erring officials of the FDA not only in not enforcing the undertakings given by Alpana Pharma but worse still, in covering up the glaring breaches committed by Alpana Pharma in wilfully flouting the undertakings given.

72. This brings me to the role of O. P. Ladda insofar as it pertains to the repacking work done. This can best be evaluated from his evidence and his own admissions.

73. To start with, he admits that before he started his repacking operation, he did not draw any sample from the two drums received by him, nor did he send any sample from these two drums for analysis. Negligence. Though according to him, the repacking from these two drums was done under his personal supervision, he admitted that he did not examine the actual contents of the drums before commencing the repacking process. Negligence. The excuse given by him that it was not possible to do so while the glycerine was actually in the drum, is too absurd to countenance. He stated that when he was repacking this glycerine it was colourless and did not smell of burnt sugar. This is false because the Government Analyst's report which O. P. Ladda was reveals that the glycerine was pale yellow in colour. This shows that O. P. Ladda had not bothered even to see what his casual labourers were repacking. He admitted that between the time that the glycerine was repacked and the sample sent to the Government Analyst, it did not change colour because glycerine does not change colour. He also agreed that pure glycerine is odourless whereas the report of the Government Analyst showed that the sample smelt of burnt sugar, that chemical odour would not generally be of burnt sugar and that he has never come across a single instance where glycerine used for medical purposes smelt of burnt sugar. These admissions are further pointers that the repacking was not done under O. P. Ladda's supervision, his protestation in his evidence to the contrary notwithstanding. If only O. P. Ladda had taken the elementary precaution of seeing what was being repacked instead of leaving the operation to his casual labourers, he would have realised that what was being repacked smelt of burnt sugar and even have the colour of glycerine. This should have put him on his guard. Thus even this elementary care and precaution O. P. Ladda did not care to take. Negligence.

74. O. P. Ladda says in his evidence that he had seen the stenciled warning " NOT FOR MEDICINAL USE " on the drums. Even so it is surprising that it should not have dawned upon him that what had been sent to him was not what he had ordered. His version is that glycerine is a dual purpose item and I. P. glycerine is not stenciled as such. He added that despite this stenciled warning, his suspicions were not aroused that the contents of these two drums were not fit for human consumption because the contents could be used internally after testing. A totally bewildering explanation. He however admitted that he did not have the contents of these two drums tested before repacking. According to O. P. Ladda despite this stenciled warning " NOT FOR MEDICINAL USE ", he proceeded on the assurance given to him by Girdhar Kasat with whom he was on very friendly terms. Pausing here for a moment, beyond O. P. Ladda's *ipse dixit*, there is no evidence that any assurance had been given to him by Girdhar Kasat or that he was on very friendly terms with him. For that matter, he came to know Girdhar Kasat only recently, having been introduced to him by Ramanlal Karwa. Even assuming O. P. Ladda acted on any such alleged assurance, the same cannot absolve him from the charge of negligence.

75. Whatever gloss O. P. Ladda may now try to put on his evidence, however he may try to wriggle out of his own responsibility, it is what he stated at the erarliest point of time which must hoist O. P. Ladda with his own petard. The earliest point of time was when he made his statement to the CID on 12th March 1986 where he admitted that he had not carefully examined the markings or labelling on the drums and that the stenciled warning on the drums had in fact been brought to his notice by Drugs Inspector Babne when he visited his factory on 29th January 1986.

76. Thus it was only on 29th January 1986 after the J. J. Hospital tragedy, it dawned on O. P. Ladda that what he had repacked was not for medicinal use. Even so, and though indisputably his Batch No. 24 also contained diethylene glycol, he did not take any step to inform any of his purchasers about this.

77. O. P. Ladda's negligence stands out supreme. An ordinary prudent person would first have taken charge of the drum and sent the samples for analysis. No instructions were given by O. P. Ladda to Chavan to take two separate samples from each of the two drums though O. P. Ladda knew that the glycerine which was ordered was in two drums of 250 Kg. each. No precautions were taken by him to see that the same drums were supplied from which the sample had been drawn. He did not even know the quantity required for analysis, nor did he care to examine the drums or its contents after they were received by him. His version that Batch No. 27 was tested twice is a myth as will appear shortly hereafter, invented to cover-up his negligence in supplying the killer glycerol to the J. J. Hospital.

78. O. P. Ladda's negligence is also apparent from the manner in which he
Ex. 389 maintained his bin card (Ex. 389). On his own showing it was not written from day-to-day, nor are the entries in the bin card based on any contemporaneous documents such as bills, invoices etc. The date of arrival of Batch No. 27 is shown in the bin card as 5th November 1985, in the teeth of the admitted position that the drums did not arrive on 5th November 1985, This is patently a false entry as the drums were despatched to Alpana Pharma on 23rd November 1985 under invoice No. 007 of that date. The reason why in the bin card the date of arrival of the drums was shown as 5th November 1985 is because on that day a sample of Batch No. 27 was sent for analysis to Chem Med. O. P. Ladda wanted to show that he himself had drawn sample after the goods had arrived in his premises on 5th November 1985. Therefore, he had to show in the bin card the physical receipt of the goods on 5th November 1985 even though he had physically received them on 4th December 1985. O. P. Ladda admitted that the entry in the bin card was not made on 5th November 1985 but on 4th December 1985. He was unable to give any reason why he did so that day so as to show that the goods had arrived on 5th November 1985. According to O. P. Ladda the goods were physically received by him on 4th or 5th December 1985 and not on 5th November 1985. This by itself shows that this entry must have been made after learning of the J. J.Hospital tragedy in an attempt to connect the glycerine supplied to J. J. Hospital with Chem Med's passing report of Batch No. 27. In this entry the number of invoice has been mentioned, but not its date. O. P. Ladda had shown the date of the invoice as 5th November 1985 ; he could not have subsequently stated that the samples were drawn from the very drum which he received in his factory.

79. In addition to O. P. Ladda's negligence there was also *mens rea* on his part. This is borne out by the fact that he sent advance samples for analysis in respect of batches yet to be purchased. Batch numbers were given by O. P. Ladda for his own convenience. He knew that the analysis work done by Chem Med took some time. O. P. Ladda's understanding was that obtaining certificates that the glycerine was of standard quality was a mere formality. In other words, he believed that he must be able to show, if questioned, that all the goods supplied by him had previously been analysed. Hence he wanted to have separate test certificates for each supply he made. What appears to be is that O. P. Ladda sent samples for analysis to Chem Med which did not have any relation to the bulk which he was ultimately going to purchase. Hence he gave batch numbers to his samples without actually having the bulk in his factory. As a result he had to change and re-change his batch numbers and there was also overlapping of batch numbers. If O. P. Ladda's records are to be believed, the fact that he used to send samples for analysis without ever receiving the goods in his factory, can be demonstrated from his own
Ex. 389 bin card (Ex. 389) which was the only record he maintained. To illustrate, he appears to have purchased glycerine which he repacked as Batch No. 22. He had never purchased any material which was repacked as Batch No. 24. He however sent the sample of Batch No. 24 to Chem Med for analysis. According to Chem Med, O. P. Ladda had also sent sample of Batch No. 22 for analysis. After receiving the report of Batch No. 24, O. P. Ladda sold the bulk material as Batch No. 22. Batch No. 22 which was sold as glycerine had a corresponding sample only in the form of Batch No. 24. Batch No. 22 which O. P. Ladda had sent to Chem Med for analysis was according to him for castor oil. He had not sold any goods under Batch No. 24, be it castor oil or glycerine, but he had sent some samples earlier to Chem Med as Batch No. 24, which when passed were conveniently co-related to the material purchased and sold as Batch No. 22.

80. By this jugglery, he was always one step ahead and did not have to wait for the analytical report, as an advance sample was sent for analysis in respect of a batch
Ex. 389 yet to be purchased or received. That is the reason why in the bin card (Ex. 389) there is no mention of any purchase of material of Batch No. 24.

81. This was a consistent piece of conduct on the part of O. P. Ladda as is manifest from the fact that after receiving the material which was repacked as Batch No. 27 on 10th December 1985 as admitted by him, he sent the samples drawn from that material as Batch No. 29 for analysis and on O. P. Ladda's own showing Batch Nos. 27 and 29 are the same. This manipulation was necessary to make preparation for the next purchase and that is the reason why there is no mention of material under Batch No. 29 in the bin card, where the last batch shown is Batch No. 27. Hence advance preparations were made by O. P. Ladda.

82. O. P. Ladda admitted that he never got any batch analysed twice, except Batch No. 27, provided his version is accepted that Batch No. 29 is a mistake for Batch No. 27 which as will appear presently, was not. If this is a mistake there is no explanation for the earlier mixing up of Batch Nos. 22 and 24. To assume a consistent course of mistake is to strain credulity.

83. The fact that Batch No. 29 is not a mistake for Batch No. 27 can be demonstrated in several ways, to wit,—

(1) According to O. P. Ladda he never knew that a sample was required to be analysed twice and according to his understanding it required to be analysed only once. In that event, there is no explanation why would he make an exception only in respect of this batch and get it analysed twice.

(2) O. P. Ladda had already committed himself to Chem Med that what he was sending was a sample of Batch No. 29 and had even received Chem Med's report of Batch No. 29. The only way for O. P. Ladda to undo this was to project it as a mistake for Batch No. 29 being shown as Batch No. 27.

(3) O. P. Ladda's own record of purchases do not support him in his suggestion that the samples of Batch No. 29 were drawn from some other sources.

(4) Chem Med's report of Batch No. 29 being of standard quality and having been drawn by O. P. Ladda from the same drum, was likely to correspond with the bulk which would afford the best defence to O. P. Ladda.

84. Hence a rear guard action was resorted to by O. P. Ladda by the stratagem of an alleged letter dated 18th December 1985 (Ex. 393) purported to have been sent to Chem Med under certificate of posting. What was stated in this letter was that Alpana Pharma had wrongly mentioned Batch No. 29 instead of Batch No. 27 on the label of the sample sent for analysis by Alpana Pharma's letter dated 10th December 1985 received by Chem Med on 14th December 1985 with a request to Chem Med to modify the same in its records with confirmation to Alpana Pharma. Ex. 393

85. There are several circumstances which indicate that this letter is a got-up and fabricated letter, never sent to Chem Med. To start with, this is the only letter which has ever been sent by Alpana Pharma to Chem Med under certificate of posting. The certificate of posting was merely a device to lend conviction, for otherwise there was no reason to do so in the case of a genuine error made by O. P. Ladda. Though Chem Med was asked to confirm the correction, Chem Med never did so ; nor did Alpana Pharma sent any reminder to that end to Chem Med, no doubt under the theory ' Let sleeping dogs lie '. A reminder would have provoked Chem Med's response that no such letter of 18th December 1985 was ever received by Chem Med as is borne out from the evidence of Chem Med's Managing Partner Sipahimalani and its Chief Chemist Karnachi.

86. Even the reason given by O. P. Ladda for writing the letter dated 18th December 1985 (Ex. 393) is most implausible. According to him on 18th December 1985 while he was filing Chem Med's acknowledgements regarding the samples received by them his eyes fell on the letter pertaining to glycerine on which Batch No. 29 had been written whereas on the other material packed by him the batch number had been given by him as 27. Thereupon according to O. P. Ladda on 18th December 1985 he dashed off his letter Ex. 393 to Chem Med informing them that Batch No. 29 had been written through oversight and that the correct batch number was 27. None of this is true. It is all an afterthought. In his evidence O. P. Ladda finally admitted (i) that he had not noticed the batch number mentioned in Chem Med's report until Drugs Inspector Babne drew his attention to it on 29th January 1986, (ii) that when he gave his statement to the police on 12th March 1986 he did not produce any documents nor did he mention that he had written any letter to Chem Med on 18th December 1985, (iii) that in his statement recorded by the police on Ex. 393

21st March 1986 it is not mentioned that he handed over to police a copy of the letter dated 18th December 1985 and (iv) that in his reply to FDA's show-cause notice he had not mentioned that he had written any such letter to Chem Med. In
Ex. 393 the light of the above, it is obvious that the letter dated 18th December 1985 (Ex. 393) is a got-up and fabricated letter, the certificate of posting not withstanding, and all done in an attempt to connect Batch No. 27 with Batch No. 29. It is also of no mean significance that there is no similar letter or communication to Chem Med to connect the mistake regarding Batch Nos. 22 and 24.

87. Even assuming for the sake of argument that this letter dated 18th December 1985 (Ex. 393) is not a fabrication, even so, its value is nil as Alpana Pharma cannot say that what was sent to Chem Med was a representative sample from both the drums.

88. Negligence and *mens rea* on the part of O. P. Ladda are manifest in abundant measure.

PART IX

CHEM MED ANALYTICAL LABORATORY

89. This brings me to the role of Chem Med in analysing the sample of Batch No. 27 and interaction with the FDA.

HISTORY AND ACTIVITIES

(*a*) Chem Med started its analysing activities in 1961. It has three laboratories. The main laboratory is at Mohata Bhavan, Worli where analysis is done by instruments and chemicals. Another laboratory is at Kakad Estate, Worli, where microbiology testing is done. The third laboratory is at Byculla where biological testing is done. The main office is at Kakad Estate.

(*b*) J. L. Sipahimalani is the managing artner. A. Q. Karnachi is the Chief Chemist ; under him are three department heads; under them are 10 approved chemists; under them are 10 senior chemists and under them are 20 junior chemists.
Ex. 430 As on 1st December 1985 the total staff strength including Sipahimalani was 39.

(*c*) Chem Med has 300 regular clients and 1,000 casual clients. 50-100 samples are analysed every day. Analysis of glycerine is done at Mohata Bhavan by a junior chemist under the supervision of an approved chemist.

(*d*) About 1,500 failure reports are prepared by Chem Med every year. Under the Rules these failure reports are required to be sent to FDA. However, Chem Med does not send all its failure reports to FDA by the device of classifying them as experimental samples, because for experimental samples failure reports need not be sent to FDA.

(*e*) Only 5 per cent to 10 per cent of the samples analysed are declared every year as not of standard quality. However, no register or record of sub-standard reports is maintained.

(*f*) Chem Med's practice is to prepare in advance a format of the protocols. Protocols are written on loose sheets of paper and not in any file or notebook. Even rough notes are made on loose sheets of paper and not in any rough book. The sample register is the only record where entries are serially numbered.

Part of Ex. 409 (colly.) (*g*) By its letter dated 22nd January 1984 Chem Med gave its consent to Alpana Pharma for carrying out its analysis work. Pursuant thereto Chem Med analysed Alpana Pharma's samples. As many as 6 samples of glycerine were analysed in the form of Batch Nos. 20, 21, 24, 26, 27 and 29. Chem Med certified them all to be of standard quality. We are concerned with Batch Nos. 24, 27 and 29 whose analyti-
Exs. 211, 212 and 213 cal reports are Exs. 211, 212 and 213 respectively.

90. I shall first take up the crucial Batch No. 27.

(*a*) The analysis work commenced on 8th November 1985 and was completed on 15th November 1985. It was done by Miss Rekha Pai who was a trainee Chemist with an year's experience and who on her own admission would not have been able to do the analysis work on her own. Her analysis is said to have been surpervised by Chem Med's approved Chemist, V. D. Barot.

(*b*) The protocols comprise of 3 pages. Barot's signature appears on the first page and Miss Pai's on the third page.

(c) On 30th or 31st January 1986 Chem Med's Chief Chemist Karnachi read in the newspaper about the J. J. Hospital tragedy. He thereupon made inquiries from Barot and Miss Pai whether the tests on Batch No. 27 had been properly carried out. After apparently verifying the reports Barot told Karnachi that the tests had been correctly carried out. According to Karnachi, Barot referred to the rough notes on that day. Karnachi however discovered a mistake in writing the normality of sulphuric acid as 0·2 instead of 0·1.

(d) On 1st or 2nd February 1986 pursuant to a telephone call received by Chem Med's managing partner Sipahimalani from the FDA, he told Karnachi to send to the FDA the reports and protocols of Batch Nos. 27 and 29. Karnachi did so through one Athawale who gave them to the Intelligence Branch of the FDA.

(e) On 12th February 1986 Chem Med was inspected by Drugs Inspectors Vadnere and Choudhari.

(f) On 21st February 1986 a show-cause notice was issued by Jt. Commissioner Dolas to Chem Med (Ex. 237) to which on 4th March 1986 Chem Med sent its reply (Ex. 238). Ex. 237 Ex. 238

91. The correctness or otherwise of Chem Med's reports and protocols regarding Batch Nos. 27 and 29 are in question. Batch Nos. 27 and 29 can be correlated to what was supplied to J. J. Hospital resulting in the tragedy there. Hence indisputably if the samples represented the bulk, then Chem Med's certification of the samples being of standard quality was false. Even otherwise there is overwhelming evidence which establishes beyond the shadow of doubt that Chem Med's reports certifying Batch Nos. 27 and 29 as of standard quality were false.

92. On 21st January 1986 the Government Analyst Dr. Pilankar certified the sample of Batch No. 27 as not to be of standard quality. This was directly contrary to Chem Med's certificate certifying the sample to be of standard quality. In addition, both Dr. R. T. Sane and the Government Analyst Dr. Pilankar certified by their respective reports dated 4th February 1986 and 19th June 1986 (Exs. 35 and 369) that Batch No. 27 was contaminated with diethylene glycol. According to the former the percentage of diethylene glycol was 18, whereas according to the latter the percentage of diethylene glycol varied between 13·873 and 14·404. Regardless of the percentages mentioned in these two reports the indisputable fact remains that the reports of both Dr. Sane and Dr. Pilankar disclose a high content of the lethal diethylene glycol enough to kill a regiment. However, in fairness to Chem Med it may be pointed out that it had not been asked to perform any toxicity test, but merely to carry out tests according to I.P. Exs. 35 and 369

93. Indian Pharmacopoeia prescribes in all 16 tests to be carried out. It is only if the glycerine sample passes all these 16 tests, can it be said to be of standard quality according to I. P. If it fails in any single test, the sample must be declared not to be of standard quality.

94. Chem Med's reports certifying the sample of Batch Nos. 27 and 29 as of standard quality showed that the sample had passed all the 16 tests. These findings are directly contrary to the official and binding report dated 29th January 1986 (Ex. 210) of the Government Analyst which says that the sample had a faint odour like that of burnt sugar and did not comply with I. P. test for (1) Acraldehyde and Glucose, (2) Certain reducing substances and (3) Fatty acids and Esters. Exs. 212 and 213 Ex. 210

95. It is however not on this ground alone that I come to the conclusion that Chem Med's report is false. Its falsity is also borne out by overwhelming evidence which suggests (*i*) that the tests were not carried out by Chem Med ; (*ii*) if indeed they were, they were not properly carried out; and (*iii*) in any event, it was in order not to displease their client that standard quality reports were typed out by Chem Med and sent to Alpana Pharma. Thus, bluntly put Chem Med's reports Exs. 212 and 213 are false and bogus.

96. To start with, a mere glance at Chem Med's protocols of Batch Nos. 27 and 29 shows *ex facie* that Chem Med's reports Exs. 212 and 213 cannot possibly be correct inasmuch as from the working given of the tests in the protocols, the sample would fail. To that end, there is the admission made by Chem Med's Chief Chemist Karnachi himself and also by Chem Med's Chemist Barot. After deposing that he assumed that the tests had in fact been carried out and that the material had passed the tests, Karnachi admitted—

" If the result is as shown in the protocols, the material has failed to pass the tests." (The underlining is mine).

In this admission, Karnachi is corroborated by Chem Med's Chemist Barot, who also admits—

> " I agree that the result as it stands in the protocols (Ex. 212-A) would not be indicative of the sample having passed the tests laid down in the Indian Pharmacopoeia." (The underlining is mine).

These admissions coming from Karnachi and Barot themselves (be it reluctantly) are sufficient to put falsity of Chem Med's reports beyond the pale of controversy.

97. However, Chem Med's witnesses tried to justify Chem Med's declaration of the sample as being of standard quality not on the basis of what is stated in the protocols, but on the basis of something not stated in the protocols. This endeavour must end in failure because on analysing their evidence it is clear that the protocols show results which are different from the results said to have been obtained. These protocols are manipulated, as the result can not be justified on the basis of what is stated in the protocols.

98. To Chem Med's discomfiture, this is not the first and only instance where it has indulged in such manipulations. They are pastmasters at the game. Since, 1972 Chem Med is the proud possessor of a previous history of manipulating reports and with the benevolence of the FDA virtually getting away with it. Since 1972 on Chem Med's own showing, the FDA issued three warnings and two orders of suspension of approval for giving false reports, issuing reports without carrying out tests and otherwise manipulating their reports. One event of recent origin pertaining to Chem Med's sister concern Semit Products Pvt. Ltd., whose product was analysed by Chem Med, also shows that Chem Med's predilection for manipulating its reports continues unabated and is updated.

99. This glorious history and energetic course of conduct, previous and subsequent, on the part of Chem Med must indeed raise a strong suspicion that their reports in the instant case were also manipulated. To that I add a rider : This suspicion is confirmed in the light of the evidence on record, *inter alia*, to wit, Dr. Sane's report, Dr. Pilankar's report and the admissions indented earlier of Chem Med's Chief Chemist Karnachi and Chemist Barot themselves.

100. All the warnings and suspensions meted out to Chem Med were over come by them with the active blessings of the FDA. In a rare burst of candour Chem Med's managing partner Sipahimalani disclosed in his evidence the secret of keeping FDA officials happy and purring with contentment. No doubt, prudence demanded that he disassociate himself from this splendid exercise of spreading happiness and contentment amongst FDA officials in order to levigate their righteous wrath. He made only two exceptions of those who were untouched by the venial sin of corruption, namely ex-Commissioner Rajadhyaksha and of course himself. Unfortunately for Sipahimalani despite the modest opinion he has of himself and the halo he chooses to adorn himself with, the facts are to the contrary and reveal that Sipahimalani has not been far behind others in spreading happiness and contentment amongst FDA officials which in turn redounded to his advantage and well-being.

101. Uptil today despite Chem Med's grim record Sipahimalani has not antagonised the FDA. Despite serious lapses in the matter of analysing life-saving drugs, he and Chem Med have been let off with punishments which were not only light, but ridiculously so, and some how or other he was always able to " persuade " FDA officials to revoke stringent orders as done as recently as in 1984 in the case of his sister concern Semit Products Pvt. Ltd. Indeed the suavity he so assiduously cultivated in the witness-box had nothing to do with this achievement.

102. In the instant case, Sipahimalani's rapport with FDA officials is highlighted by the fact that even though on 31st January 1986 the Government Analyst Dr. Pilankar reported this glycerine to be not of standard quality, no move was made in the direction of Chem Med until 12th February 1986 except that on 1st or 2nd February 1986 Sipahimalani received a telephonic request to send to FDA the reports and protocols of Batch Nos. 27 and 29. This was done through the agency of Chem Med's employee Athawale who gave the reports and protocols to the Intelligence Branch headed by Assistant Commissioner, Kochar. Intelligence Branch put these reports and protocols in cold storage till 11th February 1986. No enquiry was directed either against the manufacturer or against Chem Med, though ex facie the protocols could be seen to be false. Thus, by this expedient of shelving Chem Med's reports and protocols, Chem Med was kept away from the picture as long as

possible and instead the heat was diverted towards Bakewell India, and a complaint was drafted against Alpana Pharma which was filed in the Nanded Court on 10th February 1986. Chem Med was not made a co-accused though it deserved to be. Thereafter, on 11th February 1986 it was decided that a show cause notice should be issued against Alpana Pharma. This was done on 12th February 1986 and Joint Commissioner and Licensing Authority the worthy Dolas personally went to Nanded for service of this notice on Alpana Pharma. Thus, until 11th February 1986 Chem Med was deliberately relegated to the shade.

103. Even though xerox copies of Chem Med's reports and protocols were received by Intelligence Branch on 1st or 2nd February 1986, there was no discussion about Chem Med till 11th February 1986. On that day a meeting was held of the top officials of the FDA. Present were Commissioner Bhirud, Jt. Commissioner Dolas Ex. 549
and Assistant Commissioners Kochar (I.B.) and Raykar. The minutes of that meeting have not been signed by Bhirud but he was present nevertheless. By this time investigation against Bakewell India had drawn a blank. It was apparent that the fact that Chem Med had done the analysis was sooner or later bound to come to light, particularly when Government was insisting on reports being made to it by the FDA. Hence investigation against Chem Med by the FDA could not be put off any longer. Thus, in the meeting of 11th February 1986, without any reference to Chem Med's reports and protocols having already been received by the Intelligence Branch of FDA 10 days earlier, one of the decisions taken and minuted was—

> " To investigate at M/s Chem Med Analytical Labs to see whether has carried out analysis properly and not to draw control sample if it is less 250 gms. D. I. Vadnere and Choudhari have been asked to investigate."(sic.)

Such was the decision reluctantly and half-heartedly taken at this meeting. It was taken as if the FDA had no prior intimation whatsoever about Chem Med's role and despite having received xerox copies of Chem Med's reports and protocols as far back as 1st or 2nd February 1986. None of this finds place in these minutes. It was suppressed.

104. By 7th February 1986 it was common knowledge that Batch No. 27 was toxic. Protocols sent to the FDA stated that the control samples had been used up and that the quantity sent for analysis was less than 250 gms. Hence the decision at the meeting of 11th February 1986 that control sample must not be drawn if the quantity was less than 250 gms. was taken deliberately to suggest that Chem Med's reports and protocols had not been received by the FDA. Both Dolas and Kochar ignored the xerox copies of Chem Med's reports and protocols received by Intelligence Branch on the 1st or 2nd of February 1986 and blithely proceeded on the footing as if they knew nothing about it.

105. What is even more sinister is that such a decision ensured that no sample would be drawn from Chem Med so that it could not be sent for toxicity test, as a toxicity test could be done even with a smaller quantity of sample as expert evidence indeed suggests. Hence it is manifest that even though FDA knew that Batch No. 27 was toxic, it was anxious that the samples should not be collected from Chem Med lest a toxicity test revealed the link with the concoction supplied to the J. J. Hospital whereby Chem Med having certified the sample as of standard quality, would be in deep trouble.

106. The minutes of the meeting of 11th February 1986 indicate that though Commissioner Bhirud was present, the person in overall charge of the investigation and the moving spirit was Jt. Commissioner Dolas. In the light thereof, and by reason of the fact that Chem Med's reports and protocols were received by the Intelligence Branch in charge of Asstt. Commissioner Kochar who was also present at this meeting, the irresistible inference must be that both Dolas and Kochar were interested in protecting Chem Med. By the decision taken in the meeting of 11th February 1986 not to draw control sample if the quantity was less than 250 gms., both Dolas and Kochar also fettered the hands of the Inspectors for a proper and thorough investigation against Chem Med.

107. Realising that his complicity in this sordidity would be revealed, Jt. Commissioner Dolas tried to throw the blame on Asstt. Commissioner Raykar. According to Dolas in his evidence Raykar sent the Inspectors to Chem Med on 12th February 1986 even though Dolas had told Raykar on 3rd February 1986 to investigate Chem Med. Dolas' version is denied by Raykar according to whom instructions to investigate Chem Med were given to him for the first time at the meeting of 11th February 1986.

108. The controversy raised by these two rival versions is best decided by the wording of the minutes of the meeting of 11th February 1986. The wording of those minutes reveal that it was for the first time on 11th February 1986 that investigation against Chem Med was decided upon and ordered. If Dolas' version is correct, he would have taken umbrage and upbraided his subordinate Raykar and made a grievance in the meeting of 11th February 1986 that Raykar had failed to carry out the instructions given by him to Raykar 9 days earlier. Nothing of the kind appears in the minutes, which indeed would have if Dolas' version is true. Dolas' attempt in his evidence to shield himself and throw the blame on his subordinate Raykar is unworthy and be speaks a guilty conscience.

109. As a result of the fettering of the Inspectors' powers, all that Drugs Inspectors Vadnere and Choudhari could do when they went to Chem Med on 12th
Exs. 212 and 213 February 1986 was to take copies of Chem Med's reports Exhibits 212 and 213. They also noticed certain discrepancies about the quantity of the sample but in consonance with their instructions they did not take charge of the sample as it had been decided in the meeting of 11th February 1986 that control sample was not to be drawn if it was less than 250 gms.

Ex. 237A 110. This God-motherly treatment given to Chem Med is further heightened by the fact that even the show cause notice issued by Dolas to Chem Med was as late as 21st February 1986. In that show cause notice predictably there was no reference to the fact that the sample was found to be toxic. The gravemen of this show cause notice was that Chem Med had not followed Indian Pharacopoeia and adverted to minor discrepancies which paled into insignificance when compared to the gravity of Chem Med's mischief in patently issuing false analytical reports which its own protocols could not support. In this show cause notice what was found fault with was the method adopted by Chem Med and not with the correctness of the results shown by Chem Med. The notice was not confined as it should have been to the lethal Batch No. 27 but was complicated by reference to Batch Nos. 24 and 29, and thereby the gravity of Chem Med's misdeed was sought to be defused and played down. What is even more astonishing is that the punishment threatened by this notice was withdrawal or suspension of approval " for some period ". There was not even a whisper of a suggestion of prosecution.

Ex. 238 111. To this show cause notice Chem Med sent its reply, dated 4th March 1986. The offer of a personal hearing was declined by Chem Med, with a request that the explanation given in the reply be accepted and the matter be closed. Chem Med also stated that any action taken against them would be contempt of Court.

112. Chem Med's reply invoked no reaction from the FDA till a month later on 2nd April 1986 when FDA submitted a questionaire to the Law and Judiciary Department of the Government of Maharashtra. Opinion of 4 questions was asked. The first pertained to Alpana Pharma, the second and third directly to Chem Med and the fourth incidentally to Chem Med as under :

" (2) Whether the contention of M/s. of Chem Med (who have been given a show-cause notice) that any action against them would be contempt of court is correct and whether action can be taken against them in pursuance of the notice.

" (3) Whether legal proceedings can be started simultaneously with the departmental action for breach of the provisions of the Drugs and Cosmetics Act, 1940 against M/s. Chem Med Laboratories or whether the said Laboratories can be made co-accused in the case pending in the Court of Judicial Magistrate, First Class, Nanded against M/s. Alpana Pharma Pack.

" (4) Whether the contention of M/s. Chem Med that as the matter pertaining to re-packing of glycerine by M/s. Alpana Pharma Pack and its subsequent administration to patients is now sub-judice and also before the Commission of Enquiry any action at this stage by any one would amount to contempt of Court is correct."

113. On 28th August 1986, the Secretary and the Senior Legal Adviser, Mr. N. P. Rege gave his unequivocal written opinion against Chem Med regarding the second and third queries. Mr. Rege's opinion regarding the last query was however not as unequivocal. It reads thus—

"5. As regards the last question, contention of M/s. Chem-Med is not correct. But it would be a matter of policy for the Department to decide whether any action should be taken at present or the report of the Enquiry Commission should be awaited. It would be advisable to await the Report as the issue whether the manufacturer is guilty of breach of the Drugs and Cosmetics Act is also before the Commission."

114. As a result of this opinion given by the Law and Judiciary Department, on 9th September 1986 a policy decision was taken by the FDA not to take any action against Chem Med pending the Report of this Commission.

115. This was a totally *mala fide* act on the part of the FDA. While Mr. Rege's opinion on all these queries was absolutely correct, it was misused by the FDA as an excuse for taking no action whatsoever against Chem Med. The fourth query touched Chem Med incidentally based as it was on the matter of the prosecution against Alpana Pharma which was pending in the Nanded Court and was also before the present Commission. Hence Mr. Rege was perfectly justified in opining that while Chem Med's contention was not correct, prudence demanded that the Report of this Commission be awaited. This precaution was advised by Mr. Rege only in respect of the last query and not in respect of the earlier queries.

116. Even so FDA for some mysterious (or not so mysterious) reason decided to apply the prudence recommended by Mr. Rege not only to the last query but to the other two as well, despite the fact that Mr. Rege's opinion did not prevent FDA from proceeding against Chem Med with regard to the matters set out in the second and third queries. The result was that under the mischievous guise of acting on Mr. Rege's opinion, all action against Chem Med was stalled. And for Chem Med it was business as usual. The evil genius behind this so-called policy decision was once again Jt. Commissioner Dolas who signed it on 9th September 1986. Commissioner Bhirud signed it 2 days later on 11th September 1986, perhaps mechanically having surrendered his authority and powers into the scheming hands of that man Dolas.

117. It needs no emphasis to state that any upright FDA officer, immediately on receiving Chem Med's reports and protocols on the 1st or 2nd of February 1986, would have vigorously proceeded against Chem Med including joining it as co-accused with Alpana Pharma in the prosecution at Nanded. However none of this was done, thanks to the benevolence of Jt. Commissioner Dolas and Asstt. Commissioner Kochar (IB) whose aim was to protect Chem Med to the best of their ability and which they succeeded in doing. None of this was out of ignorance or even inefficiency. It was a cold and calculating piece of conduct on the part of these 2 high-ranking and powerful officers to protect and bestow their benevolence on an erring public analytical laboratory, Chem Med. Surely not for love. Men of neuter conscience.

118. It also needs no emphasis to state that any upright FDA officer could possibly not have twisted Mr. Rege's opinion into giving a blanket shelter to Chem Med and to assist it in putting off the day of reckoning. Only Dolas could do so assisted (perhaps unwittingly) by the weak and pliable Bhirud.

119. Regarding the analysis done by Chem Med, its Managing Partner Sipahimalani and Chief Chamist Karnachi have no personal knowledge. They rely on Barot and Miss Pai when they say that the analysis was properly carried out. I shall therefore advert to the evidence of Miss Pai and Barot.

120. Miss Rekha Pai as at present employed as an Admission Clerk in the P. D. Hinduja National Hospital and Medical Research Centre. She obtained her B.Sc. degree from the Bombay University in 1983. From July 1984 till March 1986 she was employed as a trainee chemist in Chem Med. She left Chem Med's employment on 31st March 1986.

121. Miss Pai did not remember if in November 1985 she had analysed a sample of glycerine of Alpana Pharma's batch No. 27. However she says that she did so because "these people", meaning thereby Chief Chemist Karnachi, said that she did. Shortly before she left Chem Med's employment Karnachi told her that some chemists in Chem Med had analysed the sample of batch No. 27. A few month after she left Chem Med's employment, Karnachi came to ther present place of employment, viz. Hinduja Hospital, and told her that she had analysed Alpana Pharma's batch No.27, that the protocols were in her handwriting and that she had carried out the tests. She did not say anything because she took it for granted that what Karnachi was telling her was correct.

122. On being shown the protocols, dated 15th November 1985 (Ex. 212-A) pertaining to batch No. 27 she admitted that they were in her handwriting and were signed by her at pages 1 and 3. Ex. 212A

123. According to Miss Pai the only person from whom she took the guidance at Chem Med while she was carrying out this particular analysis was chemist Trivedi under whom she was working. Normally she showed all the rasults of her tests to Trivedi but she did not remember whether she did so in the case of sample of batch No. 27. However if Trivedi was not available her practice was to take the guidance of Sr. Chemist Barot but she did not remember if she had taken any instructions from Barot while carrying out the analysis on the sample of batch No. 27.

124. Miss Pai left the employment of Chem Med after she read in the newspapers about the J. J. Hospital deaths as a result of the glycerol certified by Chem Med. Being a very emotional person she was extremely upset when she read this and gave up her chosen profession as trainee chemist and has since then not taken up this profession.

125. Whenever Miss Pai carried out analytical work she made calculations by way of notes in the rough book supplied by Chem Med to its analysts. She showed all her rough calculations to Trivedi. She thereafter stated that she must have shown
Ex. 212-A her rough book containing her rough calculations as also the protocols (Ex. 212-A) to Trivedi according to her normal practice. According to Miss pai she carried out the tests on the sample of batch No. 27 strictly in accordance with I.P. and the readings and calculations were written down by her in her rough book. After carrying out each stage of the analysis she would go to Trivedi and show the results to him. She being merely a trainee chemist, was working throughout under the instructions of Trivedi.

Ex. 212-A 126. After seeing the protocols (Ex. 212-A) and the I.P. Miss Pai admitted that the fatty acids and ester tests did not comply with I. P. She admitted that actually she had used ·1 normal sulphuric acid which normality she had mentioned in her
Ex. 212-A rough notebook. She had correctly transferred this to the protocols (Ex. 212-A). If however she made a mistake it was Trivedi's duty to correct it. She admitted that if despite her writing. ·1 normality in her rough record it was not transferred accordingly in the protocols (Ex. 212-A) she must have forgotten to do so. She admitted that in the protocols instead of ·1 normality what was mentioned was ·2081, which would be her mistake, but it was for Trivedi to check, as all work was done by her under his instructions. Unless Trivedi drew her attention to a mistake she would keep on repeating that mistake as she was constantly busy. It was for Trivedi to find out her mistakes and tell her. Miss Pai admitted that even in the protocols pertainting to batch No. 24 (Ex. 211-A) the same mistake has crept, in but attributed
Ex. 211-A it not to herself but to Trivedi as he was in-charge.

127. Everyone including Trivedi knew that only ·1 normal sulphuric acid was available at Chem Med. After the fatty acids test she saw Trivedi with her calculations which he must have checked. In the rough record she had calculated the
E. 212-A normality at ·1, however in the protocols (Ex. 212-A) the normality was mentioned as ·2. She did not remember if she had correctly copied down in the protocols what was written in the rough notebook. She admitted that there is a difference between ·1 normality and writing ·2 normality. She admitted that through oversight she had written ·2 normality in the protocols which however should have been corrected by Trivedi. She also admitted that the format also should have mentioned that ·1 normality had been taken whereas the format mentioned the normality at ·2. She admitted that since the format had not been corrected, it could not have been checked by Trivedi.

128. During her 20-month stint in Chem Med as a trainee chemist Miss Pai had sometime used ·2 normality and sometimes ·1 normality depending upon Trivedi's instructions. She could not recollect any case in which she had used ·2 normality and it was only in certain cases did she remember whether ·1 normality was used.

129. When she analysed the sample of batch Nos. 24 and 27 she had only a year's experience as a trainee chemist. She admitted that a trainee chemist requires continuous guidance, without which he or she would not be able to carry out any analytical work. She admitted that all that a trainee chemist does is to carry out the instructions given by his or her superior and if any mistake arises it is the superior's mistake. Thus if there was a mistake in the protocols pertaining to batch Nos. 24 and 27 the mistake would be not hers but of her superior Trivedi under whose guidance she carried out the tests. She admitted that unless she was told by Trivedi that she had not correctly carried out the tests she would not know whether she had done so correctly or not. Trivedi would first check the rough notebook and would return it to her if he found that the calculations were correct.

130. Miss Pai admitted that the fatty acids test is an important test and if, as merely a trainee chemist, a mistake was made by her it should have been pointed out to her. It is because this mistake was pointed out to her in her evidence that she realised it ; Trivedi should have pointed out it to her.

131. Miss Pai showed Trivedi each and every phase of the test done by her including the colour test. She wrote down the word " complies " in her rough notebook and in the protocols only after Trivedi had verified the compliance for which she had to go to Trivedi 16 times and sometimes even more to the extent of 20 times if she did not carry out any particular phase of the test correctly.

132. Miss Pai did not remember whether at the time she analysed the samples of Batch Nos. 24 and 27, Trivedi was away from the laboratory at any time, but she was categorical that she did remember that each and every stage of the tests conducted by her she showed her calculations and investigations to Trivedi and it was Trivedi who did the checking of her calculations and investigations.

133. Trivedi was supervising over 15 to 20 trainee chemists including Miss Pai who all constantly went to him for guidence and showing their results. Trivedi had to check everyday about 15 to 20 rough records and the same number of protocols.

134. Miss Pai came to know of the J. J. Hospital tragedy for the first time in February 1986 when she read about it in the newspapers. From the newspaper report she learnt that the glycerine sample had been analysed by Chem Med and 13 or 14 people had died in the J. J. Hospital. It struck her that she might have analysed the sample. There was general talk at Chem Med that this sample had been analysed by Chem Med. The name of Chem Med had also appeared in the newspaper report as having analysed the sample. As she did not like what she read in the newspaper report that Chem Med had analysed the sample and some people had died, she left the service of Chem Med on 31st March 1986.

135. Before Miss Pai left Chem Med nobody talked to her about the analysis done by her of batches 24 and 27, but something was going on in the laboratory, namely that some discussions were goning on amongst the senior staff, but they were not telling anyone what they were discussing. Soon after reading the newspaper item she rendered her resignation to Karnachi who was unwilling to accept it without telling her why, nor did she ask him the reason for his unwillingness nor did she tell him why she was handing in her resignation as she did not think it necessary for her to do so. When she handed in her resignation to Karnachi he did not tell her anything about Batch Nos. 24 and 27 analysed by her, nor did he mention anything about the J. J. Hospital incident.

136. Karnachi and Trivedi were discussing the J. J. Hospital incident among themselves, but did not tell anyone anything about it. Their secretiveness which was known to all the trainee chemists appeared strange to them. All the trainee chemists were discussing about the J. J. Hospital incident among themselves.

137. When Karnachi met Miss Pai at her present employment, namely Hinduja Hospital, he told her that she had committed a mistake in analysing the sample of Batch No. 27 and that the matter would go before the Court. She did not admit that she had committed any mistake as she was merely a trainee chemist whose work Trivedi was supervising all along. Karnachi told her that batch No. 27, the sample of which had been analysed by her, hed been sent to the J. J. Hospital and that there was some mistake regarding the normality.

138. When Miss Pai came to know that batch No. 27 had been analysed by her and that some people had died in the J. J. Hospital, she was upset and admitted that she now realised that she had committed a writing mistake. Even when Karnachi had met her at her present place of employment she admitted that she felt that the mistake could be hers but was not sure since she had not seen the Protocols.

139. Miss Pai did not remember whether on 30th or 31st January 1986 Karnachi talked to her about her analysing batch No. 27. She denied Karnachi's version in para 69 at page 1800-Z of his evidence that on 30th or 31st January 1986 he had questioned Miss Pai regarding Batch Nos. 24 and 27, as also Karnachis versional page 1798 that on 30th or 31st January he made enquiries of her pertaining to batch No. 27 as also Karnachi's evidence at page 1800-CC that he made enquiries of her or that he told her that the result was false or that she would check up. She did not remember whether any rough notes pertaining to batch No. 27 were destroyed or not. Karnachi had never given her or any other chemist any instructions to preserve the rough notes.

140. Here it may be stated that while Miss Pai was in the witness-box she was shown Sr. Chemist Trivedi who she insisted was the person under whose instructions she had carried out the tests and who she held out to be responsible for the mistakes.

141. Unfortunately for Miss Pai, during the relevant period, i.e. from Saturday the 9th till Friday the 15th November 1985, Trivedi was on paid leave as corroborated Ex. 446 from Chem Med's muster book (Exhibit 446) maintained from day-to-day in ordinary course of business. Thus Miss Pai's blatant and persistent endeavour to throw the blame on Trivedi for her own mistakes, negligence or incompetence, must fall to the ground.

142. Thereupon Miss Pai was recalled for further questioning. She then stated that she did not remember whether Trivedi supervised her carrying out the glycerine tests of Batch No. 27 between 8th and 15th November 1985, even though the previous day she had said that he had. After a great deal of prevarication she finally stated that she did not remember whether the tests carried out by her on the sample of Batch No. 27 were supervised by Trivedi from 9th till 15th November 1985 though she had stated so the previous day as she was referring merely to the general practice. She also did not remember if Trivedi had supervised over any tests carried out by her on 8th November on the sample of Batch No. 27, nor did she remember whether during Trivedi's absence from 9th to 15th November 1985, she was guided by Barot. She admitted that when she gave her evidence the previous day she did not remember that Trivedi was on leave from 9th to 15th November 1985. She admitted that if Barot had signed the 1st page of the protocols (Exhibit 212A) then it was he who had supervised over her and must have given her all the instructions for performing the tests.

143. Miss Pai admitted that she only wrote the calculations in the rough records and not the observations of the 16 tests regarding Batch No. 27 and that she recorded the results in the protocols from the rough records. When asked how she could have done so when in the rough records she had not written down the results of all the 16 tests, she replied—

> " I now say that in the rough records I wrote down the results of each and every test and therefore from the rough records I filled up the protocols (Ex. 212-A). "

She insisted that her earlier statement that in the rough records all the observations were not written by her was also correct and denied Barot's admission that she had written nothing in her rough records regarding items 1 to 5 and 7 to 14. She also denied Barot's admission that he personally had not seen her carrying out the ash test.

144. There is also evidence on record from the admissions of chemist Barot himself that he personally had never seen Miss Pai carrying out the tests nor did he actually see what tests Miss Pai was carrying out. Barot's attempt to retrieve the situation by the assertion that Batch No. 27 was actually tested by Miss Pai and was supervised by him and that the results are reliable and trustworthy, can avail him nothing in view of the admissions made by him earlier to the contrary. He does not remember which other samples Miss Pai analysed.

145. There is Barot's further admission that there are indeed certain mistakes in the protocols while copying the calculations from the rough notes and that these mistakes were pointed out to him by Chief Chemist Karnachi. Barot admitted that it was after Karnachi pointed out that the normality should have been 0·1 in order to arrive at the calculations they had that they discovered their mistake. He also Ex. 212-A admitted that the results as shown in the protocols (Exhibit 212-A) would not be indicative of the sample having passed the tests laid down in the Indian Pharmacopoeia. He further admitted that when this mistake was pointed out to them by Karnachi they did not have the rough notes for verification. He admitted to the possibility of Miss Pai having used ·1 normality, which mistake had slipped their minds.

146. It is futile for Barot to say that from where he sat he could see Miss Pai carrying out the tests and that he could confidently say that she had in fact carried out all the tests pertaining to Batch No. 27.

147. Barot's version that he had personally supervised all the tests carried out by Miss Pai loses much of its credibility by reason of the fact that on Barot's own admission he was busy doing his own work. He admitted that as part of his duty he also did analysis work of about 2 to 3 samples every day. Between 8th and

15th November he was doing chromatography work on ampicilin injections on different samples received from different parties, that chromatography is a precise test requiring his precise attention and takes about an hour to perform this test on ampicilin. Between 8th and 15th November he had analysed 3 to 5 samples of ampicilin chromatographically every day.

148. According to Barot he supervised the tests carried out by Miss Pai which he could do without actually standing near her. He admitted that he would not be able to supervise over the colour, odour, description and identity tests unless he was actually standing near Miss Pai. He protested that it was not necessary for him to stand near the chemist or supervise over Miss Pai's work, when the chemist is sufficiently experienced, which strangely according to him Miss Pai was, despite her being only a trainee chemist with only one year's experience, and despite Miss Pai's admission that she could not do her work without supervision. He supervised the analysis work done by her regarding Batch No. 27. All the supervisory work that he had done over her was to see the observations she had made in the protocols after she had carried out the tests. She showed him the rough records, therefore, the only thing that he was required to do was to check up the calculations in the rough records. In the rough records there were only three calculations, namely weight per ml., fatty acid and esters test and the ash test. The rough record maintained by her was only on loose sheets of paper.

149. Barot admitted that there was no way in which he could verify the correctness of the tests at Serial Nos. 1 to 5 and therefore, had to rely on Miss. Pai He also admitted that as the calculations in the protocols (Ex. 212-A) stand, the sample would fail in the case of item 15, namely fatty acid test. Barot admitted that the result shown in item 15 in Exhibit 212-A would not be the correct result. Pausing here for a moment, this by itself would show that the sample failed on this score alone. He admitted that he had not seen pages 2 and 3 of the protocols and that is why his signature appears only on the 1st page. He admitted that though he was supposed to supervise over Miss Pai, it was his mistake not to have gone through pages 2 and 3 of the protocols, and he did not inform Sipahimalani or Karnachi of his mistake. On an average he signs about 3 to 5 protocols every day. He only signs the 1st page because he invariably relies on the analyst and admitted that therefore, he did not carefully check the rough records and the protocols. Ex. 212-A

150. As against Miss Pai's insistence that rough notebooks were maintained, Barot has throughout emphasised jottings being made on rough pieces of paper. He says that the rough papers may have been preserved for about a week after Batch No. 27 was analysed on 15th November 1985, there being no particular reason why they were destroyed thereafter. Karnachi had never asked him to check the rough papers after 1st February because after 31st January 1986 the rough papers never existed. The rough papers are generally destroyed but not in all cases. They were in Miss Pai's custody. When Karnachi asked Barot for the rough papers he in turn asked Miss Pai who told him that they did not exist.

151. With the evidence of Miss Pai and Barot in the foreground the only conclusions which can possibly be drawn are startling.

152. Making all allowances for Miss Pai that she was an inexperienced trainee chemist, her evidence does not inspir confidence either as to its content or her veracity. Her sole and patent anxiety in the witness box was to absolve herself of negligence or ignorance or both and to pass on the blame first to Trivedi and failing that on Barot. She had admitted to her own incompetence for which, in all fairness, she cannot be blamed because she was merely an inexperienced trainee chemist. It is extremely doubtful whether she actually carried out the tests pertaining to Batch No. 27 without having the know-how and without any supervision worth the name. It is true that the protocols and format are in her handwriting but that by itself is no proof that she actually carried out the tests or in any event that she carried out all the 16 tests and that too correctly. The very fact that at first she insisted that it was Trivedi who supervised over her work and thereafter shifted her stance that it was Barot who did so, indicates that there could have been no effective supervision if indeed there was any, with the result that this raw inexperienced trainee chemist was virtually left to her own devices. It was physically impossible for a supervisor to oversee the workof 20 junior chemists like Miss Pai when 50 to 100 samples are being analyesd very day.

153. Miss Pai's evidence further shows that even if at all some tests were carried out they were not correctly carried out by her, for which once again in all fairness, as an inexperienced trainee chemist of a year, she cannot be blamed. Despite her mistakes, despite her attempt to throw the blame on the guiltless Trivedi, what can be said to her credit is that having realised the consequences on the unfortunate patients who died, in all sensitivity she tendered her resignation from Chem Med and gave up her chosen profession and preferred to work as a clerk in Hinduja Hospital.

154. Those on whom the blame must lie are those in charge of the laboratory for entrusting the tests to raw trainee chemist like Miss Pai without supervision.

155. The evidence of Chem Med's chemist Barot brings out in bold relief that he exercised no supervision over Miss Pai, with the result she was left to her own devices. Barot's evidence also shows that he relied on Miss Pai which was an act of negligence on his part knowing full well that she was a mere inexperienced trainee chemist of one year. The summation of their evidence is that the protocols show that the tests were carried out by Miss Pai under the supervision of Barot, she was obviously left to her own devices. Miss Pai tried to wriggle out of the unfortunate situation first by placing the blame on Trivedi and thereafter on Barot for the mistakes committed by her. Her admission that being only a trainee chemist with a year's experience she would not be able to carry out analysis work on her own without guidance speaks volumes and accounts for the innumerable mistakes committed by her, if at all she did carry out the tests. While according to Miss Pai rough records were maintained in her notebook, according to Barot, Karnachi and even Sipahimalani the rough notes were made on loose sheets of paper. They are not available. 'What also emerges from her evidence is that in all sensitivity and realising that she had made mistakes (if at all she had carried out any tests) that had led to the J. J. Hospitals tragedy, she not only resigned from her post at Chem Med from 31st March 1986, but also changed her profession and took up employment as a clerk in Hinduja Hospital. She says she carried out the analysis work not because she remembered doing so, but because Karnachi told her so and because of her handwriting and signature in the protocols. This casts a grave doubt whether these tests had in fact been carried out at all. She not only did not know her job due to inexperience for which no fault can be found with her but worse still, nobody supervised over her and nobody checked the result. If at all she had carried out any tests, she was far too much of a novice to know whether she had done so correctly or not. Out of 16 tests, the calculations which are required to be checked are only in respect of 3 items, *viz.*: (*i*) weight per ml., (*ii*) fatty acids and ester test, and (*iii*) ash test. In respect of the other tests she mechanically appears to have written down the word " complies " in the protocols, not on the basis of any notes but from memory. The protocols also indicate that the method adopted by her was faulty, the normality of sulphuric acid having been wrongly taken by her as 0·2 instead of 0·1. In any event, there was no material available with her in the form of notes to enable any supervisor to verify the correctness of her analysis. For that matter, there was no supervision over her at all.

156. The protection which FDA wanted to give to Chem Med is also apparent from the fact that strangely enough FDA asked Chem Med for its reports also for Batch No. 29 though the deaths were caused by the consumption of Batch No. 27. It is also curious that FDA should have asked Chem Med for its reports not officially by letter but privately by a telephone call which Sipahimalani received from Bankar who is in Intelligence Branch under Kochar. This by itself denotes a rapport between FDA and Chem Med. This coupled with the request calling for the reports of Batch Nos. 29 and 27 indicates that FDA's object was to see that for Chem Med's sake everything was in order in these reports. However, when it was discovered that it was not, they were quietly shelved till 11th February 1986, whereafter it was impossible to ignore them resulting in the truncated investigation against Chem Med which was ordered in the meeting of 11th February 1986. Otherwise there was no reason for sending for these reports unofficially on the 1st or 2nd February 1986 and thereafter putting them in cold storage till 11th February 1986.

157. That these reports were suppressed by the FDA is also borne out from the fact that though they were received by I. B. headed by Kochar himself, on the 1st or 2nd February 1986, no reference is made to them in the complaint drafted by Kochar against Alpana Pharma on 4th February 1986. As these reports have been received by I. B. on 1st or 2nd February 1986 there was occasion and opportunity enough to refer to them in the meeting of 3rd February 1986 where both Dolas and Kochar were

present. But nothing of the kind was done and the meeting proceeded as if no such reports have been received. It is of no avail now for Dolas and Kochar to profess ignorance of the receipt of these reports from Chem Med.

158. There is no reason to disbelieve Chem Med's Chief Chemist Karnachi when he says that in response to the telephone call received from the I. B. of the FDA to Sipahimalani at Chem Med's Kakad Estate Office, he, i.e. Karnachi, deputed one of of Chem Med's senior chemists Athawale to take photo copies of the reports and protocols, which Athawale did and that on his return he told Karnachi that he had given them to I.B. of the FDA. At first Karnachi did not remember the person to whom Athawale had delivered these reports and the protocols, but insisted they were not delivered to Dolas or Kochar. He thereafter admitted he was mistaken in his insistence and that Athawale had told him that he had delivered them in the room of Jt. Commissioner Dolas. Karnachi asked Athwale whether he had given them to Dolas himself, but Athawale was unable to remember to whom he gave delivery as there were several persons seated in Dolas' cabin. Thus from these admissions grudgingly made by Karnachi, the sending of the reports to FDA on 1st or 2nd February is established, the inspired denials of Dolas and Kochar notwithstanding.

159. On the other hand, there is Dolas' admission that in Alpana Pharma's file which he saw on 29th January 1986 he had noticed the name of Chem Med and he knew that Chem Med was on the telephone. Dolas also admitted that in the report which Assistant Commissioner Kamble gave him on 3rd February 1986 Kamble had mentioned that Alpana Pharma's glycerine had been analysed by Chem Med. Even so it did not occur to Dolas to telephone Chem Med to ascertain whether they had carried out the analytical work of Alpana Pharma's glycerol. Dolas also admitted that on 3rd February 1986 itself he was convinced that he should urgently direct his inquiries with Chem Med to find out their testing of Alpana Pharma's glycerol. However according to Dolas beyond giving oral instructions to Raykar he himself did nothing in the matter. Why Dolas should have contented himself by giving oral instructions in a matter of such gravity is factor he has not cared to explain. One would have thought that looking to the seriousness and urgency of the matter, the least that Dolas could have done was to have given written instructions to Raykar which Dolas did not. There is also nothing in the minutes of the meeting of 3rd February 1986 that any such instructions had been given by Dolas to Raykar. Dolas' version in the witness-box that he had, is obviously an attempt to save himself and throw the blame on Raykar. According to Dolas neither on 3rd February 1986 nor thereafter did he come to know of the test reports delivered by Chem Med to the FDA (I.B.).

160. Assistant Commissioner Kochar admitted that he did get the name of Chem Med from the report of Drugs Inspector Babne from which he understood that Chem Med had analysed Batch No. 27. Even so inexplicably it did not occur to him or Assistant Commissioner Kamble that immediate inquiries should be made with Chem Med. Kochar then side-tracked that on 3rd February 1986 he did not have Chem Med's report with him nor did he realise that Chem Med's report would give him an indication as to who was the immediate supplier to Alpana Pharma. He admitted that until 23rd February 1986 there was no discussion about Chem Med's report in any of the meetings held in the Commissioner's chamber.

161. As against all this there is Raykar's version that the did not take up the investigation with Chem Med until 12th Februarey 1986, because his superiors had told him that it was not necessary, explaining that by ' superiors ' he meant Jt. Commissioner Dolas. On this aspect Raykar's views differed from that of Dolas, but Dolas told him that investigation should not be made with Chem Med because Alpana Pharma was totally responsible for the quality of the glycerine. Raykar continued that on 3rd February 1986 Assistant Commissioner Kamble had given his report to Jt. Commissioner Dolas, that Raykar saw this report only on 19th February 1986 and that is because all these papers were kept in a separate file in the custody of Jt. Commissioner Dolas. He denied Dolas' version that on 3rd February 1986 Dolas had given him instructions to depute someone to go to Chem Med. Raykar was certain that these instructions were given not on 3rd February 1986 but in the meeting held on 11th February 1986. According to him Dolas must have come to know on 3rd February 1986 that Chem Med had done the analytical work because Assistant Commissioner Kamble had written a letter, date 31st January 1986 to Dolas which was received by Dolas on 3rd February 1986 as is manifest from the endorsement made by Dolas at the foot of this letter. According to Raykar it was at the meeting of 11th February 1986 that he received Chem Med's reports from Assistant Commissisioners Kochar, Raykar did not know, how Kochar came in their possession.

162. This shows that even apart from Chem Med's reports which were received in the FDA on 1st or 2nd February 1986, Dolas knew on 3rd February 1986 at the latest that the analysis work had been done by Chem Med. Yet Dolas made no move against Chem Med.

163. Reverting to Dolas, he says he applied his mind to the tests carried out by Chem Med and admitted that the reasons given by Chem Med certifying the sample to be of standard quality were erroneous, as also that Chem Med had violated the provisions of the Act and Rules. Yet perhaps letting his mind obliterate that not less than 14 innocent lives were lost and no doubt to protect Chem Med even from the witness-box, Dolas stated that he did not consider the violations to be of a serious nature or that Chem Med had committed an offence punishable under section 27. After a great deal of prevarication and after questions were repeated to him time and again, Dolas finally admitted that but for the test report given by Chem Med certifying the drug to be of standard quality, the drug would not have been supplied to the J. J. Hospital. While denying that he was in any manner obliged to Chem Med, Dolas stated that he did not order a prosectuion against Chem Med because they were thinking on the lines about the tests carried out. When asked whether in the matter of public laboratories, was it not incumbent upon him to launch a prosecution if an offence was disclosed, he replied that they would consider the seriousness of the merits of the case. When asked whether according to him the violations of Chem Med was not of serious nature even though 14 patients had died, he replied he could not say whether " it was the cause of that ". After I recorded my inability to understand this answer as also some of his earlier answers which in sum total disclosed an insensitive brazenness and deliberately unitelligible gibberish. Dolas finally replied—

" If 14 patients had died, because of that it would be serious."

164. The manner in which Dolas tried to protect Chem Med even in the witness-box can be seen from his assertions that Chem Med had made honest mistakes in giving its reports. They were serious mistakes but honest, for which according to Dolas suspension of licence would be an adequate punishment. Therefore, it was decided not to prosecute Chem Med. He admitted that when he takes action either to prosecute or not to prosecute a manufacturer or repacker he must record his reasons in writing but in the case of Chem Med he did not recordhis reasons in writing for not prosecuting them. According to Dolas even though the quantities of glycerol in Batch Nos. 24, 27 and 29 differed in the various registers of Chem Med, he would still call it an honest mistake on the part of Chem Med; he professed to have satisfied himself as to the honesty of this mistake after going through the Inspector's report and even though Chem Med had never contended before him that these were honest mistakes, preferring as they did, to call them clerical mistakes. Such brazenness is unbelievable for there was nothing in Chem Med's reports which could pass off a honest, much less clerical mistakes. Therefore, Dolas accepted Chem Med's explanation, I quote, " in the absence of any other proof ". It is impossible to see " what other proof " Jt. Commissioner Dolas requred in a case where not less than 14 innocent lives perished.

165. Even though there were vast discrepancies in the quantities mentioned in the various records maintained by Chem Med, the same did not arouse Dolas' suspicion whether the samples had at all been received by Chem Med from Alpana Pharma or whether the samples had at all been analysed. According to him the samples had been analysed because the protocols had been brought by Investigating Officers from Chem Med when they visited Chem Med on 12th February 1986. I would have called this naivety in the case of any other officer not having Dolas' reptilian dishonesty.

166. Dolas admitted that he knows who the partners of Chem Med are, one of them being Sipahimalani whom he knows for the past 5-6 years. Sipahimalani sometimes meets Dolas in his office for official work. Dolas also knows Chem Med's Chief Chemist Karnachi since the past 5-6 years.

167. It is not as innocuous as Dolas sets it out to be. Unless he and Sipahimalan were attuned to each other, Dolas' protection to Chem Med was impossible and unthinkable. Between Dolas and Kochar, Chem Med was protected. Corruption is writ large.

168. Karnachi admitted that between the 1st or 2nd February when FDA telephoned for Chem Med's reports and 12th February 1986 when the Drugs Inspectors visited Chem Med, he and Sipahimalani had discussions about the tests conducted

by Chem Med and that it was known in Chem Med by 12th February 1986 that Alpana Pharma's batch No. 27 was involved in the J. J. Hospital incident. Karnachi Sipahimalani were anxious that the FDA should not find any fault with Chem Med's reports. Karnachi admitted that though the had not made any note of the discrepancies which he discovered in Chem Med's reports, he knew that they were serious enough to ultimately affect Chem Med's analytical results. He admitted that because of these serious discrepancies Chem Med's certification of the samples as being of standard quality would have been affected. He admitted that in the face of these serious discrepancies Chem Med's finding certifying the samples of batch Nos. 24 and 27 would be incorrect, that he realised this after seeing the protocols and that he himself was satisfied that the results certified by Chem Med about batch Nos. 24 and 27 were incorrect. He also admitted that when he realised this he made enquiries from Barot and Miss Pai, that he told them that the results were false.

169. Karnachi admitted that certifying a not-standard drug as a standard drug amounted to a serious contravention of the Drugs and Cosmetics Act and that such a report would be a misleading, incorrect and false report. After starting that Chem Med had never given false and misleading reports, Karnachi admitted, I quote: " Chem Med has given false reports in the past", that in the past Chem Med had owned up to giving manipulated reports in the case of Magna Laboratories whereupon their approval was restored after 4 months.

170. In the teeth of these admissions reluctantly made by Chem Med's Chief Chemist Karnachi, Dolas' attempt to hold a brief for Chem Med in the witness box and earlier must collapse.

171. Though Miss Pai maintained that the rough calculations were written in a notebook, according to Sipahimalani and Karnachi they were written on loose sheets of paper. They are not forthcoming. Why not ? What has happened to them ? Answer : They have been suppressed by Chem Med because they would have disclosed that the tests were not carried out.

172. Judicial notice may be taken that just as account books can be prepared without transactions taking place, so can protocols without the tests being actually carried out. Karnachi agreed that apart from the calculations mentioned in the protocols there was no way for verifying whether the tests were actually carried out or not. Thus the only way in which it could have been ascertained whether these tests had actually been carried out would have been by reference to the rough calculations, which understandably from Chem Med's point of view are not forthcoming on the ground that they have been destroyed. Evidence indicates that these rough calculations were available in any event till 4th March 1986 when Chem Med gave its reply of that date (Ex. 238) to FDA's show cause notice. In Chem Med's reply Ex. 238 there is not a word mentioned that the rough notes were destroyed. The reply on the contrary also indicates that the rough record is the primary evidence that the tests were carried out and the manner in which they were done. For that matter, para 8 of Chem Med's reply indicates in abundant measure that it was prepared on the basis of the rough notes. There is also on record uncontrovertible evidence that the rough record was available when Karnachi taxed Miss Pai, because there is Karnachi's admission that Miss Pai remembered that the normality was on the basis of some rough record she had kept and that Barot had told Karnachi that he had checked the results from the rough record. After a great deal of prevarication, from saying that he could not say whether the rough records were destroyed or not, to the extent of saying that if they are in existence they would be with Miss Pai knowing full well that she had left Chem Med's employment as far back as 31st March 1986, and despite Sipahimalani's version that the rough notes were not in existence when Chem Med sent its reply to the FDA, the truth came out at long last from Karnachi's reluctant lips that *on 4th March 1986 when Chem Med's reply to the show cause notice was sent the rough records existed.* Despite this admission, the fact that the rough records are not forthcoming can only lead to an adverse inference being drawn against Chem Med, namely that the rough records have been suppressed as they would not have supported Chem Med's version that the analysis was done and in any event would have disclosed the manner in which it was, if at all it was.

173. The fact that Chem Med, with most of its work connected with analysing drugs, is habituated to giving false reports, is brought to the forefront by the admissions made by its Managing Partner Sipahimalani. He admitted that in the past 25 years Chem Med certified samples not being of standard quality to the extent of

5 per cent to 10 per cent. According to Sipahimalani the failure reports issued by Chem Med would be on an average of 5 per day, which would be about 1500 per year. However Chem Med did not send all these failure reports to the FDA but only such as were given in Form 39 under the Rules. The reports of samples which are on trial or on experimental basis are not prepared under Form 29 and hence are not sent to the FDA. *Sipahimalani admitted that one of the methods of obviating sending failure reports to the FDA* is to classify the samples *as experimental samples.*

174. No doubt it is salutary to good business to keep one's clients satisfied. But when the endeavour goes in the direction of and to the extent of resorting to the subterfuge of classifying failed samples as experimental samples so as to obviate sending failure reports to FDA, it is unethical and sharp practice at the cost of public health and safety, pecuniary advantage to Chem Med notwithstanding.

175. This brings me to the wider and vital question of the interaction of the FDA with manufacturers, repackers and others in the drugs industry, who depend on the goodwill of FDA.

176. In a rare outburst of candour Sipahimalani admitted to the various ways in which the FDA officials can be and are kept pleased or to put it bluntly, bribed. It is best stated in the question and answer form in which this part of the evidence was recorded :—

Ques. : Is it correct that in your kind of business you cannot afford to antagonise the FDA officers ?

Ans. : Yes, I would say that is correct.

Ques. : Cancellation of licence or withdrawal of approval would be a closure of your business ?

Ans. : Yes.

Ques. : Is it therefore always better if the FDA officers are kept pleased ?

Ans. : Generally speaking, yes.

One of the ways in keeping them pleased is not to challenge their orders.

Ques. : Are there any other ways of keeping them pleased ?

Ans. : Yes. Generally speaking if you give them presents or something like that or be a very good host by inviting them to dinners or parties.

Ques. : Is the discretion of the FDA officers in granting or revoking licences tilted by the hospitality extended to them and the presents given to them ?

Ans. : That would depend upon the officer concerned.

(*To Commission*—

Ques. : By presents do you mean presents in cash or kind ?

Ans. : In cash and in kind.

Ques, : Therefore the more munificent the present, the greater would be their goodwill ?

Ans. : That would be the general tendency.)

Questioning by Mr. Shah resumed :—

121. This general tendency applies to all analytical laboratories, manufacturers and repackers who are dependent for their licences on the FDA. This answer applies to whosoever has to deal with FDA and other authorities in general."

177. All this coming from Sipahimalani, himself dependent on the FDA, must speak volumes for the interaction of the FDA with unscrupulous elements in the industry it is expected to control in public welfare including Chem Med. Amen !

178. *I summarise.*—(1) It is extremely doubtful whether any analytical tests were carried out by Chem Med in respect of batch Nos. 27 and 29. If at all they were, a complete analysis was not carried out as revealed by the evidence of Miss Pai and Barot; and the reports are manipulated.

(2) Indisputably Chem Med's reports are false as admitted by Chem Med's own witnesses Barot and Karnachi, apart from the fact that Chem Med's reports are directly inconsistent with those of the Government Analyst.

(3) FDA did not discharge its duty in promptly or properly investigating Chem Med until 12th February 1986 when it should not avoid doing so, instead of commencing investigation against Chem Med as early as 30th January 1986 or at the latest on 3rd February 1986. FDA wanted to protect Chem Med from prosecution and other action with the result that a truncated investigation was ordered on 12th February 1986 by giving specific directions to the Inspectors not to take charge of control samples if the quantity was less than 250 gms. with the knowledge that it was. Thereby a toxicity test was obviated as even 10 gms. would be sufficient to carry out that test. Even this investigation, such as it was, consisted only of the Inspectors bringing the reports and the protocols to the FDA office and xerox copies whereof were already in the possession of FDA as early as 1st or 2nd February 1986.

(4) Action even by way of a show cause notice was belatedly taken on 21st February 1986 and that too in respect of minor discrepancies which in Dolas' words were "honest mistakes", and not in relation to the deaths which occurred in the J.J. Hospital as a consequence of Chem Med's false and manipulated reports. In the show cause notice the maximum action threatened was suspension or withdrawal of licence for some period and prosecution was ruled out as admitted by Dolas that prosecution was never contemplated against Chem Med.

(5) Even the show cause notice has not been decided under the shelter of departmental policy erroneously adopted in order to shield Chem Med. Thus a bona fide legal opinion was used as a handle not to take any action against Chem Med.

(6) Sipahimalani's evidence indicates that the role of the FDA and the laboratories and the drugs industry is mutually complementary, that the DFA exists not as the watch-dog of public health and safety but to protect the interests of unscrupulous and erring members of the drugs industry including such analytical laboratories like Chem Med, to corrupt FDA officials, which is by no means an uphill task. Thus despite serious lapses inter alia in giving false analytical reports and manipulating them even in cases of life-saving drugs, the erring laboratories like Chem Med can continue to do so and be in business with the active benediction of the FDA holding to ransom public health and safety.

(7) The tragedy in the J.J. Hospital could have been prevented if Chem Med had truthfully certified batch No. 27.

(8) The evil geniuses in protecting Chem Med are Dolas and to a slightly lesser degree, Kochar. They did not do so out of ignorance, inefficiency or love. They are corrupt. And shamelessly so. Men of neuter conscience.

PART X

179. This brings me to the interaction of the FDA with Apex Analytical Laboratories.

180. Apex was established as a partnership concern in May 1982. In 1985-86 it had 17-18 Assistant Chemists and 4 approved chemists. It received 1100 to 1200 samples a month. As against the normal failure rate of 5 per cent to 10 per cent; Apex's admitted failure rate was 0·6 per cent. Thus out of 1200 samples barely 4 to 5 were declared not to be of standard quality. As will appear presently, this miracle was with the blessings of the FDA brought about by the simple expedient of habitually issuing reports without actually analysing the samples.

181. One of the drugs under suspicion in the J. J. Hospital tragedy was mannitol injections manufactured by Trans India Transfusion Pharmaceuticals. Sample from Batch No. 1670 was drawn. The Government Analyst's report dated 21st February 1986 (Ex. 258) revealed that the sample did not comply with U.S.P. The Government Analyst had not carried out the particulate matter test. However the the Government Analyst Dr. Pilankar stated that he had analysed the sample and that it failed in the pyrogen test. Ex. 258

182. Trans India's samples of mannitol Batch No. 1670 is said to have been analysed by Apex Laboratories for particulate matter test. According to Apex's test report dated 13th August 1985 (Ex. 257) the sample had passed that test. As will appear presently this report cannot be true and even if it is true the sample could not fail in pyrogen test. Ex. 257

183. In the light of Apex's report the following events are material :—

(a) *19th February 1986.*—Drugs Inspectors Pore and Dhomne visited Apex Labora-
Ex. 288 (colly). tories. During their inspection they obtained a letter [part of Ex 288 (collectively)] from Apex's chemist Miss Leela Pawar that she had carried out the particulate matter test with her assistant Miss Ruksana Engineer and the method followed.
Ex. 288 (colly.) The Drugs Inspectors made their report [part of Ex. 288 (collectively)].

(b) *25th February 1986.*—The Drugs Inspectors made their written submissions
Ex. 287 (Ex. 287) observing that Apex was not equipped to carry out the particulate matter test. As a result, inspection of Apex was ordered.

(c) *27th and 28th February and 1st March 1986.*—On these three days Apex was inspected by Asstt. Commissioner Bijamwar, Government Analyst Dr. Pilankar, Inspector V. S. Deshpande (FDA) and Inspectors Sharma and Singh attached to the Drug Controller of India. During the course of this inspection on 28th February 1986, Apex's 16 Assistant Chemists handed over to the inspecting team a written
Ex. 260 complaint (Ex. 260) making various allegations against Apex, suggesting that they were compelled to issue reports without actually carrying out the tests. In this complaint a further grievance was made that in 1984 a similar complaint had been made by Apex's Assistant Chemists to the FDA but that no action had been taken thereon by the FDA.

(d) *1st March 1986.*—The inspecting team made a report pointing out several defects and deficiencies, not less than 24 in number, in respect of various tests carried out by Apex. Regarding the mannitol test the report stated that Apex was not equipped with a 100 magnification microscope and that particulate matter was observed through an ordinary microscope whereby suggesting that no particulate matter test had been carried out by Apex.

Ex. 286 (colly.) (e) *13th March 1986.*—A show cause notice [part of Ex. 286 (collectively)] was issued to Apex for cancellation or suspension of approval of its licence.

Ex. 286 (colly.) (f) *31st March 1886.*—In its reply [part of Ex. 286 (collectively)] Apex virtually admitted the charges set out int he show cause notice and gave assurances of good behaviour.

Ex. 286 (colly.) (g) *5th May 1986.*—FDA passed an order [part of Ex. 286 (collectively)] against Apex suspending its licence for 15 days with effect from 16th June 1986.

submitted by FDA (h) *26th June 1986.*—Apex addressed a letter to FDA stating that they had filed an appeal before the Minister and had applied for stay of FDA's suspension order, that the stay application was under active consideration and that Apex would be continuing its activities from 20th to 30th June 1986 and that they had closed their activities for 4 days, i.e. from 16th to 19th June 1986, and that if the stay application was rejected they would close their activities for 10 days.

184. In the light of the above I shall recapitulate a little earlier history.

185. In 1984 Apex Laboratories had been inspected by practically the same team including Assistant Commissioner Bijamwar when similar defects and deficiencies had been detected as were by the inspecting team in the course of their inspection on 27th and 28th February and 1st March 1986. As a result on 12th December 1984 a show cause notice was issued to Apex for cancellation of its licence. As many as 20 charges were levelled. On 26th/28th December 1984 Apex sent its reply accepting the charges, including giving reports without actually carrying out the tests. On 29th January 1985 the then Joint Commissioner and Licensing Authority N. D. Kulkarni who was due to retire 2 days hence, passed an order of warning to Apex.

186. As stated earlier the defective mannitol was manufactured by Trans India Transfusion Pharmaceuticals. It has its factory in Tarapore and its office at Bombay. On 2nd April 1985 FDA filed a complaint (Case No. SEC 472 of 1986) against Trans India in the Court of the learned Judicial Magistrate, First Class, at Palgarh for the offence of manufacturing and selling substandard mannitol punishable under Section 18A (i) read with Sections 34 and 37 of the Drugs and Cosmetics Act. On 3rd April 1986 a similar complaint (Case No. 734/S of 1986) was filed by the FDA against the distributors of Trans India Transfusion Pharmaceuticals, namely Trans India Medical Agency and its partners, in the Court of the Metropolitan Magistrate, Esplanade, Bombay, for selling substandard mannitol.

187. As far as the so-called analytical work done by Apex on the mannitol sample, there is evidence of its Managing Partner Hashmukhlal Parikh and Miss Ruksana Engineer who is supposed to have carried out the tests. From their evidence emerges that undoubtedly Apex was indulging in the malpractice of issuing test reports without actually carrying out the tests and that Apex was not well equipped either staff-wise or equipment and material-wise to carry out all the tests in respect of all the samples it accepted.

188. The seriousness of Apex's defects cannot be disputed even by the FDA and much less by Apex itself. These serious defects were known to the FDA in any event in 1984, as a result of the inspection and the complaint of the Assistant Chemists of Apex. Even so Apex was let off the hook by the then Joint Commissioner and Licensing Authority Kulkarni by mere warning apparently on assurances of good behaviour in future which both Apex and FDA knew would not be honoured. This is apparent by the fact that Apex's Managing Partner Hashmukhlal Parikh agreed with what Sipahimalani had to say about corruption in the FDA, with a rider added by Parikh that to FDA officers, I quote him, " Diwali comes more than once a year ".

189. Regarding the interaction of FDA with Apex is material the evidence of Assistant Commissioner Bijamwar who was in the inspecting team on both occasions, Jt. Commissioner Dolas to whom he reported, and the then Jt. Commissioner and Licensing Authority N. D. Kulkarni who decided the show cause notice and issued the warning order dated 29th January 1985.

190. Before I take up the evidence of Assistant Commissioner Bijamwar, it may be recalled that while two prosecutions were launched against Trans India nothing of the kind was done against Apex except passing an order on 5th May 1986 suspending its licence for 15 days. From the report of the inspecting team, not less than 23 prosecutions could have been launched against Apex, yet not a single was filed. In the show cause notice of 13th March 1986 which set out not less than 22 major defects and deficiencies, no reference was made to the earlier show cause notice of 1984 or to the earlier warning given to Apex. In the light of this, the mere 15-days suspension of Apex's licence as recommended by Bijamwar assumes sinister proportions looking to the circumstances it all came about.

191. Assistant Commissioner Bijamwar was at the relevant time in charge of public analytical laboratories and on his own admission everything concerning them had to pass through him. He admitted that para 8 of the show cause notice dated 13th March 1986 dealt with mannitol and para 7 with other drugs set out in items 1 to 22, and that FDA's observations were based mainly on the latter items which pertained to the number of defects found by the inspecting team. He had also observed a number of breaches of Rule 150 in the matter of analysis. He admitted that these defects would amount to a serious offence and even the random checking which was done during inspection at Apex revealed a persistent conduct on the part of Apex in giving false, incomplete and misleading reports. Bijamwar recommended suspension of Apex's licence for 15 days and also action against its expert staff for having misused the approval granted.

192. Bijamwar admitted that the suspension of Apex's licence for 15 days recommended by him was the mildest punishment which he alone had recommended on the excuse that at that time the seriousness of those offences was not thought of. This was an infantile excuse which is rendered even more ridiculous by his own admission that if any approved laboratory gives a false report there would be no doubt about the seriousness of the offence committed. When asked why Apex was let off with the mildest of punishments, namely a 15-day suspension, even though according to the FDA itself Apex had committed serious offences in giving false and/or incomplete and/or misleading reports, Bijamwar gave the startling answer that there was no precedent for prosecuting an anlytical laboratory. He had to eat his own words by his admission that an analytical laboratory could be prosecuted for serious offences. He shrugged off non-prosecution of Apex as a mistake but could give no reason why such a mistake was committed by him. Bijamwar tried to throw the blame on the licensing authority for not prosecuting Apex on the ground that the action for prosecution had to be taken by the licensing authority. He however admitted that he did not recommend to the licensing authority that prosecution should be launched against Apex. According to Bijamwar that was his mistake but was unable to explain how he committed such a mistake.

193. Bijamwar admitted that between 3rd and 13th March 1986 when the show-cause notice was issued to Apex, he did have a discussion with Jt. Commissioner Dolas pertaining to the inspection of Apex Laboratories and that he had told Dolas that the contraventions committed by Apex were serious. Even so Bijamwar did not recommend a prosecution. Bijamwar affected that if he had been the licensing authority he would not have imposed the least punishment of suspension on Apex for the serious offences committed.

194. Bijamwar admitted that this was the second time that Apex had committed a serious breach of the licence conditions yet nothing was done to Apex except imposing upon it the mildest form of punishment, namely a 15-day suspension of its licence.

195. Bijamwar admitted that in the show-cause notice dated 13th March 1986
Ex. 286 [part of Exhibit 286 (collectively)] Kulkarni's earlier warning order of 29th January 1985 had not been referred, and which should have been done. He admitted that those earlier breaches committed by Apex also amounted to serious offences and that he was aware that for recurring offences by manufacturers, prosecution is the normal step taken by the FDA. He also admitted that if a prosecution is contemplated, a show-cause notice is not necessary and that when a show-cause notice is issued it is an indication that FDA does not intend to launch a prosecution. Bijamwar agreed that a mere 15-day suspension of Apex's licence was not a sufficient punishment and called for prosecution.

196. Bijamwar admitted that during the course of the 1984 inspection of Apex, he had observed that Apex was merely typing out reports without actually carrying out the tests, and that beyond making his report accordingly to the then licensing authority, namely N. D. Kulkarni, he, i.e. Bijamwar, did nothing. He also admitted that during the course of his inspection of Apex in February 1986, he came to know that Apex was still typing out reports without actually carrying out the tests. In the light thereof his denial that in dealing with Apex he showed leniency, is meaningless.

197. Curiously enough as the officer controlling public analytical laboratories, what Bijamwar understood of his duties was only to make a report to the licensing authority and not to take any initiative on his own against any erring public analytical laboratory and accordingly while he was incharge of public analytical laboratories, he merely acted as a post-office. This is a pathetic reflection by Bijamwar himself both on his understanding of his duties as also his intelligence.

198. According to Bijamwar he recommended a mere suspension of Apex's licence for 15 days instead of a higher punishment because at that time he did what he thought best. Pray, best for whom ? Himself, Apex or the public whose watch-dog FDA is expected to be ?

199. Bijamwar admitted that after Apex's inspection in February 1986, he came to the conclusion that the lapses committed by Apex Laboratories were the same as those committed by it in 1984. He admitted that he did not show Apex's earlier submission to the other members of the Inspection Panel, nor did he tell them what the earlier grievance of Apex's chemists was in 1984 or why regarding that grievance no action had been taken against Apex Laboratories. He also admitted that no copies of any documents pertaining to that earlier incident were sent for given to the Inspection Panel members accompanying him in 1986. He admitted that the lapses of Apex in 1986 were more serious than those of 1984. While in 1984 Apex had made reports without actually carrying out the tests which would therefore be false reports, he admitted that Apex's lapses of 1986 were even more serious than those of 1984 because the former were a re-occurrence of the latter. He also admitted that between 1984 and 1986 there was no inspection of Apex.

200. When asked whether he as the person in charge of public analytical laboratories did not consider it as his duty to see that Apex's lapses of 1984 were remedied, particularly when a warning had been issued to Apex, Bijamwar replied that he could not do so unless he was ordered by the licensing authority, and he could do nothing on his own initiative, being merely a dummy awaiting instructions from the licensing authority. According to Bijamwar as the person in-charge of public analytical laboratories, it did not fall within his powers to follow up matters against erring laboratories even after a warning had been issued to them and to see that such lapses are not repeated. These are indeed another pathetic comments coming

from Bijamwar himself not only as to his duties as the sole in-charge of public analytical laboratories but also of his own intelligence which he makes it convenient to show as below par in an attempt to wriggle out of an impossible situation of his own making.

201. Bijamwar admitted that it was necessary for the Inspecting Panel to draw the pointed attention of the Joint Commissioner and Licensing Authority to the seriousness of Apex's lapses as also to the fact that the lapses had been continuing for over 2 years. This admission was made by Bijamwar after great deal of prevarication and after the question was repeated to him 6 times as recorded by me in the notes of evidence. He admitted that he did not draw the pointed attention of the licensing authority to the continuing serious lapses of Apex since 1984. When asked why he did not do so, he was unable to give any answer except to give a meaningless answer that there were no instructions for the second inspection of Apex in February-March 1986. When repeatedly asked what he meant by that, he gave a rambling answer which I confessed my inability to understand as recorded by me in the notes of evidence. He admitted that he did not draw the pointed attention of the Licensing Authority to the serious lapses committed by Apex even though he considered those lapses to be important. He attempted to sidetrack by saying that this behaviour on his part was not intentional or due to negligence but due to his mistake and through oversight. He admitted that Apex's was the only case where he had committed such a mistake and through oversight, and which he realised in the witness-box.

202. Bijamwar admitted that in Apex's reply dated 31st March 1986 to FDA's show-cause notice dated 13th March 1986, Apex did not dispute the lapses set out in the show-cause notice and had by implication admitted them. Bijamwar admitted that when he went through Apex's reply he did realise that Apex had not given any explanation to the written complaint made by its chemists.

203. Bijamwar admitted that in FDA's order dated 5th May 1986 no reasons were given for imposing the lesser penalty of suspension of Apex's licence for 15 days, and that before that order was passed he was consulted by the Licensing Authority, Bijamwar had informed the Licensing Authority that these were continuing lapses on the part of Apex since 1984. Bijamwar did not know if any personal hearing had been given to Apex by the Licensing Authority. Bijamwar admitted that the explanation given by Apex in its reply dated 31st March 1986 was found to be unsatisfactory, despite which the lesser punishment of suspension of licence for 15 days was awarded. However Bijamwar was not surprised as he himself had recommended it. He admitted that he did not recommend cancellation of Apex's licence even though he found Apex's reply to be unsatisfactory and even though he found that Apex had impliedly admitted their lapses and even though there was a recurrence of serious offences by Apex since 1984. The factors which he took into account in not recommending cancellation of Apex's licence was that such a step was without precedent in the annals of the FDA.

204. Bijamwar's conduct regarding the written complaint made by Apex's assistant chemists is equally infamous.

205. He repeatedly admitted that the complaint made by them in their letter dated 28th February 1986 (Exhibit 260) was genuine. Curiously enough even so there was merely a limited reference to this genuine complaint in para 12 of the show-cause notice dated 13th March 1986. He admitted that the contents of para. 2 of that letter were not even remotely reflected in FDA's show-cause notice. Bijamwar's protestation that he confronted the partners of Apex with the allegations contained in that letter is a lie. Bijamwar admitted that the complaint made by assistant chemists in their letter dated 28th February 1986 (Exhibit 260) was not brought to the notice of the partners of Apex nor was their explanation sought for by him or anyone else in the FDA. He also admitted that a copy of that letter was not sent to Apex for its comments or explanation nor was any oral explanation asked for from the partners of Apex and even though Dolas had asked him to make enquiries about this letter he did not go to Apex in that connection. Bijamwar admitted that he made no enquiries either from Apex nor did he ask for any verification from the assistant chemists because he was convinced of the genuineness of their complaint. He also admitted that he did not question the partners of Apex regarding this complaint nor did he issue any show-cause notice to them or write a letter to Apex regarding it. He admitted that regarding this complaint he did nothing. He

Ex. 260

however reported to Dolas orally that he did nothing about the complaint and that no order had been passed on this complaint. He admitted that there was nothing beyond his bare word to show that this complaint was in fact given to him by Dolas.

Ex. 260 206. Bijamwar admitted that one of the grievances made by Apex's assistant chemists in their letter of 28th February 1986 (Exhibit 260) was that nothing had been done by the FDA despite their earlier complaint to the FDA, as a result whereof the partners of Apex had threatened to ruin their future. Even so no action was taken on Apex's chemists' complaint dated 28th February 1986 other than issuing a show cause notice to Apex which, Bijamwar admitted, would have been done even without Apex's chemists' letter dated 28th February 1986.

207. Bijamwar admitted that he did not tell the licensing authority that the grievances made by assistant chemists in their letter dated 28th February 1986 were genuine and correct and that action should be taken against Apex.

208. Bijamwar admitted that in Apex's assistant chemists' letter dated 28th February 1986 there was an inward stamp of the FDA but there was no stamp showing that it was entered in the complaints Register which is always done. Whenever a complaint is entered in the Complaints Register a corresponding stamp is always put on the complaint with a running number. He admitted that the final outcome of a complaint must be communicated to the complainant and the party against whom the complaint is made must be given an opportunity of showing cause in writing. The complaint made by Apex's assistant chemists dated 28th February 1986 was delivered personally by them to Jt. Commissioner Dolas as is manifest from the latter's endorsement at the foot thereof : " Two chemists met me personally today and reported the matter ". According to Bijamwar it was Dolas' duty to get this complaint registered in the Complaints Register which was not done. He admitted that no unregistered complaint could come to him for investigation and that he did not point out to Dolas that Apex's assistant chemists' complaint had not been registered. According to Bijamwar this complaint was given to him by Dolas personally without making any endorsement to that effect on the complaint itself as is normally done, nor did he tell Dolas to make the requisite endorsement.

209. The evidence of Assistant Commissioner Bijamwar and the admissions made by him reveal his complicity with Apex. He went out of his way to help Apex with the knowledge that Apex had given a false report and was habituated to giving false reports without actually carrying out the tests. Both he and Dolas knowingly took no action against Apex despite the fact that to their knowledge its serious lapses continued unabated and unchecked from 1984 till 1986. Despite the apprehensions expressed by Apex's assistant chemists they were left in the lurch and at Apex's mercy. The earlier complaint filed by Apex's assistant chemists was fortified by the inspection in 1986. Apex admitted its serious breaches from 1984 onwards and these breaches were found to be serious by the FDA. Even so despite Dolas' statutory duty to register all complaints received, the complaint dated 28th February 1986 of the Apex's junior chemists was not registered, so that no order need be passed. No investigation whatsoever was done regarding that complaint even though the grievances made therein were found by Bijamwar to be serious and correct. By no stretch of reasoning could the order of suspension of Apex's licence for 15 days be justified. Hence advisedly no reasons were given for passing the mildest of such punishments for the simple reason that such a punishment was unsustainable by any reason or even common sense. Whereas Trans India was prosecuted twice, against Apex no prosecution was even contemplated, for which no explanation was forthcoming either from Dolas or from Bhirud. No legal opinion was even sought whether Apex should be prosecuted and from the point of Bijamwar, rightly so, because he knew that the opinion would be that this was a fit case for prosecution. Though Bijamwar knew as far back as 1984 that serious offences were committed by Apex in giving test reports without actually carrying out the tests, no inspection of Apex was carried out for 2 years till February 1986. As in-charge of public analytical laboratories, it was Bijamwar's duty to see that Apex did not persist in committing such offences by constant and vigilant inspections and surprise inspections. Nothing of the kind was done and Apex continued its merry ways as before at the cost of public health and public safety. I refuse to ascribe this passiveness on Bijamwar's part merely to negligence, indifference or inefficiency. In casting protection over Apex over the years, Bijamwar was guilty of dereliction of his duties and worse. Bijamwar is a disgrace to the service.

210. Assistant Commissioner and Licensing Authority Dolas fares no better.

211. Dolas admitted that he did not find Apex's reply dated 31st March 1986 to FDA's show cause notice satisfactory, whereupon Apex's licence was suspended by him for 15 days. He admitted that the report given by Apex pertaining to its analysis of Trans India's mannitol was a false report. Dolas admitted that he was entitled to recommend to the Commissioner prosecution against Apex on the report of the panel, but he did not do so and instead recommended suspension of Apex's licence for 15 days allegedly on the ground that on 25th February 1986 Bhirud and Kochar had decided that separate action was called for against Apex which should be brought to Dolas' notice. All this is false because no such decision is to be found in any minutes, which would have, had it been so decided in so serious a matter.

212. Dolas admitted that it was within his powers to recommend to the Commissioner a prosecution and that the prosecution is a more stringent action than mere suspension of licence for 15 days. He also admitted that he did realise that this was a case where an utterly false report was given by Apex which he would consider to be a serious matter. After seeking to take refuge under the guidelines issued by Government of India for prosecutions, Dolas had to admit that there is nothing in these guidelines that in serious matters such as giving false reports, prosecutions should not be launched.

213. Dolas admitted that Trans India had also committed serveral breaches of conditions of licence in the past which was a factor he took into consideration while recommending to the Commissioner Trans India's prosecution. It is therefore significant that in the case of Apex despite its serious lapses, which even according to Dolas were serious lapses, Dolas should have used a different yardstick and recommended to the Commissioner mere suspension of Apex's licence for 15 days instead of its prosecution as done by him in the case of Trans India.

214. Dolas admitted that there were earlier complaints against Apex Laboratories that they were forcing theire chemists to give false reports and that he had received one such complaint in the first week of March 1986. He admitted that in not recommending prosecution against Apex he had taken this complaint into consideration. He admitted that he had received this complaint on 3rd March 1986, that he found that there was substance in that complaint, that he considered the complaint to be of a serious nature which he took into consideration while recommending suspension of Apex's licence for 15 days. Even so according to Dolas a prosecution was not called for against Apex. To the best of his knowledge, FDA has never prosecuted any approved laboratory.

215. Dolas admitted that the show cause notice dated 13th March 1986 given to Apex, showed various breaches of Rule 150 committed by Apex which amounted to offences under Section 18 (c) read with Section 34 (2) of the Act.

216. Dolas' evidence makes grim reading replete with brazenness and shamelessness.

217. From this evidence of Dolas and the admissions made by him, there emerges his complicity along with Bhirud in shielding Apex from prosecution and letting Apex off by merely recommending a 15-day suspension of its licence and that too after this Commission started its sittings. Obviously neither he nor Bhirud had the same soft corner for Trans India against whom two prosecutions were rightly launched.

218. The role of Commissioner Bhirud in Apex's episode can best be described as inefficiency and indifference and perhaps not unmixed of cowardice of Dolas. his evil genius. Bhirud admitted that his department had launched a prosecution against Trans India which had manufactured the defective mannitol. During the course of the investigation he found that Apex had given a false report, but no prosecution had been launched against Apex. The decision not to prosecute Apex was taken by Jt. Commissioner Dolas. Bhirud admitted that normally both Trans India and Apex should have been prosecuted but he did not try to find out why Apex was not prosecuted or why only their approval was suspended.

219. This kind of evidence coming from the Commissioner himself is pathetic, which bespeaks inefficiency, indifference and abdication of authority in favour of Dolas whom he should have controlled, but could not. It is futile for Bhirud to say

that decision not to prosecute Apex was Dolas', when the decision to do so should have been Bhirud's himself. It was for Bhirud to have over rulled Dolas, which I suppose required courage and which Bhirud did not possess or was not inclined to show.

220. This brings me to the role of the then Jt. Commissioner and Licensing Authority N. D. Kulkarni regarding letting Apex off the hook with a mere warning on 29th January 1985.

Ex. 289 221. Kulkarni admitted that he had looked into the complaints made in the inspection report pertaining to Apex in 1984, and that he had seen the grievance of the Apex's chemists that they were being compelled by Apex to give reports without actually carrying out the tests. Kulkarni admitted that on the basis of this report he had issued a show cause notice to Apex why action should not be taken against them and that he had sternly warned Apex. According to Kulkarni warning was sufficient because this was Apex's first offence. He admitted that consistently giving false reports without actually carrying out the test was a serious offence, that the gravity of such an offence was aggravated when such false reports pertained to life-saving drugs. Even so Kulkarni merely let off Apex with a warning because according to him warning is also " a sort of punishment". This is sheer nonsense and also shows Kulkarni's anxiety to shield Apex. Warning is not a punishment under the Act or Rules, and to pass off a warning as a punishment as done by Kulkarni even where a laboratory consistently gives false reports without actually carrying out the tests, can only be ascribed to deadening of conscience. Kulkarni finally admitted that it was a mistake on his part to have let off Apex with a mere warning even though its offence was a serious one and that he realised his mistake now in the witness-box. that he should have taken stringent action at that time.

222. Kulkarni admitted that as Licensing Authority he had no discretion to award punishment other than what was prescribed by the Rules. He admitted that under Rule 150 (k) there is no provision for issuing a warning; either the approval must be cancelled or must be suspended or no action be taken. He also admitted that there is no provision authorising him to administer a warning in the case of such a breach and that in Apex's case the approval should have been withdrawn because Apex had committed a breach of the licence conditions by issuing reports without actually carrying out the tests. He also admitted that as Licensing Authority he did realise that he had no authority to let off Apex merely with a warning.

223. It is futile for Kulkarni to affect piety by purporting to expect that Apex would mend its ways after the warning. This is sanctimonious humbug which is manifest from the fact that the warning order was passed by Kulkarni on 29th January 1985, and he retired on 31st January 1985. He also admitted that he had not given any reasons in his order why he was letting Apex off merely with a warning. It is in this admission that lies the secret of Kulkarni letting Apex off the hook two days before his retirement.

224. It appears that Apex was not the only case where Kulkarni passed light orders on the verge of his retirement. Though he may now affect not to remember it in the month of his retirement, viz. January 1985, he had decided a number of show cause notices, and in January 1985 he had even given permission to one manufacturing concern for the production of additional drugs and in April 1986.i.e. after he retired, he started working as its consultant.

225. In the light of Kulkarni's evidence and his own admissions, his complicity in the affairs of Apex needs no further comment.

226. The evidence discloses the total awareness of these officers that prosecution against Apex was mandatory. Bhirud shrugged his duties by throwing responsibility on Dolas as being the person who should have recommended the prosecution, forgetting that as Commissioner it was Bhirud who alone could have been entitled to recommend prosecution of Apex. Bhirud was aware of what had transpired during the inspection at Apex and though he applied his mind in sanctioning prosecution against Trans India, the responsibility of not prosecuting Apex must fall on Bhirud. He cannot shrug his responsibility either on the ground of incompetence or cowardice towards Dolas, both of which can undoubtedly be held guilty. Dolas' justifications for the non-prosecutions of Apex are on grounds which are totally untenable. Kulkarni's justifications for not prosecuting Apex for the 1984 lapses

on the ground that warning was sufficient punishment, is not only ridiculous, but self-seeking. The fact that he administered his warning on 29th January 1985 and retired on 31st January 1985 by itself is eloquent.

227. All the three of them, namely Kulkarni, Bijamwar and Dolas were the golden gang whose affinity towards Apex outweighed their duty to their office, their conscience and the general public. Men of neuter conscience. Kulkarni and Ehirud were and Bijamwar and Dolas continue to be a disgrace to the FDA.

228. In the light of the above, to hold that no impropriety had been committed by FDA either in not prosecuting Apex or letting it off leniently by a mere warning would be contrary to all canons of law, equity and good conscience. Impropriety and worse are writ large. Nor can it be said with any justification that it was not possible for FDA to file a prosecution against Apex on the erroneous assumption that the Act makes no provision for prosecuting an analytical laboratory. This would be cynicism at its worst.

CHAPTER XIV

PART 1

1. This brings me to the role played by various Health Ministers and officers of the FDA in its working.

2. I shall start with Mr. Bhai Sawant who is and was at all material times the Health Minister. He was elected to the Legislative Council twice, first in 1978 and thereafter in 1984. In February 1983 he was appointed Minister of State for Health and continued to be so till March 1985 when he became Cabinet Minister for Health. As such he held and to-date holds charge of the Department of Medical Education.

3. And now to the narration of events subsequent to the J. J. Hospital tragedy.

(*a*) *31st January 1986.*—(*i*) At about 9-00 a.m. Health Minister Bhai Sawant was informed of the J. J. Hospital deaths by his Secretary Tripathi. The Health Minister also came to know about this from the Maharashtra Times of that day.

(*ii*) Between 11-00 and 11-30 a.m. the Health Minister accompanied by his Secretary visited the J. J. Hospital where he had discussions with the Dean and the doctors and saw two patients undergoing dialysis. The Health Minister advised on the line of treatment and also asked the Director of Medical Education who was present to add two more names to the Choube Committee. The Health Minister was in the J. J. Hospital for about 45 minutes.

(*b*) *12th February 1986.*—(*i*) Health Minister Bhai Sawant accompanied by his Secretary went to the house of the then Chief Minister Shivajirao Patil-Nilangekar and apprised him of the situation and requested him to keep this matter for an informal discussion in the Cabinet Meeting which was to be held that day.

(*ii*) Accordingly the matter was discussed in the Cabinet Meeting and three decisions were taken, namely (*a*) to appoint a Commission of Inquiry, (*b*) to have a CID inquiry, and (*c*) to take administrative action against the staff.

(*c*) *18th March 1986.*—Mr. S. B. Chavan who by then had become Chief Minister was apprised of this matter. He ordered stoppage of a parallel inquiry by the CID pending the present Commission of Inquiry. A note to that effect was signed by him on 1st April 1986 that the CID inquiry be continued after the present Commission submits its Report.

(*d*) *18th November 1986.*—On 18th November 1986 Health Minister Bhai Sawant examined himself. On 18th March 1987 he was recalled by the Commission for further questioning and was examined till 21st March 1987.

(*e*) *21st March 1987.*—While he was being questioned on recall, Health Minister Bhai Sawant's attention was drawn to the vested interests of the FDA officers in the drugs industry. Thereupon he promised to take action to transfer such officers outside the spheres of their interests. In this context, the relevant excerpts are as under :—

"*Ques.* : Therefore do you agree that those officers will continue to attend to the work of those concerns in which they have an interest ?

Ans. : Yes.

(*To Commission*:—

Ques. : As Health Minister, do you think that this is in public interest ?

Ans. : No; it is not in public interest.)"

Thereafter the question and answer ran thus :—

"*Questioning by Mr. Shah resumed*:—

Ques. : Then why is it that nothing has been done to transfer such officers outside the spheres of their interest ?

Ans. : This was not done as this Inquiry is in progress. Now that it is necessary to do so in public interest, it shall be done immediately. I am aware of the names of two officers namely Commissioner Bhirud and Jt. Commissioner Dolas.

(*f*) *24th March 1987.*—An order was passed transferring Dolas as Jt. Commissioner (Drugs) to Jt. Commissioner (Food) and appointing Akre who was Jt. Commissioner (Food) to the post of Jt. Commissioner. This stratagem was merely a farce in order to hoodwink the public and the Commission, as it merely amounted to an interchange of posts with the offices of both the posts in the same building and on the same floor with common staff.

(*g*) *25th March 1987.*—A show cause notice was issued to Dolas calling upon him to reveal all personal connections, direct or indirect, with pharmaceutical concerns/ analytical laboratories and to explain whether prior permission as required by the Civil Service Conduct Rules was obtained before developing such interests, if any, and whether Government was informed by him after such interest was established. Dolas' explaination was called for within a week from the date of the service of the notice on him.

(*h*) *30th March 1987.*—Dolas sent his reply that even though his daughter were partners in Ferico Pharmaceuticals and Ferico Laboratories, he had no vested interest in either as his daughters were not wholly dependent on him even though they were residing with him. Dolas stated that his was a Joint Hindu Family and therefore the family income was sufficient to support his daughters. Hence according to Dolas he had no direct or indirect vested interest in the drugs industry.

(*i*) *25th March 1987.*—A similar show cause notice was served on Commissioner Bhirud.

(*j*) *22nd April 1987.*—Bhirud replied denying that he had any vested interest in the drugs industry as his son was not dependent upon him.

Both these show cause notices are yet to be decided.

(*k*) *15th June 1987.*—Health Minister Bhai Sawant was again recalled and questioned till 19th June 1987.

4. An allegation was made against Mr. Bhai Sawant by one A. K. Chavan to the effect that for securing rate contract to Alpana Pharma, Mr. Bhai Sawant had received a sumptuous donation. In respect of this allegetion made against Mr. Bhai Sawant, the following facts are relevant.

(*a*) *19th March 1986.*—A newspaper report appeared in the DALIY about the J. J. Hospital incident. In this report certain allegations were made against Health Minister Bhai Sawant. This newspor report was taken on record as Exhibit 139 for the limited purpose that a report had appeared in the DALIY and not for the correctness of the allegations made therein. Regarding the allegations made against him is the DAILY, Mr. Bhai Sawant says that he issued a clarification and denial. Ex. 139 Ex. 165

(*b*) *20th March 1986.*—A news item appeared in the DAILY. This was taken on record as Exhibit 140 for the limited purpose as stated earlier. According to Mr. Bhai Sawant he issued a clarification (Ex. 166). Ex. 140 Ex. 166

(*c*) *July 1986.*—Questions were raised in the Legislative Assembly regarding the J. J. Hospital incident. They were replied to by the Health Minister on 22nd July 1986 on the floor of the House; he denied that he had any connection in the matter of the rate contract being awarded to Alpana Pharma.

(*d*) *14th July 1986.*— One A. K. Chavan addreassed a letter (Ex. 141) to this Commission making allegations against Health Minister Bhai Sawant that he had favoured Alpan Pharma by awarding it the rate contract as a *quid pro quo* for a "sumptuous donation" made by Alpana Pharma to R. U. O. In this letter Chavan had also made allegations against certain other parties. Ex. 141

(*e*) *17th September 1986.*—A. K. Chavan's letter was followed by his making an affidavit wherein the same allegations were repeated.

(*f*) *2nd October 1986.*—Health Minister Bhai Sawant made his affidavit-in-reply (Ex. 164) which was filed before the Commission on 23rd October 1986. He denied the allegations made by A. K. Chavan, he stated *inter alia* that he had not collected any donations for R. U. O. either directly or indirectly and that he had no hand in the collection of donations for R. U. O. Ex. 164

(*g*) *27th October 1986.*—Affidavits were filed by the other parties against whom A. K. Chavan had made allegations in his letter dated 14th July 1986 and his affidavit dated 17th September 1986. An affidavit (Ex. 169) was also filed by Dr. J. B. Naik, Secretary of the R. U.O. who was later served with a notice under Section 8(*b*) of the Commissions of Inquiries Act.

5. A. K. Chavan's allegation regarding Health Minister Bhai Sawant is a canard. The evidence does not disclose that Bhai Sawant had any hand in the granting of the rate contract to Alpana Pharma either for a donation or otherwise. The evidence of A. K. Chavan implicating Mr. Bhai Sawant does not inspire confidence and is purely hearsay, based as it is on what he learnt from one Shivram R. Bhosale. In not a single material particular does Bhosale support Chavan. Chavan's evidence is thoroughly unreliable seemingly on his political rivalry with Mr. Bhai Sawant. The evidence does not disclose that any donation was collected by R.U.O. from Alpana Pharma or that Mr. Bhai Sawant had any hand in awarding the rate contract to Alpana Pharma.

6. I have therefore no hesitation in exonerating Mr. Bhai Sawant from this charge of corruption levelled against him by A. K. Chavan.

7. This brings me to Rural Upliftment Organisation (R. U. O.).

8. In 1984 Rural Upliftment Organisation (R. U. O.) was started with the object of constructing hospitals and educational institutions at Sawantwadi. From its inception Health Minister Bhai Sawant was connected with this Organisation as adviser.

9. R. U. O. has constructed a hospital at Sawantwadi and there are plans to affiliate this hospital to an Ayurvedic college " Ayurvedic Maha Vidyalaya " run by Jankidevi Maternity Hospital.

10. In 1985 R. U. O. had arranged a Musical Nite in Bombay. In that connection
Ex. 168 a souvenir (Ex. 168) was brought out by R.U.O. Various advertisements were collected and published in this souvenir. Not less than 37 advertisements published in this souvenir were connected with the drugs industry. A list of such
Ex. 168(A) advertisers from the drugs industry is at Exhibit 168-A. Over and above this, in the Souvenir there were two advertisements, one from the Maharashtra State Co-operative Bank and one from SICOM. These two advertisements were admittedly obtained by R. U. O. at the instance of Health Minister Bhai Sawant. The Maharashtra State Co-operative Bank made a donation of Rs. 2,00,000 to R. U. O. The cheque for this amount was received by Health Minister Bhai Sawant as shown in a photograph in the souvenir. A full page advertisement of the FDA was also published in the Souvenir (for which incidentally payment has still not been made by the FDA.).

11. In para 4 of his affidavit Health Minister Bhai Sawant was vehement in his protestation that though some advertisements from pharmaceutical companies did appear in the souvenir, he had never procured or caused to be procured any advertisement or donation. Unfortunately for the Health Minister the facts as painstakingly extracted from him and reluctantly admitted by him in his evidence are otherwise. Though at page 906 para 18 of this evidence he asserted that R. U. O. did not collect any funds at his instance at any time, he had to admit at page 2146-JJ of his evidence that this statement was partly correct except for the SICOM incident and the Maharashtra State Co-operative Bank incident. At page 2156-KK of his evidence he admitted that he had made recommendations to SICOM for giving an advertisement. Significantly it was only after he was confronted with a photograph showing him receiving a cheque, the Health Minister also admitted to the sumptuous donation of Rs. 2 lacs made to R. U. O. by the Maharashtra State Co-operative Bank of which he is a director. Needless to say, the Bank would not have been as generous had not the Health Minister been connected with R. U. O. albeit as adviser. And thus the Bank was happy to have the good-will of the Health Minister. And the R. U. O. got a donation of Rs. 2 lacs. Nothing could be more convenient. On the part of the Health Minister this was also misuse of office but for which the Bank would not have been persuaded to part with a large amount of Rs. 2 lacs in the first place.

12. The Health Minister stated that it was on the night of the Musical Nite that he came to know that certain pharmaceutical concerns had given advertisements in the souvenir of R. U. O. and that the collections pertaining to the advertisements in that Souvenir had been made by R. U. O.'s Office bearers, Dr. Naik and Dr. Modak. However he thereafter admitted that he had received this information " very recently " from Dr. Naik pursuant to an enquiry made by him to Dr. Naik the previous week, when he learnt that uptil 1985 R. U. O. had collected Rs. 32,300 by way of donations and between Rs. 17,000 and Rs. 18,000 by way of advertisements from pharmaceutical concerns, and that the total amount of donations collected was Rs. 3,50,000 and the amounts collected from advertisements were Rs. 1,80,000.

13. Health Minister Bhai Sawant maintained that neither directly nor indirectly did he distribute any advertisement forms of R. U. O. when asked—

"*Q.* : Do you know that your Government Secretary and Under Secretaries working under you had distributed advertisement forms for the Rural Upliftment Organisation through the heads of various departments including FDA ?"

he replied—

"*A.* : No, I had never given any such forms to anyone for distribution or anyone distributed any such forms at my behest."

However he had to eat his words the following day by volunteering that after he gave his evidence the previous day he made enquiries and discovered that he had given an advertisement form to SICOM with the endorsement of his name on that form and recommending through his Personal Assistant an advertisement in the Souvenir of R.U.O. It is obvious that this volunteered statement was to extricate himself from his earlier protestation to the contrary.

14. According to the Health Minister to the best of his knowledge SICOM's case was the only one where he had recommended that an advertisement be given by them in the Souvenir, which fact he did not remember in his evidence the previous day. According to him his memory was revived after his meeting with Pathade the previous day who no longer is his P. A. According to the Health Minister the previous day was the first time he got complete enquiries made to find out whether directly or indirectly he had collected advertisements or donations for R. U. O.

15. All this is far too naive in the teeth of his admission that it was he who had given instructions for preparing his affidavit. It is an insult to the Health Minister's intelligence that he should have done so without proper verification of the facts. Thus the Health Minister's earlier evidence that he had never at any time procured any donations or advertisements for R. U. O. was demonstrably false.

16. According to the Health Minister his name was not used by anyone for collecting donations for R. U. O. to his knowledge. However he had to give a go-by to this assertion, when on being shown a letter dated 28th September 1985 from R. U. O.'s Secretary Dr. Naik to the Commissioner of FDA asking the FDA for an advertisement for the souvenir, he had to admit that in this letter it had been stated that under the Health Minister's "able guidance" Ayurvedic Medical College had been started in 1984 and that in this letter he had been described as "the Hon'ble Shri Bhai Sawant, the Minister of Rural Development, Public Health, Med. Education and Drug, Government of Maharashtra" and that the FDA would not have refused to give an advertisement because of the letter. He had also to admit that a similar letter had also been sent by his Personal Assistant to the Personal Assistant of SICOM enclosing therewith the Appeal. Health Minister agreed that in his Personal Assistant's letter to SICOM his name, rank and official designation were used.

17. Thus the evidence of Health Minister Bhai Sawant discloses that despite his initial denials, he had in at least three cases, namely SICOM, Maharashtra State Co-operative Bank and FDA, exercised his influence and misused his official position to obtain donations/advertisements. These admissions are a far cry from his categorical assertion made at the earliest point of time in his affidavit dated 23rd October 1986 (Ex. 164) that he did not procure or cause to be procured any advertisement or donation for the Souvenir or that when he made his affidavit he did not remember about SICOM. It is not as if the affidavit made by the Health Minister was prepared on the instructions of anyone else. He admitted that he had indeed stated in para 4 of his affidavit that he did not procure or cause to be procured any donation for the Souvenir, that this affidavit was prepared under his instructions and that he had signed it after reading and understanding it. The Health Minister cannot allow himself the luxury of saying that when he made his affidavit he had not made all enquiries. This is an insane excuse coming as it does from an educated person of the rank of a Health Minister. The Health Minister's assertion that when he made the affidavit he did not remember the SICOM incident strains credence. If according to the Health Minister this was the only incident, then greater the reason he should have remembered it unless of course there were several other such incidents which he would find inconvenient to remember. Ex. 164

18. There is no doubt that the name, rank and official position of Mr. Bhai Sawant as Health Minister, played a great part in inducing not less than 37 parties connected with the drugs industry to make donations and/or give advertisements to R. U. O.

19. Under these circumstances not only had Health Minister, Bhai Sawant intentionally given false evidence in order to dissociate himself with the collections made by R. U. O. but also misused his power, position and authority as Health Minister.

PART III

20. The next question that arises is : *Has Health Minister, Bhai Sawant, contrary to the policy of transfers, used the weapon of transfer to remove " inconvenient " officers and simultaneously confer favours upon a chosen few ?* If so, *has Health Minister Bhai Sawant been guilty of gross ministerial interference, favouritism for extraneous considerations and misuse of power and authority vested in him ?*

21. This topic can be sub-divided under seven heads : (A) Transfer of Assistant Commissioners, Desai, Dani and Pathak to favour Patil, Mali and Deshpande ; (B) Undeserved and out of the way promotion given to Dolas as Joint Commissioner and Licensing Authority (H. Q.) ; (C) Undue favour shown to Cyma Pharma ; (D) Mis-using official position to collect donations and advertisements for R. U. O. ; (E) Pressurising FDA officers ; (F) Asking Raykar to award rate contract to Samarth Pharmaceuticals and Welcome Laboratories and (G) Miscellaneous acts showing Ministerial interference, favouritism and misuse of power.

(A) Transfer of Assistant Commissioners Desai, Dani and Pathak to favour Patil, Mali and Deshpande.

22. These transfers were contrary to the policy and with a view to oblige 3 undeserving Assistant Commissioners, S. D. Patil, Mali and Deshpande, each of whom had got recommendations from MLAs and were trying to return to Bombay after having been transferred from Bombay to other places. To that end a thumb-nail sketch of Patil, Mali and Deshpande.

23. S. D. Patil was Assistant Commissioner in Bombay from 1977 till April 1982 when he was transferred as Assistant Commissioner to Sangli. However he did not take charge at Sangli. Hence by an order dated 15th May 1982 he was posted at Pen in Raigad district nearer Bombay. In February 1983, Mr. Bhai Sawant became Minister of State for Health. Shortly thereafter on 20th March 1983 Bhaskarrao Shingane, M. L. A., addressed a letter to Mr. Bhai Sawant requesting Patil's transfer to Bombay. For this purpose significantly no application was made by S. D. Patil himself. A copy of Bhaskarrao Shingane's letter dated 20th March 1983 was sent to Commissioner Bhirud on 18th April 1983 for his remarks. Bhirud strongly opposed S. D. Patil being brought to Bombay for several reasons, to wit, that S. D. Patil was in Pen for one year only, that there was no vacancy in Bombay, that Government should not take cognisance of individual transfer applications by officers who make efforts to get re-transferred to Bombay, that S. D. Patil's making attempt through Bhaskarrao Shingane, M. L. A., to get himself re-transferred to Bombay was an act detrimental to the healthy and efficacious functioning of the department and that S. D. Patil should complete his three years in Pen.

24. However even without considering Bhirud's objections, Mr. Bhai Sawant passed his order for transferring S. D. Patil to Bombay.

25. Thereupon, on 3rd May 1983 Bhirud again opposed S. D. Patil's transfer to Bombay. On 4th May 1983 Government sent a letter directing Commissioner Bhirud to transfer S. D. Patil to Bombay. On 10th May 1983 Commissioner Bhirud placed on record his strong disapproval of Patil's transfer to Bombay on the ground that he was thoroughly incompetent. Even so on 30th May 1983 the formal transfer order was passed specifically directing Commissioner Bhirud to post Patil in Bombay.

26. Mr. Bhai Sawant's hand in getting S. D. Patil transferred to Bombay is manifest not only from the above facts but also from certain admissions made by Mr. Bhai Sawant himself. In this connection Mr. Bhai Sawant admitted that he is aware that S. D. Patil was in Bombay as Assistant Commissioner for 5 years from 1977 till 1982 (viz. 2 years over the customary 3-years period). He admitted that when he became Minister of State for Health in February 1983 he found from the

file that despite Patil's transfer order to Sangli in April 1982 he had not taken charge there but instead was posted at Pen, Raigad district on 15th May 1982. He also admitted the letter sent to him by Bhaskarrao Shingane, M. L. A., requesting Patil's transfer from Pen to Bombay and that no application was made by Patil himself. He also admitted that Commissioner Bhirud had totally opposed Patil's transfer from Pen to Bombay, that on 30th May 1983 an order was passed by the Health Department directing the Commissioner, FDA to transfer Patil from Pen to Bombay and that that order was passed by him as Minister of State for Health. Mr. Bhai Sawant admitted that while passing his order he had not gone through the Commissioner's letter dated 18th April 1983 opposing Patil's transfer to Bombay though he had gone through the notings made by the Deputy Secretary and Secretary. Though the final order was passed by the Health Minister, Mr. Bhai Sawant agreed that it was he who had handled the matter of Patil's posting to Bombay. That he would not call his transfer to Bombay as an urgent or necessary transfer ; he agreed that Patil's transfer to Bombay had been expedited by Government and that the transfer was not in usual course. He also admitted that despite Government's letter dated 30th May 1983 to the Commissioner to transfer Patil to Bombay, the Commissioner did not do so resulting in an explanation being called from him.

27. It is of no mean significance that the explanation called for from Commissioner Bhirud was by the Desk Officer *vide* her letter dated 15th June 1983. Bhirud was thus sought to be humiliated inasmuch as it was left to a desk officer to have called for Bhirud's explanation instead of from one superior to him. No doubt, left to herself, the poor Desk Officer would not have had the temerity to do so.

28. These facts and the admissions made by Mr. Bhai Sawant himself reveal in no uncertain terms Mr. Bhai Sawant's interest in getting an officer who according to Commissioner Bhirud, who would know best, was thoroughly incompetent.

29. Mr. Bhai Sawant was not related to Patil, nor had he even heard of Patil until he became State Minister for Health. There is no reason and none was forthcoming why Mr. Bhai Sawant despite knowing that Patil had disobeyed his transfer order to Sangli, should have also ignored the vociferous protests of Commissioner Bhirud regarding Patil's transfer to Bombay for valid and cogent reasons given by Bhirud and which Mr. Bhai Sawant did not even care to read. Knowing that Patil's transfer to Bombay was neither urgent nor necessary, there is no reason why Mr. Bhai Sawant should have been instrumental in bringing an incompetent officer such as Patil to Bombay by these devious means and humiliating Bhirud for correctly opposing the transfer. The only irresistible inference that can be drawn is that Mr. Bhai Sawant's interest in getting Patil transferred to Bombay was due to extraneous considerations.

30. The other officer who was the recepient of Mr. Bhai Sawant's favour was Assistant Commissioner, Mali. In April 1977 Mali was transferred from Ratnagiri to Bombay. On 21st January 1981 a transfer order was passed against Mali but it was cancelled, with the result that Mali continued his posting in Bombay. On 30th April 1982 Mali was transferred from Bombay to Aurangabad but he did not take charge there and went on leave. Desirous as he was of being re-transferred to Bombay, Mali approached the then Chief Minister, Babasaheb Bhosale on 1st June 1982 through Shivchand Chunilal, MLA, to get Mali's transfer to Aurangabad cancelled and to get him posted at Bombay. The then Chief Minister refused to oblige. As a result Mali took charge of his post at Aurangabad.

31. A few months later in February 1983, Mr. Bhai Sawant became Minister of State for Health. Two months later on 12th April 1983 Mali made another representation to the Chief Minister for his re-transfer to Bombay. Mr. Bhai Sawant rose to the occasion with a favourable endorsement. The letter and endorsement were forwarded to the Commissioner for his remarks. On 30th April 1983 Mali went on long medical leave. On 7th May 1983 the Commissioner sent his remarks vigorously opposing Mali's transfer to Bombay on several grounds including that Mali had vested interest in Bombay. Even so on 30th May 1983 an order was passed transferring Mali to Bombay. All this apperars from the evidence of Mr. Bhai Sawant himself including the fact that a favourable endorsement had been made by him.

32. This is yet another strange case where Mr. Bhai Sawant played a role in Mali's undeserved and unwarranted re-transfer to Bombay in the teeth of the opposition of the Commissioner, who would know best. It is also of no mean

significance that Mali's first representation having been rejected by the then Chief Minister, Mali should within two months of Mr. Bhai Sawant's appointment as Minister of State for Health make another representation to the Chief Minister, Ex. 452 (colly.) which for some inexplicable reason should find favourable reaction from Mr. Bhai Sawant. Equally for some inexplicable reason Mr. Bhai Sawant should have chosen to ignore not less than four Government Resolutions which enjoin officers to make representations through the head of the department and not directly to Ministers or the Chief Minister. Before making his favourable endorsement on Mali's representation, surely Mr. Bhai Sawant would know that the earlier Chief Minister had rejected Mali's identical application and that the Commissioner had also made strident observations opposing Mali's transfer to Bombay on several grounds, including that Mali had vested interest in Bombay. All this should have put Mr. Bhai Sawant on his guard. It did not. Nor was it error of judgment.

33. In the teeth of all this Mr. Bhai Sawant was instrumental in getting Mali transferred to Bombay. Once again Mali was not friend or relation of Mr. Bhai Sawant. They were not even known to each other. Yet Mr. Bhai Sawant must go out of his way to be instrumental in Mali's transfer to Bombay. Once again, as in the case of S. D. Patil, an irresistible inference must be drawn that this was done by Mr. Bhai Sawant not for altruistic reasons but for extraneous considerations.

34. Yet another officer who was the recipient of Mr. Bhai Sawant's favour was Asstt. Commissioner P. R. Deshpande. Between 1976 and 1982 Deshpande was posted as Asstt. Commissioner in Bombay. On 30th April 1982 he was transferred to Yeotmal, but did not take charge there; instead got himself transferred to Jalgaon. On 12th April 1983 Deshpande made a representation to the then Health Minister Dr. (Mrs.) Lalita Rao requesting his transfer to Bombay. This representation was forwarded to the Commissioner. On 7th May 1983 the Commissioner recorded his opposition to Deshpande being transferred to Bombay on the ground that Deshpande had got his earlier transfer to Yeotmal cancelled through the influence of two MLAs and that Deshpande had vested interest in Bombay. The secretarial endorsement was that unless Deshpande completed his three years at Jalgaon, it would not be proper to transfer him to Bombay. This secretarial endorsement also emphasised that according to the Commissioner, Deshpande had vested interest in Bombay.

35. Even so on 16th May 1983 Mr. Bhai Sawant made an endorsement questioning the basis on which the Commissioner had arrived at his finding that Deshpande had vested interest in Bombay. On 26th May 1983 the then Health Minister Dr. (Mrs.) Lalita Rao ordered Deshpande's transfer to Bombay after the transfer of some officer who had worked for more than 3 years in Bombay.

36. The fact that Mr. Bhai Sawant who was then Minister of State for Health was instrumental in getting Deshpande transferred to Bombay, comes to the fore on several counts. No doubt as Minister of State for Health, Mr. Bhai Sawant was entitled to make his endorsement of 16th May 1983 questioning the basis of the Commissioner's objection that Deshpande had vested interest in Bombay. However it does not appear that this endorsement made by Mr. Bhai Sawant was conveyed to the Commissioner or that he questioned the Commissioner as to how Deshpande had vested interest in Bombay. If Mr. Bhai Sawant had done so, the Commissioner's reaction would have been noted in the file produced before the Commission. Obviously this endorsement made by Mr. Bhai Sawant on 16th May 1983 was only for the consumption of Health Minister Dr. (Mrs.) Lalita Rao with a view to cast a cloud on the Commissioner's opposition to bringing Deshpande to Bombay on the ground that he had vested interest in Bombay. Thus, Mr. Bhai Sawant's endorsement was merely a ploy to get round the Commissioner's emphasis that Deshpande had vested interest in Bombay. The Commissioner had also advanced two other arguments opposing Deshpande's transfer to Bombay, namely that there were general complaints of corruption against Deshpande and that Deshpande had got his transfer order cancelled through the interventon of two M.L.A.s Gaikwad and Divekar. In neither direction did Mr. Bhai Sawant make or have any enquiries made. These two grounds were by themselves sufficient for not bringing Deshpande to Bombay. It is not as if Mr. Bhai Sawant knew or had been told otherwise by anyone, as is apparent from his own admission that he did not have discussions about this with anyone. Mr. Bhai Sawant on his own admission did not even verify Deshpande's confidentials, which would have revealed more than what Mr. Bhai Sawant might have found convenient. Mr. Bhai Sawant tried to extricate himself by saying that he made his endorsement because there were general complaints of corruption

against Deshpande. This is totally absured and desperate answer coming from no less than a Health Minister in view of the fact that on Mr. Bhai Sawant's admission he made his endorsement because he wanted to verify whether Deshpande had a vested interest in Bombay. In the light of the general complaints of corruption against Deshpande as admitted by Mr. Bhai Sawant himself, there was every reason for Mr. Bhai Sawant to have agreed with the Commissioner's endorsement instead of querying it only on the ground of vested interest. Mr. Bhai Sawant also agreed that if an officer has vested interest in a particular place, he should not be posted in that place and that when he made his endorsement he knew that earlier Deshpande had got his transfer cancelled through the intervention of two M.A.L.s Thus on his own showing Mr. Bhai Sawant was instrumental in facilitating Deshpande's transfer to Bombay over the strenuous objections of the Commissioner.

37. Deshpande was yet another officer who was not a friend or relation of Mr. Bhai Sawant. Yet Mr. Bhai Sawant should have thought if fit to lend his helping hand in his transfer to Bombay. Deshpande's is another instance where an irresistible inference can be drawn against Mr. Bhai Sawant that he acted not *bona fide* or in the interest of the FDA. but against its interest, and for extraneous considerations.

38. The three officers who suffered by these transfer orders were Dani, Desai and Pathak. They filed a writ petition in the Bombay High Court being writ Petition No. 1574 of 1983 for setting aside those orders. On 14th November 1983 these transfer orders were set aside on the ground of *mala fides* and that Dani, Desai Ex. 475 and Pathak should not have been transferred until their three years had expired in Bombay. It is of no mean significance that as soon as the three years expired, Mali, Patil and Deshpande were promptly brought to Bombay, the first two to Head Quarter on 21st April 1986 and 5th June 1986 and Deshpande to Thane on 18th February 1986. At that time the Health Minister was none other than Mr. Bhai Sawant. Thus with technical compliance with the High Court's order, Mr. Bhai Sawant had his way.

(b) Undeserved and out of the way promotion given to Dolas as Jt. Commissioner and licensing Authority (Head Quarter).

39. On 31st January 1985 N. D. Kulkarni retired as Jt. Commissioner and Licensing Authority. Fadnavis was the senior most. Commissioner Bhirud recommended his name to Government for the post of Jt. Commissioner and Licensing Authority. In anticipation of Government order, Fadnavis was allowed to function by Commissioner Bhirud as Jt. Commissioner and Licensing Authority. Fadnavis held this charge till November 1985. However Bhirud's recommendation was not accepted by Government, and in November 1985 without consulting Bhirud a Government Resolution was issued transferring Fadnavis to Nagpur and Dolas to Bombay.

40. Earlier in May 1985 there had been a proposal to bring Dolas from Thane to Bombay and hand over charge to him of Additional Commissioner. On this proposal, Bhirud made an endorsement on 31st May 1985 that Dolas was in Bombay for many years and therefore it would not be proper to bring him to Bombay.

41. There was another proposal to transfer Jt. Commissioner Joshi from Nagpur to Thane and Dolas from Thane to Nagpur, and Fadnavis being retained in Bombay. The Dy. Secretary endorsed this proposal on 3rd October 1985 and it had the approval of Commissioner Bhirud.

42. Suddenly on 31st October 1985, in the middle of the year, Mr. Bhai Sawant made an endorsement transferring Dolas to Bombay and Fadnavis to Nagpur; thereby 4 seniors were superseded, namely Fadnavis, P. S. Joshi, N. R. Deshpande (not to be confused with P. R. Deshpande earlier), and V. R. Kirtane. As a result, Fadnavis and Kirtane sought voluntary retirement.

43. Fadnavis' case was a tragic case. He made a representation of 26th November 1985 to Government that his son had recently died in an accident, and that his wife was suffering from cancer and was required to attend the Tata Memorial Hospital, he furnished his wife's medical certificate. He was not even vouchsafed the courtesy of a reply. Fadnavis opted for voluntary retirement. However Fadnavis was willing to withdraw his letter of voluntary retirement if posted back in Bombay. Such was the representation made by him to Mr. Bhai Sawant on 9th April 1986. Bhirud made a favourable recommendation. Once again Fadnavis was not even vouchsafed the courtesy of a reply. However he was offered orally a posting at

Thane which he could not accept due to his wife's illness for which she was being treated at the Tata Memorial Hospital. He preferred voluntary retirement and went into the wilderness. His wife died of the terminal ailment she was suffering from.

44. All this is not mere conjecture or speculative reasoning. It is all borne out by hard and unrelenting facts appearing from admissions in the evidence of Mr. Bhai Sawant, Dolas and Bhirud themselves.

45. Mr. Bhai Sawant's evidence also reveals that on 20th May 1985, Under secretary S. M. Deshpande had prepared a note (Ex. 476-A) that Jt. Commissioner
Ex. 476(A) P. S. Joshi should be transferred from Nagpur to Thane, that Asstt. Commissioner Fadnavis who was due to retire on 1st December 1987 be retained in Bombay and that Dolas be transferred from Thane to Nagpur. In para 5 of this note Under Secretary S. M. Deshpande in terms set out that Commissioner Bhirud had informed that since 1964, out of 21 years Dolas had been in Bombay for nearly 18 years (excluding 3 years in all at Thane) and hence it would not be proper to bring Dolas to the Greater Bombay Division again. In para 6, Under Secretary Deshpande requested for orders clarifying whether Dolas should be transferred from Thane to Greater Bombay Division as Asstt. Commissioner, whereafter it would be proper to take a decision whether Dolas should be handed over charge of the post of Jt. Commissioner in Greater Bombay Division. This proposal of Under Secretary Deshpande was accepted by the Dy. Secretary and the Secretary vide their respective notings of 20th and 23rd May 1985. At the foot Health Minister Mr. Bhai Sawant made his endorsement on 31st May 1985 wherein he stated that as Dolas has been in Bombay for several years, it would not be proper from the point of view of administration to bring him from Thane to Bombay, hence the Jt. Commissioner working in Pune should be brought to Bombay and Kirtane should be transferred. Mr. Bhai Sawant's endorsement concluded that the officers who had been working in Head Quarter for many years should be transferred and that the matter should be discussed.

46. These factors reveal in no uncertain terms Mr. Bhai Sawant's initial opposition in May 1985 for bringing Dolas to Bombay as replacement for Fadnavis.

47. Yet within 5 months thereafter Mr. Bai Sawant inexplicably changed his mind, and over the strenuous opposition of his own secretarial staff and Commissioner Bhirud, insisted that Dolas should be transferred to Bombay as Jt. Commissioner and Licensing Authority and passed an order accordingly on 31st October 1985. Even as late as 3rd October 1985 the submission made by Mr. Bhai Sawant's secretarial staff indicates that Jt. Commissioner P. S. Joshi was to be transferred from Nagpur to Thane, N. R. Deshpande from Pune to Bombay Division, that Fadnavis was to continue in the Bombay office, that Kirtane was to be transferred from Bombay Division to Aurangabad, that S. S. Deshpande from Intelligence, Bombay to Pune, that Rahim from Aurangabad was to be relieved of additional charge and that Dolas was to be transferred from Thane to Nagpur. In this submission it was recorded that in preparing this proposal, senior persons had been considered, hence whenever the post of Jt. Commissioner was decided to be filled up in the regular manner, as far as possible minimum changes would have to be made. This Submission ended with a statement that P. S. Joshi, Deshpande, Fadnavis and Rahim would not be put to much trouble by the said transfers. This submission was signed by the Dy. Secretary and Secretary on 3rd October 1985 and 14th October 1985 respectively. Under this submission, Mr. Bhai Sawant made his endorsement on 31st October 1985 accepting the proposals made except insofar as they pertained to Dolas and Fadnavis. Mr. Bhai Sawant's endorsement reads under :

> " Shri Dolas may be transferred to the Commissioners' office at Bombay and Shri B. G. Phadnis may be transferred to Nagpur. Further, if the Asstt. Commissioner at Dhule has been at that place for a longer period, he may be transferred. The rest of the proposal is accepted."

As a result, came Government Resolution, dated 21st November 1985 whereby inter alia Fadnavis got transferred from Bombay (H.Q.) to Nagpur and Dolas from Thane to Bombay (H.Q.) in the place of Fadnavis. Accordingly Dolas took charge on 29th November 1985.

48. The pertinent question that arises is—*What happened between 3rd October 1985 when Mr. Bhai Sawant vetoed Dolas' transfer to Bombay and 31st October 1985 when in the teeth of the opposition of Commissioner Bhirud and Mr. Bhai Sawant's own secretariat, he changed his mind and brought Dolas to Bombay (H.Q.) holding*

charge as Licensing Authority? To that end, opportunities were offered to Mr. Bhai Sawant in his evidence to give an explanation. However the explanations assailed by him are so ludicrous as to strain credence and leave one in wonderment whether such could be the answers from a presumably responsible minister holding cabinet rank.

49. With this background I shall advert to Mr. Bhai Sawant's evidence.

50. That Mr. Bhai Sawant and Dolas did not know each other personally prior to October 1985 was admitted by them both. Mr. Bhai Sawant also admitted that he did not even know Dolas' background and before bringing him to Bombay had not even gone through Dolas' confidential reports which according to Mr. Bhai Sawant he did for the first time after the present Inquiry started. Thus on Mr. Bhai Sawant's own showing in any event till he brought Dolas to Bombay, they were total strangers and he had not gone through Dolas' confidential reports.

51. Mr. Bhai Sawant was asked—

"*Ques.* : What circumstances weighed with you in differing from the note made by your Dy. Secretary on 3rd October 1985 ?"

To which the following was Mr. Bhai Sawant's answer—

"*Ans.* : I found that Fadnavis was in the same post for more than 3 years and that Dolas's posting at Thane was less than 2 years. Keeping in view the judgement given by the High Court in Desai's writ petition, I took the decision to transfer Dolas from Thane to Bombay instead of transferring him from Thane to Nagpur as per the office note."

To imagine an answer as absurd as this and that too coming from a Minister holding Cabinet rank is difficult to envisage. But Mr. Bhai Sawant gave it. Perhaps the Health Minister in his anxiety to assail some reason for his act, momentarily (and certainly conveniently) lost sight of the fact that Fadnavis was due to retire on 1st December 1987 and that under the Rules he should have been given a choice of posting. Health Minister Bhai Sawant also seems to have momentarily (and certainly conveniently) lost sight of the fact that if Dolas' posting at Thane was less than 2 years (it actually was only one year and 7 months) greater the reason why he should have been continued at Thane until he completed his three years there, instead of bringing him to Bombay on the ground that he was at Thane for less than 2 years. Health Minister Bhai Sawant also momentarily (and certainly conveniently) lost sight of the fact that all that was ordered by the Bombay High Court in the writ petition filed by Desai, Dani and Pathak was that those particular three officers should not be transferred until they had completed their three years. This totally absurd answer given by Mr. Bhai Sawant is borne out neither by the order passed by the High Court in that writ petition nor by the Rules governing transfers. Ultimately Mr. Bhai Sawant conceded :

"I agree that Dolas should not have been transferred to Bombay and should have been retained at Thane."

52. Contrary to his earlier evidence that he had gone through Dolas' confidentials " only recently ", Mr. Bhai Sawant says that before passing his order on 31st October 1985 he had gone through Dolas' confidentials. Even if this is true, he must have realised that Dolas' confidentials were far from inspiring and would hardly justify his being brought to the prized and coveted post of Licensing Authority over the heads of not less than 4 officers senior to him. If Mr. Bhai Sawant did so after seeing Dolas' confidential records, he wantonly ignored Dolas' bad record in his anxiety willy nilly to bring him to Bombay. With a view to extricate himself from this situation of his own making, Mr. Bhai Sawant again contradicted himself by saying that prior to the present Inquiry he had not gone through Dolas' confidentials.

53. In these mental gymnastics indulged in by the Health Minister he may draw consolation that among the witnesses who gave evidence, his was not the only unique distinction in amnesia and mendaciousness.

54. The only irresistible inference for Mr. Bhai Sawant thus obviously favouring Dolas is extraneous consideration.

55. Mr. Bhai Sawant was asked—

'*Question* : Since you were differing from your office proposal, did you not think it proper to find out from the Commissioner whether if such a proposal as desired by him had been made, was it likely to disturb anyone's seniority ?"

To this came the unintelligible reply :—

"*Answer* : This note does not indicate that the proposal had come from the Commissioner."

This was no answer at all to the question put to the Health Minister.

56. When asked whether he had always appointed Jt. Commissioner-*cum*-Licensing Authority in head quarters on the basis of merit, Mr. Bhai Sawant replied—

"*Answer* : This appointment is always made by the department and I am not supposed to do this type of work. "

In view of this answer he was asked—

" *Question* : Therefore, this work is left to the bureaucrats and you as Minister do not interfere ?

Answer : " Yes."

Later however he added that as Minister he goes through the proposals of the bureaucrats who do the routine work and he takes his own decision. He however admitted that officiating appointments are made by the Secretary of the Health Department, that officiating appointments of Commissioner and Director are sometimes sent to the Health Minister for perusal. Thereupon he was asked,—

" *Question* : Do you mean that since these appointments are sent for your perusal, they are final ?

Answer : Yes. "

57. Indisputably Dolas' appointment to Bombay as Jt. Commissioner and Licensing Authority was an officiating one. In the light of the above answers given by Mr. Bhai Sawant, it is difficult to understand why in Dolas' case and despite his initial opposition to Dolas' transfer to Bombay to the same post 6 months earlier, Mr. Bhai Sawant should have over-ridden the strong opposition of the Commissioner and the bureaucrats and taken a personal interest in getting Dolas transferred to Bombay.

58. FDA witnesses (excluding Dolas of course) admitted that the post of Licensing Authority is a coveted and a most powerful post. To that end, Mr. Bhai Sawant himself admitted that while the posting of Licensing Authority is equivalent to the post of Jt. Commissioner in all its aspects, the Licensing Authority has powers regarding issuing, cancelling and suspending licences, and that generally the senior most person is transferred to the more responsible post taking into consideration his efficiency. Significantly enough, Dolas did not measure to any of this.

59. Bhirud spoke of the vast powers enjoyed by the Licensing authority, which unlike the post of Joint Commissioners elsewhere, is a statutory post carrying more powers than even that of the Commissioner. While other Joint Commissioners are amenable to the directions of the Commissioner, the Licensing Authority (H.Q.) being responsible only to Government, is not. He need not even consult the Commissioner except as a matter of courtesy. The Commissioner has no supervisory power or control over the Licensing Authority. Hence though the Commissioner's post is senior to that of the Licensing Authority, it is the latter who has greater power than even the Commissioner himself in so far as drugs are concerned. Bhirud would therefore, consider the post of Licensing Authority as a coveted post which was given to Dolas by the grace and favour of Health Minister Bhai Sawant.

60. Dolas' inefficiency as appearing from his confidential records was indisputable, as also the fact that there were at least 4 others who were senior to him. Mr. Bhai Sawant agreed that since 1960 the practice has been to appoint an officer from Bombay itself to act in an officiating capacity even though such officer may be junior to other officers outside Bombay. Even by this standard, Dolas' transfer to Bombay cannot be justified, because Fadnavis who was the senior most and was officiating as Licensing Authority in Bombay, whereas Dolas, junior to Fadnavis, was Assistant Commissioner in Thane.

61. Mr. Bhai Sawant admitted that in Fadnavis' confidential records there was nothing against him, as also that an officer who is due to retire should generally not be transferred unless there are serious complaints against him and that a person due to retire is given a posting of his choice. In the light thereof, it is all the more significant that on Mr. Bhai Sawant's own admission, the aspects of Deshpande retiring in February 1987 and Fadnavis in December 1987 were not considered.

62. Health Minister Bhai Sawant further admitted that it was only because he differed from his secretarial staff that Dolas was brought from Thane to Bombay in November 1985 and even before his three year tenure at Thane was over. This admission by itself goes to show that it was Mr. Bhai Sawant and Mr. Bhai Sawant alone who was instrumental in getting Dolas transferred to Bombay as Licensing Authority in the teeth of opposition from his own secretarial staff and Commissioner Bhirud. It is futile for Mr. Bhai Sawant to say that Bhirud was not against Dolas transfer from Thane to Bombay. After seeing the file, Mr. Bhai Sawant had to admit that Bhirud was indeed not in favour of bringing Dolas from Thane to Bombay, and also that in May 1985 both he and Bhirud were against the proposal of bringing Dolas to Bombay.

63. To a specific question as to what happened between May 1985 when Mr. Bhai Sawant vetoed Dolas' transfer to Bombay and October 1985 when Mr. Bhai Sawant brought Dolas to Bombay, Mr. Bhai Sawant replied—

> "*Answer*—Jt. Commissioner Joshi was proposed to be posted from Nagpur to Thane and Dolas was proposed to be transferred from Thane to Nasik. I discussed these proposals with the assistance of Dy. Secretary, from whom I came to learn that Bhirud and Joshi were not on good terms, and hence it would not be desirable to post Joshi at Bombay (H.Q.). There was also a ruling given by the Bombay High Court that a person who had not completed the requisite 3 years in his posting, should not be transferred. Therefore, Dolas was posted from Thane to Bombay (H.Q.) and Fadnavis who was holding charge as Jt. Commissioner in Bombay, was transferred to Nagpur".

Excuses, excuses and more excuses. Assuming that Bhirud and Joshi were not on good terms, did it not strike the worthy Health Minister, that with Bhirud's opinion of Dolas and his strenuous opposition to his transfer to Bombay, the situation could be no better ? The construction put by Mr. Bhai Sawant on the decision of the Bombay High Court in the writ petition (Ex. 475) is deliberately twisted to suit his own ends, for the simple reason that the High Court's order which was confined to those three particular officers, namely Dani, Desai and Pathak and also that Dolas had not completed his three years in Thane (he had only completed one year and 7 months) before he was brought to Bombay. Ex. 475

64. Ultimately the only reason (such as it was) that Mr. Bhai Sawant could give in the witness-box for his sudden effusion towards Dolas and his insistence on bringing him to Bombay in October 1985, was that if Dolas had been transferred from Thane to Nagpur, Dolas would have gone to Court. Thus Mr. Bhai Sawant finally admitted that the only consideration which he took into account while ordering Dolas' transfer to Bombay was the possibility of his filing a writ petition. However, Mr. Bhai Sawant had to retract this thoughtless assertion by admitting that no one had told him that Dolas would have gone to Court and that it was only his assumption because of the High Court's order in writ petition (Ex. 475). According to Mr. Bhai Sawant, Dolas would not have filed a writ petition if Mr. Bhai Sawant transferred him to Bombay, because Thane is not far from Bombay. On what basis Health Minister Bhai Sawant should make such a categorical assertion, he did not care to specify. Taking Mr. Bhai Sawant's answer at face value it is astonishing that the Health Minister should have allowed himself and Government to be held at ransom by a vague possibility of a writ petition, which he must know would be without merit. Further, Mr. Bhai Sawant should have considered that if Dolas was brought to Bombay from Thane which was the post of his choice and to obtain which Dolas had made special efforts, the likelihood of Dolas filing a writ petition for his premature transfer from Thane to Bombay would be greater. Ex. 475

65. Mr. Bhai Sawant admitted that in October 1985 he did consider that as Commissioner and a responsible officer, Bhirud would know about the proper administration of the FDA and that as Commissioner Bhirud was in a better position than

he to know the background of his own officers. Even so, Bhirud's opinion was not sought by Mr. Bhai Sawant for the obvious reason that it would be against Dolas.

66. Fadnavis' case though deserving of consideration was met with a brutal silence after grave injustice was done to him.

67. The evidence of Commissioner Bhirud reveals that the order transferring Fadnavis from Bombay to Nagpur and appointing Dolas as Jt. Commissioner to hold charge in the place of Fadnavis came as a surprise to him and that Bhirud came to know of this order for the first time when Dolas showed him his own copy of that order and asked him to hand over him charge of the post. This expedient of Dolas struck Bhirud as unusual because officers do not bring their own copy of orders and ask the Commissioner to hand over charge. Bhirud was surprised at Dolas being asked to take charge as Joint Commissioner over the heads of not less than 4 other officers senior to Dolas, namely P. S. Joshi, N. R. Deshpande, B. G. Fadnavis and V. R. Kirtane. Bhirud was categorical that he had not recommended Dolas' name to hold charge as Joint Commissioner and that Dolas was the choice of Government. In order to supersede 4 senior officers very strong influence with Government is required and from the fact that Dolas had indeed superseded 4 officers senior to him it did appear to Bhirud that Dolas had a strong political hold on Health Minister Bhai Sawant. Bhirud's opinion was that Dolas did not deserve this post in supersession of 4 other officers senior to Dolas, and that left to himself Bhirud would not have recommended Dolas' name for this post. He admitted that to some extent he was afraid of Dolas because Dolas could go to the Health Minister and tell him anything about Bhirud without Mr. Bhai Sawant cross-checking with Bhirud, that until Bhirud retired he was afraid of Dolas to some extent and even today after his retirement Bhirud is still to some extent afraid of Dolas because of what he can do to him, and that it is possible that Dolas can influence the Health Ministe in the inquiry regarding the show cause notice issued to Bhirud in connection with Bhirud's vested interest in the drugs industry.

68. Bhirud confirmed that if Fadnavis had been posted to the Food Department as Jt. Commissioner, it would have been difficult to appoint Dolas in the Drugs Department as Jt. Commissioner because Fadnavis was more senior to Dolas and that that was the only reason why Fadnavis was removed from Bombay even though his was a fit case for retention in Bombay. Bhirud was surprised that Government had not even acknowledged Fadnavis' letter seeking cancellation of his transfer and repatriation to Bombay.

69. Mr. Bhai Sawant admitted that there was nothing against Fadnavis which impelled or could have impelled Government from exercising its discretion in his favour to retain him in Bombay in the light of his impending retirement. Even so, Mr. Bhai Sawant maintained that Fadnavis was transferred according to Rules. Once again in his anxiety to cover up for Dolas and to prevent the injustice meted out to Fadnavis coming to light, Mr. Bhai Sawant ignored the fact that the very Rules on which he relied gave an option to an officer due to retire his choice of place of posting.

70. The brutality with which Fadnavis was treated is borne out by the fact that his representations were met with stony silence. And from Mr. Bhai Sawant's point of view, understandably so, as Dolas had at all cost to be accommodated in Bombay.

71. Mr. Bhai Sawant says that Fadnavis' representations were taken into consideration but were rejected by the Chief Minister despite Mr. Bhai Sawant's recommendation, and Fadnavis was offered a posting at Thane by the Chief Minister. This attempt on the part of Health Minister Bhai Sawant to pass on the blame to the Chief Minister is as unworthy as his attempts to pass on the blame to his secretarial staff on other aspects. On 7th June 1986 Mr. Bhai Sawant made an endorsement that as a special case Fadnavis be transferred to Thane. To that endorsement the Chief Minister agreed. The Chief Minister had no reason not to, on the material placed before him. Thus it was not as if the Chief Minister turned down Fadnavis' representation but merely acted on Mr. Bhai Sawant's andorsement. If at all a special case was required to have been made in favour of Fadnavis against whom there were no complaints and whose confidential records were clean, it could have been done by retaining him in Bombay. But that would have interfered with the plan to bring Dolas to Bombay some how or other. Ultimately the proposal to post Fadnavis to Thane was withdrawn, as with his wife dying of a terminal ailment, he had preferred to opt for voluntary retirement with effect from 20th June 1986. And thus the day was saved for Mr. Bhai Sawant and Dolas.

72. Mr. Bhai Sawant's version that a reply given by Government to Fadnavis' representation was late, is false. No reply was given to him at all. He was due to retire on 1st December 1987. By virtue of the rules he was entitled to a posting of his choice. His wife was dying of a terminal ailment. His record was good. Bhirud had recommended his case as a really deserving case for sympathetic consideration. But Health Minister Bhai Sawant was unmoved, and from his point of view, understandably so. For it Fadnavis was to be retained in Bombay, Dolas could not be brought to Bombay. If Dolas was brought to Bombay, Fadnavis would be seniormost, already holding charge as Joint Commissioner and Licensing Authority, with the result that he and not Dolas would have to be appointed Jt. Commissioner and Licensing Authority, more so as Bhirud had strongly recommended Fadnavis for the post. In that event it would be Fadnavis and not Dolas who would be Jt. Commissioner and Licensing Authority. But Dolas had to occupy that post. Thus, Fadnavis had to be sacrificed at the altar of Dolas.

73. It was not as if Mr. Bhai Sawant's desire was merely to bring Dolas to Bombay, for if such had been the only desire, the post of Jt. Commissioner (Food) was then vacant in Bombay. Mr. Bhai Sawant's desire was to bring Dolas to Bombay only to the coveted post Jt. Commissioner and Licencing Authority. Fadnavis could have been appointed as Jt. Commissioner (Food), but that would have given rise to litigation as there was no guarantee that the other three seniors would keep quiet. Fadnavis had therefore, to be axed out /to make room for Dolas in Bombay as Jt. Commissioner and Licensing Authority.

74. Despite the numerous opportunities given to Health Minister Bhai Sawant in the witness box, he has failed to give any convincing explanation for Dolas' transfer to Bombay in preference to four others senior to him. Neither seniority-wise, nor experience-wise, nor qualification-wise was Dolas fit to be brought to Bombay as Officiating Licensing Authority. Mr. Bhai Sawant even did not know Dolas' background nor had he read his confidential reports, hence it cannot be said that he was brought to Bombay because of any exceptional merits, even a flicker of which Dolas never had or had ever shown before or after. There was no reason why Mr. Bhai Sawant should have over ruled his own secretarial staff in bringing Dolas to the prized post of Licensing Authority at Head Quarter in Bombay. As Licensing Authority, a man of Mr. Bhai Sawant's choice, such as a grateful Dolas, would be controlling a 2000 crore rupee drugs industry in Maharashtra with a large chunk of it in Bombay. Heavy stakes were involved. As Licensing Authority, Dolas would be all powerful, accountable to none except his mentor, the Health Minister.

75. No anxiety was shown by Government to have a regular Licensing Authority appointed, with the result that Dolas continued as officiating Licensing Authority until he was transferred recently as Joint Commissioner (Food.)

76. Once again the irresistible inference that can be drawn is that Mr. Bhai Sawant manoeuvred to get Dolas to the lucrative post of Joint Commissioner and Licensing Authority for extraneous considerations. Corruption is writ large.

77. Commissioner Bhirud agreed that bringing Dolas to Bombay as Joint Commissioner (H.Q.) over the heads of other officers senior to him (*i.e. Dolas*) was not merely a matter of transfer and that it virtually amounted to Dolas' promotion over the heads of officers senior to him, and that in the circumstances in which Dolas was brought to Bombay as Joint Commissioner, Bhirud as Commissioner, regarded it as a bounty conferred on Dolas by the Health Minister Bhai Sawant. Bhirud acknowledged that when Dolas was brought to Bombay as Joint Commissioner, he had no experience whatsoever as licensing authority for the manufacture of drugs. (This was unlike Fadnavis who had this experience).

78. Bhirud admitted that as Commissioner he considered it to be unusual for Dolas to be brought to Bombay in October 1985 when barely 5 months earlier he was ordered to be retained in Thane and that he gathered that this was done in order to confer a favour on Dolas. Bhirud did not agree when Mr. Bhai Sawant laid the blame upon him by stating that whosoever placed the facts before him regarding Dolas, did not place the full facts before him. Bhirud was categorical that this observation of the Health Minister did not apply to him because in the case of Dolas he was asked nothing by Government, and if, as Commissioner he had been, it would have been his duty to place the full facts before Government.

79. Dolas admitted that his posting to Bombay as Licensing Authority for manufacturers and repackers was his first experience. Though he professed to be well

acquainted with the Rules and procedures in that behalf, his evidence points to the contray.

80. All these circumstances disclose in abundant measure the manner in which Dolas' undeserved promotion to the post of Licensing Authority was manoeuvred by Health Minister Bhai Sawant, as stated earlier, extraneous considerations are writ large.

(C) Undue favour shown to Cyma Pharma

81. This brings me to the appeal of Cyma Pharma decided by Health Minister Bhai Sawant.

82. *Was undue favour shown to Cyma Pharma in the appeal decided by him, and if so, was it for extraneous consideration ?*

83. Hereunder narration of the events leading to the appeal and the Health Minister's decision :—

(*a*) Cyma Pharma is a pharmaceutical manufacturing concern having as its partners brothers Deepak and Bharat Gandhi. It has a factory at Bassein. Cyma Pharma had two licences one in Form No. 28 for the manufacture of Chloramphemical capsules for typhoid and the other in Form No. 25 for the manufacture of cymastrep for gastroenteritis and diarrhoea. Both are essential and life-saving drugs. In chloramphenicol the active ingredient must be between 92·5 and 107·5 in a capsule of 250 mgs.

(*b*) On 7th April 1984 FDA, Gujarat, made a written complaint to the FDA, Bombay, that the active ingredient in Cyma Pharma's cymastrep Batch Nos. 8 and 10 was less than the minimum prescribed.

(*c*) On 31st May 1984 a show cause notice was issued by FDA, Bombay, to Cyma Pharma for withdrawal of permission to manufacture cymastrep. Cyma Pharma did not bother to reply. On 25th July 1984 FDA sent a reminder to Cyma Pharma. It was ignored.

(*d*) On 5th November 1984 permission to manufacture cymastrep was withdrawn and Assistant Commissioner B. K. Kochar was directed to keep a watch on the activities of Cyma Pharma. He did not.

(*e*) On 20th June 1984 a second show cause notice was issued by the FDA to Cyma Pharma for cancellation of both its licences in Forms 25 and 28. Cyma Pharma sent no reply. The matter was attended to by Assistant Commissioner Kochar and Jt. Commissioner N. D. Kulkarni.

(*f*) On 15th October 1984 an order was passed by Joint Commissioner N. D. Kulkarni for cancellation of Cyma Pharma's licences. This order was drafted by Kochar on 29th November 1984 and signed by N. D. Kulkarni. However this order was neither drawn up nor communicated to Cyma Pharma.

(*g*) On 12th December 1984 discussions took place between Commissioner Bhirud, Joint Commissioner N. D. Kulkarni, Assistant Commissioner Kochar and Law Officer Deshpande. As a result, it was decided to dilute the order passed against Cyma Pharma and restrict it only to the extent of the offending drugs.

(*h*) On 2nd January 1985 this order was drawn up and on 7th January 1985 was served on Cyma Pharma.

(*i*) Cyma Pharma filed an appeal to Government. The stay application came directly to Health Minister Bhai Sawant who made an endorsement—

" D. S. (Med. Edn.) Examine and put up for stay.

Signed .....
2nd April 1985.

Parawise comments were called for from the FDA.

(*j*) On 26th July 1985 the appeal was heard by Health Minister Bhai Sawant. On behalf of the FDA were present Commissioner Bhirud and Assistant Commissioner Kochar. The Gandhi brothers representing Cyma Pharma appeared in person.

(k) On 21st August 1985 the appeal was decided by Health Minister Bhai Sawant who passed the following order :—

" Appeal admitted. Cancellation order set aside now in view of the fact that the petitioners (i.e. Cyma Pharma) have already stopped manufacturing their products ."

Thereafter appeared the words in ink,—

" However the firm will submit the tests reports in respect of batches of this product manufactured for a period of 6 months ."

In the last para in the body of the order, this phraseology was also added in ink.

(l) Thus by the appellate order, the diluted order of FDA of 12th December 1984 was watered down.

84. With this background, I shall answer the questions posed at the commencement of this part. I shall do so from the evidence of Mr. Bhai Sawant himself and draw permissible support from the evidence of Bhirud. I however do not wish to rely on Kochar's evidence as he has sought to falsely implicate Mr. Bhai Sawant in matters other than Cyma Pharma.

85. Commissioner Bhirud was categorical that he had taken with him the files pertaining to Cyma Pharma and had placed them before the Health Minister during the hearing of the appeal. The last is denied by Mr. Bhai Sawant. According to Bhirud he pointed out to the Health Minister the grievances of the FDA against Cyma Pharma from the beginning culminating in FDA's order dated 12th December 1984. This is also denied by Health Minister Bhai Sawant. Bhirud was categorical that before Mr. Bhai Sawant, Gandhi brothers did not argue the matter on merits or challenge the actions taken by FDA and did not controvert any of the allegation made against Cyma Pharma in the show cause notices or state why they had not sent any reply to them and that the only argument advanced by Gandhi brothers before the Health Minister was that they had stopped manufacturing chloramphenicol and cymastrep capsules, as a result they were already suffering a loss.

86. Bhirud says that to his surprise, during the hearing of the appeal, the Health Minister resorted to the unprecedented expedient of telling the Gandhi brothers that they could manufacture chloramphenicol and cymastrep capsules and submit the analytical reports regarding these two drugs whereby announcing the ord er in advance. This is denied by Mr. Bhai Sawant. As an experienced FDA officer Commissioner Bhirud expected FDA's order dated 12th December 1984 to be upheld by the Health Minister, in a case as gross as this, with the result that Cyma Pharma would never be allowed to manufacture those two life-saving drugs, namely chloramphenicol and cymastrep capsules in futures.

87. Commissioner Bhirud denied Mr. Bhai Sawant's version that the oral statements made by the Gandhi brothers during the hearing of the appeal were not contradicted by FDA officers. Commissioner Bhirud was categorical that the Gandhi brothers did not argue before Mr. Bhai Sawant that this was their first offence or that their chloramphenicol and cymastrep capsules were not substandard and that Mr. Bhai Sawant's evidence to the contrary is untrue. Bhirud was categorical that the Gandhi brothers never told Mr. Bhai Sawant at the hearing of the appeal that they had been manufacturing these two drugs of this quality since the past several years and denied as untrue Mr. Bhai Sawant's evidence to that effect. According to Bhirud, Mr. Bhai Sawant's evidence that it was not brought to his notice by anyone that even during the 7 months Cyma Pharma had actually not stopped the manufacture of these two drugs, was incorrect as also was incorrect Mr. Bhai Sawant's evidence that at the hearing of the appeal the question of public interest had not been brought to his notice by the FDA officers. Bhirud did not agree with Mr. Bhai Sawant placing the blame on FDA officers for the passing of his order.

88. Bhirud was categorical that when Mr. Bhai Sawant passed his order in appeal it was evident to him that he was favouring Cyma Pharma which he realised for the first time during the hearing of the appeal itself, as also that the hearing of the appeal by the Health Minister was a mere formality. Bhirud could however attribute no reason why Mr. Bhai Sawant appeared to have favoured Cyma Pharma for this being done. He could not say if the Gandhi brothers were known to the Health Minister. Bhirud was disappointed with the outcome of this appeal as such an order was not justified on merits.

89. Bhirud did not know that Cyma Pharma had actuallly not stopped manufacturing chloramphenicol and cymastrep capsules during the time that the FDA's order was in operation. In Bhirud's experience as an FDA Officer and Commissioner and to the best of his recollection Mr. Bhai Sawant's order was an unprecedented and unusual order.

90. Bhirud did not remember in what circumstances the handwritten portion in page 3 of the body of the draft appellate order (Ex. 566-A), namely—

"This stoppage of production can be considered as a punishment, in my opinion, is sufficient punishment to meet the ends of justice,"

came to be written. It could have been at his suggestion when he discussed the matter with the Law Officer and admitted that this had been written in the body of the draft order of his recommendation and has been incorporated in the original
Ex. 566 order (Ex. 566) with the handwritten rider in ink that Cyma Pharma must submit tests reports in respect of batches of these products manufactured by them for a period of 6 months. This rider in ink was not at the suggestion or recommendation of the FDA.

Ex. 566 91. According to Bhirud the addition of this rider in the final order (Ex. 566) militated against and watered down the punishment of stoppage of production for 7 months as suggested by him in the margin of draft appellate order (Ex. 566-A).

92. *Now what does Health Minister, Bhai Sawant have to say.* It is in essence a strident reiteration that he was misled by Bhirud and other officers who kept him in the dark buttressed by the sanctimonious admision that if they had told him then what he has come to know now, he would not have passed such an order and would have upheld FDA's order dated 12th December 1984. In short he passes on the blame to Bhirud and the other officers. He did so by the expedient of saying that—(*a*) when he heard Cyma Pharma's appeal, he did not know that there were several complaints against Cyma Pharma and that he did not know whether Cyma Pharma's licence in Form No. 28 for all the drugs had been cancelled by the FDA on 15th October 1984 nor did he know that such cancellation order had later been modified restricting the cancellation only to chloramphenicol, and that it was not brought to his notice that there was a complaint from Gujarat FDA. He was falsified by his admission that in every appeal parawise comments are called for from the department which the Minister is expected to go through while deciding the appeal and that he had gone through parawise comments in the case of Cyma Pharma as also the show-cause notices ; (*b*) that though the Gandhi brothers had contended before him that they had not manufactured these drugs in the past 7 months, this contention was not contradicted by the FDA officers during the hearing of the appeal. He however admitted that this has not been mentioned by him in the order. According to Mr. Bhai Sawant it was not brought to his notice by anyone that even during the 7 months Cyma Pharma had actually not stopped the manufacture of these two drugs and admitted that in May-June 1986 it was discovered that the same Cyma Pharma were manufacturing the same drugs which were again substandard ; (*c*) after maintaining that the FDA officers did not argue before him in support of the FDA's orders dated 12th December 1984. Mr. Bhai Sawant finally admitted that,—

"..... Aruguments were indeed, advanced by the FDA officers in support of the order of 12th December 1984.",

that he had partly rejected and partly accepted the FDA's arguments, which he now realises were wrongly rejected by him.

94. Thus at the time of the hearing of the appeal Mr. Bhai Sawant had the benefit of arguments of the FDA officers in support of FDA's order.

95. Mr. Bhai Sawant was categorical that he was not on close terms with Gandhi brothers and that he came in contact with them for the first time when they had filed Cyma Pharma's appeal and thereafter when they appeared before him at the hearing of the appeal. After some hair-splitting between the meaning of life-saving essential and ordinary drugs, Mr. Bhai Sawant admitted (1) that chloramphenicol is the only effective drug against typhoid and is absolutely necessary to be administered in typhoid cases. He also admitted that cymastrep is absolutely essential in cases of gastroenteritis and diarrhoea ; (2) that he knows that active ingredient in chloramphenicol should be between 92·5 to 107·5 in a capsule of 125 mg. and that if the active ingredient is less than the minimum required, the drug would not be

effective to that extent ; (3) that he knew that show-cause notices had been issued to Cyma Pharma which elicited no reply from them ; (4) that he had noted the arguments advanced before him by the FDA officers at the hearing of the appeal, namely that all the 9 samples of these two drugs had failed in the contents of active ingredients ; (5) that he agreed with that contention urged by FDA ; (6) that it was also urged before him by the FDA that it was not in the interest of the public to allow Cyma Pharma to continue the manufacture of such preparations and therefor the FDA had cancelled Cyma Pharma's licence ; (7) that with these contentions urged by the FDA he had also agreed ; (8) that he was satisfied that Cyma Pharma did manufacture for sale these two life-saving and essential drugs which were not of standard quality ; (9) that he knew that two batches of Cyma Pharma's chloramphenicol tablets were found to be of sub-standard quality ; (10) that it was not urged before him by the FDA that the punishment so far suffered by Cyma Pharma would be adequate ; (11) that Commissioner Bhirud had advanced arguments regarding public interest, that Bhirud was emphatic before him in his arguments that the FDA order should be upheld ; (12) that all points canvassed before him by Commissioner Bhirud are not reflected in the appellate order and that in the body thereof Mr. Bhai Sawant had not stated his apprehension that the party was likely to continue manufacture of sub-standard drugs ; (13) that nowhere in the Memo of Appeal had Cyma Pharma stated that it had not manufactured chloramphenicol or cyamstrep capsules for 7 months, namely from January to July 1985 volunteering that this was so stated by the Gandhi brothers during the hearing of the appeal. According to him this was recorded by him in his notes ; (14) that these notes are not in the file produced befor this Commission as the notes had not been preserved ; (15) that he had not mentioned in his notes that this contention of Cyma Pharma had not been contradicted by the FDA officers before him ; (16) that in his order he had not recorded the arguments of the Gandhi brothers that they had not manufactured these two drugs from January to July 1985 and that he had not given all reasonings in his order ; (17) that even in the first batch of November 1983, the percentage of active ingredient varied from 72·7 to 84·24 and that even the amount of 84·24 was far below the prescribed minimum of 92·5 ; (18) that in the batch of December 1983 the active ingredient, namely chloramphenicol in the capsules varied from 81·06 to 74·20 percentage and that the active ingredient in a given batch must be uniform ; (19) that he had rejected Cyma Pharma's contention that analytical reports were not correct ; (20) that the contents of the active ingredient was less than what was mentioned on the label and that normally any sample from the same batch must give the same result on anlysis ; (21) that he did not ask Cyma Pharma's partners to put down in writing that they had stopped manufacturing of these drugs for 7 months.

96. Faced with his own admission, Mr. Bhai Sawant was driven to excuses that this, according to Gandhi brothers, was Cyma Pharma's first offence, though these two drugs were life-saving drugs. According to Mr. Bhai Sawant the argument of Gandhi brothers was that they had been manufacturing these drugs of this quality since the past several years and were not sub-standard. This excuse trotted forth by Mr. Bhai Sawant is grotesque in the light of Mr. Bhai Sawant's admission that these two essential and life-saving drugs manufactured by Cyma Pharma were sub-standard and instead should have been an eye-opener to Mr. Bhai Sawant that even in the past Cyma Pharma had manufactured and was habituated to manufacturing sub-standard chloramphenicol and cymastrep capsules.

97. However according to Mr. Bhai Sawant even though Cyma Pharma had committed this offence twice, he regarded it as a first offence. He attempted to explain away this ministerial gymnastics by saying that the appeal pertained to both the offences, meaning thereby that it was the first time that these two offences had been detected in the case of Cyma Pharma.

98. Mr. Bhai Sawant new advances from the ridiculous to the absured. He says it is because Cyma Pharma should not manufacture such sub-standard drugs that he took the precaution of adding the rider in ink at the foot of his order, which is the precaution he takes in all matters. He piously added that thereby he took the general interest of the public into consideration when passing his order because public interest would not have been served if the punishment imposed by the FDA on Cyma Pharma had been upheld. This shows the utter insensitivity of this Health Minister towards truth and the general public for whose welfare he was appointed Health Minister. Worse is manifest from what follows.

99. In modifying FDA's order Mr. Bhai Sawant says he took two facts into consideration, namely general public interest and justice to Cyma Pharma. He was then asked—

" *Q* : Minister, in your anxiety to do justice to the party, namely the manufacturer, did you think you were doing justice to thousands of unwary purchasers of substandard chloramphenicol and cymastrep capsules which on your own showing are essential drugs ?

A : Yes ; by putting the rider at the foot of my order.

Q : Even so, you were perpetuating or encouraging the act of the manufacturer in selling sub-standard chloramphenicol and cymastrep capsules in the first place to the risk of public health and public life ?

A : According to the rider, my officers would have to keep a watch over the manufacturing activity of Cyma Pharma. "

100. Though Mr. Bhai Sawant affected his concern for public interest by the rider added in ink at the foot of the appellate order, on his own aidmission he did not consider whether it would be in public interest that in the case of Cyma Pharma, sub-standard cymastrep capsules had gone to the public once, and sub-standard chloramphenicol capsules had gone to the public twice, and if this aspect had been taken into consideration by him, his order would have been different, namely that he would have confirmed FDA's order of 12th December 1984. His excuse was that this aspect did not occur to him. Bravo, Minister. Except for this aspect he says he took into consideration practically all the other aspects of the case. He was asked.

" *Q* : Did you not consider it to be in public interest to permanently cancel the licence of a manufacturer of sub-standard life-saving drugs and more so when such offence was repeated as in the case of Cyma Pharma ?

A : Yes. "

However, predictably he denied that there was any extraneous consideration for him for passing his order.

101. It is sheer hypocrisy for the Health Minister to say that while he confirmed FDA's order, only the punishment was reduced. By passing his order, Mr. Bhai Sawant did not reduce the punishment—he let off Cyma Pharma, a habitual manufacturer of sub-standard life-saving drugs, scot-free, as he himself had ultimately to admit that the virtual effect of his order was that Cyma Pharma would be allowed to manufacture these two life-saving drugs.

102. He denied having told the Gandhi brothers during the hearing of the appeal that they could manufacture chloramphenicol and cymastrep capsules and submit the analytical reports regarding these two drugs.

103. Regarding Cyma Pharma's appeal, Bhirud's evidence is corroborated by the admissions made by Mr. Bhai Sawant himself.

104. Mr. Bhai Sawant's own evidence brings to the fore that the appeallate order passed by him was not on merits but for extraneous consideration. It cannot even be said that he passed his order by mistake because he himself does not say so. The admitted facts themselves rule out any possibility of mistake.

105. Mr. Bhai Sawant's order which virtually set aside FDA's order of 12th December 1984 cancelling Cyma Pharma's licence to manufactute these two life-saving drugs, is a fraud on the unsuspecting general public, whose health and safety should have been his primary concern. It makes a mockery of the Act and Rules which as Health Minister it was his duty to have enforced. In that duty he lamentably failed, not out of ignorance or mistake but deliberately in order to favour Cyma Pharma. No argument had been advanced by Cyma Pharma on merits which resulted in such a grotesque appellate order being passed, and in the teeth of the arguments of the FDA officers as admitted by Mr. Bhai Sawant himself.

106. No person would possibly pass such an order as done by Health Minister Bhai Sawant except for a strong motivation in which public health and safety played no part. While on his own showing Mr. Bhai Sawant disbelieved Cyma Pharma's contention that these two drugs were not sub-standard it is inconceivable that he

should have accepted at face value the statement of Gandhi brothers that Cyma Pharma had stopped production for 7 months. On Mr. Bhai Sawant's own admission he accepted the contentions of the FDA and admitted that the FDA was correct, yet curiously enough found the punishment imposed by FDA to be too harsh. Therefore in the witness box he resorted to a stratagem. He proclaimed that it was from the guidelines of the Drugs Controller that he formed his opinion that the punishment imposed by the FDA was too harsh and required to be modified. He agreed that the FDA had passed its order in accordance with those guidelines. When asked what were the compelling reasons for him to have modified FDA's order, Mr. Bhai Sawant repplied that he did so after going through the guidelines, which however he did not refer to in his order on the ground that he did not think it necessary to do so. All this was an inspiration in the witness box, because there is not a single provision in the guidelines (Ex. 261) to support such an order, as passed by the Health Minister. Ex. 261.

107. Decisive however is Mr. Bhai Sawant's won admission that he did not apply his mind to the aspects of public intrest because according to him this did not occur to him at that time, coupled with his admisson that if his attention had been drawn to this aspect he would not have passed such an order. Mr. Bhai Sawant's protestation that he would not have passed such an order if all the facts had been placed before him, does not cater to his own admission that the officers had placed all the facts before him.

108. The admitted facts also rule out the possibility of Mr. Bhai Sawant passing his order on an erroneous understanding of the law. In the light of Mr. Bhai Sawant's admission that chloramphenicol and cynastrep maunfactured by Cyma Pharma were indeed substandard, it would have been expected that as Health Minister, he, being conversant with the provisions of the Act and Rules, would never have let off Cyma Pharma and instead enforced the Act and Rules. Section 18 of the Act makes it an offence to manufacture and sell a substandard drug, the minimum mandatory punishment being one year rigorous imprisonment plus fine, and in case of death or grievous hurt the minimum mandatory punishment being 5 years rigorous imprisonment. Thus while Mr. Bhai Sawant found Cyma Pharma guilty of manufacturing substandard drugs, namely two drugs and three batches, and where 9 different samples were involved which would have entailed 9 prosecutions, Mr. Bhai Sawant let Cyma Pharma off the hook instead of exercising his power of directing the Commissioner to prosecute Cyma Pharma. In Mr. Bhai Sawant's order no justification is stated for not resorting to the penal provisions of the Act. All this is yet another indication that Mr. Bhai Sawant's resort to the guidelines in the witness box in the teeth of the provisions of the Act was merely a ploy to willy-nilly justify his order in the witness-box. His only anxiety was to protect Cyma Pharma and since in law the FDA had no redress he would have got away with it but for the exposure in this Inquiry.

109. Departure from normal practice must be substantiated by reasons. In Mr. Bhai Sawant's order no reasons have been given, as a result whereof even Rule 85 (i) was breached. Narration of facts can never be equated with reasons.

110. Despite opportunities given to him, no plausible explanation has been forthcoming for this most unusual and unnatural order passed by Mr. Bhai Sawant against the provisions of the Act and Rules.

111. In these circumstances, failure to perform his statutory duty is even more obvious and from circumstances of the case and his own admissions, this dereliction of duty on Mr. Bhai Sawant's part was deliberate.

112. During the course of the evidence of Joint Commissioner Kulkarni, I ordered service of notice under Section 8-B of the Commissions of Inquiry Act on the partners of Cyma Pharma. Pursuant thereto, on 27th April 1987 they appeared before me and made a statement which I recorded that Cyma Pharma did not desire either to ask any questions to Joint Commissioner Kulkarni or lead any evidence. Apparently Cyma Pharma considered discretion to be the better part of valour which would not have been so, if everything had been above board.

113. All this shows that this order was passed by Mr. Bhai Sawant not on merits, but that he was motivated into doing so by extraneous considerations other than the normal considerations which an appellate authority exercises. This order cannot be justified on any ground other than extraneous considerations to wit, (i) To Mr. Bhai Sawant's knowledge these were life-saving drugs. Hence he knew or should

have known that there could not be any leniency ; (ii) Cyma Pharma had committed repeated breaches and had even ignored the 2 show cause notices, knowledge of which must be attributed to Mr. Bhai Sawant. (iii) There was no evidence before Mr. Bhai Sawant that Cyma Pharma had ceased to manufacture or sell these two substandard drugs during pendency of the appeal, nor did he collect any information or make any inquiry, and instead just chose to believe the bare statement of the Gandhi brothers which also subsequently proved to be false. (iv) The evidence suggests that no arguments were advanced by Gandhi brothers on merits at the hearing of the appeal and that they did not contest FDA's order on merits. (v) The manner in which the order was dictated also suggests that the appeal was not decided on merits. (vi) Mandatory provisions of the Act and Rules were openly flouted and instead in the witness-box justification was resorted to guidelines which did not apply. (vii) Public health and safety were thrown over-board in the Health Minister's anxiety to protect Cyma Pharma. (viii) Mr. Bhai Sawant passed his order not on merits.

114. From the above, the only irresistible inference that can be drawn is that Health Minister Bhai Sawant passed his order for extraneous considerations.

(D) Misusing official position to collect donations and advertisements for R.U.O.

115. The evidence on record also discloses that Mr. Bhai Sawant used his official position for the purpose of collecting donations and advertisements for Rural Upliftment Organisation (R.U.O.). The admitted position is that his Secretary/Under
Ex. 168(A) Secretary may have distributed forms for this purpose, that 37 pharmaceutical concerns under the control of the FDA in Maharashtra and mostly in Bombay, and the FDA, all had in fact given advertisements. Even though initially Mr. Bhai Sawant denied having a direct or indirect hand in the matter of obtaining advertisements, he finally admitted that in two cases, namely in the case of Maharashtra State Co-operative Bank and SICOM, he had recommended to SICOM to give advertisements and in the case of the Maharashtra State Co-operative Bank he was a party to the requisite resolution for giving a donation of Rs. 2 lacs to R.U.O.

116. This was misuse of official power and authority. Such misuse can be established from the admitted facts and evidence of Mr. Bhai Sawant himself without the necessity of going into controvertial facts.

117. R. U. O. with which Mr. Bhai Sawant has been associated as advisor since
Ex. 168 its inception in 1984, brought out a Souvenir (Ex. 168) in connection with its Musical Nite held on 21st October 1985. This Sourvenir contained a photograph of Mr. Bhai Sawant receiving a cheque of Rs. 2 lacs from the Chairman of the Maharashtra State Co-operative Bank of which he is a Director. It also contained a full page advertisement from SICOM and a full page advertisement from the FDA which was given by reason of Mr. Bhai Sawant being the Health Minister. The Souvenir also contained advertisements given by 37 pharmaceutical concerns including some
Ex. 168(A) multi-national concerns. A list of such pharmaceutical concerns is at Exhibit 168-A. Mr. Bhai Sawant's evidence discloses that all these 37 pharmaceutical concerns are in Maharashtra and most of them are in Bombay, that most of them are drugs manufacturing concerns and all of them are under the control of the FDA.

Ex. 541 118. Exhibit 541 is an appeal for donations issued by R.U.O. It was produced by Asstt. Commissioner Raykar. It is not disputed that R.U.O. had solicited donations and advertisements by issuing such appeals. In this appeal, Mr. Bhai Sawant has been described by name and ministerial designation as the inspiration behind the project.

119. Mr. Bhai Sawant admitted that he was instrumental in getting a Rs. 2 lac donation for R. U. O. from the Maharashtra State Co-operative Bank and an advertisment from SICOM.

120. On 28th September 1985, a letter was addressed by the Secretary of the R.U.O.
Ex.598(colly.) to the FDA using the name and ministerial designation of Mr. Bhai Sawant. This letter was an accompaniment to a printed appeal for advertisement and an advertisement form. In the appeal Mr. Bhai Sawant's name and ministerial designation appeared topmost in the list of advisors. From the fact that this letter and accompaniments do not have any foldmarks, it is obvious that they were hand-delivered. On 15th October 1985 Commissioner Bhirud made an endorsement on a printed appeal that a full page advertisement be given. On 16th October 1985 FDA wrote

to Directorate of Information for permission to give advertisement. Never has the FDA moved as fast as this, no boubt thanks to the very mention of the Health Minister being associated with R.U.O., and so unlike the lackadaisical attitude of the FDA even in issuing show cause notices against erring manufacturers and worse still in leisurely sending reminders. This permission was given on 4th November 1985. On 11th January 1986 R.U.O. sent its bill for Rs. 1,000. On 5th May 1986 FDA wrote to R.U.O. asking for two copies of the Souvenir.

121. The fact that the FDA had given an advertisement was something which Mr. Bhai Sawant says he did not consider to be important. Pray, why not? Did he not think that FDA would not have gone through the trouble of seeking permission from the Directorate of Information but for Mr. Bhai Sawant being the Health Minister ? What other reason could FDA have in giving an advertisement in a Souvenir of R.U.O. with which it had no concern ? Mr. Bhai Sawant admitted that FDA would not have refused to give an advertisement because of R.U.O.'s letter dated 28th September 1985.

122. The question that also arises is : *Did the 37 pharmaceutical concerns give their advertisements in the Souvenir because of Mr. Bhai Sawant being the Health Minister ? And if so, did Mr. Bhai Sawant know it ?*

123. On this aspect Mr. Bhai Sawant gave two conflicting versions. His earlier version was that he came to know of these advertisements on the night of the Musical Nite itself. His later version was that he came to know this during the course of his evidence. Whichever be the correct version, it is not his version that he took any exception with R.U.O. for collecting advertisements from pharmaceutical concerns for an organisation with which he was associated albeit as advisor, nor did he warn R.U.O. that no donations in any form should be taken from pharmaceutical concerns while he was Health Minister. It is in evidence that forms were distributed in the FDA and a quota was fixed for each officer.

124. The appeal for donation (Ex. 541) was a document produced by Raykar from his custody stating that this was one of the 5 forms given to him. How did advertisement forms of R.U.O., otherwise unconnected with the FDA, come in the possession of Raykar? That they did come in his possession is certain, because he produced one. This by itself is sufficient to establish that Health Minister Bhai Sawant used FDA, a department under him for the purpose of collection of funds for R.U.O. Ex. 541

125. There can be no doubt that the advertisements given by the 37 pharmaceutical concerns were at the instance of the FDA. There is otherwise no reason why they should do so in a Souvenir connected with R.U.O. and with which they had no concern, except to be in the good books of Mr. Bhai Sawant. It is not as if the FDA never collects donations. The evidence suggests that the FDA thus collects donations at the behest of Government for humanitarian purposes like floods, famine, drought and so forth. No explanation was forthcoming how these 37 pharmaceutical concerns could by themselves have given donations to R.U.O. otherwise than through the FDA, more so when one such advertisement, form was produced in evidence by Raykar. There is, on this aspect, Dolas' admission that as far as he knows, out of these 37 pharmaceutical concerns, 28 are dependent upon the FDA for grant or renewal of licence. It is inconceivable that the remaining pharmaceutical concerns could afford to displease the FDA. For that matter Bhirud admitted that such contributions are not willingly made and that parties make contributions not for love of the FDA, but only because FDA officers approach them and for fear of displeasing them.

126. In these circumstances, judicial notice can be taken of the usual modus operandi by certain ministers who have given evidence of indirectly coercing the department under them to collect donations or advertisements, knowing full well that the department will in turn indirectly coerce the licencees who in turn will have but to submit to such pressure for fear of displeasing the department on whose goodwill they must depend and which, in the words of Sipahimalani, they cannot afford to antagonise. Hence the element of *quid pro quo* in one form or other has necessarily to emerge.

127. The above by itself is sufficient to bring home that Mr. Bhai Sawant misused his ministerial office and his official position to collect donations and advertisements R.U.O., his protestations to the contrary notwithstanding.

(E) Pressurising FDA Officers

128. Mr. Bhai Sawant's evidence also discloses that during the course of this Inquiry, he attempted to exert pressure on Commissioner Bhirud after the evidence of Asstt. Commissioners Kochar and Raykar was recorded and that he also attempted to contact another witness Dr. R. D. Kulkarni, for this purpose. He also exerted further pressure on Bhirud in the matter of the show cause notice issued against him regarding his interest in the drugs industry. Mr. Bhai Sawant also attempted to exert pressure on Raykar by withholding orders permitting him to cross the efficiency bar.

129. To that end, there is the evidence of Mr. Bhai Sawant himself. He admitted that he telephoned Bhirud round about 23rd or 24th May 1987, after Raykar gave his evidence on 22nd May 1987. Mr. Bhai Sawant asked Bhirud whether Raykar had told him anything; Bhirud's reply was that he did not remember anything. At this time Bhirud was still in service as Commissioner. Mr. Bhai Sawant realised that Bhirud had merely given a diplomatic answer. Mr. Bhai Sawant also admitted that he attempted to contact Dr. R. D. Kulkarni as stated hereafter. This was the sequel to Raykar's evidence that Mr. Bhai Sawant had instructed him over the telephone to " look after " Samarth and Welcome in the matter of awarding rate contracts.

130. By then Dr. R. D. Kulkarni, who at the relevant time was a member of the Selection Committee, had already retired. He was however residing in the campus of the J. J. Hospital. Hence during the course of the present Inquiry, Mr. Bhai Sawant attempted to get Dr. Kulkarni to meet him through the instrumentality of the Dean, Dr. Ware. Dr. Kulkarni however proved elusive. Hence the Dean told Mr. Bhai Sawant that he would get back to Mr. Bhai Sawant on his tracing Dr. Kulkarni. Mr. Bhai Sawant admitted that he thought Dr. Ware would be the proper person to contact Dr. Kulkarni as he might be able to persuade Dr. Kulkarni to come and see Mr. Bhai Sawant. And obvioulsy Mr. Bhai Sawant thought of Dr. Ware as the best person to do the persuasion as Dr. Ware was under Mr. Bhai Sawant, which Dr. Kulkarni, having already retired, no longer was.

131. The only inference that can be drawn from this desparate attempt is that Mr. Bhai Sawant wanted to over-awe Dr. Kulkarni by his power, position and authority as Health Minister, lest Dr. Kulkarni corroborates Raykar as Bhirud had done. On Mr. Bhai Sawant's admission he had also made enquries from Bhirud, who with some diplomacy, told Mr. Bhai Sawant that he did not remember anything. The fact that Bhirud who then was still in service gave a diplomatic answer and Dr. Kulkarni who then had retired evaded meeting Mr. Bhai Sawant is as eloquent of the former's sense of self-preservation and the latter's sense of discretion, in contrast to the blatant misuse of authority by Mr. Bhai Sawant in approaching either of them.

132. Mr. Bhai Sawant admitted that the inquiry against Bhirud arising from the show cause notice issued against him is kept pending but he says not purposely. His department, namely Medical Education, would be consulted by GAD before taking action against Bhirud on the show caue notice and that his department would be guided by the advice given by the Law and Judiciary Department. Mr. Bhai Sawant however admitted that in Bhirud's case there is a possibility of pressure on Bhirud if there is the hanging sword of reduction of pension.

133. In passing it may be stated that regarding Kochar, rightly or wrongly, Mr. Bhai Sawant made no bones about his feelings against him. Mr. Bhai Sawant admitted that he has told the Secretary, Medical Education to make a note of the false evidence given by Kochar against Mr. Bhai Sawant and to take steps after the Report of the Commission is received.

134. While perhaps Kochar and Mr. Bhai Sawant deserve each other (and the public, neither), no doubt whatever be the Report of this Commission, it will be Bhirud who at the hands of Mr. Br. Bhai Sawant is in for the rough end of the stick.

135. The fact that Raykar was under pressure even prior to his stepping in to the witness-box, is apparent from his initial unwillingness to come out with the truth This was due to the fact that the matter of his crossing the efficiency bar had been held up, he was facing some investigation on an anonymous complaint and was being

held responsible for expenses incurred on account of his being required to remain in Bombay for the work of the Commission. It was only after being assured of protection under the Act, that he could overcome his unwillingness and come out with the truth which is corroborated by Bhirud and to a certain extent by Dr. Kulkarni, and by circumstances.

(F) Asking Raykar to award rate contract to Samarth Pharmaceuticals and Welcome Laboratories.

136. The next question that arises is : *Did Mr. Bhai Sawant misuse his ministerial power and authority in the grant of the rate contracts to Samarth Pharmaceuticals and Welcome Laboratories?* The answer must be in the affirmative.

137. Samarth Pharmaceuticals is a drug manufacturing concern. Its partners are Gunwant Shah and Pandit.

138. For the period 1982-84 Samarth Pharmaceuticals had been given a rate contract for 24 items both in CSPO and ESIS. Against Samarth there were a number of complaints in respect of the supplies made during the rate contract period of 1982-84. Hence it was decided not to place any orders with Samarth. Thereupon Samarth made a representation to Government.

139. At the material time two of the members of the Rate Contract Committee were Dr. Dhakappa and Commissioner Bhirud. However Mr. Bhai Sawant selected one Dr. Hulsure to inquire into the matter and to make his report in the matter of Samarth's representation. Dr. Hulsure was the Director of the ESIS, but at the material time was not a member of the Rate Contract Committee. Dr. Hulsure gave a favourable report and recommended that Samarth be made a co-supplier and that orders be placed with Samarth.

140. When Dr. Hulsure's report was received by the Department of Medical Education, its Secretary Mrs. Shanta Shastri in a strongly worded note objected to the report having been called for from Dr. Hulsure and made observations to that effect over her signature on 6th March 1984. Mr. Bhai Sawant lacked the courage to contradict this courageous officer. Indeed Mr. Bhai Sawant could not, for he knew that what she had stated in her observation was correct. Hence below her signature Mr. Bhai Sawant put his signature on 14th July 1984 withot demur. Ex. 569

141. The impropriety of getting Dr. Hulsure to conduct the investigation and make his report is therefore obvious from the strident observations made by that independent minded lady Mrs. Shanta Shastri. All credit to her.

142. Thus instead of having a Committee member to investigate into Samarth, Mr. Bhai Sawant took the precaution of having a person of his choice, viz. Dr. Hulsure. It is a matter of no consequence that Dr. Hulsure had been appointed to the post of Director, ESIS not by Mr. Bhai Sawant but by the Maharashtra Public Service Commission. What is of consequence was his competence and integrity and that even though not competent to give the report was entrusted with the task by Mr. Bhai Sawant.

143. It is not unwisely said that coming events cast their shadows beforehand. It was perhaps poetic justice that not long thereafter there was an inquiry against Dr. Hulsure in respect of certain serios allegations against him. Dr. Hulsure was found guilty. The punishment imposed was reduction in rank from Director to Superintendent or Administrative Officer.

144. Such was the person deliberately chosen by Mr. Bhai Sawant to investigate against Samarth and make a favourable report. That this was deliberately done is clear from the strong protest put up in writing by the Secretary of the Department of Medical Education herself as also her remark to the effect that there was no necessity for calling for any report from an officer of the rank of Dr. Hulsure.

145. FDA recored also reveals that Samarth Pharmaceuticals had a loan licence arrangement with one Kirti (Works) Tablets and that the drugs manufactured by Samrth was found to be of sub-standard quality resulting in FDA cancelling Samarth's loan licence.

146. Such was Samarth's background prior to its being awarded the contracts for the period 1984-86.

147. Welcome Laboratories are a drug manufacturing concern in Madhya Pradesh. It manufactures *inter alia* sodium chloride injections which is an emergency intravenous drug. For the period 1984-86 Welcome Laboratories tendered for 42 items. In the comparative statement Welcome was at Serial No. 6 for the item sodium chloride injections. Welcome being based in Madhya Pradesh, FDA did not have any record of its performance. To the FDA in Bombay Welcome of Madhya Pradesh was a dark unknown horse.

148. Rate Contract Committee meetings for the period 1984-86 were held between 17th and 24th July 1984. For this period, Samarth was given the rate contract for 13 items, one of which was Analgin tablets. Even though the unknown Welcome was 6th in serial number for sodium chloride injections, an emergency intravenous drug, it was also given the rate contract by the simple expedient of giving the contracts to the five above it in the comparative statement. Thus was Welcome accommodated. The unknow Welcome was given the rate contract for 13 items.

149. *How did Samarth with its lurid past and Welcome with no known background meanage to bag the rate contracts* ? It is here that the machinations of Mr. Bhai Sawant came into sharp focus.

150. It is the version of Assistant Commissioner Raykar in his evidence that the rate contracts given to Samarth and Welcome were thanks to Mr. Bhai Sawant's intercession. Raykar's version is that one morning between 11 and 11-30 a.m. while the Rate Contract Committee meetings were in progress, Mr. Bhai Sawant telephoned and asked for Commissioner Bhirud. However as Bhirud was hospitalised Raykar was deputising for him. Hence Raykar took the call. At the other end was Mr. Bhai Sawant's P. A., Sule. He put him on to Mr. Bhai Sawant. Mr. Bhai Sawant gave Raykar the names of Samarth and Welcome and told him that they had filled in tenders and to looks after them "*यांनी टेंडर भरलेले आहे यांचे बघा*" Raykar told Mr. Bhai Sawant that he would convey the message to Dr. R. D. Kulkarni who was one of the members in the committee meeting. Raykar took this as an order from Mr. Bhai Sawant that the rate contract should be given to Samarth and Welcome, and accordingly conveyed Mr. Bhai Sawant's message to Dr. Kulkarni who understood the purpose of the message. The same evening Raykar reported this incident to Commissioner Bhirud during his visit to the hospital. According to Rayker, Samarth and Welcome did not deserve the rate contracts. The attempts made by Mr. Bhai Sawant's advocate Mr. Ghag to elicit from Raykar in cross-examination, that he would not have recognised who spoke to him over the teleplone, was frustrated by Raykar's assertion that he recognised the voice of the Health Minister whom he had occasion to meet and talk to in the past.

151. Raykar's version is supported by Bhirud in particular, to the extent of Raykar narrating this incident to him in the hospital the same evening, and broadly albeit cautiously, by Dr. Kulkarni. He says that once or twice during the meetings in July 1984 Bhirud or Raykar had mentioned to the committee members that they were getting telephone calls from ministers to favour a particular tenderer and that sometimes Bhirud and Raykar got telephone calls while meetings where in progress ; however Dr. Kulkarni does not remember if Bhirud or Raykar told the committee members that the minister had telephoned.

152. Raykar's version is totally denied by Mr. Bhai Sawant. According to him, he never spoke to Raykar over the telephone that he was occupied with Assembly sessions and advances the theory of a conspiracy between Raykar and Bhirud with the object of extricating themselves and throwing the blame on him. Mr. Bhai Sawant says that after Raykar gave his evidence, he made inquiries from his P. A., Sule, whether he, *i.e.* Mr. Bhai Sawant, had indeed telephoned Raykar and on the, basis of what was told to him by Sule, says he made no telephone call to Raykar.

153. Raykar deposed to the telephone call in his evidence on 22nd May 1987. His evidence lasted till 25th May 1987. In the meanwhile on 23rd or 24th May 1987 Mr. Bhai Sawant contacted Bhirud, in Bhirud's words, " to gather facts ". But Bhirud gave a diplomatic answer that he did not remember anything. After Raykar's evidence was over, Mr. Bhai Sawant also caused inquiries to be made from the Industries Department and ESIS and went through the papers to find uot the correct facts. He also attempted to contact Dr. R. D. Kulkarni through Dr. Ware, the Dean of the J. J. Hospital. But Dr. Kulkarni's whereabouts (though he was residing in the campus of the J. J. Hospital) could not be traced. Obviously

Dr. Kulkarni preferred to take evasive action rather than be pressurised by the all powerful Health Minister. Mr. Bhai Sawant also contacted Dr. Shaligram to make certain inquiries about welcome.

154. On this aspect Bhirud was questioned between 27th May and 5th June 1987 and Mr. Bhai Sawant between 15th June and 19th June 1987.

155. The crucial question that arises is : *Is Raykar telling the truth or is Mr. Bhai Sawant* ? From the evidence on record I have no doubt in my mind that the answer must be against the Health Minister.

156. To start with, from the record there cannot be slightest doubt that neither of these concerns deserved any rate contract. Samarth had a previous bad record as stated in Exhibit 569. Welcome not being registered in Maharashtra, the FDA, Bombay had no record at all. The fact that Welcome's record was no better is demonstrated by the fact that out of 582 drugs manufactured by Welcome, its sodium chloride injection comprising 5 different batches was found to be substandard and 8 different show cause notices had been issued against Welcome by the FDA, Bombay. Thus *ex facie* the rate contracts given to Samarth and Welcome were not on merits as there was nothing to commend either of them. Even so, rate contracts were bagged by them. The only irresistible inference that can be drawn is that the rate contracts would not have been given to them but for Mr. Bhai Sawant's intercession on their behalf by the expedient of the telephone call and which was construed by Raykar, as was inteded to be, as an order from the Health Minister for giving the rate contracts to these two concerns. Bx. 569

157. Mr. Bhai Sawant admits that after Raykar gave his evidence, he made enquiries from his former P. A., Sule, to ascertain whether Mr. Bhai Sawant himself had telephoned Raykar as deposed to by Raykar. This is totally ridiculous, for if Mr. Bhai Sawant had not made the telephone call, he would know it himself and would not required his P. A. to confirm a negative.

158. Even more significant is the attempt of Mr. Bhai Sawant to prove as sought to be done by his Advocate Mr. Ghag in Raykar's cross-examination, that Samarth was a concern deserving of the rate contracts given to it. The attempt resulted in a disaster of no mean order far from achieving the desired result, the opposite emerged from documents which Mr. Ghag accidentally got on record, his protestation that he was out to get at the truth, notwithstanding. Thereafter no such exercise was embarked upon regarding Welcome and no doubt wisely so. Raykar's cross examination by Mr. Bhai Sawant's Advocate Mr. Ghag on the contrary reveals that Samarth had committed several breaches in the past and was a concern least deserving to have received the bonus of a rate contract in as many as 13 items.

159. It is clear that on 14th July 1984, Mr. Bhai Sawant was aware about Samarth's bad record, he having signed Mrs. Shastri's observations. Mr. Bhai Sawant was therefore aware that unless special efforts were made by Samarth, Bhirud as a Committee member of ESIS, who aware of Samarth's bad record, was likely to recommend the rejection of Samarth's tender. Hence arose the necessity of telephoning Bhirud and finding him not there, giving instructions to Raykar.

160. As stated earlier, Welcome's antecedents were not known to the FDA as Welcome operated from Madhya Pradesh. Even though Welcome was sixth in the serial number all the earlier 5 serial numbers were also given rate contracts and Welcome also was given a rate contract, no doubt as a matter of accommodations. None of this has ever happened before and there is no reason why it should have happened in the case of Welcome but for the telephone call of Health Minister Bahi Sawant.

161. Mr. Bhai Sawant's telephone call was apparently nothing unusual, for Bhirud's evdence also suggests that apart from this incident, Health Ministers are prone to telephoning Committee members telling them what to do.

162. In holding against Mr. Bhai Sawant on this aspect, I ignore Raykar's evidence that after the contracts were given to Samarth, its partner Pandit came to thank Raykar and Raykar told him that he should go and thank the Health Minister.

163. There is no reason why Raykar, a comparatively junior officer, still in service, should falsely implicate the all powerful Health Minister. Career-wise, it would have

been in his interest to have protected the Health Minister, as indeed, he initially tried to do. It is not as if Raykar wanted to tell the truth at the outset. It had to be extracted from him gradually and relentlessly. And it was only after he was assured of protection under Commission of Inquiries Act that he came out with Mr. Bhai Sawant's telephone call. His helplessness is disclosed from his saying that if he told a lie he would come in trouble with the Commission, and if he told the truth he would come in trouble with his office and that he was already in trouble in his office. After being warned by the Commission that he was expected to tell the truth and being assured of protection under the Act, Raykar ultimately and with reluctance came out with his version of the telephone call made by Mr. Bhai Sawant. Finding himself between the devil and the deep, he decided to make a clean breast of it all, come what may.

164. But then, Mr. Bhai Sawant says Raykar did this to save his own skin. This is not correct because (i) as a Committee member Raykar alone could not have granted any contract either to Samarth or Welcome, (ii) Samarth's bad record was not known to Raykar, but only to Bhirud as he was a member of the ESIS Rate Contract Committee and nobody knew Welcome's record or past performance ; (iii) by reason of Bhirud's hospitalisation Raykar happened to be in the meeting as Bhirud's substitute and would therefore act as instructed by Bhirud, (iv) at the earliest opportunity, that is the very same evening Raykar narrated this incident to Bhirud in the hospital.

165. Further, Raykar's version about his narrating this incident to Bhirud in hospital is corroborated by Bhirud himself. This corroboration did not come willingly but had to be extracted from Bhirud's reluctant lips. Initially, he gave diplomatic answers to the Commission (as indeed he had done to Mr. Bhai Sawant when he told him he did not remember anything), but later had to admit the truth. Bhirud's earlier reluctance in the witness-box can only be attributed to the fact that while he was Commissioner till 31st May 1987 he was under pressure from the Health Minister. It was only from 1st June 1987 on his retirement that he opened up and came out with the truth, and that too when faced with no other alternative.

166. Bhirud had no enmity towards Mr. Bhai Sawant or any animus against him. Actually in his evidence Mr. Bhai Sawant has referred to Bhirud as a responsible officer. There was no reason for this responsible officer to falsely implicate Mr. Bhai Sawant, be it indirectly, unless what he ultimately came out with was the truth.

167. If Bhirud had stood his original diplomatic ground in the witness-box, his action would undoubtedly be met with the approval of Mr. Bhai Sawant and Bhirud would have gained much favour, instead of incurring the Health Minister's wrath, inviting repercussions against himself even after retirement and against his son who is connected with the drugs industry.

168. On the other hand there is no evidence that Bhirud was obliged to Raykar in any way, or wanted to oblige him, or that he would have in any event obliged Raykar against the interest of Mr. Bhai Sawant. On the contrary Bhirud's evidence indicates that he wanted to protect Mr. Bhai Sawant and hence initially was reluctant to corroborate Raykar, but did so after persistent questioning.

169. Thus in supporting Raykar, Bhirud had nothing to gain and much to lose. As it is, rightly or wrongly, Raykar is in trouble with his office with a threat of the matter of the efficiency bar and disciplinary action hovering over him, Bhirud is in no better position. The show cause notice issued against him for his interest in the drugs industry is still kept pending. He apprehends reduction in pension. His son is in the drugs industry and must therefore depends on the FDA and can possibly expect no sunny smile from the Health Minister for the evidence given by his father. Both Raykar and Bhirud have placed themselves in an unenviable position qua the Health Minister. No doubt it would have been advantageous to them to have " conspired " in Mr. Bhai Sawant's favour.

170. Despite repeated opportunities given to Mr. Bhai Sawant, no explanation has been coming forth from him why Raykar and Bhirud or Dr. Kulkarni should conspire against him except that they wanted to save themselves at his cost. Testing this argument, why should they point an accusing finger only at Mr. Bhai Sawant, who on Mr. Bhai Sawant's own showing had not harmed them. Instead of blaming Mr. Bhai Sawant they could have blamed each other or thrown the entire blame on

the Industries Department. Bhirud could easily have escaped by saying he was not present at the meeting, as he indeed was not ; Raykar and Dr. Kulkarni could have escaped by stating that the facts were known only by Bhirud. Further, it is against human nature and self-interest and self-preservation to conspire against one's own superior and face retribution from him. It is of no mean significance that though Kochar blamed Mr. Bhai Sawant for watering down FDA order of 29th November 1984, Bhirud came to the defence of Mr. Bhai Sawant and took the responsibility upon himself.

171. Further, a conspiracy must necessarily suggest a pre-conceived and pre-determined plot. There was neither time nor the opportunity nor the necessity for Bhirud, Raykar and Dr. Kulkarni to enter into this so-called conspiracy against Mr. Bhai Sawant because they had not the slightest inkling of the nature of the questions that they would be asked in cross-examination and were examined at different times. It is futile to say that they impinged the Health Minister in order to save their own skins. The facts are eloquent to the contrary.

172. Mr. Bhai Sawant's theory of " conspirarcy " is but a last ditch attempt to extricate himself from his involvement in this episode. The only reason given by him is that the issue of the working of the FDA has been referred to the Commission which is going into the details and therefore these officers are going to be in trouble with Government, the Commission and the Police Department. Surely if these officers are already in trouble, would they put themselves even into greater trouble by falsely implicating their Lord and Master ? The question answers itself. It is significant that the allegation of conspiracy made by Mr. Bhai Sawant was only when he was recalled for the second time in June 1987 and only when he was cornered in cross-examination and no other excuse was possible or available to him.

173. Hence in the matter of granting rate contracts to Samarth and Welcome, the only irresistible inference that can be drawn is that Mr. Bhai Sawant is guilty of misuse of ministerial power and authority. The fact that he had no other interest in them is manifest from the fact that there is nothing on record to show that he knew them or their partners. Hence this wanton abuse of ministerial interference can but lead to the only irresistible inference that it was motivated by extraneous considerations.

G

Miscellaneous acts showing Ministerial Interference, Favouritism and Misuse of Power

I

174. The evidence on record discloses a strange affinity that Bhai Sawant has towards one of the most unworthy officers of the FDA has had the misfortune of having—S. M. Dolas.

175. The blatant manner in which Bhai Sawant brought Dolas to Bombay as Joint Commissioner and Licensing Authority over the heads of not less than 4 officer senior to him and more deserving than him over the strong objections of Bhai Sawant's own secretarial staff, is on record and has been dealt with earlier in this Report. But Bhai Sawant's goodwill towards his blue-eyed boy did not end there. Undeservedly it continues to this day, and thanks to the benediction of the Health Minister, Dolas continues to be posted in Bombay.

176. In December 1986 when Bhirud and Dolas gave evidence before this Commission, their interest in the drugs industry came to light. The Health Minister came to know this from newspaper reports. He was unmoved and took no steps or showed the least anxiety to ensure that in public interest the duty of Bhirud and Dolas as the top-most FDA officers should not further conflict with their interests. Three months later, on 18th March 1987 Bhai Sawant was recalled for further questioning, during the course of which on 21st March 1987 his attention was specifically drawn to the vested interests of Bhirud and Dolas in the drugs industry. The following excerpts from Bhai Sawant's evidence of 21st March 1987 are revealing :—

" *Q.* : As Health Minister are you aware that various officers in the FDA have direct or indirect interest in the drugs industry ?

" *A.* : This has been revealed from the newspaper reports regarding certain FDA officers. Prior to that I was not aware of it.

" Under the Drugs and Cosmetics Act as also under the General Guidelines for officers, no officer shall have an interest direct or indirect, in the drugs industry. .... He must disclose it to Government. .....

Q. : After you came to know about this, have you as Health Minister taken any steps ?

A. : The Secretary, Medical Education and I have had a discussion about this and after taking legal opinion and after holding an inquiry necessary action will be taken against such erring officers.

Q. : Has any immediate action been taken to ensure that the interest of such officers does not conflict with their duty ?

A. : No.

Q. : Therefore, do you agree that these officers will continue to attend to the work of those concerns in which they have an interest ?

A. : Yes.

To Commission :

Q. : As Health Minister do you think that this is in public interest ?

A. : No it is not in public interest.

" Questioning by Mr. N. A. Shah resumed :

Q. : Then why is it that nothing has been done to transfer these officers outside the spheres of their interests ?

A. : This was not done as this Inquiry is in progress. Now that it is necessary to do so in public interest it shall be done immediately.

" I am aware of the names of the two officers, viz. Commr. Bhirud and Jt. Commr Dolas. I do not know about S. D. Patil but in the light of the revelations in this Inquiry, the requisite inquiry will be made against S. D. Patil ".
(The underlining is mine).

Even after his attention was specifically drawn to these two officers having a vested interest in the drugs industry, the easiest thing which any responsible Health Minister could and should have done was to have transferred Dolas away from Bombay. More so, in view of the fact that Dolas was only holding charge as Joint Commissioner and Licensing Authority, for such a transfer no inquiry was necessary in the light of the evidence given by Dolas himself in December 1986, when with the greatest reluctance he admitted that his two daughters were partners in pharmaceuticals concerns. It is also not unknown to place an officer under suspension pending inquiry. Instructions could also have been given that Dolas should not handle any matter pertaining to Ferrico Pharmaceuticals and Ferrico Laboratories in which his daughters are partners. None of this was done.

177. Of course Bhirud being the Commissioner could not be transferred elsewhere. He was served with a show-cause notice. However Dolas who was holding charge in Bombay could certainly have been transferred out of Bombay where his interest in the drugs industry lies. Bhai Sawant came to his rescue and on 24th March 1987 transferred him from Drugs to Food, retaining him in Bombay. This was, on the Health Minister's Part, a breach of faith and breach of a solemn assurance given on oath to this Commission to transfer Dolas outside the sphere of his interest in the drugs industry, in public interest. This was a calculated fraud on the public and this Commission, for which I hold Bhai Sawant responsible. Unfortunately for him, he has succeeded in hoodwinking.

178. The Drugs and the Food departments are units of the same department viz., the FDA. Both these departments are in the same building and on the same floor. To suggest as done by Bhai Sawant that by thus shifting Dolas from one master bed-room to another master bed-room in the same house and on the same floor, would be placing him outside the sphere of his interest is wickedness and beats the machination and cynicism of the Health Minister in aiding and abetting Dolas to perpetuate his interest in the drugs industry, contrary to public interest. This is brought to the forefront by Dolas' reluctant admission that on 4th July 1986 (i.e. actually during the pendency of this Commission) he had granted approval to Ferrico Pharmaceuticals in which his daughter is a partner, without the Inspector's report.

179. Bhai Sawant's anxiety to willy nilly retain Dolas in Bombay even after coming to know of his vested interest is also obvious. He admitted that he came to know of Dolas' vested interest during the course of the present Inquiry, and was asked whether he had considered the possibility of transferring Dolas outside Bombay instead of the Food Department. Bhai Sawant however affected not to follow the question, but while professing that Dolas' transfer to Food was merely a temporary arrangement, admitted that it could have been possible to transfer Dolas temporarily out of Bombay beyond the sphere of his influence in Bombay. When asked why then he did not do so, he replied that because a final decision would be taken after the Secretary returned from leave, viz. on 15th June 1987. He admitted that it was possible to transfer Dolas outside Bombay, but he and the Secretary thought it better to transfer Dolas from Drugs to Food in Bombay. On his protestation that Drugs Administration is altogether different from Food Administration, he was asked the following question :—

Q. : Did you think Dolas to be incapable of exerting his influence in the Drugs Section from the Food Section ?

A. : I did not think so.

Q. : In the light of your last answer, do I take it that you did think that Dolas was indeed capable of exerting his influence in the Drugs Section from the Food Section ?

A. : I cannot give my definite opinion on this. "

During the course of his evidence on 15th June 1987 Bhai Sawant finally had to admit,—

" I now realise that it is not in public interest to retain him (i.e. Dolas) any longer in Bombay ",

and that nevertheless he intended to keep him in Bombay. Since this admission was made by Bhai Sawant, and this Report 6 months have elapsed and Dolas is still in Bombay.

180. Thus the assurance given by Bhai Sawant to this Commission on 21st March 1987 to transfer Dolas outside the sphere of his interest was not sincere, and was given as he found himself with no alternative but to do so if he was to avoid certain irresistible influences and conclusions being drawn against him.

181. From all this, the only irresistible inference that can possibly be drawn is that Bhai Sawant has been instrumental to this day in retaining Dolas in Bombay within the sphere of his interest and against public interest, because Dolas has the strongest possible hold over him on account of one or more extraneous considerations. Misuse of power and favouritism are manifest. This is further fortified by the fact that as stated earlier, even though in evidence Bhai Sawant gave a solemn assurance that requisite inquiry would be made against S. D. Patil (Assistant Commissioner, F. D. A.), to this day the Commission has not been informed whether this has been done or not and if not, why not.

II

182. The evidence also reveals that Health Minister, Bhai Sawant misused his power to devalue the position and authority of Commissioner Bhirud and made him subservient to Dolas, and took away from Commissioner Bhirud the power to transfer Class-I officers of the FDA, to such an extent that in the matter of these transfers even an ordinary Superintendent of the FDA was consulted but not the Commissioner himself. In short, Bhai Sawant misused his ministerial position by holding up the seniormost officer of the F. D. A., namely the Commissioner, to ridicule and contempt.

183. There is Bhirud's evidence that though he had sent a proposal to Government that the post of Joint Commissioner and Licensing Authority should be filled in, the same had not been acted upon by Government with the result that Dolas was holding charge as Joint Commissioner (H. Q.), since November 1985 until he was transferred to Food. Bhirud also made a grievance that until two years ago the power to transfer Class-I and II officers was vested with the Commissioner with the approval of Government; but that power has been taken away from the Commissioner in the case of Class-I officers with the result that the Commissioner is no longer consulted regarding the transfer of those officers. In 1986, certain Class-I officers

were transferred but the Commissioner was not consulted, instead the only person who was consulted in the FDA was Superintendent Sawant. Bhirud does not know if Sawant was close to Dolas.

184. Despite Bhirud's recommendation of Fadnavis for the post of Joint Commissioner, who was the seniormost and most competent, his recommendation was ignored and in November 1985 without asking Bhirud, Fadnavis was transferred from Bombay to Nagpur and Dolas was appointed as Joint Commissioner and Licensing Authority in the place of Fadnavis. There is also Bhirud's evidence that to some extent he was afraid of Dolas because Dolas could go to Health Minister and tell him anything about Bhirud without the Health Minister cross-checking with Bhirud. Even after his retirement Bhirud was afraid of Dolas to some extent about what he can do to him and that it is Bhirud's apprehension that it is possible that Dolas can influence the Health Minister in the inquiry regarding the show cause notice issued to Bhirud in connection with his vested interest in the drugs industry.

185. Health Minister Bhai Sawant's interference over the head of Commissioner Bhirud was also manifest in the matter of transfers of Assistant Commissioner Patil, Mali and Deshpande. What is even more extraordinary is that in Patil's case a mere Desk Officer had the temerity to ask for the explanation of Commissioner Bhirud ?

186. The above illustrations go to show to what extent Health Minister misused his ministerial powers and position in devaluing the post of the highest officer of the FDA, namely the commissioner himself, thereby demoralised the entire FDA hierarchy and made them subservient either to himself or Dolas. It is apparent that Bhirud was denied the measure of independence which, as head of the FDA he was entitled to, subject to his adhering to Government policy. On none of these aspects was Bhirud cross-examined by Bhai Sawant though he had engaged Mr. Ghag, Advocate, to represent him.

III

187. The inefficiency and dereliction of duty on the part of Health Minister Bhai Sawant is also brought to the forefront by the fact that he did not bother and keep himself informed about important matters and events pertaining to the FDA. One such illustration is the total ignorance expressed by Bhai Sawant regarding drugs Inspector Kalia who was arrested on 30th June 1984 on the charge of illegally smuggling out of India tablets containing methaqualone (Mandrox) which had been banned. Thereafter no steps either by way of prosecution or even departmental inquiry, were taken against Kalia. It was only after Bhai Sawant's attention was drawn to this during the course of his evidence that some action was belatedly taken against Kalia. Kalia being a Government employee, it was Government's duty to have taken strong and prompt action against him which Government failed to do.

CONCLUSION

188. While the record does not disclose any nexus between Alpana Pharma and Bhai Sawant or that any donation was received by R. U. O. From Alpana Pharma, the record reveals that the role played by Bhai Sawant as Health Minister was, for the FDA and the general public, a disaster of the first magnitude. (A) He has not set an example either of efficiency or rectitude by complying with the Act and Rules. (B) He has intentionally given false evidence replete with contradictions and even contrary to what was stated by him in his affidavit on oath. If he missed a perjury notice, it was but by a hair's breadth. (C) His evidence disclosed that he is guilty of gross ministerial interference and favouritism for extraneous consideration and misuse of power and authority vested in him coupled with dereliction of statutory duties to enforce the provisions of the Act and Rules. (D) He has used the weapon of transfer to remove " inconvenient " officers and simultaneously to confer favour upon a chosen few. (E) He a granted undeserved and out of turn promotion to S. M. Dolas with a view to appointing him to the coveted post of Joint Commissioner and Licensing Authority in the teeth of the opposition of his own secretariat and the Commissioner and thereby ignored the claims of not less than 4 FDA officers entitled to be appointed to this post both by way of seniority and competence. This action was arbitrary, mala fide and for extraneous consideration which Bhai Sawant was unable to support on the merits of the case and finally conceded was not in public interest. (F) With a view to favour Cyma Pharma, Bhai Sawant wrongly set aside in appeal the order passed by the FDA and thereby restored Cyma Pharma's licence

who continued to manufacture substandard life-saving drugs. Despite Bhai Sawant's assertion that his appellate order was in public interest, he was unable to explain how such an order could possibly have served public interest, and when cornered falsely attempted to lay the blame on FDA officers for supposedly not bringing the full facts to his notice. (G) Bhai Sawant misused his ministerial position for the collection of donations and advertisements for R. U. O. but not from Alpana Pharma. (H) He attempted to exert pressure on Bhirud, Raykar and Dr. R. D. Kulkarni during this Commission with a view to coerce them into giving evidence favourable to himself. (I) The transfer of Doals from Drugs to Food was an attempt to delude the Commission and the public after giving an assurance to remove Dolas from the sphere of his interest. (J) Bhai Sawant has continued to protect not only Dolas but also S. D. Patil who had been brought to Bombay by Bhai Sawant in the teeth of the opposition of his own secretariat. Against S. D. Patil even a show cause notice has not been issued. (K) Bhai Sawant misused his ministerial powers in securing rate contracts for Samarth Pharmaceuticals and Welcome Laboratories. (L) He devalued the office of the Commissioner and otherwise demoralised the entire FDA hierarchy and made them including Bhirud subservient to himself and Dolas. (M) He took away the Commissioner's power of transferring Class-I officers to the extent that in the matter of these transfers the ordinary Superintendent of the FDA was consulted but not Commissioner Bhirud. (N) He denied to the Commissioner the measure of independence as head of FDA he was entitled, subject to his adhering to Government policy. (O) Bhai Sawant's endeavour to explain away unfavourable evidence against him on the ground that certain FDA officers had conspired against him and laying blame on his subordinates, was pathetic, and unworthy. (P) Bhai Sawant failed in his duty in not keeping himself informed about important matters and events concerning the FDA as is manifest from his total ignorance about Kalia and taking prompt action in respect thereof.

189. Bhai Sawant is guilty of corruption, misuse of power and deliberate dereliction of duty. He is unfit to hold a ministerial post.

CHAPTER XV

PART I

1. Dr. Baliram Waman Hiray is a medical practitioner at Malegaon. From 1972 till 1985 he was a Member of the Legislative Assembly representing Malegaon Constituency. From 1978 till 1980 he was Cabinet Minister for Education in the Government of Maharashtra, From June 1980 till 1982 he was Cabinet Minister for Health. Thereafter till February 1985 he held additional portfolios, one of which was prohibition.

2. During Dr. Hiray's tenure as Health Minister from 1980-82, V. C. Sane was holding charge as Commissioner from 2nd October 1979 till 21st July 1981 on which day he was appointed Commissioner. V. C. Sane retired on 31st October 1981.

3. Dr. Hiray was examined from 22nd to 29th April 1987 (Saturday and Sunday excluded), on 4th and 5th May 1987, and on 8th and 9th June 1987.

4. On several aspects, to wit, ministerial interference, misuse of power and authority, collection of donations, et al, Dr. Baliram Hiray does not lag far behind Health Minister Bhai Sawant and even outstrips him.

PART II

5. As Health Minister, Dr. Baliram Hiray spread his tentacles far and wide.

6. One Tolia was connected with Tolson Drugs Laboratories and Atul Pharmaceuticals. He has been described by Commissioner Venkatachalam as a tout and a habitual loiterer in the FDA office who Venkatachalam drove out. Prior to June 1978 before Venkatachalam was appointed Commissioner, Tolia had repacked dry zinc oxide powder without a licence. Predictably nothing was done to Tolia by the FDA. He was quite popular there. However after Venkatachalam came on the scene as Commissioner, Tolia's affinity with the FDA suffered a steep decline. Venkatachalam promptly did two things : he threw Tolia out of the FDA office and he got Tolia's file re-examined. A prosecution was launched and Tolia was arrested on 27th July 1983. What a fall there was my cuntrymen !

7. So Tolia made an application to the then Chief Minister for withdrawal of the prosecution. On 29th August 1978 the Chief Minister's secretariat wrote to Commis-
Ex. 448 (colly.) sioner Venkatachalam inviting his views. Venkatachalam did so by a detailed note dated 8th September 1978 to the then Chief Minister setting out cogent reasons why the prosecution against Tolia should not be withdrawn. There the matter rested and no order was passed regarding the withdrawal of the prosecution against Tolia.

Ex. 467 8. About two years later Tolia addressed an undated letter to the FDA (Ex. 467) for the withdrawal of the prosecution against him on the ground that Tolia had merely committed a technical breach. On this letter a decision was taken on 18th May 1980 by the FDA not to withdraw the prosecution.

9. A month later in June 1980 Dr. Hiray became Health Minister. Within two months thereafter on 14th August 1980 Dr. Hiray personally received from Tolia a copy of his undated letter (Ex. 467). The same day and even without the copy letter being sent to the department for inwarding, Dr. Hiray made an endorsement on it over his signature as under :—

" Commissioner (Food and Drugs) Examine and consider sympathetically, if necessary discuss,"

The words " consider sympathetically " were deleted and in their place Dr. Hiray inserted the word " remarks ". On the same day a copy of this letter was sent to the Commissioner, FDA, for his remarks, who by then was none other than V.C. Sane.

10. Two days later on 16th August 1980 Tolia's copy letter which had been personally received by Dr. Hiray 2 days earlier, was sent to the department for inwarding. Dr. Hiray was unable to explain why in the case of Tolia's letter the reverse process was adopted, namely that the copy was first sent to the Commissioner on 14th August and the letter received on 14th August 1980 was inwarded in Dr. Hiray's department on 16th August.

11. Commissioner Sane made his undated report of September 1980 (Ex. 468) from which it appears that on 26th August 1980 Dr. Hiray had discussed this matter with him. According to Commissioner Sane he made a favourable report because Dr. Hiray wanted him to do so. Sane's report also refers to the opinion of the Law Officer that the case against Tolia was very weak as the records had not been seized and preserved and no panchanama had been made. Though according to Sane the Law Officer had given such a report, it is to be found nowhere, and Sane finally admitted that there was no written report made by the Law Officer. In Sane's report there was reference to the earlier application made by Tolia to the then chief Minister. Hence Dr. Hiray had knowledge that Tolia had made an earlier application to the then Chief Minister which had not been acceded to. Ex. 468

12. Sane's report was persued by Dr. Secretary Lobo (since deceased). He prepared a note that Tolia's contravention was minor and that he was likely to get the benefit of the doubt. Below Lobo's note Dr. Hiray put his initials.

13. On Sane's report a decision was taken to withdraw the prosecution against Tolia. And on 29th November 1980 the Dy. Secretary wrote a letter to Commissioner Sane that Tolia's was not a fit case for prosecution. Ex. 513

14. On this aspect the evidence of Dr. Hiray was most unsatisfactory. He started by saying that he did not recall any person by name of Tolia or whether he had ordered the withdrawal of any prosecution. He admitted that as Health Minister he did not have the power to order withdrawal of a prosecution independently, which without the concurrence of the Home Department would be an illegality, which Dr. Hiray pontificated is what he would not do. This, as will appear later, has been proved to be false. Dr. Hiray attempted to shift the responsibility on his department by saying that he might have agreed with the department to withdraw the prosecution against Tolia. He finally admitted that as Health Minister and final authority it would be up to him to withdraw or not to withdraw the prosecution against Tolia. Dr. Hiray could not say whether in Tolia's case he gave his decision after application of mind. On seeing the letter written by Tolia, Dr. Hiray admitted that the signature in the left hand margin of this letter was his. He also admitted that contrary to normal practice Tolia's letter came directly to him first (namely on 14th August 1980) and after he made his endorsement it was sent for inwarding on 16th August 1980. He could however give no explanation why in respect of Tolia's letter the reverse process was adopted, namely that the copy of Tolia's letter was first sent to the Commissioner, on 14th August 1980 and the original letter was inwarded in Dr. Hiray's department on 16th August 1980. When he received Tolia's letter he did realise that somebody had played a mischief in delivering it directly to him. He never made endorsements on letters suspected to have been mischievously delivered to him. When asked why he made his endorsement on Tolia's letter, even though he realised it had been mischievously delivered to him directly, he gave a rambling answer that his intention was that Tolia's letter should go to his (i.e. Dr. Hiray's) Secretary, but it appeared that the letter went directly to the Commissioner. When Dr. Hiray's evidence was resumed the following day, he retracted his earlier admissions and stated that Tolia's application had not been given to him directly by Tolia or anyone on his behalf, and that Tolia's letter had been placed before him for his signature with the endorsement already made along with other letters. He admitted that he had gone through Tolia's letter, which according to him necessitated ministerial interference on his part, because Tolia had stated in his letter that he was only guilty of a technical mistake not involving *mala fides*.

15. After starting with the bland assertion that he never asked Sane for any report or have any discussion with him regarding the prosecution pending against Tolia, Dr. Hiray admitted that he had asked Dr. Sane to give his report on Tolia's application in which Tolia had admitted that he had committed an offence, albeit technical. He never took Tolia's interest into account and for that matter took nobody's interest into account. He came out with the breath-taking statement that he thought that he was upholding public interest by ordering the withdrawal of the prosecution against Tolia. He had to agree that by withdrawing the prosecution against Tolia, public interest would not be served. He agreed that public interest would not be served by not prosecuting or withdrawing a prosecution against a person who on his own admission had manufactured a drug without a licence, and that Tolia had admitted that he had manufactured zinc oxide without a licence, that it would be hazardous to public health if somebody manufactures zinc oxide without a licence and that the department should come down heavily against such persons as a deterrent to others like-minded. He agreed that the minimum punishment for such an offence is one year R. I. and fine, and the maximum punishment is 3 years

R. I. and fine, and that in such cases there is no such thing as a technical offence. Dr. Hiray finally agreed that by continuing the prosecution against Tolia public interest would have been served better than by withdrawing the prosecution, and that the public interest was not served by withdrawing the prosecution against Tolia.

16. To a question whether he agreed that the decision taken by him at that time to withdraw the prosecution (against Tolia) was a wrong decision taken by him, Dr. Hiray stated that he could not say.

17. Like Dr. Hiray, V. C. Sane also started with a weak memory. He did not remember having made any report. Even after seeing Tolia's application, he affected to remember nothing. After his report was shown to him, he admitted he had made it. V. C. Sane admitted that Tolia's zinc oxide was found not to be of standard quality, that an F.I.R. had been filed against Tolia by the FDA in 1978 after re-examining the entire matter, and that the offence of repacking a sub-standard drug without a licence would not be a minor contravention of the Act. He concurred with the opinion of the Law Officer who was under him, in recommending the withdrawal of prosecution against Tolia, on the ground that no panchanama had been made and that the records were not available. The Law Officer must have given his written opinion which has not been stated by Sane in his report. He admitted that in Tolia's matter Dr. Hiray had asked him to prepare a report, and that it was on the strength of his report that the prosecution against Tolia was withdrawn. However he could not say one way or the other whether Dr. Hiray was taking more than usual interest in the withdrawal of the prosecution against Tolia. He admitted that normally when such prosecutions are filed, the opinion of the Police Prosecutor who is the best person to give an opinion and the Law Officer are taken, but in Tolia's case the opinion of the Police Prosecutor was not taken, nor was his report called for.

18. Sane admitted that it did strike him as unusual that the Health Minister should call him with the papers for a personal discussion regarding the case against Tolia but it did not appear to him that Dr. Hiray also knew Tolia. After Sane showed Dr. Heray Tolia's papers, neither did Dr. Hiray nor Sane express any opinion whether the prosecution against Tolia should be withdrawn or not. Dr. Sane's personal opinion was that the prosecution against Tolia should not be withdrawn but did not say so to Dr. Hiray because Sane wanted the entire matter to be examined by the Law Officer, though not by the Police Prosecutor who was incharge of the prosecution, because Sane thought that the examination by the department's Law Officer was the quickest way for Sane preparing and sending his report.

19. This is a totally baseless explanation given by Sane; surely the person who could best have given his opinion expeditiously would have been the Police Prosecutor handling the case rather than a comparative outsider like the Law Officer to whom everything would have to be explained and who would be reading the papers for the first time. Thus the person best equipped to give an opinion, namely the Police Prosecutor in charge of the prosecution, was side-tracked. The inference is irresistible, namely that there being no such thing as a technical offence as admitted by Sane and Dr. Hiray in the light of Tolia's admission that he had committed an offence, the Police Prosecutor would never have recommended a withdrawal of the prosecution against Tolia.

20. According to Sane he gave the department's Law Officer all the facts and papers pertaining to Tolia's prosecution as also Sane's personal opinion that the prosecution should not be withdrawn. Sane says he considered it necessary to have a written opinion of the Law Officer and accordingly asked the Law Officer, who was his subordinate, to give his written opinion which the Law Officer did.

21. This is a palpably false statement as no such opinion is to be found either in the Government file or the FDA file.

22. Sane admitted that he had not stated in his report that the opinion given by the Law Officer was a written opinion, nor had he mentioned the date of such opinion. He admitted that if the Law Officer had given a written opinion, it would be in the file, and that if the opinion had been an oral opinion there would be a noting by Sane or by the Law Officer in the file.

23. All this indicates that no legal opinion was sought for and Sane's version of the Law Officer giving a written opinion is a canard.

24. Sane admitted that he considered it to be an important thing that the prosecution against Tolia should be withdrawn, and then said that he was of the opinion that the prosecution should not be withdrawn, because it was a serious matter; even so he did not express this opinion of his in his report.

25. The reason given by him for his not doing so was because perhaps Government, meaning thereby Health Minister Dr. Hiray, might have been interested in withdrawing the prosecution against Tolia.

26. He admitted that he gave his report in order to please Dr. Hiray. Sane made his report asked for by Dr. Hiray. He did not realise what kind of report Dr. Hiray wanted as Dr. Hiray did not tell him to make any particular kind of report. Even so, he made his report recommending the withdrawal of the prosecution against Tolia despite his opinion to the contrary, because it appeared to him that such a report was desired by Government, meaning Dr. Hiray, by reason of the meeting he had with Dr. Hiray. Dr. Hiray had told him whether anything could be done regarding the withdrawal of the prosecution against Tolia. He admitted that from his conversation with Dr. Hiray it was a hint to him that Dr. Hiray desired a favourable report regarding the withdrawal of the prosecution against Tolia and that Sane's report to the contrary would dis-please the Government, meaning Dr. Hiray, whereby he would have incurred the wrath of Dr. Hiray.

27. Sane admitted that as it is he had already incurred the wrath of Minister Sarnayak and had suffered thereby, and therefore he did not want to further suffer by incurring the wrath of Dr. Hiray. Hence he made his report (Ex. 468) so as to actually coincide with the wishes of Dr. Hiray. Dr. Sane finally admitted that Dr. Hiray was taking more than usual interest in the matter of withdrawal of the prosecution against Tolia. Ex. 468

28. None of the admissions made by Sane were voluntary nor were they easily made. He tried his best to protect his erstwhile master Dr. Hiray and it was only when he found it no longer possible to do so, did he throw in the towel and drag himself down with it.

29. From the evidence of Dr. Hiray and Dr. Sane read as a whole, there can be no doubt that Dr. Hiray showed more than usual interest in the withdrawal of the prosecution against Tolia. This interest was not to remedy an injustice done to a citizen, but to relieve Tolia, a self-confessed adulterator, of the consequences of the the serious breach of the Drugs and Cosmetics Act. Dr. Hiray knew of the earlier two unsuccessful attempts made by Tolia to have the prosecution against him withdrawn. Dr. Hiray's asking for a report from Commissioner Sane was not as innocuous as may appear at first flush. Dr. Hiray wanted a favourable report from Commissioner Sane in order to lend verisimilitude to his resolve to have willy nilly the prosecution against Tolia withdrawn, and thereby give colour of legality and propriety to an otherwise improper and illegal action. There was otherwise no reason for asking Commissioner Sane to make his report, because Tolia had himself in his letter admitted the offence, classify it though he might as a technical one.

30. It is impossible to see how manufacture or repacking sub-standard zinc powder (which even according to Dr. Hiray is hazardous and cannot amount to a technical offence), could be a " technical " offence. Hence the very basis of the so-called opinion said to have been given by the department's Law Officer had no merit, based as it was, on the fact that no papers had been seized or preserved and that no panchanama had been made. None of this had any relevance to the success of the prosecution in the light of Tolia's own admission of guilt.

31. In Commissioner Sane, Dr. Hiray found a pliable officer to carry out his wishes. Sane's affectation of being a stranger to Tolia is false as Sane's evidence shows that he was closely associated with Tolia who after Sane's retirement, had even provided Sane with his (Tolia's) office facility. Tolia was, in the words of Commissioner Venkatachalam, a tout, who loitered in the FDA office until he was thrown out by Venkatachalam.

32. It is therefore evident that Dr. Hiray wanted to oblige Tolia and therefore entertained his application (Ex. 467) directly and made an endorsement thereon to consider it " sympathetically " which was struck out and the word " remarks " was written later on. The fact that this application was given to FDA even before Ex. 467

it was inwarded shows that was given directly by Dr. Hiray to Sane. This is supported by the fact that Sane's report was tailor-made to coincide with the desire of Dr. Hiray. The documents were therefore cooked up to apparently show that the prosecution was withdrawn after due consideration in usual manner.

33. According to Venkatachalam, Tolia has corrupted the FDA by following corrupt practices and that he had become a "family friend and a welcome guest of FDA". Venkatachalam had for these reasons driven Tolia out of the FDA. With this background of Tolia's activities in the FDA, coupled with the highly suspicious circumstances in which Dr. Hiray ordered the withdrawal of the prosecution against Tolia, the irresistible inference against Dr. Hiray that his actions in extricating Tolia out of an impossible and serious situation were motivated by extraneous considerations and none other.

34. The above evidence unmistakably indicates anxiety on the part of Dr. Hiray to withdraw the prosecution against Tolia at any cost. He knew that Tolia's attempt with the Chief Minister had failed on account of cogent reasons given by Commissioner Venkatachalam in his report made to the Chief Minister. In Sane's report
Ex. 468 (Ex. 468), Sane had referred to Venkatachalam's report. A secretarial note was prepared on the basis of Sane's report but it omits to make any reference to Venkatachalam's report or the order passed by the Chief Minister. This omission was at Dr. Hiray's behest as indicated by the fact that he had asked Sane to prepare a report favourable to Tolia, which Sane did without actually obtaining any legal opinion. Dr. Hiray admits that in order to withdraw a prosecution, sanction of the Home Department is necessary. To get over this difficulty he unjustifiably seeks to make a distinction in his evidence between "withdrawal" of prosecution and "dropping" of prosecution, and says that for "dropping" of prosecution, sanction of the Home Department is not necessary. He therefore, seeks to give an impression in the witness-box that FDA had not launched a prosecution with a view to explain away his deliberate omission to obtain sanction of the Home Department. This is contrary to his own evidence and the record which indicates that the prosecution against Tolia had already been launched. This finds verisimilitude from Tolia's
Ex. 467 own application wherein he himself had asked for withdrawal of the prosecution filed against him.

PART III

35. This brings me to the role played by Dr. Hiray in the case of Assistam Commissioners V. D. Deshmukh and N. D. Kulkarni and in promoting V. D. Deshmukh to the post of Jt. Commissioner and Licensing Authority.

Hereunder the sequence of events :

A

30th April 1977.—A prosecution was launched by the FDA against Naval Medico Distributors at Nasik.

2nd May 1977.—V. D. Deshmukh took charge as acting Commissioner. The same day he received a trunk call from the then Health Minister Sarnayak from Jalgaon. Sarnayak gave Deshmukh a dressing down for harassing Naval Medico and ordered Deshmukh to see him on 4th May 1977 at Mantralaya.

4th May 1977.—Deshmukh did so. Sarnayak told Deshmukh to make enquiries why Naval Medico was being harassed by a prosecution.

7th May 1977.—Deshmukh asked N. D. Kulkarni to make a report.

25th May 1977.—Kulkarni made his report stating that the offence committed by Naval Medico was a minor and technical offence. The same day Deshmukh wrote to the Assistant Commissioner at Nasik not to proceed further with the case against Naval Medico. A copy of this letter was sent to Health Minister Sarnayak who made an endorsement the same day that the Home Department be requested to sanction withdrawal of the prosecution. However, the Home Department did not agree to do anything of the kind. The prosecution against Naval Medico is still pending.

B

1978.—(*i*) An anonymous complaint was received by the Lokayuktta against V. D. Deshmukh and N. D. Kulkarni that they had hushed up Naval Medico's case for an illegal gratification of Rs. 25,000.

(*ii*) The Upa-Lokayukta made enquiries against these two officers and issued the requisite process and also wanted to do the same against Sarnayak, but could not, as by then he had ceased to be a minister.

(*iii*) V. D. Deshmukh and N. D. Kulkarni filed their respective written statements before the Upa-Lokayukta, in substance their defence being that the report recommending the withdrawal of prosecution against Naval Medico was made to please Health Minister Sarnayak.

4th July 1980 — The Upa Lokayukta made his report. He found V. D. Deshmukh and N. D. Kulkarni guilty of improper conduct and directed Government to censure them with mention in their CRs.

10th October 1980.—The Upa Lokayukta's report was received by Government. Dr. Hiray made his endorsement agreeing with the findings of the Upa Lokayukta.

22nd October 1980.—Show cause notices were issued to N. D. Kulkarni and V. D. Deshmukh.

December 1980,—V. D. Deshmukh and N. D. Kulkarni sent their replies in the same terms as their written statements before the Upa Lokayukta.

28 th July 1981.—Dr. Hiray made an endorsement that after hearing these two officers and reading their replies, he did not find their action mala fide or lacking in good faith, hance the question of censuring them did not arise ; that he dit not accept the Upa Lokayukta's findings and asked his secretariat to convey this to the Upa Lokayukta.

10th October 1981.—Dr. Hiray made an endorsement directing the Secretary, Medical Education to convey the views of the Upa Lokayukta verbally to N. D. Kulkarni and V. D. Deshmukh.

30th October 1981.—Pratap Wagh, M. P., wrote to Dr. Hiray requesting for V. D. Deshmukh's transfer from Pune to the FDA's Bandra office at Bombay as " at the fag end of his outstanding carreer it is necessary that he stays with his family at Bombay and also settles down peacefully after retirement ". This letter was handed over by Pratap Wagh to Dr. Hiray personally on 30th October 1981. At the foot of this letter, Dr. Hiray made his endorsement "may be done " under date 13th December 1981.

3rd November 1981.—(i) The Under Secretary had a discussion with the Upa-Lokayukta who did not accept Government's views.

(ii) Mrs. Shastri, Secretary, Medical Education, made an endorsement that the Minister for Public Health desired that an oral warning be given to V. D. Deshmukh and N. D. Kulkarni for which purpose they may be called to see the Minister, namely Dr. Hiray.

22nd December 1981 and 28th December 1981.—Mrs. Shastri verbally communicated the Upa Lokayukta's views to V. D. Deshmukh and N. D. Kulkarni.

19th January 1982.—An order was passed transferring V. D. Deshmukh from Pune to Bombay.

36. With this sequence of events in the forefront, the questions that arise are : (*a*) *Was Dr. Hiray's refusal to accept the order of the Upa Lokayukta justified in the facts and circumstances of the case* ? (*b*) *Was the order of 19th January 1982 transferring V. D. Deshmukh to Bombay to the prized and coveted post of Joint Commissioner and Licensing Authority merely a disinterested transfer in the interest of the service (be it at the behest of Pratap Wagh, M. P.), or was there something more behind it them meets the eye* ?

37. In bringing V. D. Deshmukh to Bombay despite the known background of V. D. Deshmukh and the inquiry and the findings of corruption against him by the Upa Lokayukta, did Dr. Hiray act bona fide ? The answers are to be found from the evidence of Dr. Hiray himself.

38. True to form, Dr. Hiray started by affecting that it was from the newspaper reports of the proceedings of this Commission that he came to know that an inquiry had been pending against V. D. Deshmukh before the Upa Lokayukta and that Dr. Hiray had given a hearing to V. D. Deshmukh. After some prodding he recollected that he had accepted the Upa Lokayukta's finding against V. D. Deshmukh and ultimately followed the Upa Lokayukta's orders pertaining to V. D. Deshmukh. Dr. Hiray remembered that N. D. Kulkarni and V. D. Deshmukh had been charged before the Upa Lokayukta for having accepted a briebe of Rs. 25,000 for hushing up some matter pertaining to Naval Medico Distributors, that the Upa Lokayukta had submitted a report to Government finding those two officers guilty and recommended to Government that a warning be given to them, that Government had informed the Upa Lokayukta that his findings were accepted by Government and Government had also issued a show cause notice to those two officers. Dr. Hiray also remembered that thereafter he, as Health Minister differed from the findings of the Upa Lokayukta, as a result under his directions his Under Secretary had discussions with the Upa Lokayukta that he, *i.e.* Dr. Hiray, did not accept his findings and directions regarding those officers. Dr. Hiray also remembered that the Upa Lokayukta did not agree with his views but suggested that some warning should be given to those two officers. Accordingly on 18th November 1981 Dr. Hiray made a noting that the action of V. D. Deshmukh and N. D. Kulkarni was not *mala fide* and that a warning should be issued to them. On 13th December 1981 Dr. Hiray made his endorsement regarding the transfer of V. D. Deshmukh from Pune to Bombay.

39. Thereafter Dr. Hiray attempted a face saving device by saying that at that time he did not know that V. D. Deshmukh whom he was transferring from Pune to Bombay was the same person who had been found guilty by the Upa Lokayukta because when Dr. Hiray passed his transfer order of V. D. Deshmukh, V. D. Deshmukh was not in front of him and Dr. Hiray was not aware of his initials. He was however aware that Deshmukh was an officer in the FDA and that when he made his endorsement on 13th December 1981 he was aware that the Upa Lokayukta had passed his order against two high-ranking FDA officers. But surprisingly enough Dr. Hiray did not try to find out whether the FDA officer, namely V. D. Deshmukh, referred to by Pratap Wagh in his recommendatory letter of 30th October 1981 was the same person as has been castigated and found guilty by the Upa Lokayukta. When Dr. Hiray made his noting of 13th December 1981, he did not remember that V. D. Deshmukh of Pratap Wagh's letter was the same V. D. Deshmukh who had been found guilty of corruption by the Upa Lokayukta, even though in the noting made by Dr. Hiray's secretial staff Deshmukh had been mentioned by name and initials as he was also in Pratap Wagh's letter. The excuse given by Dr. Hiray was that surnames are more easily remembered than intitials.

40. To put it most charitably, all this is too absurd for words, coming as is does from a person of undoubted intelligence as Dr. Hiray.

41. Dr. Hiray's version that even though when he made his noting of 18th November 1981 he knew that the two officers found guilty by the Upa Lokayukta were N. D. Kulkarni and V. D. Deshmukh, he might have forgotten this when he made his endorsement " may be done " on 13th December 1981 at the foot of Pratap Wagh's recommendatory letter, is too puerile for words. He could not say whether on 13th December 1981 when he made his noting for transferring V. D. Deshmukh to Bombay and promoting him as Licensing Authority, he had forgotten that he had noted on 18th November 1981 that V. D. Deshmukh had been found guilty of corruption by the Upa Lokayukta.

42. Dr. Hiray admitted that he was not dissatisfied with the findings of the Upa Lokayukta against N. D. Kulkarni and V. D. Deshmukh. Even so, he did not order a censure and written warning as directed by the Upa Lokayukta because a show cause notice had been issued to those officers who filed their written statements, which were placed before him as Health Minister. He might have given a hearing to them by way of natural justice and after going through their oral representations might have thought that certain facts might not have been brought by these two officers before the Upa Lokayukta, namely that they had acted under the pressure of two previous ministers. This is untrue, because the same defence had been taken by these 2 officers before the Upa Lokayukta. The other factor which according to Dr. Hiray weighted with him was that Naval Medico had shifted the licenced godown temporarily becuase the lofts and pillars had decayed and that they wanted to repair the godown. He remembered all this even though 6 years had since then elapsed. It is

surprising that Dr. Hiray's otherwise good memory should have failed him when it came to his remembering that V. D. Deshmukh whom he was bringing to Bombay in the prized and coveted post of Joint Commissioner and Licensing Authority was the same person who a few weeks earlier had been castigated and found guilty by the Upa Lokayukta.

43. Dr. Hiray agreed that his Secretary and the GAD Secretary had both accepted the Upa Lokayukta's findings *in toto* against these two officers. He admitted that before the show cause notices were issued on 22nd October 1980 he was aware of the findings of the Upa Lokayukta and the stand taken by his own Secretary and the Secretary of the GAD, namely that these findings should be accepted and that on 10th October 1981 when he made his endorsement in the file he was in agreement with his Secretary and the GAD Secretary that the findings and recommendations of the Upa Lokayukta be accepted and carried out *in toto*.

44. Dr. Hiray agreed that a part from his order dated 28th July 1981 there is nothing in the file to show that he had given a personal hearing to N. D. Kulkarni and V. D. Deshmukh on 15th July 1981 and that no minutes or record of such personal hearing are in existence. Dr. Hiray admitted that cogent reasons must be given if he differeed from the order under challenge in the case of a personal hearing. He admitted that he did not differ from the Upa Lokayukta insofar as his finding was concerned but he may have come across " certain things which are not on record " which may have led these two officers to conclude that the offence of Naval Medico was a technical offence. It is impossible to see how anyone, much less a minister holding cabinet rank, could relagate evasion of octroi duty to the category of a technical offence.

45. Dr. Hiray admitted that when he made his order dated 28th July 1981 he agreed with the findings of the Upa Lokayukta that these two officers were guilty of grossnegligence and carelesseness and that according to him the punishment should be a warning in writing to be reflected in the confidential reports. He admitted that that was precisely what the Upa Lokayukta had recommended. Even so, he differed from the Upa Lokayukta on the question of punishment. Dr. Hiray finally admitted that he did not consider Naval Medico's offence to be a technical offence and to that extent the report made by those two officers was wrong.

46. Dr. Hiray admitted that as senior officers of the FDA they should have known that under the Act there is no offence which can be classified as a technical offence, that as Health Minister he also should have known it and he did and that the report made by those two officers was bad due to gross negligence and carelaessness whatever may have been the other reasons or considerations for making it. He agreed that what the Upa Lokayukta had recommended was the minimal punishment possible under the Rule of Service.

47. Dr. Hiray agreed that the office of the Upa Lokayukta is an independent office with quasi judicial powers and that when Government differs from the Upa Lokayukta in any matter, Government should have strong and convincing reasons for doing so which must appear on the record. By " Government " Dr. Hiray went his department or the GAD.

48. Dr. Hiray admitted that he did not seek the views of the GAD on the order passed by him on 28th July 1981 even though in the case of those two officers, namely V. D. Deshmukh and N. D. Kulkarni, consent of the GAD had been taken before issuing a show cause notice against them. He admitted that the GAD also agreed to the Health Department taking action against those two officers as recommended by the Upa Lokayukta. He admitted that even though he differend from the Upa Lokayukta on the question of punishment, he did not bring it to the notice of the GAD for which unworthily he lay the blame on his staff.

49. The discussion of the above evidence indicates that Dr. Hiray, even thouth he was willing to accept the Upa Lokayukta's report *in toto* on 10th October 1980, he changed his mind on 28th July 1981. It is apparent that during this interregnum some thing happened whereby Dr. Hiray decided to spare V. D. Deshmukh " the harsh punishment ". There was no change of circumstance nor were the contentions of V. D. Deshmukh and N. D. Kulkarni different from what they had advanced before the Upa Lokayukta. The record does not show any apparent reason why Dr. Hiray should take this unusual or lenient view. The reason must therefore be one which Dr. Hiray could possibly not put on record. His subsequent conduct

in appointing V. D. Deshmukh to the coveted post of Licensing Authority at H. Q. in Bombay, must unequivocally point to extraneous considerations, particularly when this was contrary to the recommendation of the Commissioner and Dr. Hiray's secretarial staff. As minister Dr. Hiray must have known that the reputation of the FDA was at the lowest ebb when V. D. Deshmukh was holding charge as Commissioner and to improve which Venkatachalam was appointed. To that end, Venkatachalam transferred V. D. Deshmukh to Pune. Dr. Hiray brought him back to Bombay to the same post of Licensing Authority which according to V. D. Deshmukh is a coveted post and for which special efforts are required to be made, which V. D. Deshmukh did by asking Pratap Wagh, M. P. to put in a word with Dr. Hiray. From all this, the inference of extraneous considerations on the part of Dr. Hiray is irresistible and must so be drawn.

50. In view of the above, it is impossible to hold that the murky background of V. D. Deshmukh was not known to Dr. Hiray. Even so, he passed the order transferring V. D. Deshmukh to the prized and coveted post of Joint Commissioner and Licensing Authority in Bombay. As was his wont, Dr. Hiray tried to pass on the responsibility to his secretarial staff on the ground that they might have made some noting. However the worthy doctor's genius to that end failed him, when after going through the file, he had to admit that the notings made by his secretarial staff were after 13th December 1981 when he had passed his transfer order in the case of V. D. Deshmukh and by those notings they had merely carried out his own order passed on 13th December 1981.

51. It was futile for Dr. Hiray to attempt to explain away his noting " May be done " at the foot of Dr. Pratap Wagh's recommendatory letter dated 30th October 1981 by saying that what he intended thereby was that his secretarial staff should make enquiries about V. D. Deshmukh and the feasibility of the proposal to transfer him to Bombay. Dr. Hiray's noting " May be done " suggests nothing of the kind. It is a clear direction of what Dr. Hiray wanted to be done. This was yet another unworthy attempt on the part of Dr. Hiray to throw the blame on his secretarial staff.

52. Dr. Hiray admitted that his secretarial staff had got reports from the Commissioner on 15th and 22nd January 1982 and that far from either of these reports suggesting that V. D. Deshmukh be transferred from Pune to Bombay, were actually against V. D. Deshmukh's transfer from Pune to Bombay and that the secretarial noting of 15th January 1982 was that in the light of these two reports (sic) it was not possible to transfer V. D. Deshmukh and that Kulkarni should be transferred to Bombay (H.Q.). Dr. Hiray agreed that the secretarial staff wanted to bring Kulkarni and not Deshmukh and thereby his secretarial staff agreed with the proposal of Commissioner Bhirud. In the light thereof, it is cavlier for Dr. Hiray to say that he was not bound to agree with secretarial notings and that he was entitled to exercise his own discretion in transferring V. D. Deshmukh from Pune to Bombay.

53. It is true that a minister does have discretion but the discretion must be exercised judiciously and in the interest of the department and not arbitrarily and in the teeth of reports which otherwise are beyond challenge, or because they are inconvenient to countenance. Further, whenver discretion is exercised contrary to the secretarial notings, some brief reasons must be recorded, which Dr. Hiray did not do. Moreover, this was not a case of exercise of discretion judiciously but was one of discretion having tilted in favour of V. D. Deshmukh on account of extraneous considerations as discussed above.

54. Dr. Hiray admitted that prior to 19th January 1982 when he passed his order refusing Kulkarni's transfer to Bombay and ordering Deshmukh's transfer to Bombay, a copy of Pratap Wagh's letter dated 30th October 1981 had not been sent to the FDA for its comments nor had comments been otherwise called for from the FDA. The reason for this deliberate omission is not far to seek. Dr. Hiray wanted to pre-empt an unfavourable reaction from the FDA to bring V. D. Deshmukh to Bombay. Little wonder then that when Bhirud came to know of Dr. Hiray's order dated 19th January 1982 that Bhirud wrote a letter to Government on 22nd January, 1982 strongly protesting against Deshmukh's transfer to Bombay. However Dr. Hiray took no cognizance of Commissioner Bhirud's protest of 22nd January 1982 on the plea that the transfer order regarding Deshmukh had already been passed. *Mala fides* could not be more obvious.

55. Dr. Hiray agreed that the first noting made by his secretarial staff pertaining to Deshmukh's transfer to Bombay was of 15th January 1982 which referred to Commissioner Bhirud's proposal to appoint N. D. Kulkarni as Jt. Commissioner Bombay (H.Q.) and that this noting was made after Commissioner Bhirud's letter of 15th January 1982. He also admitted that in Bhirud's letter of 15th January 1982 after he had given his comments in respect of every officer, he had stated that N. D. Kulkarni should be brought to Bombay as Jt. Commissioner (H.Q.) Dr. Hiray also admitted that in Bhirud's letter dated 15th January 1982 he had given reasons why Deshmukh had to be transferred from Bombay to Pune and why he should not be brought back to Bombay and that Bhirud had expressed his doubts as to the fitness of V. D. Deshmukh being posted at Bombay.

56. Dr. Hiray admitted that as Commissioner, Bhirud would be the best person to evaluate the qualities, merits and demerits of his subordinates, that he had not read Bhirud's letter of 15th January 1982, that he had read the secretarial noting pertaining to V.D. Deshmukh and N. D. Kulkarni, that he might have gone through the secretarial noting pertaining to V. D. Deshmukh containing the reference to Bhirud's letter of 15th January 1982 and that he might also have gone through the secretarial noting pertaining to N. D. Kulkarni containing the reference to Bhirud's letter of 15th January 1982.

57. After a great deal of prevarication and after questions were repeated to him, Dr. Hiray finally admitted that when he passed his order on 19th January 1982 transferring Deshmukh to Bombay, he was aware that there was only one post of Licensing Authority in the whole of Maharashtra and that it was a key post and might also have been the most coveted post. He also admitted that he knew that the post of Jt. Commissioner and Licensing Authority carries more powers than the post of Jt. Commissioner simpliciter. So thus at last the real object and to attain it, the devious mind of the good doctor was revealed in its object contrast with his frigned ignorance of V. D. Deshmukh's background of the charge of curruption.

58. Dr. Hiray admitted that the retirement of V. D. Deshmukh was on 30th April 1984 and of N. D. Kulkarni just 9 months hence and that both could have asked for a posting of their choice prior to retirement. He also admitted that while V. D. Deshmukh's C. R. written by Venkatachalam was adverse, he did not find anything adverse against N. D. Kulkarni. Realising that he had blundered in giving his last answer, it suddenly struck Dr. Hiray that he did not remember.

59. While pretending that it was his duty to be just and fair both to V. D. Deshmukh and N. D. Kulkarni, Dr. Hiray admitted that in his order of 19th January, 1982 transferring Deshmukh to Bombay, there is not a word about the rival merits or demerits of V. D. Deshmukh and N. D. Kulkarni. According to Dr. Hiray, he did not know either V. D. Deshmukh or N. D. Kulkarni but was unable to say why in that event he did not rely upon the judgment of the Commissioner and his own secretarial staff. According to Dr. Hiray, despite the fact that Commissioner Bhirud had by his letter dated 15th January 1982 made adverse remarks against V. D. Deshmukh and though Bhirud by that letter and given other names for being brought to Bombay as Jt. Commissioner, Dr. Hiray did not heed Bhirud because V. D. Deshmukh was due for transfer and was due for retirement. He admitted that one of the names given by Bhirud in his letter of 15th January 1982 was that of P. S. Joshi whose date of appointment as Jt. Commissioner was the same as V. D. Deshmukh. According to Dr. Hiray, he did not know that P. S. Joshi had been out of Bombay for over 6 years from 1976 to 1982. He admitted that he did not consider all the 5 names suggested by Commissioner Bhirud in his letter of 15th January 1982 because those names were not in the noting made by his secretarial staff. He finally had to admit that it would have been better if he had made it a point to consider all the 5 names suggested by Commissioner Bhirud in his letter of 15th January 1982 as he, i.e. Dr. Hiray, was making an appointment to a key post. He admitted that this important decision was taken by him without applying his mind to all the facts of the case but he had taken into consideration that Deshmukh was due for transfer, that he was due for retirement and that the post was vacant in Bombay and possibly that the adverse remarks made by Venkatachalam or Bhirud were not convincing enough to him. All this is a myth as none of this is reflected in Dr. Hiray's transfer order of 19th January 1982. The reason is not far to seek. Somehow or other Dr. Hiray wanted V. D. Deshmukh in Bombay and the others far more deserving than V. D. Deshmukh had to be sacrificed.

60. Dr. Hiray further admitted that in passing his transfer order of 19th January 1982 he had made a mistake which he realises today in the light of the material shown to him. This is sheer sanctimony in the light of his own admission that the same material was available to him if only he had wanted to see it before passing his order and which he could have asked for, but did not. This indicates that even according to Dr. Hiray, his action could not have been justified on any proper or legitimate ground and would lead to an inference of corruption against him. This was therefore, a feeble attempt on his part to prevent such an inference being drawn.

61. Dr. Hiray was shown a letter dated 10th December 1981 from the Desk Officer, Mrs. M. R. Navalkar to N. D. Kulkarni. He agreed that his Desk Officer had called for remarks regarding Pratap Wagh's recommendatory letter dated 30th October 1981 from N. D. Kulkarni and not from Commissioner Bhirud. Dr. Hiray was unable to say why the head of the department, namely Commissioner Bhirud had not been sent a copy of Wagh's letter for his remarks. Dr. Hiray admitted that his Desk Officer should indeed have addressed this letter not to N. D. Kulkarni but to the head of the department, namely, Commissioner Bhirud. According to Dr. Hiray when he made his endorsement on 13th December 1981 on Pratap Wagh's letter he had not seen the Desk Officer's letter of 10th December 1981 addressed to N. D. Kulkarni. He agreed that the normal practice would have been to address such a letter to the head of the department, in this case Commissioner Bhirud. He was unable to say if the Desk Officer would on her own have followed the abnormal practice of sending such a letter to N. D. Kulkarni and not to the head of the department, namely Commissioner Bhirud and that it was unusual that this should have been done by the Desk Officer. However, Dr. Hiray affected his inability to say that this letter may have been sent by the Desk Officer to Kulkarni not on her own initiative but at the behest of someone else. Ultimately after a great deal of prevarication, he agreed that as it was not the job of the Desk Officer to have addressed the letter dated 10th December 1981 to N. D. Kulkarni, she must have done so not on her own initiative but at the behest of someone else. This is yet another unworthy attempt on the part of Dr. Hiray, this time to lay the blame on some poor innocent Desk Officer.

62. Dr. Hiray had to admit that it was surprising that a copy of Dr. Wagh's letter dated 30th October 1981 should not have been sent to Commissioner Bhirud even though he was the head of the department. This is an affectation which deludes no one.

63. The evidence of Dr. Hiray and the admissions made by him reveal that he had taken more than usual interest in ordering Deshmukh's transfer to Bombay to the key and coveted post of Jt. Commissioner and Licensing Authority. This unusual interest made itself manifest after Dr. Hiray had agreed with the findings and recommendations of the Upa Lokayukta against V. D. Deshmukh and the stand taken by his own secretarial staff. In normal circumstances, it is inconceivable that thereafter Dr. Hiray should suddenly have a change of heart towards V. D. Deshmukh and despite the opposition of his own secretarial staff should have over-ruled them and insisted on bringing V. D. Deshmukh to Bombay merely on the strength of his ministerial discretion, which was misused for ulterior ends. No opinion was sought from the person best qualified to give it, namely Commissioner Bhirud himself. Even after Bhirud strongly protested against V. D. Deshmukh being brought to Bombay, his protest was over ruled. No reference was made to the GAD who would have been qualified to give an opinion in the matter. Even though Kulkarni was to retire shortly, no such consideration prevailed in his favour, as it did in the case of V. D. Deshmukh.

64. It is childish for Dr. Hiray to attempt to escape culpability on the specious ground that he did not know that V. D. Deshmukh who he was transferring to Bombay was the same person who had been castigated and found guilty by the Upa Lokayukta for corruption.

65. No minister knowing Deshmukh's background and the findings of the Upa Lokayukta, as indeed did Dr. Hiray, could have appointed Deshmukh to the prized and coveted post of Jt. Commissioner and Licensing Authority, despite the adverse remarks in his C. R. by Commissioner Venkatachalam which Dr. Hiray went through.

66. Even though on 15th January 1982 Bhirud had proposed 5 names and had given rival merits and demerits of the Officers including V. D. Deshmukh and even though P. S. Joshi was the senior most in that list and was out of Bombay for six

years and hence entitled to be transferred to Bombay, in the eyes of Dr. Hiray the scales tipped heavily and mysteriously in favour of V. D. Deshmukh with a shady background and a corrupt past and to him was gifted the key and coveted post of Licensing Authority which was tentamount to a virtual promotion.

67. On Dr. Hiray's own admission, in order to differ from the Commissioner and his own secretarial staff, he was required to give cogent reasons after considering all aspects. Nothing of the kind was done by him either then or now, except to affect mistake or take shelter under ministerial discretion must be exercised judiciously and in favour of the department and not in favour of a person such as V. D. Deshmukh despite the Upa Lokayukta's recommendations and findings against him of corruption with which Dr. Hiray himself had initially agreed.

68. The inescapable and irresistible influence from all this is that the dilution of the action on the report of the Upa Lokayukta and the promotion of V. D. Deshmukh by Dr. Hiray to the prized and coveted post of Jt. Commissioner and Licensing Authority was not on merits, or in the interest of the department, but to unjustly confer favour on him for extraneous consideration. Dr. Hiray is guilty of misuse of ministerial office and corruption.

PART IV

69. Dr. Hiray also had a hand in the underserved appointment of V. C. Sane as full-fledge Commissioner despite his known bad record for inefficiency and corruption and the adverse report of the Anti-Corruption Bureau.

70. *Hereunder the sequence of events leading to this appointment.*

(*i*) Sane officiated twice as Commissioner once for 3 months in1970 and thereafter for 40 days in 1971.

(*ii*) Between October 1972 and May 1976, V. C. Sane was posted as Jt. Commissioner at Nagpur.

(*iii*) In 1976 he was transferred to Pune.

(*iv*) In 1978 Commissioner Venkatachalam from the I.P.S. was appointed Commissioner, FDA.

(*v*) In the middle of December 1978, Venkatachalam got Sane transferred to Bombay.

(*vi*) On 2nd October 1979 Venkatachalam was repatriated to his parent department and V. C. Sane was given additional charge as Commissioner which he held till 21st July 1981. At that time the Health Minister was Dr. (Mrs.) Pramila Tople.

(*vii*) On 21st July 1981, V. C. Sane was appointed full-fledged Commissioner By then Dr. Hiray had become the Health Minister.

(*viii*) On 31st October 1981, V. C. Sane retired.

71. Indisputably, V. C. Sane's track record was grim. His confidentials reveal that at best he was " an officer of average capabilities " and at worst right from 1969 was found unfit for promotion. Sane's confidentials make grim reading. On Sane's own admission his own assessment pertaining to his ability and competence was not accepted by the various Commissioners and Government. Indisputably, he had rightly been overlooked for promotion not less than three times. The only way of sunshine was the C. R. made by the man instrumental in getting Sane to Bombay—Commissioner Venkatachalam. On 11th May 1979 he wrote in Sane's C. R. for 1978-79 that he was hardworking, capable, ordial, intelligent, technically well-informed, having initiative and drive, fit for the present post, with no special aptitude and " may be tried in turn " for promotion; " a mature officer who knows his job fairly well". Commissioner Venkatachalam's euphoria over Sane was shattered when he realised that his import from Pune was far from desirable and that in Venkatachalam's words, he had committed the biggest blunder of his life in getting Sane to Bombay. On 23rd May 1980 the Special Secretary, Public Health Department made an endorsement that V. C. Sane is a very competent officer. There is also on record a letter dated 16th July 1981 [part of Ex. 464 (colly.)] from the Dy. Secretary of Government to the Secretary to Government, where in it is stated that Sane's record is such that he cannot be considered to be either absolutely suitable or unsuitable for promotion as Commissioner and that he does not come out as an acceptable

Ex. 464 (colly.)

choice, but because he had been holding additional charge of the post of Commissioner and is the seniormost among the Jt. Commissioners and is due for superannuation on 31st October 1981, the Board recommended that he may be appointed to officiate as Commissioner until his supperannuation or until such time as a candidate was selected by the Maharashtra Public Service Commission. The letter continued that before orders were issued regarding Sane, the papers shoud be shown to the C. M.'s Secretary as the question of appointment of some other officer as FDA Commissioner, was under consideration in the C. M.'s secretariat.

72. In an anonymous complaint dated 26th April 1980 several instances of corruption were levelled against V. C. Sane. This anonymous complaint was taken on record and marked X-8 for identification not for the correctness of its contents but to the limited extent that a complaint had been received. One instance was that no action had been taken by Sane against Tolia of Atul Pharmaceuticals. He is the same Tolia referred to earlier. I refer to this instance because it has been referred to in the Report made by the A. C. B. after investigation into this complaint. This Report does not bear a date but a copy which A. C. B. sent to the Secretary to
Ex. 466 Government, Public Health Department, was marked as Ex. 466. In this Report it was stated *inter alia* that while the allegation that no action was taken by V. C. Sane against Tolia of M/s. Atul Pharmaceuticals, was not unfounded, it was not possiblee to find out the exact part, if any, actually played by V. C. Sane as the relevant papers were not traceable in the office of the FDA. The Report concluded that the Commissioner be directed even at this late stage to take action against Tolia's Atul Pharmaceuticals and to launch a prosecution under section 27 of the Drugs and Cosmetics Act against Tolia, and that the Commissioner should further be directed to fix the responsibility for the loss of papers from his office and take action against the officials concerned.

73. It is not difficult to come to the irresistible conclusion that the only person vitally interested in the " loss " of these papers was the persons who would be most adversely affected if they fell into the hands of the A.C.B.—that person could be none other than V. C. Sane himself.

74. By a letter dated 26th June 1981 addressed by one Pankaj Zaveri of Beacon
Ex. 464 Pharmaceuticals (Ex. 464), a specific complaint was made to the Commissioner that Sane was demanding a bribe of Rs. 50,000 through Tolia for not taking action against Beacon Pharmaceuticals. This also finds place in para 9 of the A.C.B. Report (which erroneously mentions the date of the letter as 11th June 1981), wherein it is stated that the A.C.B. had written to the Secretary, Home Department soliciting Government's instructions whether inquiry should be made into this complaint but no advice had been received by the A.C.B. and that as V. C. Sane had retired in October 1981 " it is presumed that no further action in this behalf is considered necessary".

75. In Beacon's letter dated 26th June 1981 (Ex. 464) one of the allegations against Sane was that he was in the habit of luring parties into making admissions of guilt by extending false promises that no action would be taken against them.

76. Sane admitted that Beacon's letter dated 26th June 1981 to the Commissioner was forwarded to Sane in his official capacity in token whereof he put his initials after reading it. Sane however did not react to this letter even though on his own admission he did realise that Beacon was alleging fraud and deceit against him and had also sent a copy of this letter to Government. The excuse given by Sane was that Beacon's allegation were baseless, incorrect and frivolous and Beacon was in the habit of writing such letters. Surely then greater the reason why Sane should have made such a nothing on the letter which was forwarded to him in his official capacity. Sane cannot get away with it merely by saying that he does not remember why he did not do so. The inference is loud and clear. A guilty conscience.

77. Yet despite this murky background, rotten C. Rs. and a known reputation for corruption, Dr. Hiray still appointed Sane full-fleged Commissioner. The key to this riddle is best found in the evidence of Dr. Hiray himself. Dr. Hiray admitted—

" Sane was indeed confirmed as Commissioner on 21st July 1981. Before that I must have gone through his confidentials. I would not have agreed to or recommended his confirmation if I had found anything against him in his confidential records."

Hence, Government advocate Mr. Tulpule cannot be heard to say as he did at the conclusion of the submissions of Mr. N. A. Shah, Counsel assisting the Commission, that Sane's appointment was made through the Establishment Board and not by Dr. Hiray. The subtlety of this distinction sought to be made by Mr. Tulpule is nullified by the fact that the Establishment Board does not make appointments but merely confirms the recommendations made to it.

78. Dr. Hiray admitted that Sane's confirmation to the post of Commissioner was held up for 21 months though normally a person holding charge as commissioner is confirmed to that post, if there is nothing against him. After some hedging Dr. Hiray admitted that there might have been something against V. C. Sane which prevented Government from recommending his name to the Public Service Commission for confirmation to the post of Commissioner and that it was possible that as Health Minister he would have known the reasons why Sane's name was not suggested to the Public Service Commission for confirmation for 21 months.

79. At first Dr. Hiray affected not even to remember if he had gone through Sane's confidential records. He thereafter admitted that he might have gone through Sane's confidential records before he was confirmed as Commissioner and admitted that as Health Minister it was his duty to know everying about an officer, who was about to be promoted or confirmed. After a great deal of verbal jugglery preceding and succeeding Dr. Hiray stated that before Sane was confirmed on 21st July 1981 he must have gone through his confidentials and admitted that his attention might have been drawn to Sane's confidential records at the time of Dy. Secretary writing his letter dated 16th July 1981.

80. When he was shown the departmental notes pertaining to Sane's promotion Dr. Hiray agreed that there were charges of corruption against V. C. Sane, but said he saw the departmental notes for the first time in his evidence. When he was shown the Dy. Secretary's letter dated 16th July 1981 (Ex. 463), Dr. Hiray stated that apparently this letter was not brought to his notice, and despite his earlier admission that Sane was confirmed as Commissioner on 21st July 1981, he had the temerity to say that Sane was apparently appointed Commissioner without his (*i.e.* Dr. Hiray's) knowledge. Dr. Hiray even went to the length of saying that while he was Health, Minister, he did not even know that Sane had been confirmed as Commissioner, because nobody told him about it, that Sane's confirmation as Commissioner was without the knowledge and consent of Dr. Hiray, that no papers pertaining to Sane's confirmation was ever shown to him and that it was only while giving evidence in Court that Dr. Hiray came to know for the first time that Sane had been confirmed as Commissioner, which came to him as a surprise. According to Dr. Hiray though the proposal to confirm Sane as Commissioner emanated from his Health Ministry, it did not emanate with his knowledge and consent. Ex. 463

81. I am constrained to observe that all these statements, like several others, made by Dr. Hiray are deliberately false, as he could not even remotely justify his actions.

82. That a person of undoubted intelligence as Dr. Hiray should make these false statements can only be described as an exercise at desperation in washing his hands off Sane.

83. On whom can Dr. Hiray pass on the blame, as was his wont but to his guiltless secretarial staff ? Even in that cowardice he must once again fail for even in Sane's case he was unable to give any reason why his secretarial staff should suppress vital information from him, which on his own admission it had never done before. Dr. Hiray cannot thus distance himself away from Sane and the attempt to blame his secretarial staff is as unworthy as his ignorance of Sane's confirmation to the post as Commissioner.

84. Whenever Dr. Hiray found himself cornered, he blightly and without batting an eye-lid passed on the blame to his secretarial staff in a desperate attempt to save himself at the cost of his guildless secretarial staff.

85. It is abundantly clear that Dr. Hiray knew everything about Sane, and knowing so still confirmed him as Commissioner. The evil genius was Dr. Hiray and not his secretarial staff on whom Dr. Hiray now unjustfy and unworthily passes on the blame.

86. Sane was not a friend or relation of Dr. Hiray. There was no reason why Dr. Hiray should have gone all out of his way to have the FDA and an unwary public foisted with an incompetent and corrupt officer like V. C. Sane unless there was some motive behind it. The only irresistible inference that can be drawn in these circumstances, is that Dr. Hiray was motivated to confirm Sane in the post of Commissioner not on merit, not in the interest of the department, not for the public weal but for extraneous considerations and to have a pliable Commissioner to do his bidding, as in fact Sane did while submitting a favourable report for withdrawal of the prosecution of Tolia.

87. In all this Dr. Hiray misused his ministerial office, power and position for extraneous considerations.

PART V

88. The evidence of the FDA witnesses who preceded Dr. Hiray as also a perusal of Government files indicated that Dr. Hiray was guilty of certain acts of ministerial interference as also certain actions which were contrary to the provisions of the Drugs and Cosmetics Act which had adversely affected the working of the FDA. As a former Health Minister-in-charge of FDA, Dr. Hiray would have been an automatic witness for investigation of the questions referred to this Commission.

89. Further, the Commission was in possession of certain information of Dr. Hiray's involvement in withdrawal of Tolia's prosecution by the FDA as also in bailing out Jt. Commissioner V. D. Deshmukh and Assistant Commissioner N. D. Kulkarni of FDA from the recommendations of the Upa-Lokayukta regarding action to be taken against them.

90. The Commission was also in possession of information that while Dr. Hiray was Health Minister, he got a resolution passed on 25th July 1981 authorising him to collect funds for the Bhausaheb Hiray Smaranika Samiti Trust whereof he was the President and that thereafter Dr. Hiray had collected funds misusing his ministerial position.

91. In order to verify this information, I ordered production of the Minute Book and other documents of the Trust. I did find such a resolution in the Minutes of the meeting held on 25h July 1981 at page 26 of the Minute Book. From the very look at the Minute Book it was obvious that it had been tampered with. From the Minute Book I also found that the Trust had also obtained a plot of land from Government of Maharashtra at a concessional rate while Dr. Hiray was Health Minister and President of the Trust. I also found from the records seized that the Trust had no funds and it was decided to collect funds in order to pay the purchase price to Government and to put up a construction on the land.

92. I was *prima facie* satisfied that except Dr. Hiray no other trustee had any influence to collect funds required by the Trust.

93. I therefore decided to verify whether Dr. Hiray had misused his position to collect such funds, particularly when from the information which the Commission had, it was suggested that Dr. Hiray did collect funds from pharmaceutical concerns with the help of FDA and from other parties through the concerned departments on which they were dependent.

94. If established, this would indicate a course of conduct on the part of Dr. Hiray of misuse of ministerial power and authority.

95. Evidence reveals that Dr. Hiray had floated 2 Trusts and was closely associated with them. Prior to 1976 he had floated the Bhausaheb Hiray Memorial Trust. In 1976 he floated the Bhausaheb Hiray Smaranika Samiti Trust with himself, naturally, as the founder President. According to Dr. Hiray, he held that post till May 1981 when he asserts he resigned and severed all his connections with that Trust (referred to hereafter as " the Trust " or " the Samiti Trust "). The trustees of the Samiti Trust were Dr. Hiray's nominees, comprising his relatives or persons of his confidence. The main source of funds of the Samiti Trust was by way of collecting donations in cash or by advertisements. In August 1981 the Trust acquired a plot of land admeasuring 1927 sq. mts. at Bandra on payment of Rs. 3,09,268·75 P. The object was to construct a hostel for students. A structure is partly constructed on that land. The Trust collected a vast amount aggregating

to Rs. 40-50 lacs, including a sum of Rs. 5 lacs from Mahendra and Mahendra. 42 donors belonged to the category of distillers and/or holders of vendor licences and 86 donors were hoteliers having licences for running beer bars. A combined list of these 42 and 86 donors is at Ex. 516. 13 Pharmaceutical concerns also gave donations for advertisements. They are set out in Ex. 517. Ex. 516 Ex. 517

96. Dr. Baliram Hiray was issued a witness summons by this Commission. On 12th March 1987 Dr. Hiray appeared through his learned Advocate Mr. Parshurami and made a statement before me that since May 1981 he has not been in management or a Trustee or even a member of the Samiti Trust or the Memorial Trust and has since then ceased to have any connection whatsoever with either of the two Trusts. Thereupon on 12th March 1987 I directed Dr. Hiray to make an affidavit in those terms and also to give certain other particulars.

97. On 13th March 1987 Dr. Hiray made an affidavit which however did not conform to the requirement of my order of the previous day. I therefore directed Dr. Hiray to make a fresh affidavit in consonance with my earlier order. Dr. Hiray filed a fresh affidavit on 14th March 1987. The substance of this affidavit is that Dr. Hiray had severed all his connections with the Trusts since May 1981. Ex. 465 Ex. 465(A)

98. The evidence on record discloses that with a view to create false evidence that he had resigned from the Samiti Trust with effect from May 1981, false and fabricated minutes were prepared and false information was given to the Charity Commissioner even though Dr. Hiray continued to function as the President of the Trust till October 1981.

99. Even a bare superficial glance at this Minute Book (Ex. 521) shows that it has been tampered with inasmuch as *inter alia* pages 18 onwards have been torn and removed. Pages 16 to 17 constitute minutes of the meeting of 2nd March 1981, and so did page 18 which was removed. Page 17 had to be retained because on 23rd October 1981 the Assistant Charity Commissioner, Maharashtra, had inspected this Minute Book and had appended his signature at the foot of page 17 in token thereof. This was presumably to indicate that minutes were written till page 17 only. Ex. 521

100. The material witnesses in this connection were G. N. Patil, the Founder Secretary of the Trust and Dr. Baliram Hiray. In order to show that minutes written in the Minute Book were torn, they were confronted with xerox copies of the torn pages. The xerox copies of the original minutes show that they are signed *inter alia* by G. N. Patil and Dr. Hiray. G. N. Patil initially disputed, thereafter reluctantly admitted, and thereafter disputed his signatures on the ground that he has no faith in xerox copies. The matter was therefore referred to the handwriting expert Mr. H. T. Gajjar for his opinion. In view of his evidence and report (Ex. 534), I am satisfied that the signatures on the xerox copies of the original minutes are indeed of G. N. Patil. Dr. Hiray admitted his signatures on the xerox copies of the original minutes. Ex. 534

101. In these circumstances there can be no doubt that the xerox copies (Exs. 522, 523 and 524) are the original minutes which had been written in the Minute Book before they were torn. There is also internal evidence in the xerox copies to show that no meeting could have taken place or did take place on 12th May 1981. I am also convinced that pages 18 and onwards in the Minute Book are re-written after 23rd October 1981 for the purpose stated hereinafter. The above findings draw support from the facts appearing hereafter.

102. Indisputably the minutes of the first 13 meetings are not tampered with. The xerox copies (Ex. 527) of the minutes of these first 13 meetings accord with pages 1 to 16 of the Minute Book. Ex. 527

103. Dr. Hiray admittedly attended these 13 meetings and also the 14th meeting held on 2nd March 1981. He admitted his signature in the minutes of the 14th meeting. Even the Trust's founder-Secretary G. N. Patil unhesitatingly admitted Dr. Hiray's signatures in the minutes of these first 14 meetings. The dispute regarding the 14th meeting is confined only to page 18 of the Minute Book which has been signed at the foot both by Dr. Hiray and G. N. Patil.

104. Xerox copies of the minutes of the 14th meeting held on 2nd March 1981 are at Ex. 522 and indicate what appeared in the original page 18 before it was removed from the Minute Book. Ex. 522

105. In the Minute Book the paging till page 16 appears at the top in blue ink. The reverse side of the pages bears no page numbers. There is no page 17 but the next page after page 16 is page 18 and from page 18 ownwards both sides of the pages are numbered till page 36. Thereafter the pages are not numbered though the minutes are written.

106. At pages *19 to 21* there are minutes of the *15th* meeting allegedly held on 12th May 1981 when in fact no such meeting took place for the reasons stated hereafter.

107. At pages *22 to 27* there are minutes of a meeting which is also numbered *15*.
Ex. 521 Such a meeting did take place but its proceedings are not as written in the Minute
Ex. 523 Book (Ex. 521) but as are shown in the xerox copy of the genuine minutes (Ex. 523).

108. Page *18 to 31* of the Minute Book contain minutes of the 16th meeting held on 19th October 1981. This meeting also took place but the minutes as appearing in the Minute Book are not the genuine minutes. Xerox copies of the genuine
Ex. 524 minutes are at Ex. 524.

109. The Minute Book has been tampered with to show that Dr. Hiray resigned as President and trustee of the Samiti Trust from 1st March 1981, whereas the genuine minutes show that he resigned from 19th October 1981. The purpose of this exercise is to falsely show that Dr. Hiray's resignation was effective from 1st March 1981. Xerox copy of the agenda dated 16th October 1981 of the meeting to be held on 19th
Ex. 525 October 1981 is at Ex. 525. It relates to the consideration of letter of resignation of the President and Trustee Dr. Hiray. This indicates that this was the first meeting ever called to consider Dr. Hiray's letter of resignation and that it was not considered at any time earlier.

110. Dr. Hiray's first alleged request for resignation was an oral one on 2nd March 1981, purportedly recorded at page 18 of the Minute Book and which page has been wholly re-written. Thereafter he is said to have addressed two written requests to that end on 1st May 1981 and thereafter on 14th October 1981. According to Dr. Hiray his written request was accepted at the meeting of 12th May 1981 (which meeting, as found by me earlier was never held and the minutes thereof are bogus), but he was authorised to nominate a new President and was asked to look after the affairs of the Trust until the new President was elected. Dr. Hiray recommended as President one Shankar Ananda Sawant. The son-in-law of Dr. Hiray's sister and he was appointed President on 19th October 1981.

111. On 12th March 1987, Dr. Hiray made a statement before me through his learned Advocate Mr. Parshurami (which was recorded by me) that since May 1981 Dr. Hiray has not been in management or a trustee or a member of both Trusts and has since then ceased to have any connection wih the Trusts. This statement did not appear to be correct in view of the information in possession of the Commission. I therefore directed Dr. Hiray to make a detailed affidavit in terms of my order dated 12th March 1987. Dr. Hiray filed an affidavit on 13th March 1987
Ex. 465 (Ex. 465). This affidavit did not conform with my order dated 12th March 1987. Hence I directed Dr. Hiray to make a fresh affidavit which he did and filed on 14th
Ex. 465-A March 1987 (Ex. 465-A). The substance of the oral statement and the two affidavits is that from and after May 1981, Dr. Hiray had no connection whatsoever with either of the 2 Trusts. In the light of the facts found by me, Dr. Hiray's oral statement and affidavits on oath were deliberately false.

112. The discussion which follows will establish in abundant measure that both Dr. Hiray and G. N. Patil are responsible for tearing out the pages from the Minute Book and fabricating new minutes in the place of the genuine ones.

113. To start with the founder-Secretary of the Trust, G. N.Patil admitted that he sought the advice and guidance of Dr. Hiray because the other trustees " are the people of Dr. Hiray himself " and that Dr. Hiray is the controlling factor of the Trust and nothing can be done without his concurrence.

114. The genuine Resolution No. 41 passed on 2nd March 1981 and written at
Ex. 522 page 18 of the genuine minutes (Ex. 522) pertained to starting a college at Igatpuri. This was torn off from the Minute Book. Minutes were re-written on what is now numbered as page 18 which does not show that any such resolution for starting a college was passed, but shows a statement altogether deleted and allegedly made by Dr. Hiray expressing his desire to be relieved from the Trust.

115. Pages 16 and 17 of the Minute Book tally with the xerox copies at Ex. 522. Ex. 522
Pages 18 onwards of the Minute Book are written in a different ink. Xerox copy of page 18 shows the same handwriting as in pages 16 and 17. Looking to the obvious tear mark in the Minute Book, it can be safely concluded that pages 18 onwards have been removed. This is also indicated in the difference in ink from pages 18 onwards and doing away with the earlier system of numbering the pages on one side only.

116. In the Minute Book at page 19 are to be found minutes of 12th May 1981 purporting to be meeting No 15. This meeting never took place, but was shown to have been held in order to demonstrate that Dr. Hiray had sent in his resignation letter on 1st May 1981. There is documentary evidence which shows that no such meeting was held. To start with, the meeting is significantly numbered as 15. The next meeting which was admittedly held was on 25th July 1981 and is also numbered 15. Xerox copy of the minutes of the meeting of 25th July 1981 which is at Ex. 523 Ex. 523
and thereby suggests that after 2nd March 1981, the next meeting which was held was only on 25th July 1981.

117. There is another significant aspect, because the 2nd page of this xerox Ex. 523
copy Ex. 523 is numbered as page 19. The last page of the minutes of the meeting of 2nd March 1981 was 18 which ended on the right-hand side of the Minute Book. The minutes of the meeting of 25th July 1981 were commenced from the left-hand side of the Minute Book, namely on the reverse of page 18. Hence the next page of these minutes would be page 19. Therefore it is clear that this Book contained minutes of the meeting of 25th July 1981 as meeting No. 15 after meeting No. 14 of 2nd March 1981 and that no meeting of 12th May 1981 was ever held.

118. There is an additional supporting factor. In the genuine minutes of the meeting of 25th July 1981 (Ex. 523), the accounts are approved till 24th July 1981, Ex. 523
whereas the bogus minutes of 12th May 1981 purport to show that accounts are approved till 11th May 1981. Needless to say, if accounts were approved till 11th May 1981, it would be inconceivable that they would again be approved till 24th July 1981.

119. No agenda of the bogus meeting of 12th May 1981 was produced on the ground that agendas were not preserved. This meeting was called mainly to consider Dr. Hiray's letter of resignation dated 1st May 1981.

120. The additional ground to suppo[rt] my finding that no such meeting could have been called on 12th May 1981 is to be found in the agenda dated 16th October 1981 (Ex. 525), in pursuance of which a meeting was held on 19th October 1981. Ex. 525
Since neither Dr. Hiray nor G. N. Patil were willing to produce copies of agenda of any of the meetings, they were confronted with copy of the agenda dated 16th October 1981 (Ex. 525), which unequivocally indicates that a meeting was being called for Ex. 525
the first time to consider Dr. Hiray's resignation.

121. The minutes of 12th May 1981 purport to show that Dr. Hiray's resignation was accepted. But on Dr. Hiray's own showing he continued to act as President and Trustee even after 12th May 1981 and sent in his letter of resignation dated 14th October 1981. This is yet another indication that the minutes of 12th May 1981 are bogus.

122. Xerox copies of the minutes dated 25th July 1981 and 19th October 1981 show that Dr. Hiray attended the meetings and signed the minutes in token of his attendance, and that in both these minutes it is recorded that the President of the Trust Dr. Hiray presided. These facts bring to the forefront that the minutes of the bogus meeting of 12th May 1981 have been significantly not signed by Dr. Hiray and have been created in order to show that Dr. Hiray's alleged oral request made on 2nd March 1981 was followed by his letter of resignation dated 1st May 1981.

423. Indisputably a meeting was held on 25th July 1981. Xerox copy (Ex. 523) Ex. 523
of the minutes of this meeting consists only of two pages, i.e. on the reverse of page 18 as originally numbered and torn off and the front side of page 19. However the fabricated minutes consist of 6 pages, i.e. pages 22 to 27 as now numbered in the Minute Book. The genuine minutes of this meeting show that 7 trustees were present whereas the fabricated minutes disclose only the presence of 6 trustees, excluding Dr. Hiray.

Ex. 523 124. In the genuine minutes (Ex. 523) Dr. Hiray has signed at Serial No. 1 and Shankar Ananda Sawant at Serial No. 7. Whereas in the fabricated minutes the name of Dr. Hiray and his signature are not to be found and the signature of G. N. Patil appears at Serial No. 1 and though Serial No. 7 is mentioned, there is no name or signature.

125. In the genuine minutes it is stated that the President of the Trust Dr. Hiray presided. But in the fabricated minutes it is stated that because the President of the Trust Dr. Hiray could not remain present, H. M. Tisge presided.

126. If on 12th May 1981 Dr. Hiray had indeed resigned as President and Trustee, it is inconceivable that he could have been described as the President of the Trust in the fabricated minutes of 25th July 1981. This is indicative of the fact that on 12th May 1981. Dr. Hiray never resigned.

127. The genuine minutes show that minutes of 2nd March 1981 were confirmed in this meeting of 25th July 1981. A Resolution was passed approving whatever had transpired and also the accounts for the period 2nd March 1981 till 24th July 1981 were passed. A further Resolution was passed giving approval to the position of the assets and properties of the Trust till 24th July 1981.

128. However the fabricated minutes purport to approve the minutes of the bogus meeting of 12th May 1981, and also the affairs and accounts till 24th July 1981. The distinction between the genuine and bogus meeting on this aspect is that the commencing date viz. 2nd March 1981 in the bogus minutes is missing.

129. What is written in pages 23 to 27 of the Minute Book is not be found in the xerox copies of the minutes. Pages 23 to 27 of the fabricated minutes inter alia refer to the amalgamation of the two Trusts, the decision to open a Bank account in Bombay in the Bank of Maharashtra, Mantralaya Branch, and the persons authorised to do so G. N. Patil and R. M. Shewale.

130. However the Bank card requesting for opening the account was signed by Dr. Hiray and on the reverse appears his specimen signature as President. This account was opened on 1st September 1981. The Resolution sent with this account opening form and the letter dated 1st September 1981 of the Bank of Maharashtra, Malegaon Branch, to its Mantralaya Branch, Bombay is alleged to have been passed on 23rd July 1981. No such Resolution was ever passed as no such meeting was held on 23rd July 1981. Hence the Resolution sent to the Bank of Maharashtra, Mantralaya Branch, Bombay is a fabricated one.

131. The fabricated minutes of the meeting of 25th July 1981 contain a Resolution to the effect that the Trust is about to get possession of land in Bombay, that the Trust has no funds, that it has obtained exemption under Section 80(G) of the Income Tax Act, that funds should be collected and that all rights and authority to make collections are given to the President Dr. Hiray and Secretary of G. N. Patil. Significantly enough, in the minutes of the meeting of 25th July 1981. Dr. Hiray has been referred as the President of the Trust even though he allegedly resigned and his resignation was accepted in the meeting of 12th May 1981.

132. In the fabricated minutes of 25th July 1981. there is a statement that Tisge, who presided, had received a telephone call from Dr. Hiray who regretted his inability to attend that meeting, that a new President be elected and that Dr. Hiray should be relieved of Presidentship as early as possible. Tisge also proposed that the decision of Dr. Hiray as to who should be President, be acceptable. This is an additional circumstance that Dr. Hiray continued as President till that day, his protestations to the contrary notwithstanding.

133. The ostensible reason for his resignation as given by Dr. Hiray in his resignation letter dated 1st May 1981 was ill-health and ministerial work. Patently this was not a genuine reason. There is Patil's evidence that not more than

4 meetings of the Trust were held in a year. Beyond attending these meetings there was no other work which Dr. Hiray, as President, was required to do, as all the day to day work was done by G. N. Patil, a person of Dr. Hiray's confidence and who was the full-time Secretary of the Trust in whose house the office of the Trust was situate. Hence beyond signing cheques and collecting funds. the President was virtually required to do nothing.

134. In the meeting of 25th July 1981, Dr. Hiray was authorised to collect funds according to fabricated minutes in the minute book (Ex. 521). At this time the Trust was about to obtain possession of the land at Bandra as recorded in the minutes. Funds were to be collected mainly from Bombay, hence the bank account was to be opened in the Mantralaya Branch of the Maharashtra Co-operative Bank. All this is to be found in the minutes of 25th July 1981 in the minute book. Ex. 521

135. The question which may be asked is : *Why was this subterfuge of resignation resorted to by Dr. Baliram Hiray* ?

136. It is on record that Rs. 40-45 lacs were collected by way of donations and advertisements. It needs no emphasis that such a large amount could never have been collected, but on the strength of Dr. Hiray's name, ministerial position and influence. The Trust had already applied to Government for the Bandra land and possession of the land was obtained in August 1981, and the purchase price of Rs. 3,09,268·75 p. for 1927 sq. meters was paid after August 1981. If therefore Dr. Hiray continued to officially associate himself with the Trust, eye brows would have been raised, and the manner in which the collections were made on the strength of his name and position in office would come in for criticism. Hence it was in Dr. Hiray's political interest to officially disassociate himself from the Trust, lest he be justifiably accused of having misused his ministerial influence in obtaining this prime land form Government at a throw away price or collecting donations on the strength of his ministerial power, position and authority.

137. Thus came into being the anxiety to relate back the purported resignation to May 1981 in an endeavor to show that even before the Bandra land was given to the Trust in August 1981, Dr. Hiray had ostensibly severd his connections with the Trust.

138. The minutes of the meeting of 25th July 1981 in the minute book show that the Trust had no money to pay for the land, much less for the structure thereon. Hence evidence was created to show that Dr. Hiray was not present in any meeting on and after 12th May 1981. All this was a stratagem on the part of Dr. Hiray that no finger should be pointed at him as having misused his ministerial position and authority.

139. Coming to the meeting of 19th October 1981, the genuine minutes are at Exhibit 524. They show that 7 trustees had attended this meeting, that Dr. Hiray's name is at Serial No. 1, that he has signed the minutes, that Shevale signed at Serial No. 5 and that Dr. Hiray presided at the meeting. Ex. 524

140. On the other hand, in the fabricated minutes of 19th October 1981 in the minute book (Ex. 521), only 5 trustees are shown to have attended that meeting. The names and signatures of Dr. Hiray and Shevale are conspicuous by their absence, and at Serial No. 1 the name and signature of G. N. Patil appear. In these fabricated minutes, it is stated that the President of the Trust Dr. Hiray is not present, hence Tisge presided. Ex. 521

141. The genuine minutes give the impression that Dr. Hiray tendered his resignation on 14th October 1981 and that it is was accepted. Whereas the fabricated minutes in the minute book show that he had orally tendered his resignation on 2nd March 1981 followed by a written resignation on 1st May 1981, which was accepted in the meeting of 12th May 1981. It is however stated that even though Dr. Hiray was relieved as the President, he was requested to look after the important matters of the Trust and the Trust appreciated Dr. Hiray doing so still the date of the meeting of 19th October 1981. It is further stated that by his letter dated 14th October 1981 Dr. Hiray again expressed his inability to continue and therefore his resignation as a trustee was also accepted.

Ex. 524 142. In the genuine minutes (Ex. 524), a resolution was passed accepting Dr. Hiray's resignation as President, but in the fabricated minutes in the minute Ex. 521 book (Ex. 521) it is shown as if he resigned as President in the meeting of 12th May 1981.

143. The genuine minutes contain a resolution authorising withdrawal of amounts from the accounts in the Bank of Maharashtra (Malegaon and Mantralaya Branches) but the fabricated minutes contain a resolution authorising Shankar Ananda Sawant and G. N. Patil to operate these accounts and sign the signature cards.

Exs. 522-524 144. It is established that the xerox copies (Exs. 522-524) are the genuine minutes. The admitted position is that in respect of the first 13 meetings, the xerox copies Ex. 527(colly.) (Ex. 527 colly.) exactly tally with the minutes appearing in the minute book (Ex. 521). In the xerox copies, signatures were admitted by Dr. Hiray and ultimately even by G. N. Patil despite his protestation in having no faith in xerox copies which led the Commission to examine the handwriting expert Mr. Gajjar, who opined that the signatures on the xerox copies are indeed those of G. N. Patil. Further, as far as the first meeting of 2nd March 1981 is concerned, pages 16 and 17 tally exactly with the minutes. There is an agenda (Ex. 525) dated 16th October 1981 of the meeting of 19th October 1981. This agenda does not refer to any earlier resignation alleged to have been given by Dr. Hiray. It merely says, " to consider resignation of Dr. Hiray". That agenda is reproduced verbatim in the xerox copy of the minutes of 19th October 1981. These are clear-cut and unmistakable indications that the xerox copies are indeed the genuine minutes.

145. The question that next arises is : *Who has fabricated the minutes of 2nd March 1981 (last page), 12th May 1981, 25th July 1981 and 19th October 1981 and who had the motive for doing so?*

146. The evidence discloses that till 1981 the minutes were in the handwriting of one Satbhai, an employee of the Trust, on whom fell the duty of writing out the minutes because of his good hand-writing. Since December 1981 Satbhai ceased to be in the employment of the Trust. According to G. N. Patil the minute book was tempered with by Satbhai by tearing off certain pages. According to Patil the minutes which were removed were re-written by Satbhai from the rough minutes which were in Patil's possession. It is the admitted position that the minute book and other records of the Trust throughout remained in possession of G. N. Patil.

147. Many discrepancies can be found in Patil's attempt to throw the blame on Satbhai for tempering with the minute book. According to Patil after the Lok-ayukta served Dr. Hiray with a copy of Nihal Ahmed's complaint, he saw the minute book and found that it was tampered with. Patil fixes the time of this knowedge in 1982, 1983 or 1984.

148. It is curious that despite the admitted position that the minute book remained throughout in Patil's possession and was thereafter signed by the trustees from time to time, nobody including G. N. Patil should have noticed that the minute book had been tampered with right until 23rd September 1982, when according to Patil, Dr. Hiray drew his attention to it as a sequel to the complaint filed against Dr. Hiray by one Nihal Ahmed on 23rd September 1982 before the Lokayukta. The allegation in that complaint *inter alia* was that Dr. Hiray had manipulated the Trust minutes in order to show that while he was a minister he was not connected with the Trust.

149. It is also not without its own significance that thought the complaint filed by Nihal Ahmed with the Lokayukta was on 23rd September 1982, Dr. Hiray did not controvert the allegations in the complaint but merely went on asking for time to file his reply. In February 1985 Dr. Hiray ceased to be minister and the inquiry before the Lokayukta lapsed.

150. Apart from the visual evidence of tempering, undoubtdely the Minute Book has been tampered with, as admitted by G. N. Patil himself. The essential difference

in the genuine and fabricated minutes is the date of Dr. Hiray's resignation. What is sought to be alleged is that Dr. Hiray did not resign on and from 19th October 1981 but had requested to be relieved from 2nd March 1981 and had severed all his connection with the Trust from 12th May 1981. Indisputably no outsider would have or had the opportunity to lay his hands on the Minute Book which on G. N. Patil's own showing always remained with him. Hence the tempering was necessarily done by someone connected with the Trust and most interested in doing so. Ex. 514

151. G. N. Patil attributes this mischief to Satbhai saying that Satbhai did so on his own. This is not correct. Satbhai was merely a paid employee of the Trust, one of whose duties was to write the Minute Book. He had no reason to tamper with it on his own. He had nothing to gain thereby, though no doubt he had a hand in it as the fabricated pages are in his hand-writing. For that matter even G. N. Patil had nothing to directly gain by indulging in this fabrication on his own, except the goodwill of Dr. Hiray who controlled the Trust and whose blind follower he is, as revealed in his evidence. The trustees can also be safely ruled out, being as they were Dr. Hiray's relatives or confidants controlled by Dr. Hiray without whose bidding nothing could be done. Having signed the minutes, no doubt the trustees were also in this exercise but not on their own initiative. The guiding light was the by-now panicky Dr. Baliram Hiray, who in his political interest had everything to gain by this fabrication and much to lose if the original minutes came to light. The only person who had the strongest motivation for this fabrication was none other than Dr. Hiray himself. His exercise was to distance himself officially from the Trust lest he be accused (albeit justly) of misuse of his official position and authority in getting prime land at Bombay from Government at a throw-away price and collecting donations for his Trust. I have no doubt that this fabrication of the Minute Book was done at the instance of the good doctor, through the instrumentality of his confident G. N. Patil, who got Satbhai to do the dirty work, which Satbhai did. While those two were the pawns, the hand that directed their moves was Dr. Hiray's.

152. There is on record a printed undated appeal (Ex. 514) showing Dr. Hiray as President of the Trust. This appeal invited donations for the Trust. Though this appeal is undated, the time when it was issued can be ascertained from its internal evidence. In it there is a reference to the Bandra land, namely that " it is proposed to build a hostel at Bandra area in Bombay ". Now the Bandra land was received by the Trust from Government in August 1981. Until then, asking for donations for putting up a structure on that land would be premature. This would indicate that at some period of time after the Trust got possession of the Bandra land in August 1981, that this printed Appeal was issued. That period of time, as will immediately appear was 1984. Ex. 514

153. On the basis of this Appeal describing Dr. Hiray as President of the Trust, funds were collected. It is difficult to believe that if Dr. Hiray had actually ceased to have any connection with the Trust even from October 1981 as alleged by him, why he should have been described in this Appeal as President of the Trust for which the funds were collected in 1984. This is yet another indication that Dr. Hiray's version that he resigned from the Trust and had nothing to do with it from May 1981 is not true, and that even in 1984 Dr. Hiray was very much associated with the Trust and that even his purported resignation in October 1981 was merely on paper and not as a matter of fact.

154. As a result of this Appeal donations from 128 different parties listed at Ex. 516 from all over Maharashtra were collected. They comprised of 3 categories, to wit, (*i*) distillers, (*ii*) holders of liquor vendor licences and (*iii*) persons running beer bars in Maharashtra. All of them were necessarily dependent upon the good-will of the Prohibition Department of which Dr. Hiray was in charge as Minister. Each of these categories gave donations at more or less an uniform rate. The books of accounts of the Trust do not reveal any travelling expenses incurred throughout Maharashtra for making the collections. This rules out the possibility of the Trust's office bearers or employees of the Trust going around Maharashtra to make collections. All these factors coupled with the fact that these 128 parties were spread all over Maharashtra, indicate that the collections were made from them through the officers of the Prohibition Department. It is inconceivable that these officers would do so on their own initiative. None of these categories could have had the slightest interest in the construction at Bandra, nor could they all have suddenly developed *Ex. 516*

altruistic motivations of charity. These amounts at a more or less uniform rate were collected from them hafta-like and given not to displease Dr. Hiray who was the Minister-in-charge of Prohibition.

155. The same comments also apply *mutatis mutandis* to the 13 pharmaceutical
Ex. 517 concern listed in Exhibit 517 who made their contributions in September/October 1984 through the instrumentality of the FDA. Needless to say these pharmaceutical concerns required the " goodwill " of the FDA and the Health Department. Even if Dr. Hiray may not have been Health Minister in 1984, he still held cabinet rank regarding other portfolios. Hence in any event, it is manifest that irrespective of the fact whether or not Dr. Hiray was in charge of a particular department, he misused those departments, including the FDA, to collect funds for the Trust. It is inconceivable that the FDA could do so on its own.

156. All this reveals a course of conduct in the total misuse of ministerial office and power on the part of Dr. Hiray for making collections for his Trust. Hence little wonder that Dr. Hiray should have exerted himself to the assiduous falsification of the minutes to the extent of fabricating them so as to make believe that he had severed his connections with the Trust from May 1981 when in fact he had not. Dr. Hiray misused his official power and position to confer a private benefit to the Trust controlled by him and of which he was the genius.

157. The next question that arises is : *When was this fabrication done* ?

158. Page 17 of the Minute Book shows that on 23rd October 1981 the Assistant Charity Commissioner had signed the minutes at the foot of that page. Thereafter the remaining pages were removed. The tampered pages are in Satbhai's handwriting. Satbhai left service of the Trust in December 1981. Thus the tampering was obviously done sometime between 23rd October 1981 when the Assistant Charity Commissioner signed at the foot of page 17 and December 1981 when Satbhai left service. Having thus secured himself, the versatile doctor lulled himself into a false sense of security and exuberantly went on a donation collecting spree.

159. In holding against Dr. Hiray, I have relied essentially on unimpeachable documentary evidence and the admissions made by Dr. Hiray himself and have eschewed aspects such as the interpolations in the Change Report dated 31st October 1981 and the Homoeopathic College incident.

160. The record unmistakably discloses that Dr. Baliram Hiray was guilty of misuse of his ministerial office and corruption. As a result, Dr. Hiray was not in a position to exercise control and authority over the FDA in the implementation of the Drugs and Cosmetics Act. As Health Minister, he must be held responsible for his acts which affected the working of the FDA and encouraged corruption in the FDA which can be shown by the above course of conduct on his part.

161. The record reveals that (*a*) Dr. Hiray was guilty of gross ministerial interference. He passed orders for extraneous considerations. He misused his office and official position as Minister with a view to collect funds for his Trust. (*b*) He is guilty of using the weapon of transfers and promotions, not in the interest of the FDA, but with a view to confer favours so as to have at his beck and call pliable officers known to be corrupt. (*c*) As Health Minister he undid whatever Commissioner Venkatachalam tried to do by improving the working of the FDA. To that end Dr. Hiray (*i*) transferred and/or promoted V. D. Deshmukh, (*ii*) allowed the prosecution against one Tolia to be withdrawn with full knowledge of the fact that Tolia's earlier attempts in August 1978 with the then Chief Minister and in May 1980 with the FDA, had failed. (*d*) Dr. Hiray appointed V. C. Sane as full-fledged Commissioner on 21st July 1981 in order to reward him and despite his known bad record and the adverse report of the Anti Corruption Bureau. (*e*) Despite Dr. Hiray's knowledge of Dolas' bad record, and that Dolas was transferred to Chandrapur in lieu of suspension, Dr. Hiray was instrumental in transferring Dolas to Bombay without consulting the FDA and immediately on receiving Bhaskarrao Chalukya's letter dated 15th July 1980. (*f*) Despite the clear-cut finding of the Upa Lokayukta that Asstt. Commissioner V. D. Deshmukh and N. D. Kulkarni were guilty of

improper conduct and should be censured by Government which should be reflected in their confidentials, Dr. Hiray refused to accept this finding or administer even this mildest of punishments. On protest being made by the Upa Lokayukta, Dr. Hiray agreed to orally convey the Upa Lokayukta's views to these two officers. Government conveyed to the Upa Lokayukta that it accepted his findings. Show cause notices were issued to V. D. Deshmukh and N. D. Kulkarni. Thereafter something happened. And on 17th July 1981 Dr. Hiray made an endorsement differing from the views of the Upa Lokayukta. Extraneous consideration on the part of Dr. Hiray is writ large. (*g*) Commissioner Bhirud sent certain proposals suggesting 5 different names for appointment to the post of Jt. Commissioner and Licensing Authority (H.Q.), the first preference being N. D. Kulkarni. Despite Commissioner Bhirud's strong written opposition to the appointment of V. D. Deshmukh to this post, and despite the opposition of Dr. Hiray's own secretariat, Dr. Hiray appointed V. D. Deshmukh as Jt. Commissioner and Licensing Authority. Extraneous consideration on the part of Dr. Hiray is writ large. (*h*) With a view to create false evidence to show that Dr. Hiray resigned from the Samiti Trust with effect from May 1981, false and fabricated documents were prepared and false information was given to the Charity Commissioner, even though Dr. Hiray continued to function as the President of the Trust till October 1981.

CHAPTER XVI

PART I

1. I shall now deal with the acts of ministerial interference in the working of the FDA by certain other erstwhile Health Ministers. To that end, I will place the brief history of various FDA Commissioners, Joint Commissioners and Health Ministers.

2. Starting with the Commissioners, in 1960 M.K. Rangnekar was appointed Director of the Drug Control Administration (as the FDA was known prior to 1974). After 1974, Rangnekar's designation was Commissioner, FDA which he continued to be till June 1977 when he died. Prior to his death, he was on leave and V. D. Deshmukh acted as Commissioner from 2nd May 1977 till 16th July 1978. On 16th July 1978 Venkatachalam of the I.P.S. was appointed Commissioner. He was repatriated to his parent department on 2nd October 1979. Thereafter from 2nd October 1979 V. C. Sane held charge as Commissioner for 21 months till 21st July 1981 when he was appointed Commissioner. Sane retired on 31st October 1981. On 1st November 1981 S. D. Bhirud was appointed Commissioner. He was due for retirement on 30th November 1986, but was re-employed for 6 months till 31st May 1987.

3. Coming to the Joint Commissioners, in 1978 the Joint Commissioner was V. D. Deshmukh and thereafter V. C. Sane. At that time the Commissioner was Venkatachalam. Between January 1982 and 30th April 1984, V. D. Deshmukh was the Joint Commissioner. Between June 1984 and 31st January 1985, N. D. Kulkarni was Joint Commissioner. On his retirement on 31st January 1985 B. G. Fadnavis was asked to look after the post of Joint Commissioner. On 29th November 1985 S. M. Dolas held charge as Joint Commissioner till 24th March 1987 when during the course of the present Inquiry he was transferred to the Food Department.

4. Coming to the Health Ministers, between July 1975 and October 1976, K. M. Bapu Patil was the Health Minister. During his tenure, Rangnekar was the Commissioner. 1977 saw the advant of G. S. Sarnayak. In 1978 the Health Minister was Shivajirao Patil Nilangekar, with Sushilkumar Shinde as Minister of State for Health. The Chief Minister was Vasantrao Dada Patil. It was at this time that Venkatachalam was appointed Commissioner of the FDA. Between August 1978 and February 1980 Dr. (Mrs.) Pramila Tople was the Health Minister; Sharad Pawar was the Chief Minister. During her tenure, Venkatachalam ceased to be, Commissioner and was repatriated to his parent department and V. C. Sane became officiating Commissioner. Between June 1980 and February 1983 Dr. Baliram Hiray was the Health Minister ; till 1985 he held charge of the several portfolios including Prohibition. Between February 1983 and March 1985 Bhai Sawant was Minister of State for Health ; in the first week of March 1985 he became Minister for Health and Medical Education, which portfolio he holds to this day. Between February 1983 and March 1985 Dr. (Mrs.) Lalita Rao was Health Minister.

5. Till 1974 there was only one post of Joint Commissioner (Drugs) at Nagpur which was held by V. C. Sane. In that year i. e. 1974, 4 additional posts of Joint Commissioners (Drugs) were created, one at H. Q. in Bandra, one in the Bombay Divisional Office in the Fort area, one at Pune and one at Aurangabad.

6. On 4th February 1975 postings were made to these newly created postes. P. S. Joshi was appointed Joint Commissioner at Pune, S. D. Bhirud at H. Q. M. V. Rajadhyaksha in the Bombay Divisional Office and V. D. Deshmukh at Aurangabad.

7. On 12th February 1975 these postings were changed to a limited extent, namely P. S. Joshi was appointed Joint Commissioner at the Bombay Divisional Office, M. V. Rajadhyaksha as Joint Commissioner at Aurangabad and V. D. Deshmukh as Joint Commissioner at Pune.

8. P. S. Joshi was senior to S. D. Bhirud, In 1974 P. S. Joshi was at Bombay Divisional Office.

9. In 1975 Commissioner Rangnekar proceeded on leave and he recommended to Government that during his leave period, Bhirud should be asked to officiate as Commissioner. Thereupon P. S. Joshi staked his claim by virtue of his seniority making an appeal to Government that he should be appointed to officiate as Commissioner. This was taken cognizence of by Government and P. S. Joshi was appointed to officiate as Commissioner during the time that Rangnekar was on leave.

10. It appears that Rangnekar was interested in S. D. Bhirud. As a result relations between Rangnekar and S. D. Bhirud on the one hand and P. S. Joshi on the other became strained. Consequently, two rival groups sprang up which in the FDA parlance came to be known as the Rangnekar group and the Joshi group. Apparently, the influence with Government of the Rangnekar Group exceeded that of the Joshi Group, with the result that the Joshi Group came to be disliked by Government and the higher officers of the FDA. As a result, in 1976 P. S. Joshi was transferred by Rangnekar to Nagpur and V. D. Deshmukh was brought to Bombay.

11. In 1977 Commissioner Bhirud was sent on deputation to Ajanta Pharmaceuticals Ltd, an enterprise of the Government of Maharahstra. Rangnekar recommended that V. D. Deshmukh should take charge of the post of Joint Commissioner (H. Q.,) P. S. Joshi was senior to V. D. Deshmukh and so also was V. C. Sane. V. D. Deshmukh was appointed to hold additional charge as Joint Commissioner (H. Q.)

12. In June 1977 Rangnekar died. Superseding the claims of P. S. Joshi and V. C. Sane, Deshmukh was appointed to hold charge as Commissioner. Sane and Joshi were senior to Deshmukh by 10 years and 4 years respectively. All this led to relations between Sane and Joshi on the one hand and V. D. Deshmukh on the other becoming strained. As a result, Sane and Joshi did not cooperate with Commissioner Deshmukh, who in turn was unable to control them. All this affected the entire working of the FDA.

13. In addition, V. D. Deshmukh was not a good administrator and was not above-board Corruption in the FDA became rempant. The public image of the FDA was extremely poor and the morale of its officers was very low. The entire drugs industry was extremely unhappy with the working of the FDA. Group and factions were found in the FDA. There was a great deal of criticism of the FDA in the press and the Legislative Assembly. In these circumstances Government had no option, but to take remedial measures to salvage the image and reputation of the FDA.

14. To that end, in April 1978, Home Secretary R. D. Pradhan sounded Venkatachalam of the I.P.S. whether he would care to take up the challenging, post of Commissioner of the FDA. Venkatachalam agreed.

15. However, thereafter it took three months for Venkatachalam's file to be cleared which was done in June 1978, though his file had been expeditiously cleared in May 1978 by the then Minister of State for Health Sushilkumar Shinde. Even so, the file did not reach the Health Minister Patil-Nilangekar for a month. Obviously it was held up somewhere perhaps in some quarters, Venkatachalam being appointed as Commissioner was not exactly welcome. Venkatachalam however followed up the matter of the reluctant file and thereafter on 15th June 1978 Government passed its order appointing him as Commissioner of the FDA. The following day Venkatachalam took charge. His appointment was for a period of one year. It was extended by the then Health Minister Dr. (Mrs.) Pramila Tople till September 1979.

16. When Venkatachalam took charge on 16th June 1978 he found the FDA in shamble. To his horror he discovered that as many as 900 applications were pending in the Licensing Department which was under V. D. Deshmukh. Venkatachalam gave a time limit to V. D. Deshmukh for disposing of these pending applications.

17. Venkatachalam also found that Drugs Inspectors were not to be found in their seats in the office that there was no check on their movements and that they were not accountable to any one. Hence he introduced the movement diary for Inspectors and weekly diaries for Joint Commissioners. He strengthened and toned up the Intelligence Branch of the FDA.

18. Venkatachalam also encountered liason men including Tolia and other undesirable elements habitually loitering in the FDA offices. He threw them all out.

19. Venkatachalam also examined certain files, as a result whereof he lodged certain prosecutions whenever necessary, including a prosecution against Tolia. He also ordered a departmental inquiry against S. M. Dolas.

20. Venkatachalam also made a detailed Report to Government to improve the working of the Government Analytical Laboratory. That Report has never been acted upon and is gathering dust.

21. Venkatachalam found that injustice had been done to V. C. Sane as his seniority had been overlooked. Hence he brought Sane from Pune to Bombay and placed him in charge of the Licensing Authority. As a result of all this drastic action taken by Venkatachalam in order to improve the working of the FDA and bolster its sagged image, predictably Venkatachalam became thoroughly unpopular in the FDA. After threatening voluntary retirement, V. D. Deshmukh, thought better of it and opted for transfer to Pune. Even V. C. Sane to whom Venkatachalam did justice by taking into account his seniority and bringing him to Bombay from Pune, turned against Venkatachalam and asked him not to seek extention of his term on the ground that Venkatachalam being from the I.P.S., was an outsider. At that time a number of representations were made to Government by disgruntled FDA officers, who did not approve Venkatachalam's steps at toning up the working and administration of the FDA. At that time the Health Minister was Dr. (Mrs.) Pramila Tople.

22. Dr. (Mrs.) Pramila Tople did not want Venkatachalam to continue as Commissioner of the FDA as he was a Police Officer and did not have scientific academic qualifications. She however admitted that Venkatachalam's lack of scientific knowledge did not impede his work in the FDA. She admitted in her evidence that Venkatachalam was a man of intergrity and that she was satisfied with the work done by him in the FDA. She also admitted that she was under tremendous pressure not to extend Venkatachalam's term.

23. The evidence of Dr. (Mrs.) Pramila Tople also discloses that Venkatachalam had resented the action taken by her in changing Venkatachalam's transfer order pertaining to Assistant Commissioner Bijamwar, which Venkatachalam recorded
Ex. 290 by his letter dated 29th May 1979 (Exh. 290) and in changing Venkatachalam's transfer order pertaining to Dani and Merchant which Venkatachalam recorded
Ex. 460 by his letter dated 31st May 1979 (Exh. 460).

24. Obviously the latter did not entirely relish the idea of this uncalled for ministerial interference on her part being placed on record by an independent minded officer like Venkatachalam. This coupled with the tremendous pressure on her not to extend Venkatachalam's term. his days in the FDA were numbered. And on 2nd October 1979 Venkatachalam was repatriated to his parent department.

25. Dr. (Mrs.) Pramila Tople appointed V. C. Sane as officiating Commissioner after going through his C. Rs.

26. She has stated in her evidence that when she appointed V. C. Sane, she had no material before her that Sane was not a man of intergrity. However, significantly she made no inquiries from the person who would best be in a position to throw light on V. C. Sane namely Venkatachalam as to who would be the proper person to succeed him.

27. From the fact that V. C. Sane held charge of the post of Commissioner for an unprecedented period of 21 months by itself shows that all was not well concerning him. It was Dr. Baliram Hiray who appointed Sane as Commissioner on 21st July 1981 which post Sane held till his retirement on 31st October 1981 and thereafter from 1st November 1981 came Bhirud as Commissioner.

28. P. S. Joshi who was the senior-most, was overlooked for promotion throughout. He retired this year in September. There is reasonable material to suggest that Bhirud was re-employed for 6 months after his superannuation on 30th November 1986 with the object only not to appoint P. S. Joshi, because the incumbent to that post in view was none other than S. M. Dolas.

29. The above are some startling instances of ministerial interference regarding appointments and transfers.

PART II

30. G. S. Sarnayak is an erstwhile Health Minister. Prior to his advent into politics, he was a practising lawyer at Akola and President of the Akola Zilla Parishad. He knew one Sakarchand Shah since 1967 as they both belonged to the same political party. From 1972 till November 1974 Sarnayak was Minister of State for Health in the Maharashtra Cabinet. From 1974 to 1975 he was a Cabinet Minister in charge of Transport and Fisheries. In 1975 he ceased to hold office. In 1977 he was Cabinet Minister in charge of Health.

31. His evidence and his own admissions disclose in embarrassing detail that though himself a qualified lawyer and at one time Health Minister, he was totally innocent of the provisions of the Drugs and Cosmetics Act and Rules as also was he of his ministerial responsibilities and duties. Out of all the erstwhile Health Ministers who vied with each other in projecting weak memories, Sarnayak surpassed them. Even after documents were shown to him Sarnayak's amanesia got the better of his memory. However to his credit it must be said that he was frank enough to admit that as Health Minister he exercised no supervision whatsoever over the FDA, leaving all to his Secretary.

32. However even in this he is not entirely correct, in the light of the instances stated below of Sarnayak's venture into the realm of ministerial interference :—

A

He saw to it that the FDA made a report to enable Government to withdraw the prosecution launched against Naval Medico Distributors. This also finds place earlier in this Report while discussing Dr. Hiray. Sarnayak attempted to justify this totally wrong action on his part on the ground that it was his duty to interfere in public interest. It is difficult to see how withdrawal of a prosecution against an errant party can be attributed to public interest, nor was the venerable ex-minister in a position to throw any light. Mercifully his recommendation to the Home Department for the withdrawal of the prosecution vide letter dated 25th May 1977 (Ex. 281) Ex. 281 was turned down by the Home Department.

B

(*i*) Sarnayak's evidence discloses his close connection with his political compatriot Sakarchand Shah of National Medical Agency, Nagpur. On 14th December 1972 their premises were raided by the FDA. Ten thousand spurious sulphadiazine tablets were seized. They had been stored for public sale. This by itself would constitute an offence under Section 18(*a*)(2) of the Act attracting a minimum punishment of one year's rigorous imprisonment plus fine. In addition National Medical Agency had already sold 5,000 such tablets to the unsuspecting and gullible public. At that time the Assembly was in Session at Nagpur. Sarnayak desperately tried to contact V. C. Sane who was the Joint Commissioner at Nagpur. Two or three telephone calls were put through by Sarnayak but Sane was not available. Ultimately late that night when Sane learnt of Sarnayak's telephone calls, he called back. Sarnayak ordered him to see him immediately at that late hour. Sane did so. At that time Sakarchand Shah was with Sarnayak. Sarnayak instructed Sane not to prosecute National Medical Agency.

(*ii*) There is documentary evidence in the form of Exhibits 453 to 457 which suggests that Sane was directed not to prosecute National Medical Agency or its proprietor who was none other than the son of Sarnayak's friend Sakarchand Shah but to cite them as witnesses only. Sane's reaction was that at that time Sarnayak was aware of all the facts. Accordingly Sarnayak's instructions were carried out and the prosecution was launched only against the supplier one Agarwal; National Medical Agency was cited only as a witness. Agarwal was convicted for one year's rigorous imprisonment plus a fine of Rs. 2,000. The case against Agarwal was obviously a weak case, for in appeal, the High Court confirmed the conviction and fine but reduced sentence from one year R.I. to one day S.I. Thus thanks to Sarnayak's intervention, National Medical Agency, the real culprit, which had stored the 10,000 spurious sulphadiazine tablets for public sale and had already sold 5,000 such tablets to the public, went unscathed. No amount of amanesia can avail the worthy ex-minister in the face of the documentary evidence Exhibits 453 to 457, brought to his pointed attention.

C

For lack of documentation, and since Sarnayak's memory does not come to his rescue, I propose to ignore Sane's evidence that while he was in Nagpur, Sarnayak had instructed him not to launch a prosecution against a party from whose premises adulterated groundnut oil was seized by the FDA.

D

(*i*) In 1976-77 there was a case of the spurious Novalgin (not to be confused with Novalgin) tablets. A raid had been carried out by Assistance Commissioner Kochar. The culprit in that case was once again Sarnayak's close friend, Sakarchand Shah. Predictably, Sarnayak remembers nothing except that Sakarchand Shah had seen him regarding an appeal concerning the Novalgin tablet incident. Why Sakarchand Shah should do so, Sarnayak is silent. Thus the connection between these two and the Novalgin tablet incident is established.

E

(*i*) There is also the incident pertaining to the transfer of Drugs Inspector P. R. Deshpande to Bombay. His transfer order dated 16th June 1977 was signed by
Ex. 451 Sarnayak. He admitted that he was instrumental in posting P. R. Deshpande at Bombay, yet at the same time claims he does not even know that as a result of his note Drugs Inspector Deshpande was posted to Bombay. He claims he did not take any specific interest in him.

(*ii*) The mystery of this transfer is that Deshpande had not even made an application for that purpose nor is there any departmental note for bringing P. R. Deshpande to Bombay. Neither is to be found in the files produced by the FDA before this Commission.

33. These are some glaring instances of ministerial interference on the part of the then Health Minister G. S. Sarnayak.

34. I am not prepared to accept his amnesia at face value. The highest I am prepared to go is to dub him as an ignorant dabbler with an exalted opinion of his duties and not over-burdened with brains. He was unable to explain with any degree of coherence how his interference with the due process of law could possibly have enured for the public welfare. Perhaps his cumbrous mind never needed to think and felt free to indulge in its infinite capacity for self delusion. A man of monumental denseness.

PART III

35. The next Health Minister guilty of ministerial interference is K. M. Bapu Patil. He was Health Minister from July 1975 to October 1976. Not less than two instances of ministerial meddling can safely be brought home to him.

A

K. M. Bapu Patil was instrumental in sending Bhirud on deputation to Ajanta Pharmaceuticals in order to facilitate the appointment of V. D. Deshmukh as Joint Commissioner. He cannot evade responsibility merely by his lament that it was not he but his department which may have done so, nor by feigning ignorance whether this was done in order to facilitate V. D. Deshmukh's appointment as Joint Commissioner. Here is another ex-minister who has had no compunction in foisting the blame on his department as the panacea for his own misdeeds.

B

(*i*) According to Joint Commissioner Deshmukh Bapu Patil had given him instructions regarding the case of Naval Medico Distributors by calling him two or three times and telling him to remove the injustice done to them. Bapu Patil told Deshmukh he knew them very well. According to Deshmukh, Bapu Patil did not actually suggest to him that the prosecution against Naval Medico Distributors be withdrawn but his administration should take a very lenient view of the matter, without spelling out what the lenient view should be. All this is denied by Bapu patil.

(*ii*) There is no reason to disbelieve Deshmukh on this aspect, looking to the fact that Deshmukh's appointment to Bombay was thanks to Bapu Patil himself. It is also difficult to see what lenient view could possibly be taken in the light of the fact that the prosecution against Naval Medico had already been launched. Hence Bapu Patil's implication to Deshmukh could only be that the case against Naval Medico should be withdrawn.

(*iii*) Deshmukh's evidence against his benefactor did not spring from willing lips. And even then he sugar-coated it, as best as, in the circumstances, he could.

PART IV

36. There are two acts of ministerial interference in the case of the erstwhile Health Minister Dr. (Mrs.) Pramila Tople which are discussed in the next part while dealing with Commissioner Venkatachalam.

PART V

37. Venkatachalam was one of the few witnesses, who in the witness-box was in his answers as upright as he was by his actions as Commissioner of the FDA.

38. He occupied the post of Commissioner of the FDA for a very limited period, from 16th June 1978 till 2nd October 1979. He was specifically brought from his parent department of the I.P.S. to the FDA for cleaning augean stables. And to some extent, despite forces working against him, he succeeded.

39. His evidence discloses that he was the one man of integrity the FDA had the good fortune to have at the helm of its affairs. He exerted himself to the utmost to put the FDA on an even keel. I have already detailed the steps taken by him to that end. His evidence bears testimony of his exertions to improve the working and the tarnished image of the FDA. If only he had been allowed to function for a longer time as Commissioner, he would have picked up the FDA from the gutter into which it had fallen and restored to it the prestige and the image it once had as the best in all Asia.

40. The question that then arises is : *Why was Venkatachalam not continued as FDA Commissioner for doing the good work he had started* ?

41. Venkatachalam's C.Rs. were good and he had a reputation for efficiency and uprightness, which were the reasons which brought him from the I.P.S. to the FDA as Commissioner. The evidence does not even remotely indicate that as Commissioner he displayed qualities other than efficiency, integrity and administrative capability and independence. Ironically enough, these were the very qualities which in the topsyturvy world of ministerial interference resulted in his downfall. Unfortunately the evidence in its entirety suggests that it was the entire system, including power brokers and touts, unscrupulous manufacturers and the FDA officers themselves who were against Venkatachalam and thwarted his endeavours to restore the FDA to its pristine position. It did not suit the boot of any of them that he should continue as Commissioner of the FDA. Hence he was eased out. And the Health Minister weak enough to do so was Dr. (Mrs.) Pramila Tople, who, unfortunately succumbed to the pressure of the corrupt V. C. Sane, her protestation to the contrary notwithstanding. It must indeed be the Devil's Delight (to borrow a literary title) that an officer as corrupt, and known to be so, as Sane should have replaced an upright and efficient officer like Venkatachalam at the helm of the FDA.

42. It is inconceivable that the circumstances and Venkatachalam's merits had impelled Government to have lifted Venkatachalam from his parent department and placed him at the head of the FDA would have been unknown to the then Health Minister Dr. (Mrs.) Pramila Tople. She knew the good work he was doing for the FDA and was satisfied. Unfortunately for him, the FDA and the public at large, Venkatachalam became too " inconvenient " for Health Minister Dr. (Mrs.) Pramila Tople to handle. He committed the unpardonable sin of resisting ministerial interference) and worse still, the greater crime of placing his resentment on record that what he did was at the ministerial bidding of Dr. (Mrs.) Pramila Tople. He dashed off 2 letters, one dated 29th May 1979 and the other dated 31st May 1979 (Exhs. 290 and 460) to the Secretary to Government of Maharashtra, Urban Development and Public Health Department. In the first letter he recorded that the Health Minister, namely Dr. (Mrs.) Pramila Tople had told Venkatachalam on the telephone on 20th May 1979 that Assistant Commissioner Bijamwar who was under orders of transfer to Chandrapur " shall be posted " at Beed instead of at Chandrapur. Commissioner Venkatachalam further recorded that he had told the Health Minister that he had suggested the transfer of Bijamwar out of Aurangabad Division as there were complaints against him, despite which, as desired by the Health Minister, Venkatachalam had given telephonic instructions to Bijamwar to report at Beed and take charge. By the second letter dated 31st May 1979 also addressed to the Ex. 290, 460

Secretary to Government of Maharashtra, Urban Development and Public Health Department Venkatachalam recorded that he had received telephonic instructions from the Health Minister [viz. Dr. (Mrs.) Pramila Tople] on 30th May 1979 that Chief Inspector Dani, who was under orders of transfer to Pune, should be retained at Bombay and that the Health Minister had also desired that Chief Inspector Merchant should be transferred to Bombay on compassionate grounds.

43. All this recording of ministerial directions (or rather to put it more aptly, mis-directions) could not exactly have warmed the cockles of Health Minister's heart.

44. And finally, in not extending Venkatachalam's term, Dr. (Mrs.) Pramila Tople, unfortunately succumbed to pressure. She admitted she was satisfied with his work, that she had nothing against him and that

"but for the representations made by others I would have continued Venkatachalam as Commissioner".

While the then Minister of State for Health, Sushilkumar Shinde and the then Health Minister, Mr. Patil Nilangekar were instrumental in Venkatachalam's appointment to the FDA, the succeeding Health Minister, Dr. (Mrs.) Pramila Tople found Venkatachalam far too independent minded to handle. Hence Venkatachalam had to go.

45. It was not as if Venkatachalam was urgently or at all required in his parent department. For that matter, after his repatriation he was not given any posting for three months. Even so, Venkatachalam had to go. He went with the same dignity he had come.

46. Dr. (Mrs.) Pramila Tople's successor Dr. Hiray was instrumental in confirming Sane to the post of Commissioner despite his having gone through Sane's C.Rs. and the A.C.B. Report. And Dr. Hiray's successor Mr. Bhai Sawant was instrumental in appointing Dolas.

47. Thus successive Health Ministers from Dr. (Mrs.) Pramila Tople right upto the present incumbent, Mr. Bhai Sawant, were not interested in having upright, independent and efficient officers at the helm of the FDA. As long as such be the attitude of Health Ministers who represent Government, there can possibly be no hope that the FDA will ever improve or that the public for whose benefit the FDA is intended, will ever have the benefit of its activities for which it was created.

48. The buck however does not stop there. In descending order, FDA officers were also responsible for Venkatachalam's ouster. It was not in their interests that he should continue as Commissioner. To them Venkatachalam stood out like a sore thumb. They resented his independence, disliked his uprightness and found his efficiency distasteful. The very fact that on finding 900 applications for licences pending he gave a time limit for their disposal, went counter to the unofficial financial aggrandisement of the FDA officers; for the longer that licences were kept pending, the greater would be the anxiety of the manufacturers to strike a bargain with the officers. With one stroke Venkatachalam took away those pickings.

49. Venkatachalam's driving away touts and power brokers from the FDA office must also be resented by the officers who would necessarily be thwarted in their misdeeds without the medium of the worthy gentlemen through whom they could establish a monetary dialogue with unscrupulous manufacturers and licence holders. One such was Tolia described by Venkatachalam as "family friend of the FDA", who for long had kept FDA officers purring with contentment.

50. Venkatachalam also committed the heinous crime of launching prosecutions and reopening files conveniently closed and the greatest sin of all was resurrecting Tolia's file and launching a prosecution against him. That in certain quarters was the unkindest out of all.

51. Venkatachalam's introduction of the system of the maintenance of movement diaries must have come as a hard blow to the drugs inspectors, as thereby they would have to put in solid unaccustomed work by actually inspecting the required quota of 19 units a month and to account for their work and movements.

52. Venkatachalam could also not have been exactly popular with the Joint Commissioners by reason of his introduction of the system of maintaining weekly diaries. Thereby Joint Commissioners would have to effectively supervise over the work of the subordinates, an exercise which they had for long not indulged in.

53. Venkatachalam even ordered a departmental inquiry against S. M. Dolas who by then had achieved a formidable political clout and could not have possibly endeared himself to that fast becoming powerful man. Venkatachalam's strictness and rectitude with manufacturers and licence holders could not have endeared him to them, because several like Tolia would not have been able to survive. Hence representations were made by them against Venkatachalam. Though Venkatachalam tried to take manufacturers into confidence with a view to know their difficulties, all he succeeded in getting from them was oral general allegations of corruption of FDA officers. But none came forward to say so in writing. In Venkatachalam's words,—

> " these drug manufacturers gave me the reason for their not giving me written complaints, because they said that I was merely a passing phase as Commissioner, whereas they would have to deal throughout with Dolas. "

54. The Health Minister, Dr. (Mrs.) Pramila Tople found him too independent to countenance; he crampted the style of the FDA officers; unscrupulous elements in the drugs industry found him unbearable and the scrupulous ones were cowardly. Venkatachalam was the best hated man in the FDA. He had to go.

55. Despite the fact that the steps he had introduced were rejuvenativ and healthy, it was not in the interest of the FDA officers themselves to have a healthy or rejuvenated department. Venkatachalam had to go.

56. Unfortunately for the FDA and the general public, while Venkatachalam did succeed in curbing within the short span of time the ills which had overtaken and bedevilled the FDA, he was prevented from eradicating them altogether, which he could have done if only he had been allowed to function as Commissioner for a longer time. Once he left, the ills which he curbed erupted once again. Those ills can best be compared to wild horses held in check on a tight rein and which go out of control once the rein is loosened. And so it was with the FDA. Once Venkatachalam left, the ills with which the FDA was fraught, burst with greater vigour, and its general picture became even worse than what it had been before the advant of Venkatachalam.

57. The result can best be illustrated in the case of V. D. Deshmukh and S. M. Dolas. Venkatachalam had transferred them for having vested interests in Bombay, once he left, they succeeded in their triumphant return to Bombay. No sooner had Venkatachalam left, V. C. Sane fulfilled his life's ambition and became Commissioner, Tolia was rehabilitated in the FDA and the prosecution against him was withdrawn. Maintenance of daily diaries was rendered a farce, because they were not maintained daily, but periodically and only the names of the places visited (if at all) were mentioned. Senior officers did not bother to check the movements of the Inspectors as written in the daily diaries. The Licensing Authority succeeded in making the two thousand crore rupee drugs industry dance to his tune and corruption increased by leaps and bounds. Even according to Sipahimalani, the managing partner of Chem Med, the entire system of the FDA depends upon bribery and corruption. Apex's partner Hashmukh Parikh was even more forthcoming. He corroborated Sipahimalani and went up a step further that to the FDA officers Diwali comes more than once a year.

58. Such has been the state of the FDA since Venkatachalam's departure, which could have been prevented if only Health Ministers like Dr. (Mrs.) Pramila Tople and her successors had the will and desire to do. Not a single Health Minister who has given evidence before this Commission, has demonstrated any such will or desire. On the contrary, their evidence discloses in no uncertain measure that this department has been utilised more to serve their private interests rather than be allowed to operate for the public good for which it is intended. Health Ministers cannot possibly descipline their subordinates, if they themselves commit flagrant breaches of Rules and Regulations and indulge in acts prompted by extraneous considerations. Corrupt masters make for corrupt servants.

59. And thus ends the saga of Venkatachalam, brief as it unfortunataly was.

PART VI

60. The evidence of V. C. Sane reveals that he had come well decided to thwart the Commission, a distinction he shares with many other witnesses of his ilk. Despite his self-adulation at the commencement of his evidence, he stands condemned by his own evidence and unimpeachable documentary evidence.

61. He was senior to Bhirud. He was superseded thrice in 1974, 1977 and 1981. Documents show his amenability to ministerial influence and that he was more than willing to carry out their orders. For this he was rewarded by his ultimately being confirmed as Commissioner after holding charge for an unprecedented period of 21 months. That Sane did not deserve this post is apparent from documents such
Ex. 462 as the file Exh. 462 containing his C. Rs., a letter dated 16th July 1981 from the
Ex. 463 Deputy Secretary to Government to the Secretary to Government (Exh. 463), the minutes dated 9th July 1981 regarding his temporary promotion, the Report of the
Ex. 466 A.C.B. (Exh. 466) and the incident regarding Beacon Pharmaceuticals starting with
Ex. 464 their letter dated 26th June 1981 to the Commissioner (Exh. 464). All these documents have already been referred to earlier.

62. After he retired from the FDA, Sane started a consultancy business in the name of G.M.P. Consultants, G.M.P. standing, with unintended irony for Good Management Practice. He had his office in Tolia's office premises at T. V. Industrial Estate, behind Glaxo Laboratories, Worli, Bombay. G. M. P. Consultants is merely a facade for Sane's activities as a liaison-man with the FDA where several of his erstwhile comrade-in-arms are. Initially he disclaimed total knowledge of or connection with Tolia. Thereafter with the utmost reluctance and a great deal of prevarica-
Ex. 469 tion admitted to a pamphlet (Exh. 469) of G.M.P. Consultants, which in bold letters, contains Tolia's office address stated earlier, and an introductory letter signed by
Ex. 470 him on G.M.P's letterhead (Exh. 470) wherein Tolia's office address is stated.

63. Sane's evidence also discloses that an anonymous circular (X-8 for identification) levelling serious charges against him had been published. This circular was taken on record not for the correctness of its contents, but only for the limited purpose that such a circular had been published. However some of the allegations in this circular are corroborated by documentary evidence. All this has also been dealt with earlier.

64. Sane's avidence also discloses that he issued several show-cause notices without any basis and finally did not take any action. This was an obvious invitation to the licence holders to approach him and to come to a " deal " with him.

65. Sane also obliged the then Health Minister, Sarnayak in the case of Sakarchand Shah by not prosecuting him for the spurious Sulphadiasine tablets.
Ex. 453-457 This aspect has also been dealt with earlier.

66. According to Sane he also obliged Health Minister, Sarnayak by withdrawing the prosecution for adulterated ground-nut oil.

67. He also obliged Dr. Hiray in the matter of the withdrawal of the prosecution
Exs. 476, 468 and 513 against Tolia. This aspect has also been dealt with earlier.

Ex. 471. 68. Sane's evidence reveals that he had sanctioned prosecution against Food Inspector Hogale on charges of corruption; *viz.* that Hogale had illegally collected funds allegedly on Sane's instructions. However after he himself sanctioned that prosecution, Sane gave evidence in Hogale's favour that the funds had been collected by Hogale for the exhibition of the FDA. The trial court convicted Hogale for, 2 years R.I. and a fine of Rs. 1,500. Hogale was acquitted by the Appeal court on Sane's evidence.

69. When Sane succeeded Venkatachalam, Government knew that he was known to be corrupt, that he had been superseded three times in the past, that his C.Rs. were bad and about the A.C.B. inquiry against him. Even so, he was confirmed as Commissioner despite the adverse secretarial note. The object obviously was that there should be a Commissioner pliable enough to be at the back and call of the Health Minister himself (in this case Dr. Baliram Hiray) and to do his bidding, which Sane joyously did by making his report for the withdrawl of Tolia's prosecution.

PART VII

70. N. D. Kulkarni was Joint Commissioner at Thane from April 1977 to October 1981. On 31st October 1981 he was transferred to Nagpur where he remained for a year and a half.

71. In 1977 Dolas was Assistant Commissioner under N. D. Kulkarni at Thane. In 1978 Kulkarni initiated a general inquiry against Dolas and submitted his report dated 29th July 1981(Exh. 483), based as it was,on documentary evidence. According Ex. 483
to this report, Dolas was guilty of several acts of misconduct, negligence, inefficiency, definace and insubordination.

72. On the basis of this report, Commissioner Venkatachalam recommended to Government a departmental inquiry against Dolas. This was done, Charges based on Kulkarni's report were framed. In the departmental inquiry N. D. Kulkarni gave evidence as a witness on behalf of the department in September 1982. This was during the ministership of Dr. Baliram Hiray. Surprisingly enough in the teeth of his own report which was the foundation for the departmental inquiry, N. D. Kulkarni in his evidence resiled from his own report and contended in the inquiry that Dolas had not committed any acts of misconduct, was not negligent, inefficient, defiant or insubordinate. On this evidence of N. D. Kulkarni given contrary to his own report, Dolas was honourably acquitted. It need hardly be said that Kulkarni's retraction of his own report was a sordid plot to bale out Dolas.

73. As a reward for thus helping Dolas out of a nasty situation which would well have led to his dismissal N. D. Kulkarni was transferred from Nagpur to Bombay within a year-and-a-half of his being posted at Nagpur. It is the admitted position that N. D. Kulkarni's transfer to Bombay was not a routine but a premature transfer as he had been in Nagpur only for one-and-a-half years. His evidence suggests that he himself did not know why he was transferred to Bombay. He admitted in his evidence before this Commission that his evidence before the inquiry officer was at variance with his own report but was unable to explain why that was so, except to say that he made a mistake while giving his evidence before the Inquiry Officer, at the same time maintaining before the Commission that the report made by him was correct. Then pray, why did he not say so before the inquiry officer. He is not afraid of S. M. Dolas. Since 1982 N. D. Kulkarni has been in Bombay. No doubt he " Justly deserved " his " reward ".

74. On 25th May 1977 N. D. Kulkarni made a report in the matter of Naval Medico Stores (Exh. 281). On this report the then Health Minister, Sarnayak made Ex. 281
his endorsement the same day. On the strength of this report Sarnayak made a recommendation to the Home Department for sanctioning the withdrawal of the prosecution against Naval Medico Stores which was also the subject-matter of the inquiry before the Lokayukta which had dealt with the corruption charges against N. D. Kulkarni. All this has been dealt with earlier.

75. A show-cause notice dated 12th December 1984 was issued against Apex Laboratories which habitally gave false and fabricated analytical reports without actually carrying out the tests. To this show-cause notice Apex gave a reply on 20th December 1984. On 29th January 1985 Kulkarni passed his order letting off Apex with a mere warning. And two days later on 31st January 1985 Kulkarni retired.

76. On 10th January 1985 Emcure Pharmaceuticals at Pune made an application for additional products. This application was received by the FDA office at Pune on 14th January 1985. The FDA Inspector inspected Emcure's premises on 28th January 1985, and the same day the Joint Commissioner at Pune gave his recommendation. The very next day, i.e. on 29th January 1985, the papers addressed to the Commissioner were received by the FDA in Bombay but were handed over by one Satish Mehta on behalf of Emcure not to the Commissioner but to N. D. Kulkarni personally. Emcure's application for additional products was immediately sanctioned by N. D. Kulkarni and the permission was handed over to Satish Mehta personally the same day. Two days later on 31st January 1985 N. D. Kulkarni retired.

77. From April 1986, though N. D. Kulkarni has no technical knowledge, he has been employed as consultant by Emcure the concern which he had generously benefited two days prior to his retirement.

78. N. D. Kulkarni gave various show cause notices to various parties threatening prosecution. Never, however, did he ever carry out this threat of prosecution and never did he give any reason for not doing so. He admitted that the Act gives no choice not to prosecute but professed he committed an error in not prosecuting. From this the only irresistible inference that can be drawn beyond reasonable doubt is that there was some extraneous consideration which prompted Kulkarni not to prosecute erring manufacturers even of life-saving drugs.

79. There is also the instance of Vikas Chemicals and Kokila Pharmaceuticals involved in the manufacture of the banned mandrex tablets. As Joint Commissioner N. D. Kulkarni was in-charge of this matter. However, he took no steps against either of these concerns. S. D. Patil was connected with them. This shows clear collusion between Kulkarni and Patil in the dereliction of the duty cast on Kulkarni to have taken adequate steps against these two concerns but which he did not at all.

80. Show cause notices had been issued to Cyma Pharma and 5 other drug manufacturing concerns. On 29th October 1984 the FDA passed an order cancelling the entire licence of Cyma Pharma in Form 28. This order was approved by N. D. Kulkarni. Thereafter for nearly a-month-and-a-half nothing happened. On 12th December 1984 there was discussion between N. D. Kulkarni the Licensing Authority, Commissioner Bhirud, Kochar in-charge of I.B. and the Law Officer S. S. Deshpande. The cases of all the 6 firms were considered and it was decided to restrict the cancellation of the licence to the drug concerned.

81. As far as Cyma Pharma was concerned, there was no reason to thus dilute the earlier cancellation order of 29th October 1984. To start with, the drugs chloramphenicol and cymastrep manufactured by Cyma Pharma were life-saving drugs which were found to be substandard. FDA's show cause notice had been met by Cyma Pharma with contemptuous silence. The earlier order of 29th October 1984 was not even served on Cyma Pharma. Thus though Cyma Pharma had manufactured substandard drugs, it merrily continued selling them in the market at the cost of public health and safety. Further, Cyma Pharma itself had never applied for diluting FDA's order of 29th October 1984, nor was there any mistake on the part of FDA in passing that order because it was done in terms of the show cause notice itself. It is futile for the FDA officers now to say that FDA's original order of 29th October 1984 was diluted on 12th December 1984 merely to bring it in conformity with the other concerns to whom show cause notices had been issued. This is a totally absurd excuse because each case must necessarily be judged on its own merits.

82. From these aspects the only irresistible inference that can possibly be drawn beyond reasonable doubt is that in not serving the earlier FDA order of 29th October 1984 on Cyma Pharma and thereafter diluting it on 12th December 1984, the element of extraneous consideration had come into play and from which it is impossible for N. D. Kulkarni, and the other FDA officers to dissociate themselves from.

83. The other 5 drug manufacturing concerns who had also been issued show cause notices along with Cyma Pharma were Mukhtavan, Panacea, Hem Pharma, Winsun Laboratories and Semi Products (Pvt.) Ltd. From all these concerns, substandard chloramphenicol tablets were seized by the FDA in which the active ingredient was less than prescribed.

84. Starting with Mukhtavan, they did not dispute the show cause notice and the FDA findings but claimed that some of their employees had played some mischief. The punishment imposed on Mukhtavan was suspension of licence for 10 days. This order was passed by the Licensing Authority N. D. Kulkarni shortly prior to his retirement on 31st January 1985. This punishment was awarded after the decision had been taken on 12th December 1984 to restrict the cancellation of licence insofar as it pertained to the offending drug. Thus in Mukhtavan's case by awarding the punishment of suspension of licence, even the diluted decision taken on 12th December 1984 to cancel the licence confined to the offending drugs, was not adhered to.

85. Hem Pharma's proprietor was one Dolar Maniar. He was the nephew of one Dr. Maniar, a "family friend of the FDA" who gave free medical treatment to the FDA officers. 7 batches of substandard chloramphenicol tabets were seized, the active ingredient varying from 10.5 per cent to 66.91 per cent. Hem Pharma

Hem Pharma File Ex. 204

did not send any reply to the show cause notice. In Hem Pharma's case the "uniform action" decided in the meeting of 12th December 1984 was not taken and its entire licence was cancelled by an order passed by Kulkarni in the beginning of January 1985. Kulkarni's explanation is that the "uniform action" decided on 12th December 1984 was to be made applicable on merits.

86. Kulkarni's explanation is make-believe. The real reason for this apparent show of strictness on the part of Kulkarni is that through Dr. Maniar it was known to the FDA officers that his nephew's Hem Pharma had closed down. Hence the cancellation order was returned unserved to the FDA just as was the Notice given to Hem Pharma under section 8-B of the Commissions of Inquiry Act with the postal endorsement "Business closed".

87. Winsun Laboratories' samples of chloramphenicol tablets were found to be substandard containing 87 per cent of the active ingredient (the requisite being 92.5 per cent to 107.5 per cent). On 20th June 1984 the usual show cause notice was issued threatening cancellation or of suspension of licence. By their reply dated 25th June 1984 Winsun challenged the report of the Government Analyst. On 15th October 1984, N. D. Kulkarni passed an order that warning should be issued. Ex. 489 And on 2nd January 1985 in the month of Kulkarni's retirement the warning order was issued. Thus was Winsun let off the hook.

88. This is all the more sinister in the light of Kulkarni's admission that after receiving Winsun's reply dated 25th June 1984, he did not call for remarks from the Government Analyst because he did not accept the correctness of Winsuns' reply. He admitted that the order dated 2nd January 1985 letting off Winsun with a mere warning was contrary to the dicision taken earlier on 12th December 1984, and that there was no specific reason why he should have let off Winsun with a mere warning.

89. Panacea sent a reply dated 15th July 1984. No personal hearing was asked for nor given. The dicision of 12th December 1984 was made applicable to Panacea. On 31st December 1984 the order was prepared and on 2nd January 1985 N. D. Kulkarni signed it. Panacea's licence was cancelled in respect of 2 products.

90. Semit's Managing Director Sipahimalani was also the managing partner of Chem Med Analytical Laboratories. Samples of Semit's chloramphenicol tablets from 10 different batches were seized. The active ingredient was less than prescribed. One batch of ampicilin was also involved. On 20th June 1984 a show cause notice was issued to Semit. On 27th June 1984, Semit sent its reply challenging the Government Analyst's report and stating that the samples had been analysed by Chem Med. On 7th November 1984, Kulkarni wrote to the Government Analyst enclosing the show cause notice and Semit's reply and asked for his comments. On 15th November 1984, the Government Analyst sent his comments; he pointed out that Semit's contentions were baseless and that the same Chem Med had also analysed the samples of other manufacturers whose samples had been seized in the sample drive carried out by FDA and that majority of such samples analysed by Chem Med had failed. This should have been enough to have put any honest officer on his guard. It did not put N. D. Kulkarni on his guard.

91. In the meanwhile by a letter dated 21st September 1984, Semit had asked for an adjournment of the personal hearing to some date in the middle of October 1984. On the reverse of this letter, there is N. D. Kulkarni's endorsement under his signature on 22nd October 1984—"Given personal hearing on 22nd October 1984 and the persons were heard". This endorsement is also signed by Kochar.

92. On 13th December 1984, an order was passed cancelling Semit's licence for chloramphenicol and ampicilin. However the admitted position is that no such order was served on Semit. Here it may be stated that by this time N. D. Kulkarni, no doubt with an eye to his retirement in the offing on 31st January 1985, and with a heart dripping with the milk of human kindness, had taken decision not to prosecute any of the parties including Semit.

93. On 15th January 1985, Sipahimalani and one other person from Semit met Commissioner Bhirud. In the course of discussion, Sipahimalani convinced Bhirud about certain discrepancies in the Government Analyst's report. Though Sipahimalani denies meeting Bhirud, the latter is positive that one or two meetings had taken

place between himself and Sipahimalani. Bhirud was persuaded to take a decision that Semit's case did not call for cancellation of licence. He decided on stern warning being issued to Semit. Regarding this meeting a note was prepared; it was signed at the foot by N. D. Kulkarni on 22nd January 1985 and by Bhirud on 24th January 1985.

94. On 29th January 1985 N. D. Kulkarni sent his warning letter to Semit which was promptly acknowledged by Semit on 31st January 1985. The next day N. D. Kulkarni retired.

95. The purport of all this is not to come to a finding that these 6 concerns had manufactured substandard drugs. The purport is to show the working of the FDA when under the Act and Rules it comes to taking stringent action against licence holders who according to the FDA were guilty of manufacturing substandard life-saving drugs.

96. In respect of these 6 concerns, oral and documentary evidence indicates—

(*a*) a sample drive was undertaken by the FDA;

(*b*) action was proposed against manufacturers whose samples were found to be substandard;

(*c*) the drugs involved were life-saving drugs;

(*d*) the offences of the delinquent concerns were under sections 18 (a) (1) and 18(a)(2) of the Act; the offences attracted a minimum punishment of one year R. I. and fine;

(*e*) none of the officers who showed their anxiety for "uniform action" over recommended prosecution;

(*f*) none of these officers considered that to permit the manufacturer of such sub-standard life-saving drugs entailed hazard to public health and safety; if they did, they exhibited a neuter conscience;

(*g*) Kulkarni admits that it is unusual not to prosecute in these circumstances;

(*h*) according to Bhirud there is no policy of the FDA to stop the manufacture of substandard drugs ; that the FDA policy is not to launch prosecutions against such manufacturers ; and that guidelines provide that prosecution should be launched only if such drugs cause death. The utter shamelessness of these assertions is comment enough.

97. It is therefore manifest that the decision taken on 12th December 1984 for "uniform action" against these 6 concerns was not inspired by any desire to protect the public from the hazards of sub-standard life-saving drugs. For that matter, on paper no reason has been shown why any "uniform action" was even thought to be necessary. Nobody had approached FDA to that end. Documents show that initially the Joint Commissioner had decided to take stringent action by way of cancellation or suspension of the entire licence of the delinquent manufacturers. This is stated in all the show cause notices. Even so, suddenly the hearts of these officers melted and on 12th December 1984 they toned down the touch and correct decision taken earlier on 29th October 1984.

98. It is also of no mean significance that there is nothing uniform in the enforcement of the so-called decision of 12th December 1984 to take uniform action. All these 6 concerns were dealt with differently, entailing loss or misfortune to none of them.

99. FDA's contention is that though the stringent order against Cyma Pharma was ready, it was not dispatched because there were similar other cases of 5 other concerns vis. Mukhtavan, Hem Pharma, Winson, Panacea and Samit, hence N. D. Kulkarni wanted to take uniform action.

100. This is sheer nonsense. The common denominator touching all these 6 licence holders was that their samples drawn by the FDA in the sample drive were found not to be of standard quality. All the drugs were life-saving drugs, and show cause notices were given to them all.

101. Even so, under the guise of taking uniform action (which was the excuse trotted forth for not serving the strengent order on Cyma Pharma, the action decided on 12th December 1984 against these 6 concerns was not uniform. Mukhtavan's

licence was suspended for 10 days; Hem Pharma's entire licence was cancelled with full knowledge that it has ceased business; Winsun was left off with a warning; Panacea's licence for 2 products was cancelled and Semit was let off with a warning. Pray, where did the much-vaunted uniformity of action disappear ?

102. Oral and documentary evidence reveals that the stringent and correct orders passed earlier cancelling the entire licence were deliberately not served on the licence holders, so that a " deal " could be struck across the table. To that end Commr. Bhirud, the Licensing Authority N. D. Kulkarni and Kochar made common cause. The only irresistible inference beyond reasonable doubt can be that they did so for extraneous consideration. I have not the slightest doubt that the earlier stringent orders were never intended to be enforced but were merely a bait to the licence holders to get them to the conference table so that the orders could thereafter be suitably modified.

103. I shall give my reasons why I impinge all these officers in this.

104. To start with the proper and only person to pass such orders was the Licensing Authority N. D. Kulkarni. Yet, Commissioner Bhirud very much appears in the picture, when he need not have at all. Why would Bhirud make common cause with the others ?

105. As Commissioner, Bhirud was associated as this arose out of a sample drive initiated by the department. It is not unlikely that like Semit, other parties may also have approached Bhirud, On Bhirud's own admission in the meeting of 12th December 1984 he was the only person who was of the veiw that cancellation of the license should be limited to the drugs involved; yet significantly on his own showing, he did not have the matter referred to the Law Officer to support his veiw. Bhirud does not know if he had any discussion with the Law Officer. He then said that he referred the matter to the Law Officer as there was a difference of opinion between himself on the one hand and the Law Officer and the Assistant Commissioner (IB) (namely Kochar) on the other. He admitted that there was no material before him to enable him to disagree with the views of the Licensing Authority and Kochar, but gave his advice in his capacity as administrative head, even though the matter was entirely and exclusively within the purview of the powerers of the Licensing Authority, viz. N. D. Kulkarni, According to him, he had similarly been approached in the past, but could not name a single such instance.

106. It dawned on Bhirud while giving evidence that it was unusual that the final order passed by the Licensing Authority in the case of Cyma Pharma should have been sought to be revised or diluted. He professed ignorance that a final order had been passed and protested that to that extent he had been kept in the dark. He admitted that he could give no reason why he suggested a uniform action against all these 5 concerns without going through their background and conceded that he was wrong in doing so, adding that he was honestly wrong. Commissioner Bhirud, doth protest too much, methinks. He admitted that in the matter of Cyma Pharma he went out of his way in recommending partial cancellation of Cyma Pharma's licence instead of the entire cancellation as suggested by the Licensing Authority, namely N. D. Kulkarni. Pray, why should Commissioner Bhirud thus go out of his way to do so? The question answers itself. According to Bhirud he came to know of the passing of this order for the first time when the office note came to him on which he gave his advice which he admits he did without reading the accompanying file. Significantly enough, this office note gives no material whatsoever which could have enabled Bhirud to have given the "advice" he did.

107. Regarding Semit, Bhirud fared even more dismally. Sipahimalani's denial notwithstanding Bhirud admitted that Sipahimalani had seen him on one or two occasions and that Semit did not agree with the report of the Government Analyst. There was also before Bhirud the written reaction and comments of the Government Analyst stating that Semit's contentions were baseless and that it had been discovered that Chem Med had analysed samples of other manufacturers and that the majority of such samples had failed. On his own showing, Bhirud was not well conversant with the technicalities of analysis. Hence it is startling that Bhirud should have taken at face value Sipahimalani's protestation that Chem Med's reports were correct without resorting even to the simple expedient of calling the Government Analyst who was in the same building and on the same floor and confronting him with Sipahimalani. Surely as Commissioner, Bhirud knew that under section 25(3)

and (4) of the Act, Government Analyst's report is final and binding, subject to appeal only to Central Drug Laboratory, Calcutta. The mandatory legal provisions and the legal, official and binding report of the Government Analyst were all waived by Commissioner Bhirud in Semit's favour and he allowed himself to be persuaded by Sipahimalani to accept Semit's contention that the Government Analyst's reports were wrong and that Chem Med's were correct. There is no convincing reason for any of this nor was Bhirud himself able to give any. Ultimately came Bhirud's object and reluctant admission that in revoking the order in Semit's case, and disregarding the legal, official and binding report of the Government Analyst he was obliging Sipahimalani. Commissioner Bhirud stands condemned from his own lips, other factors apart. Sipahimalani's certificate of rampant corruption in the FDA, corroborated by Apex's Managing Partner Hashmukhlal Parikh with the addenda that to FDA officers, Diwali comes more than once a year, is not without significance and its applicability could not have been lost on Commissioner Bhirud.

109. The hand of the Licensing Authority N. D. Kulkarni is also manifest. His culpability exceeds that of Commissioner Bhirud. These were N. D. Kulkarni's last few months in the FDA. Sufficient has been stated about him which shows in dark colours that he himself was far from being a paragon of virtue, was also amenable to influence. It does not brook repetition. The sample drive was initiated by the FDA in January 1984. Till October 1984 the show cause notices had not even been decided to be issued; thereafter some were decided to be issued but orders were not served. For these lapses, no explanation has been forthcoming and the culpability must fall squarely on the Licensing Authority N. D. Kulkarni. It was all a part of a manoeuvre charted by him. It was he who got the note pertaining to the so-called uniform action prepared by Kochar and had it put up before Bhirud. It was not necessary for N. D. Kulkarni to have done so, because as Licensing Authority he himself could have taken the so-called uniform action without Bhirud's benediction. Bhirud knew this, and in any event as Commissioner, should have known it. By doing so N. D. Kulkarni was merely mending his fences by way of self-protection. What Kulkarni wanted was the sanctity of the Commissioner's imprimetur which Bhirud knowingly and willingly gave without even the background of the parties having been brought to his attention of his caring to ask for it. If therefore Bhirud allowed himself to be a happy and willing tool in the hands of N. D. Kulkarni, it was N. D. Kulkarni who was the evil genius in the manoeuvre directed for his own aggrandisement and not in the interest of the FDA. Of course the hapless general public was merely a necessary evil. In his evidence N. D. Kulkarni was unable to justify his actions and finally attributed them to mistakes committed by him.

110. Assistant Commissioner Kochar is no paragon of virtue either. He was in charge of the Intelligence Branch of the FDA. His duty was to prepare show cause notices and orders and have them served. All the delays regarding show cause notices attributed to Kulkarni can also be attributed to Kochar. The note given to Bhirud was prepared by Kochar. It gave no particulars nor background of the parties. All attempts on the part of Kochar to dissociate himself from Bhirud and Kulkarni must fail.

111. Thus it can be seen that even in 1985 the FDA was working not for public health and safety but for its own amelioration and that of the licence holders who had come within its net.

PART VIII

112. V. D. Deshmukh was yet another officer who did not exactly cover himself or the FDA with glory.

113. He was Joint Commissioner from January 1982 to 30th April 1984. Before that the he had acted as Joint Commissioner while Commissioner Rangnekar was on leave. When Rangnekar died in June 1977 V. D. Deshmukh acted as Commissioner for 13 months till 16th June 1978, when Venkatachalam was appointed Commissioner. While during Rangnekar's regime there were no serious grievances against the FDA, it was mainly on account of the deterioration that took place in the FDA during V. D. Deshmukh's time and his inability to control the FDA, that grievances were made against the FDA in the press and the Legislative Assembly.

114. V. D. Deshmukh's acts of commission and omission are legion, to name a few.

A

115. On 24th April 1984, i.e. 6 days prior to his retirement on 30th April 1984, he approved the grant of licence to Alpana Pharma. It has already been stated earlier Ex. 277
that the order granting this licence does not bear V. D. Deshmukh's signature as also the top speed in which it was passed and without the basic requirements having been met. It is manifest that in the last week of his retirement V. D. Deshmukh was instrumental in improperly granting the licence to Alpana Pharma, more so, as stated earlier, *inter alia*, when the circumstances in which even the list of drugs was not approved till June 1984. Ramanlal Karwa has also admitted that he had put in a word with V. D. Deshmukh.

B

116. As stated earlier, V. D. Deshmukh was also involved in the episode of Naval Medico Distributors where he improperly recommended the withdrawal of prosecution.

C

117. There were serious allegations of corruption against him before the Upa Lokayukta. His defence that he had acted at the instance of the minister in order to be in his good books was none too happily received and the Upa Lokayukta found his conduct improper. V. D. Deshmukh however escaped his due punishment, thanks to the benevolent intervention of Health Minister Dr. Baliram Hiray.

D

118. He and Dolas were good friends. He was a witness for the department in the enquiry against Dolas, yet gave evidence favourable to Dolas.

E

119. Despite knowing Dolas' bad record V. D. Deshmukh made a favourable remark in Dolas' C. R. for the period 1st April 1983 to 31st March 1984. Bhirud Ex. 263
totally differed and made a correct appraisal of Dolas' inimitable talents. Bhirud's endorsement was that V. D. Deshmukh's report was exaggerated, that Dolas was never punctual, that the cases he handled were always delayed, that he indulged in influencing his colleagues and superiors by political forces and that not having headed any office independently, did not have administrative experience.

120. V. D. Deshmukh, who on Venkatachalam taking charge as Commissioner had preferred to be posted out of Bombay to Pune, made his triumphant return to Bombay as Joint Commissioner and Licensing Authority on Venkatchalam's departure. V. D. Deshmukh made no secret of the fact that the post of Licensing Authority is the most coveted post and that special efforts must be made to get that post and that he indeed had made those special efforts in order to get it.

121. It is ironical that from his parent department Venkatachalam was specially brought in as Commissioner due to V. D. Deshmukh's inefficiency, and yet after Venkatachalam was repatriated to his parent department, it was none other than the same V. D. Deshmukh who was back in the saddle. Such were the inscrutable ways in which, thanks to ministerial interference and favour, were key appointments made in the FDA.

122. Nothing of what is said above about V. D. Deshmukh redounds to his credit.

PART IX

123. P. K. Kochar is yet another bright star in the FDA constellation who must take his fair share of responsibility for his actions and in ragging the FDA deeper into the mire.

124. Prior to June 1986 and since 1982 he was in Bombay (HQ) as Assistant Commissioner (Intelligence Branch). His duties were to investigate into complaints pertaining to spurious drugs and to do such other work assigned to him.

125. It would be through Kochar that the FDA would come to know of the existence of substandard and spurious drugs and other malpractices. As Venkatachalam rightly put it, the Intelligence Branch is eyes and ears of the Commissioner.

126. Kochar's sins of commission and omission even outstrip V. D. Deshmukh's. They are legendary.

A

127. As Assistant Commissioner (IB), Kochar was instrumental for the sample drives undertaken by the FDA between 1982 and 1986. In consequence, Kochar's duty was to take follow-up action and recommend steps to be taken against miscreant licence-holders. And once an action was recommended by him, it was his duty to keep an eye on its progress. Kochar did nothing of the kind.

B

128. With Dolas and Raykar, Kochar was in charge of the investigation regarding the J. J. Hospital deaths. The evidence discloses that Kochar manipulated the entire investigation by preventing and thwarting the early detection of the prime source of supply and worse still, by diverting attention towards Bakewell India who he knew was not the prime supplier. This has been stated earlier in this Report and does not brook repetition.

C

129. It has also been stated earlier that Kochar suppressed vital information given to him as early as 30th January 1986 by Assistant Commissioner Kamble of Nanded that Kailash and Company were the suppliers to Alpana Pharma. In spite of the report made to Kochar by Assistant Commissioner Kamble giving all material particulars, Kochar deliberately suppressed this vital report from the others. Kochar deliberately gave the impression that according to the information given by Kamble, Alpana Pharma's supplier was Haresh Chemicals in an endeavour to foist Bakewell as the prime supplier.

D

130. Kochar's attempts to prevent an investigation being made for the purpose of connecting the supply to Alpana Pharma by Kailash and Company have also been stated earlier as also that he directed the investigation to be made against Haresh Chemicals and then against Bakewell India as also that he deliberately prepared a legally untenable complaint against Alpana Pharma and stating that the prime source was Bakewell India.

E

131. He deliberately did not recommend the filing of any complaint against Kailash and Company or Chem Med Laboratories. And ultimately as a face saving device, all he did was to recommend the filing of an F. I R. against Kailash and Company, Haresh Chemicals and other simply for selling or purchasing drugs without a licence.

F

132. Till 19th February 1986 Kochar prevented and/or thwarted investigation against Ganesh Chemicals, despite the fact that his attention was drawn to this aspect by 3rd February 1986, and by the 10th February 1986 he had practically closed the investigation against Bakewell India.

G

133. Even after the admission of Jethalal Soni that he had mixed diethylene glycol, Kochar steadfastly refused to accept that Batch No. 27 contained diethylene glycol or that it was the glycerine of Ganesh Chemicals which was ultimately supplied to Alpana Pharma.

H

134. The evidence also discloses that Kochar's sole anxiety was to foist the responsibility for the J. J. Hospital tragedy solely on Alpana Pharma and to shield the persons who had sold the concoction to Alpana Pharma.

I

135. There is also reasonable suspicion that the words/letters " IW " were added in Invoice No. 007 dated 23rd November 1985 at the instance of Kochar.

J

136. The FDA reports sent to Government were based mainly on the investigation conducted by Kochar and as stated earlier, concealed more than they revealed. Thanks to Kochar's machinations, in none of these reports was any blame sought to be apportioned either to Kailash and Company or Chem Med.

K

137. (*i*) Pending Cyma Pharma's appeal before Mr. Bhai Sawant there were further breaches committed by Cyma Pharma. It appears that there was some proposal to carry out a raid on Cyma Pharma. At that time there were complaints against Cyma Pharma by the Drug Administrations of Calcutta, Madras and Chandigarh regarding chloramphenicol capsules manufactured by Cyma Pharma. Kochar who was attending to this matter had written to those Administrations assuring them that action was being taken against Cyma Pharma for manufacturing sub-standard chloramphenicol capsules.

(*ii*) On 4th June 1986, samples drawn of cymastrep were found to be sub-standard. On 15th July 1986 a submission was made to Commissioner Bhirud by Assistant Commissioner, Akre that no action be taken against Cyma Pharma by way of raid in the matter of the sub-standard cymastrep capsules. On 11th September 1986 an F.I.R. was filed against Cyma Pharma in connection with the sub-standard cymastrep capsules.

(*iii*) However despite Kochar's assurance given to the Drug Administrations of Calcutta, Madras and Chandigarh, he never recommended that any complaint be filed against Cyma Pharma for sub-standard chloramphenicol capsules. Kochar's explanation for this deliberate lapse, viz. that if he had done so he would have been transferred, can avail him nothing.

L

138. (*i*) Inspector Kalia of the FDA was apprehended for illegal export of mandrax tablets whose basic ingredient is methaquolene. In 1982 the manufacture of mandrax was prohibited and the FDA had stopped giving permission for the manufacture of methaquolene. Vikas Pharmacy at Dombivli had illegally manufactured methaquolene. As an officer in-charge of I. B., Kochar would certainly be concerned in detecting if a prohibited drug was being manufactured and on learning this it was his duty to take appropriate steps.

(*ii*) Early in 1983, Kochar knew of the illegal manufacture of methaquolene by Vikas Pharmacy and of Kalia's involvement. However, Kochar's only reaction was of double surprise, one that it should be manufactured though banned and two, that Inspector Kalia of the FDA should be involved. Kochar admitted that he did nothing in the matter, excuse being that it did not concern I. B. but the manufacturing department. He admitted that he did not bring this to any one's notice his excuse being that the Commissioner and others knew about it. All this is too ridiculous for comment for in Venkatachalam's words, the I. B. is the most important branch of the FDA, as it is the eyes and ears of the Commissioner.

M

139. Kochar made no secret of the fact that by going out of his way he has obliged several parties, namely Cyma Pharma, Mukhtavan, Semit, Panacea, Hem Pharma and Winsun Laboratories, that he also obliged N. D. Kulkarni, S. D. Bhirud, Fadnavis, Commissioners and Joint Commissioners without a pang of conscience and that it was in breach of his duty to do so.

140. Kochar deliberately gave false evidence and knowingly contradicted himself at several places. He did so with 3 objects in mind, namely (*i*) to protect the interest of Girdhar Kasat and his concerns, (*ii*) to disown any participation by him in the investigation in the J. J. Hospital tragedy and (*iii*) to pass the responsibility for defective investigation on to his colleagues. In all his 3 objects he has utterly failed, for in none of them can he escape the consequences of his own culpability.

141. Though Kochar was part of the investigating team, all field work was mainly done by him except in respect of 3 matters attended to by Raykar, namely (*i*) drawing of samples in the J. J. Hospital on 28th January 1986. (*ii*) sending Inspectors to Chem Med on 12th February 1986 and (*iii*) accompanying Kochar to Nanded.

142. But for the dilatory tactics deliberately indulged in by Kochar the entire investigation could have been completed by 3rd February 1986, by which time Kochar had in his possession complete information. He chose to ignore it. The deliberately defective drafting of the complaint by Kochar on 4th February 1986 is significant and reveals the tortuous working of his mind. His intention was to pre-empt any action against Kailash and Co. It matters not that in the complaint drafted by him

on 4th February 1986 he has skillfully sought to protect himself by addition in the draft " Subject to change ". However no efforts were made to amend the untenable draft.

143. All this cannot be attributed purely to bonafide mistakes or errors of judgment or the result of ignorance or lack of proper understanding. All this was deliberate, calculated as it was with one objective in mind, namely to protect Girdhar Kasat and his concerns.

144. Kochar's track record was also not far too edifying. He was a pastmaster at the game of deliberately conducting defective investigation. *Not less than 3 such instances appear on record.*

I

In 1976-77 in respect of the investigation done by Kochar in the case of Novaigin (not to be confused with Novalgin) tablets against a firm of Sakarchand Shah, charges were levelled against Kochar by Joint Commissioner Joshi of Nagpur of deliberate defective investigation with a recommendation that Kochar should be suspended. This is admitted by Kochar.

II

(*i*) Mangaldas Raghavji and Company were exporters of Dhania powder. In 1982, 6 samples of dhania powder were drawn from this firm which were found to be substandard. The deviation in purity in these samples exceeded the permissible 5 per cent.

(*ii*) Even so, on 15th September 1982 Kochar misrepresented to the Commissioner that Mangaldas Raghavji's dhania powder was within the permissible limit on the ground that the permissible limit was 10 per cent that no useful purpose would be served by taking legal action and only a warning to be given. In his submission of 15th September 1982, Kochar suppressed the fact that the sub-standard dhania powder seized from Mangaldas Raghavji was intended for export and that Kochar himself had ordered the destruction of the stock.

(*iii*) There was an earlier case where this firm had manufactured and sold substandard haldi powder. The partners had been prosecuted, convicted and sentenced to six months R. I. The conviction was upheld by the High Court and the Supreme Court. This vital information was also suppressed by Kochar in his submission of 15th September 1982.

(*iv*) As a result of this submission, replete as it was with suppressio veri and suggestio falsi, Mangaldas Raghavji and Company escaped with a warning despite its earlier sentence and conviction.

(*v*) To conclude the narration, unfortunately for Kochar the matter did not rest there. Somebody made a complaint to the Anti-Corruption Bureau that Kochar had taken a bribe for not prosecuting Mangaldas Raghavji and Company. On, 31st June 1985. Commissioner Bhirud asked for Kochar's explanation. Nine months later on 3rd March 1986, Kochar gave his written explanation that he had recommended the giving of a warning to Mangaldas Raghavji and Company because he did not know that the permissible deviation was 5 per cent and not 10 per cent. This matter is still pending.

III

Kochar was in-charge of drafting and issuing the show cause notices against Cyma Pharma. Regarding the show cause notice dated 7th April 1984 an order was passed on 5th November 1984 withdrawing permission given to Cyma Pharma to manufacture cymastrep capsules. Kochar was directed to keep watch on the activities of Cyma Pharma. He admitted that he did not do so.

IV

Kochar was also responsible for the delay in issuing the show cause notice and passing orders in the case of Cyma Pharma. He was in charge of putting up papers before the Joint Commissioner which he dallied as much as possible.

145. By the time the J. J. Hospital investigation started, surely Bhirud knew of the proclivities of Kochar and also about the ACB inquiry against Kochar as Bhirud himself had asked for Kochar's explanation on 31st June 1985 in the case of Mangaldas Raghavji and Company.

146. It is inconceivable that a person with a record as dismal as Kochar's should at all have been allowed to associate in the investigation into a matter as serious as the J. J. Hospital tragedy.

147. Nothing that Kochar has done or said inspires confidence (except where he is corroborated by unimpeachable documentary and other evidence as in the matter of Mr. Bhai Sawant's hand in the decision of Cyma Pharma's appeal). Otherwise whenever Kochar found himself cornered he had no compunction in throwing the blame on others including Health Minister Bhai Sawant as he did in the matter of Godama Laboratories and Talreja Bros. as also that Mr. Bhai Sawant had a hand in diluting on 12th December 1984 the stringent order passed by the FDA on 29th October 1984 against Cyma Pharma.

148. The mysterious and inscrutable working of the FDA is also made manifest by the fact that though the prime duty of the FDA must, in the interest of public health and safety, be to weed out spurious and substandard drugs from public reach, a person such as Kochar should have been appointed to head the I. B. instead of an officer known not only for his efficiency but also for his integrity. That Kochar should have occupied such a position can only be ascribed to a tragic joke. It is not as if those instrumental in appointing Kochar in I. B. were unaware of his background. The evidence discloses as it does that beyond protecting the vested interest of manufacturers and licence holders and obliging superiours by currying favour with them, Kochar did nothing in advancement of his duties.

149. Corruption is so patently seen in Kochar's case that it defies comment or elucidation. He is yet another officer who is a disgrace to the FDA.

150. His FALSTAFFIAN bonhomie did nothing to conceal the machiavellian deviation of his mind nor the theatrical attitudes he struck to dispel the shrewdness of his intellect used alas, towards self-aggrandisement and unworthy ends.

PART X

151. Coming to Assistant Commissioner Raykar, enough has been said earlier in this Report. What remains to be said about him is in connection with the presence of diethylene glycol in the killer glycerol.

152. Assistant Commissioner Rahim says that on 29th January 1986 he received a trunk call at Aurangabad from Raykar in Bombay, Raykar told him that batch No. 27 may contain diethylene glycol and Rahim made a note at page 5 of the file (Exhibit 423). Raykar denies having told anything of the kind to Rahim over the telephone as Raykar himself did not know of the presence of diethylene glycol at that time. File Ex. 423

153. Rahim says that he conveyed this information over the telephone to Babne at Nanded. Babne made a report (Exhibit 422) in which he recorded having made an inquiry on 29th January 1986 with O. P. Ladda whether he had any stock of diethylene glycol. This is corroborated by O. P. Ladda. Ex. 422

154. If this is true and if indeed Rahim's note and Babne's report were contemporaneously made on 29th January 1986 itself, the responsibility must squarely fall on Raykar for not having disclosed this vital information to Commissioner Bhirud and the investigating officers Dolas and Kochar.

155. But is it true? Or is it the result of some inter-officer rivalry in order to foist culpability on Raykar? The latter seems to be more probable.

156. The first circumstance is that on 29th January 1986 none of the doctors, or for that matter no one, not even experts like Dr. Kulkarni, Dr. Sane or Dr. Kripalani, even remotely suspected the presence of diethylene glycol in the killer glycerol. For that matter, between 28th January and 3rd February 1986, out of the three suspect drugs mannitol, diamox and glycerol, the last was least suspected to have caused the tragedy. It was only on 6th February 1986 by analysis that the presence of diethylene glycol in the killer glycerol was discovered by Dr. Sane. Even then it was not taken seriously by the FDA, whatever be the reason as is clear from the FDA reports to Government. There is no satisfactory evidence on record even remotely to suggest that Raykar knew about the presence of diethylene glycol on 29th January 1986. Hence he could possibly not give any such information to Rahim, who in turn could not have possibly conveyed it to Babne.

157. It is, therefore, difficult to see how Rahim could have made his noting
Exs. 423 & 422 in the file (Exhibit 423) and Babne his report (Exhibit 422) on 29th January 1986. One of the three is not telling the truth and in these circumstances the probabilities are weighed heavily against Rahim and Babne.

158. There is yet nother way to test the validity of the claim made by Rahim and supported by Babne and incidentally by O. P. Ladda. For Raykar to come to know of the presence of diethylene glycol on 29th January 1986, it must follow that without any known deaths having taken place in the past in India by reason of diethylene glycol contaminated glycerine, Raykar by reason of his being FDA officer was able to pinpoint the contaminant without any analysis, which even the doctors and experts could not do until the analysis was actually carried out. Raykar is not a technical officer nor does even the FDA claim that he is. It was also humanly impossible for him to have known or identified the contaminant as diethylene glyco merely from the symptoms, which even the experienced doctors of the J. J. Hospital were unable to do. Further, Raykar did not and could not have known either from Alpana Pharma or from any of its suppliers about the presence of diethylene glycol, for to have done so knowledge must be attributed to him prior to the J. J. Hospital tragedy or in any event prior to 29th January 1986. There is not a whisper of evidence to suggest anything of the kind. The only person who knew about the presence of diethylene glycol was the manufacturer, *viz.*, Jethalal Soni of Ganesh Chemicals. There is nothing even remotely to suggest that Jethalal Soni conveyed this information to any of this purchasers, much less to Raykar.

159. To suggest as done by Government's Counsel Mr. Tulpule that Babne, Kochar, Rahim or Raykar or all of them must have knowledge of the presence of diethylene glycol even prior to the repacking done by Alpana Pharma and the re-packed glycerine being sent to J. J. Hospital in December 1985 is a venture into the realm of conjecture and speculative reasoning not at all borne out by the record. So also is Mr. Tulpule's suggestion that these officers or any of them knew in December 1985 that Alpana Pharma's glycerine contained diethylene glycol and that they maintained conspiratorial silence about it till 29th January 1986, as also that diethylene glycol could not have come into the picture on 29th Janury 1986 unless these 4 officers or any of them knew about its presence in December 1985, more so as there were no prior deaths in India due to diethylene glycol poisoning. Diethylene glycol never came into the picture as suggested by Mr. Tulpule on 29th January 1986 at all. To say, as Mr. Tulpule does, that the evicdence to prove his assertions is lack of evidence, is meaningless. Needless to say I have referred to these submissions of Mr. Tulpule not for their validity but as a concession to the apparent seriousness with which they were advanced.

160. There is yet a third test, namely internal evidence, which reveals that Rahim's note and Babne's report are not contemporaneous documents.

161. If this information had been given by Raykar to Rahim on 29th January 1986 as claimed by Rahim, it would indisputably be a most vital piece of information. There is no reason, and none was given by Rahim, why despite the routine practice admitted by him of writing an official recording letter to a person giving important
p. 1662-B information, no such letter should have been written by him to Raykar. Rahim admits that he should have written such letter, but did not. Now if at all this undeniably important and vital information had indeed been given by Raykar to Rahim over the telephone on 29th January 1986, there is no reason, and none was given by Rahim, why in this instance he did not follow the routine practice of writing an official recording letter to Raykar.

162. Looked at yet another way, the record does not disclose that Kochar and Dolas (and possibly Bhirud) are exactly enamoured of Raykar. They would have been delighted to do Raykar in on this aspect. Yet none of them speak of this information allegedly given by Raykar to Rahim or of Rahim's note or Babne's report, and which they would have been only too happy to do because that would have pointed the finger of culpability to Raykar.

163. Significantly enough, the file (Exhibit 423) containing Rahim's note was not
Ex. 423 produced by Rahim on his own. It had to be specifically called for by the Commission from Nanded, and Rahim's evidence had to be adjourned for the purpose.

164. If Rahim's admission that he never showed this noting to Raykar is curious, his admission that he did not even show it to anyone else at Head Quarters assumes sinister proportions. No doubt realising this Rahim then stated that in the presence of Bhirud and Dolas, this noting was shown to the Government Advocate by Kochar after the present Inquiry commenced. Neither Kochar nor Bhirud nor Dolas say anything of the kind, and which they would have had Rahim's version been true. Rahim goes a step further and says that the file (Exhibit 423) containing his note Ex. 423 remained with Kochar. This is incorrect because apart from Kochar not saying so, Rahim's evidence had to be adjourned to enable him to fetch the file from Aurangabad where he had kept it under lock and key.

165. Rahim sailed from one absurdity to another. According to him there were two meetings held with the Government Advocate when he, Bhirud, Dolas, Kochar and Raykar and Drugs Inspectors were present and that in these meetings Rahim showed his note in the file (Exhibit 423) which was brought to Bombay by Kochar for those meetings. Once again neither Dolas nor Kochar nor Bhurud say anything of the kind. Rahim says that at these meetings it was decided that this note would be produced before the Commission if required. Surely one would have thought that Rahim would have himself produced the note at the earliest stage of his evidence without waiting for the Commission to call upon him to produce written corroboration. It was then that this note was forthcoming. I have no doubt that this note and Babne's report are got-up documents and are not contemporaneous. Rahim cannot get round all this merely by saying that he forgot to stage in his examination-in-chief that he had recorded Raykar's telephone conversation of 29th January 1986 in the form of a note. In so asserting Rahim displayed a convenient memory lapse about a vitally important aspect, not unlike several other witnesses. Nor could Rahim give any explanation why Bhirud, Dolas and Kochar should have stated in their evidence that they had no knowledge of the presence of diethylene glycol prior to 6th February 1986.

166. Apply any of these tests, and only one conclusion is possible. Rahim's note and Babne's report bolstering the note are got-up documents designed to frame Raykar. The attempt was unworthy.

167. Whatever be Raykar's sins of commission or omission, the one imputed to him is not one of them.

PART XI

168. S. D. Bhirud was the first Joint Commissioner and Licensing Authority of the FDA. From 1981 he was Commissioner. He was a prominent member of the Rangnekar group and became Commissioner after superseding P. S. Joshi. He was due to retire on 30th November 1986. He was re-employed for six months till 31st May 1987.

169. As Commissioner he was ex-officio member of the Drug Selection Committee of CSPO and ESIS.

170. The evidence discloses that Bhirud was a total misfit. In the J. J. Hospital deaths investigation he took absolutely no interest and virtually did nothing except to hold a few conferences in his chamber and blindly sign reports to Government which were tailor-made by Dolas. Had Bhirud taken the slightest interest as to what was going round him, he would have realised that those reports were far from what they should have been and realised the machinations of Dolas and Kochar. Unfortunately, the evidence disclosses, Bhirud was mortally afraid of Dolas and obediently signed those reports presented to him by Dolas.

171. His evidence suggests that he know precious little about the J. J. investigation for the simple reason that he never bothered to get himself acquainted with it at any stage.

172. His evidence discloses that he was the weakest possible Commissioner the FDA ever had and was amenable to influence and corruption. As already stated, he had obliged Cyma Pharma and the other 5 concerns including Semit, despite the fact that as Commissioner he was not concerned with diluting on 12th December 1984 the stringent FDA order of 29th October 1984. For that matter Semit's order was diluted twice when ultimately in January 1986 Bhirud let off Semit with a mere warning, which on Bhirud's admission he did to oblige Semit's managing partner Sipahimalani.

It is impossible to come to any conclusion other than the irresistible one beyond reasonable doubt that all this was done by Bhirud not in the interest of administration and certainly not in the interest of the public whose interest should have been paramount, but for self-interest and extraneous consideration.

173. While he was Commissioner, Bhirud framed and followed policies which were inconsistent with the Act and the Rules. He blithely waived the mandatory requirement of every manufacturer having his own quality control laboratory (in-house laboratory) in his premises, Thus licences were given to parties without their having an in-house laboratory merely on their giving an undertaking to have one. Predictably those undertakings were never enforced. It was only after the present Inquiry started that 350 notices were issued to such parties for cancellation of their licences. So far no action has been taken against them.

174. Bhirud attributes this relaxation to ministerial sanction and to that end cited a precedent when Dr. (Mrs.) Lalita Rao as Health Minister had waived this requirement in the case of 2 sister concerns. The fallacy of this exercise indulged in Bhirud is that those two cases were of exceptional hardship, with the result the then Exs. 249-250 Health Minister Dr. (Mrs.) Lalita Rao had ordered that those two sister concerns must have a quality control laboratory within two months. Such could never be taken as Government policy or as a precedent on which a so-called policy could be framed for indiscriminately issuing licences to persons not having their own in-house laboratories unless of course the motive behind such a "policy" was extraneous consideration.

175. Bhirud also followed the disastrous "policy" that no action by way of prosecution should be taken by the FDA even against manufacturers of life-saving drugs found to be adulterated or sub-standard or contaminated drugs unless death resulted as a result of their administration. Unscrupulous manufacturers thereby escaped and were encouraged.

176. The FDA "policy" was that licences could not be terminated except at the end of the year and if not terminated, were automatically deemed to be renewed This was yet another disastrous "Policy" which could ensure to the benefit of none except unscrupulous licence holders and officers of the FDA in whose "Interest" it would be to "induce" such licence hodlers to settle the matter across the table to the mutual benefit of both. Such a policy was in direct contravention of Rules 71 and 71 (3). Even so, Bhirud took no steps to reverse such a "policy" which could be a breeding ground for corruption.

177. No steps were taken by Bhirud to improve the working and administration of the FDA or to control S. M. Dolas. of whom on his own admission he was frightened and is so even today for what he can do to him. Bhirud had no hold over the administration and allowed Dolas to have his sway.

178. All in all, Bhirud was weak. Inefficient and lazy, and not above the general predilection of FDA officers of conferring favours for extraneous considerations.

179. I have not touched upon Bhirud's interest in the drugs industry because he has been served with a show cause notice to which he has sent his reply and the matter is pending.

180. It is impossible not to draw the irresistible inference beyond reasonable dout that Bhirud was guilty of dereliction of duty and corruption.

PART XII

181. The thread of S. M. Dolas and his doings have run through the earlier pages of this Report. Repetition would therefore be oppressive. It is now enough to set out his meteoric rise in the FDA. the manner in which he attained it and the consequences of his machinations.

182. At the material time, S. M. Dolas was holding charge as Jt. Commissioner and Licensing Authority (HQ). Hereunder a chronology of his rise in the FDA.

1958 .. Dolas Joined the FDA as Inspector at Baroda.

1960 .. Transferred to Aurangabad where he came to be on close terms with V. D. Deshmukh who then was the Chief Inspector at Aurangabad.

1963–64	—	Transferred to Bombay.
1971–72	—	Promoted as Chief Inspector (HQ) which post was designated as Assistant Commissioner in 1975.
1976	..	Transferred to Thane where he remained for one year and 4 months only.
1978	..	(*i*) While at Thane he was proposed to be transferred to Raigadh. The transfer order had been passed but Dolas managed to get himself transferred to Bombay (HQ).
		(*ii*) Venkatachalam was not satisfied with his work and conduct and instead of suspending him transferred him from Bombay to Beed and Chandrapur.
		(*iii*) Dolas however did not join duty and went on long leave for 23 months.
1980	..	Through the good offices of Dr. Hiray, Dolas got himself transferred to Bombay (HQ) where he remained as Assistant Commissioner till 1984.
1984	..	Through unwitting exertions of Mrs. Shalinitai Patil Dolas got himself transferred to Thane on grounds which were shown from his evidence to be false.
November 1985	..	Through the good offices of Bhai Sawant, Dolas was brought to Bombay as Joint Commissioner and Licensing Authority superseding 4 other senior officers.
24th March 1987	..	Bhai Sawant transferred Dolas from Drugs to Food, FDA where he is to this day.

183. Thus out of his 28 years service, Dolas managed to remain for 20 years in Bombay and 3 to 4 years at Thane.

184. Dolas' evidence discloses in no uncertain measure his close proximity to Government and closer still to Bhai Sawant. No person other than one having such powerful connections could have had the temerity to go on leave for 23 months at a time so as not to take a posting not to his liking, or could have had the ability to get himself transferred and posted to the place of his choice, namely Bombay, where Dolas is to this day, despite enquiries about his vested interest in the drugs industry.

185. The evidence on record unmistakably discloses that as Jt. Commissioner Dolas was thoroughly inefficient, that he rarely did his work, flaunted his political patronage and encouraged corrupt practices, and indulged in them himself. None of this could have been possible without a strong political clout (which Dolas enjoys to this day), and in the FDA became a law unto himself and a name to reckon with. Of him Commr. Venkatachalam has aptly said that his subordinates were afraid of him and he put his seniors in his pocket ; except Venkatachalam who ultimately paid the price of repartriation to his parent department.

186. Since the departure of Venkatachalam, the deterioration which had set in the FDA hit rock bottom during the time of Dolas. The only person who could control Dolas was the indominable and to Dolas the inconvenient Venkatachalam. He was eased out. And poor Bhirud afraid of Dolas, and still is for what he can do to him, was unable to control him. Thanks to his political influence, Dolas was in a position to get anyone transferred anywhere.

187. The largest measure of responsibility for the down fall of the FDA must rest on Dolas. Between the inept Bhirud and the unscrupulous Dolas, the degradation of the FDA was complete.

188. Dolas had no previous experience as Jt. Commissioner as he himself admits. This coupled with inefficiency and irresponsibility and dereliction of duty would for anyone else have earned instant dismissal from service. But Dolas sailed on untroubled, thanks to his political clout and smiles of favour from Health Minister Bhai Sawant.

189. His appointment as Joint Commissioner and Licensing Authority demoralised the FDA officers senoir and Junior to him because his appointment to that key and coveted post over his seniors was the signal of strong political patronage which Dolas had no compunction in flaunting.

190. All this in not of recent origin. Dolas' track record before his total descent down the scale of ineptitude and venality was no less spectacular. In 1976 serious charges of inefficiency and corruption were made against him while he was at Thane. On N. D. Kulkarni's report, a departmental enquiry had been instituted against him. He succeeded in scuttling that enquiry by the expedient of winning over the author of the report himself. Thus N. D. Kulkarni though a witness for the department, resiled from his own report and gave evidence in Dolas' favour. It can avail N. D. Kulkarni nothing to dismiss this while giving evidence before me as his mistake. The fact that Dolas had signed several blank licence forms was also suppressed from the Enquiry Officer. In his evidence before me, Dolas claimed that he had not signed even a single such form. However after 5 such blank forms were shown to him, he
Ex. 262 admitted that he had not brought these facts to the notice of the Enquiry Officer. As a result, from the one isolated instance, the Enquiry Officer came to the conclusion that Dolas was not in the habit of signing blank licence forms.

191. Thus as a result of Dolas' machinations and N. D. Kulkarni's "mistake" in resiling from his own report was Dolas undeservedly exonerated in the departmental inquiry. Dolas was happy. N. D. Kulkarni was also happy; he was rewarded by a premature transfer to Bombay.

192. In the witness-box Dolas attempted to disown his reponsibility in the investigation of the J. J. Hospital incident and tried to convey the impression that he was in no way connected with that investigation. The attempt must meet with failure, understandable though it may be from his point of view, intended as it was to cover up his own mischief and his various acts of commission and omission. Even for the moment ignoring the voluminous oral evidence from FDA witnesses including Commr. Bhirud, there is on record documentary evidence which unmistakably establishes that Dolas was very much connected with the FDA investigation into
Ex. 549 the J. J. Hospital tragedy. To ilustrate, Ex. 549 comprises of 11 files of submissions made by various FDA officers to Dolas regarding the investigation into the J. J. Hospital deaths. The reports to Government though signed by Bhirud were actually prepared by Dolas. He was present and took active part in the meetings in Bhirud's chamber as is evidenced by a number of minutes. It is true he took no interest in the investigation; but that cannot be equated with his having nothing to do with it as he now seeks to make out.

193. He issued a show-cause notice on 3rd February 1986 to Alpana Pharma and curiously enough, himself took it to Nanded for service on 13th February 1986.

194. After the investigation was made against Apex, he issued a show-cause notice on 13th March 1986 to Apex. After receiving Apex's reply dated 31st March 1986 Dolas passed on order on 5th May 1986 suspending Apex's licence for a mere 15 days.

195. As seen earlier, the evidence discloses Dolas' inordingate anxiety to protect Chem Med at all costs. On 21st February 1986 Dolas served a show-cause notice to Chem Med. Chem Med sent its reply dated 4th March 1986. No action was taken on the ground that the present Commission is in progress and despite the opinion given by the Law and Judiciary Department on 19th September 1986.

196. On 5th February 1986 Dolas issued a show-cause notice to Trans India and after receiving its reply dated 14th February 1986 suspended its licence for a mere 7 days.

197. He prosecuted Trans India but did not join Apex. Neither did he launch an independent prosecution against Apex, even though the case against Apex was stronger than against Trans India because Apex's was a recurring offence with the background of the written complaints of Apex's chemists that they were being forced to give false reports without the tests actually being carried out.

198. Dolas admits having passed an order for 2 additional products in favour of a drug manufacturing unit in which his own daughter is a partner.

199. The evidence indicates that far from exhibiting his investigative prowess or efficiency, Dolas was endowed with the gift of using, to his ends, persons who could influence people in power. He knew exactly who was the right person to approach as an intermediary on his behalf.

200. To that end, through a relation Dani, Dolas approached Bhaskarrao Chalukya to put in a word on his bahalf to Dr. Baliram Hiray. With fiendish cleverness Dolas suppressed from Chalukya the fact of the departmental inquiry against Dolas and that it was in lieu of suspension that Dolas had been transferred to Chandrapur and Beed. If these inconvenient facts had been brought to the notice of Bhaskarrao Chalukya, I have not the slightest doubt that the true Gandhian that he showed himself to be in the witness-box, he would never have obliged. Unfortunately, poor dear Bhaskarrao Chalukya took Dolas at face value and obliged, little knowing that he was being taken for a ride.

201. Likewise Dolas had also no compunction in approaching Mrs. Shalinitai Patil which he did through her trusted party worker Nirbhay Singh for getting his work done through the good offices of her husband who was then the Chief Minister. Relying upon Nirbhay Singh on whom she had the fullest confidence, Mrs. Shalinitai Patil unwittingly obliged.

202. The manner in which Dolas managed to supersede 4 other officers senior to him and get himself appointed in charge of the post of Jt. Commissioner and Licensing Authority in 1985 is also suggestive of his having approached Health Minister Bhai Sawant through someone. To supersede 4 officers senior to him must take some doing.

203. Dolas was a manipulator of no mean order.

204. While Dolas was Jt. Commissioner, 852 drugs where found to be sub-standard. This was suppressed from this Commission by the FDA officers while giving evidence. I handed over to the Government Advocate three sets of tabulated statements for three quarters between 1st January 1986 and 30th September 1986. I directed Dolas to file explanatory affidavit by 18th March 1987, which Dolas did on 7th April 1987 (Ex. 492). The tabulated statements read with Dolas' affidavit disclose that practically no action had been taken regarding these 852 drugs and that even show-cause notices had not been issued in most cases. After I passed my order on 12th March 1987, 138 show-cause notices were issued. Most of the cases are still pending. Even where decisions were taken, only warnings were administered though life-saving drugs were involved, and not a single prosecution has been launched on the specious plea that it is not the policy of the FDA to launch prosecution. Ex. 492

205. Dolas preferred to follow guidelines and not the Act and the Rules, losing sight of the fact that even the guidelines do not advocate that no prosecution can be launched. Dolas, like Bhirud, proceeded on the absured "policy", no death no prosecution, losing sight of the fact that all deaths do not necessarily come to the knowledge of the FDA.

206. According to Dolas, it is not the policy of the FDA to cancel licences and even in cases of repeated breaches only warning is given. He was however unable, and rightly so, to substantiate this so-called policy either from the Act, the Rules, or the guidelines.

207. Slight of build, soft of speech, initially unperturbed, S. M. Dolas radiated old-world courtesy. None of this however could disguise the deviation of his mind or his absured and fanciful pretentions to rectitude. He believed not in force but in subtlety; and he believed he was subtle. That was his mistake. His conduct was as negligible towards the efficient and honest discharge of his duties as his tortuous mind was as Shylockian in its capacity for intrigue. Dolas wielded absolute power in the FDA. Absolute power corrupts absolutely and there is nothing by way of Dolas' activities in the FDA to doubt the authenticity of that axiom. With him in virtual control and Bhirud as his assiduous sycophant and compliant toady, the whole order of the FDA corresponded with the rapacious capacity of its members and resulted in the ridiculous difference between their supposed aims and their actual achievements. To Dolas can be attributed the corruption of power reinforced by disdain of consequence, conceived in political patronage and his infinite capacity to use others for the fulfilment of his objectives. It is unfortunate for

Bhirud and the FDA and the public at large, that he should have surrendered himself so totally to the disastrous influence of Jt. Commr. Dolas. If I conclude that in Dolas' moulding hands, Bhirud was a moral coward, Bhirud has only himself to blame for that deliberate revelation. Dolas left the witness-box a deflated man, of cringing manners, indifferent to truth as he was to his duties. It is difficult to see how a man so utterly lacking could even have been thought of to hold charge a post as sensitive as Licensing Authority even for a short span of time and with a limited possibility of choice.

208. An officer of neuter conscience to whom moral boundaries are unknown. No doubt Dolas' loyalty to Bhai Sawant in the witness-box will increase his claim to consideration in that august quarter.

CHAPTER XVII

The only questions that remain are questions (*i*), (*j*) and (*k*). Those questions and my answers thereto are, in the light of the earlier discussion, as under :

Question (*i*).—" Whether there was any administrative lapse on the part of the J. J. Hospital authorities; Directorate of Medical Education and Research in promptly assessing the gravity of the situation in J. J. Hospital, Bombay, and reporting to the higher authorities; "

Answer.—Yes, in so far as J. J. Hospital authorities are concerned. No, in so far as the directorate of Medical Education and Research is concerned.

Question (*j*).—" Adequacy of otherwise of the existing statutary and administrative procedures/measures in J. J. Hospital/Directorate of Medical Education and Research/ Office of the Commissioner of Food and Drugs Administration to prevent and to effectively deal with such incidents; and to suggest remedial measures to avoid such incidents in future; "

Answer.—No comment is necessary as far as the Directorate of Medical Education and Research is concerned.

As far as J. J. Hospital is concerned, by far and large, the administrative and statutory provisions are adequate. However there is much to be desired *inter alia* in the manner in which the Dean, Superintendent, certain doctors and staff reacted to this incident, as also the manner in which Medical Store operates, the total lack of adequate inter-communication facility, the manner in which Drugs are recalled and total non-accountability. Further, the procedure prescribed by Dr. Pruthi in 1973 which remains to be implemented should be implemented. Chapter III of his Report (pages 20 to 39, Exh. 25) deals with purchase and storage of drugs in the J. J. Hospital. Even though Government has accepted those recommendations in toto, all that has been done is to place Medical Store in the charge of the Professor of Pharmacology.

The statutory and administrative procedures/measures in the Office of the Commissioner, FDA, to prevent and effectively deal with such incidents, are adequate. However what has been woefully lacking is the desire to enforce them due to inter-officer rivalry and undercutting, lack of control, political clout, indiscipline, non-enforcement of the provisions of the Act and Rules, corruption, and non-accountability.

All these factors contributed to this unnecessary tragedy which could have been averted had these factors not been present.

Remedial measures pertaining to J. J. Hospital, Directorate of Industries and FDA as well are suggested in the Recommendations hereafter.

Question (*k*).—" Such other matters as may be germane to the above. "

Answer.—What are matters germane regarding J. J. Hospital ?

These 14 unfortunate patients are only the known patients who died in this unnecessary tragedy. There are several others unknown who must have died and more, who must have been crippled for life as a result of the administration of this lethal glycerol, Batch No. 27.

In addition to the 14th who died, 34 patients who found their way to Nephrology had been given glycerol, Batch 27. They did not die in the Hospital. Dr. Kripalani says that there were 34 such cases under his supervision. He and his team where actively looking for signs of renal deterioration but there were none. They were concentrating on all the problems including those of liver, kidney and brain. He says that while the patients who did not die in the Hospital did not seem to be affected by the contaminated drug while they were in the Hospital, it is possible that the contaminated glycerol could have a delayed effect and that their condition could have aggravated after the first dosage on 25th. However that condition was not manifested by them.

Dr. Panda (Reader in Neurosurgery, Unit I) who treated Hemant Ranade, Bapu Thombre and Ramji Balu Kasar produced a list (Ex. 78) prepared by the sister-in charge of the patients who were given glycerol orally in his Unit No. 1 from January

1985 till the end of January 1986. Between 7th and 25th January 1986, 12 patients out of this list had received glycerine orally. Out of them 6 were discharged or relieved (i.e. they would be required for follow-up treatment); 2 patients got themselves discharged against medical advice; one patient survived for another three months and died due to respiratory infections from tracheotomy in March 1986 in the J. J. Hospital. The remaining 3 were Hemant Ranade, Bapu Anand Thombre and Ramji Balu Kasar who were amongst the 14 who died.

Dr. Wagholikar (Professor of Pathology) cannot say whether the human body can neutralise diethylene glycol in small quantities as medical knowledge on this aspect is imperfect. He adds that it is difficult to say why no deaths were caused by the administration of glycerol which contained only 3 per cent diethylene glycol (namely Alpana Pharma's Batch 21) even though from that batch glycerol was given to a number of patients for several days on end. However, animal experiments showed that if they are given water with diethylene glycol upto 5 per cent they can withstand it for a period of 2 months. According to Dr. Wagholikar, long term effects of diethylene glycol are possible. He only differs from Dr. Kripalani in that in the case of diethylene glycol poisoning, there is no question of delayed primary reaction. Dr. Wagholikar goes on to say that the extent of the damage to the kidneys would be related to the dose, duration and percentage of diethylene glycol in the contaminated glycerol. Presence of 3 per cent diethylene glycol (as in Batch No. 21) is not permitted and any percentage over that would lead to fatality, and as much as 18.5 per cent (as in Batch No. 27) would certainly be fatal. O. P. Ladda of Alpana Pharma was unable to dispute that Batch 21 contained 3 per cent diethylene glycol. Even if the presence of diethylene glycol is 3 per cent or less, there is danger of damage to the kidneys, if not death of the patient. Dr. Wagholikar is positive that administration of diethylene glycol of the percentage of 18.5 per cent as in Batch 27 would certainly cause damage to the kidneys and other organs even if it is given once and even if death is not caused thereby. In some cases the manifestation may be to a minor degree which may subside; in a few cases there may be no manifestation at all; and in some cases the mainfestation may be more severe. Dr. Wagholikar is equally categorical that a normal healthy kidney will not remain so if a person is given diethylene glycol in the percentage of 18.5 even in a single dose.

Over and above the 34 patients who went to Nephrology, pray, what has happened to the other patients who were given Alpana Pharma's glycerol of Batch 27 or Batch 21 prior to their discharge ? Are their whereabouts known ? Is their condition known ? Out of those how many are dead and how many crippled? It was not possible for this Commission to trace them or to enquire as to their well-being. That is for Government to do and to offer them adequate compensation because for no fault of theirs, they were administered contaminated glycerol in a Government Hospital. This is the duty and responsibility of Government to discharge, which in law and good conscience it should do.

There is another matter germane to the J. J. Hospital though not strictly within the terms of this reference. The living conditions of the resident medical doctors are pitiable. Their quarters are cramped, insanitary and uninhabitable. Such living conditions of these young budding doctors, male and female, can contribute neither to morale or efficient discharge of duties. Government may do well to look into this matter and give redress.

Matters germane to the Industries Department, F.D.A. and other connected matters are set out in the Recommendations hereafter.

CHAPTER XVIII

CONCLUSIONS

I

J. J. HOSPITAL

1. The killer drug was Alpana Pharma's glycerine Batch No. 27 contaminated as it was with the lethal diethylene glycol.

2. The Dean Dr. R. S. Chandrikapure and the Superintendent Dr. V. G. Deshmukh were negligent and guilty of dereliction in the discharge of their duties in not taking any action after receiving information of adverse drug reaction in the J. J. Hospital.

3. (*a*) Credit must go to the doctores of Nehphrology, namely Dr. A. L. Kripalani, Dr. (Mrs.) R. A. Sirsat and other doctors under them as also Dr. D. A. Palande of Neurosurgery Department and Dr. Wagholikar of Pathology Department, for their commendable and expeditious detection of the suspect drug as also for the preventive and curative steps taken by them.

(*b*) Credit must also go to Dr. R. D. Kulkarni for sending the samples to Dr. R. T. Sane for toxicity test on glycerine Batch No. 27.

4. (*a*) Pharmacology Department consisting of Professors of Pharmacology Dr. R. D. Kulkarni and Dr. S. V. Shaligram, and Associate Professor Dr. (Mrs.) P. S. Worlikar, Pharmacist A. K. Jamadagni and Compounder N. R. Soudi are guilty of negligence and desreliction of duty in not taking prompt and effective steps to stop further dissemination of the suspect drugs.

(*b*) However since Dr. (Mrs.) Worlikar was all along acting under and/or was dependent upon the orders and directions of Dr. Shaligram, her negligence is mitigated to a considerable extent by the follow-up work which she did in the matter of detection of the suspect drugs.

(*c*) Soudi's negligence is also mitigated inasmuch as he acted under the directions of Pharmacist Jamadagni.

5. (*a*) The affected departments of the J. J. Hospital, namely Neurosurgery and Neurology, were prompt in withdrawing the suspect drugs.

(*b*) There was however gross negligence in the Ophthalmology Deapartment which did not stop the administration of the suspect drugs till the morning of 28th January 1986.

(*c*) No responsibility can be attributed to Dr. (Miss.) M. A. Kamble for her failure to withdraw the suspect dugs earlier than 28th January 1986, inasmuch as she was not aware about the drugs being suspected nor of any withdrawal circular.

(*d*) In this episode Dr. (Miss) M. A. Kamble is sought to be falsely implicated on the ground that she got the nurses order book tampered with and/or that she allegedly knew earlier than 28th January 1986 about the suspect drugs.

6. It was an error of judgment on the part of Dr. P. P. Pargaonkar of Nephrology in not adequately bringing home to Dr. (Miss) Parul Shah of Opthalmology the gravity of the situation and the urgency of stopping the administration of the suspect drugs, nor was the gravity and urgency sufficiently understood by Dr. (Miss) Parul Shah by reason of her inexperience and being the junior-most doctor in the department.

7. Administration of even a small dose of contaminated glycerol is likely to affect and/or endanger the health of patients to whom it was administered.

8. The living conditions of resident medical doctors are pitiable being cramped, insanitary and uninhabitable, necessarily a affecting their morale and efficient discharge of duties.

9. Pharmacist Jamadagni was responsible for improperly placing order exceeding 11% on Alpana Pharma contrary to the mandate of the Industries Department.

II

Rate Contracts

1. In the matter of awarding of rate contract to Alpana Pharma, the Industries Department including Industries Officer P. K. Torvi and Addl. Director of Industries S. B. Satalkar are guilty of favouritism and/or corruption right from the matter of entertaining the tender of Alpana Pharma, examining the same, preparing and verifying the comparative statement and not placing the conditions of Alpana Pharma before the Rate Contract Committee or drawing the attention of the Committee members that Alpana Pharma's tender being a conditional tender merited rejection at the threashhold.

2. The members of the Rate Contract Committee Dr. C. J. Mistry, the Addl. Director of Industries S. B. Satalkar and Asstt. Commissioner L. V. Raykar are guilty of negligence and dereliction of duty in not peroperly applying their minds to the matter of awarding the rate contract to Alpana Pharma and being solely guied by Dr. R. D. Kulkarni who was the moving spirit in awarding the rate contract to Alpana Pharma.

3. Dr. R. D. Kulkarni awarded the rate contract to Alpana Pharma for extraneous considerations flowing from Ramanlal Karwa.

4. (*a*) Dr. R. D. Kulkarni, Joint Director of Industries N. D. Dharap and Industries Office P. K. Torvi joined hands in the matter of granting improper rate revision to Chem Pack and consequently to Alpana Pharma so as to benefit these two parties and themselves and at a loss to Government.

(*b*) S. D. Bhirud and Dr. C. J. Mistry were negligent in not preventing the said improper rate revision. However no deliberate motive can be attributed to them in ths behalf.

III

Manufacturers, Merchants, Traders and Suppliers

1. No negligence, malfeasance or misfeasance can be attributed to Alpana Pharma in the matter of placement of the order for glycerol with Girdhar Kasat.

2. Even though Alpana Pharma placed an order for glycerine I.P., Kasats supplied to Alpana Pharma industrial glycerine without informing Alpana Pharma that the glycerine was not of the quality ordered.

3. The concoction prepared by Jethalal Soni, the proprietor of Ganesh Chemicals comprised mainly of lethal diethylene glycol and sorbitol with a dash of glycerine. It was this concoction which ultimately reached the J. J. Hospital as Alpana Pharma's Batch No. 27.

4. Jethalal Soni however did not know that this glycerol would be used as drug.

5. There has been a manifest conspiracy between Girdhar Kasat, Mahendra Doshi, S. R. Dafatary the Warehouse Manager of M/s. Edgar Handley, and Jethalal Soni to falsely suggest, that the two drums from which samples were drawn and analysed were not sold to Alpana Pharma, with a view to absolve themselves from the liability for supplying industrial glycerine to Alpana Pharma.

6. Evidence discloses sufficient material to prosecute Mahendra Doshi, Girish Doshi, Girdhar Kasat, Bharat Kasat and O. P. Ladda for having committed offences punishable under Section 27(*a*) of the Drug and Cosmetics Act, 1940 and also under Section 304-A of the Indian Penal Code.

IV

FDA

A

From the evidence on record the following facts emerge in grisly detail :—

1. The entire structure of FDA has been corroded by rampant and unabashed corruption, deleterious indiscipline, naked favouritism, crude nepotism and gross ministerial interference at every stage and a sense of non-accountability all round.

2. As a result, there is hardly any control or supervision by superiors over their subordinates in the matter of carrying out their statutory obligations and strict compliance with the provisions of the Act and Rules which are deliberately breached and knowingly flouted.

3. Health Ministers who have given evidence have rarely shown any anxiety to control the unbridled power and rapacity of the FDA officers. On the contrary, such Health Ministers have encouraged corruption, favouritism, deliberate violation of the Act and Rules by their own acts of omission and commission intentionally and knowingly performed with a view to confer favour or ministerial largesse in the form of transfers and postings of choice, undeserved promotions of FDA officers and concessions, cancellation of stringent orders or withdrawal or withholding of mandatory prosecutions in accordance with the provisions of the Act against the licences *viz.* manufacturers, repackers, etc.

4. The respective Health Ministers not only failed to discharge their duties in ensuring proper enforcement of the provisions of the Act and Rules but each of them was guilty of violating the provisions of the Act and Rules and of gross misuse of their position, power and authority, knowingly done for extraneous considerations and for all considerations other than equity, justice and good conscience required of them in the discharge of their duties.

5. Health Ministers who have given evidence have not allowed FDA to function as an independent organisation vested with certain powers and authority and obligated to ensure public health and safety by properly regulating the manufacture, sale and distribution of drugs and preventing manufacture, sale and distribution of sub-standard, spurious and misbranded drugs, and have thereby rendered FDA to be an important organisation, existing merely for collection of licence fees officially and vast sums of money unofficially.

6. Gross ministerial interference, misuse of powers and failure to enforce the provisions of the Act and Rules in all matters have been done for the benefits of or to suit the convenience of licence holders with the knowledge of the same being against public interest, public health and public safety.

7. Most of the Health Ministers who gave evidence and FDA officers lack basic knowledge or understanding of the provisions of the Act and Rules and/or their respective duties and/or their authority thereunder.

8. Attempts by Commissioner Venkatachalam to improve the working and restore the image of the FDA and to root out corruption were deliberately thwarted by officers of the FDA with the active connivance of the Health Ministers concerned.

9. Large powers are vested in the Joint Commissioner (Head Quarters) who is the Licensing Authority. He is not even amenable to the supervision and control of the Commissioner. Subject to an appeal to the Minister, the Licensing Authority is the final authority and last word in matters vitally concerning the licence holders. Such vast and untramelled powers in the hands of unscrupulous Jt. Commissioners and Licensing Authority were an instrument of harassment and a device to make vast sums of money added to the inducement of the manufacture of substandard, spurious and misbranded drugs and total lack of fear of the consequences provided by the Act and Rules.

10. The procedure followed by the FDA for granting licences is faulty and contrary to the provisions of the Act and Rules, and is deliberately moulded to suit the convenience of the licence holders instead of protecting the interest and health of the general public, for which the FDA is intended to function.

11. The procedure for inspection before and after grant of licence is not only defective and faulty, but is also cursory and contrary to the provisions of the Act and Rules.

12. FDA has formulated certain " policies " and " procedures " which are not only contrary to provisions of the Act and Rules but are in violation of the stringent provisions therein and are highly dangerous from the point of view of public interest, public health and public safety.

13. These " policies " are formulated and procedures followed only with a view to benifit the licence holders and to circumvent the stringent requirement of the law.

14. There is hardly any machinery worth the name in the FDA to take up any follow-up action after grant of licences and receipt of complaints.

15. Records maintained by FDA in respect of receipt of complaints and follow up action are faulty, totally inadequate and misleading. Recurring breaches are therefore permitted to go unnoticed and /or unpunished.

16. For the FDA penal provisions of the Act and Rules, even though mandatory, do not exist. These penal provisions have deliberately not been enforced in almost all cases. Such actions if taken by the FDA against erring licence holders, are initiated after procrastination and reluctance, by which time the mischievous drug, be it a life-saving drug continues to be sold to an unwary public and continues to be prescribed by unwary medical practitioners.

17. The Analytical Laboratory of the FDA is ill-equipped and inadequate to meet the requirements of sampling. There is no guarantee that samples are correctly analysed as records maintained of the analysis are not such as inspire confidence as to their accuracy or veracity.

18. Even though, subject to an appeal to the Central Drug Laboratory, the report of the Government Analyst/Analytical Laboratory is final and binding on all concerned including FDA, the FDA has omitted to abide by or follow such reports so as to favour licence holders for extraneous considerations.

B

Investigation by FDA into the J. J. Hospital tragedy

1. The investigation was faulty, slipshod, leisurely and deliberately defective and misleading.

2. Either the FDA did not know how to tackle the situation (which is difficult to believe) or deliberately omitted to take steps for expeditious investigation or to file a legally sustainable complaint against Alpana Pharma.

3. The FDA investigation was marred by group rivalries, the desire to undermine the work of colleagues, casualness of approach, negligence and dereliction of duty resulting in faulty clues deliberately being persued and the correct clues being deliberately ignored.

4. The provisions of the Act and Rules are adequate to serve the purpose for which they are enacted. However lack of integrity on the part of those in charge of the enforcement of the Act has resulted in the present situation. The improvements will have to include proper enforcement of the provisions of the Act and from time to time accountability to the general public in that behalf.

5. The real and active culprit in negligence and dereliction of duty was Asstt. Commissioner Kochar who was virtually in charge. It was in Kochar's interest to see that a defective complaint was filed against Alpana Pharma at Nanded suppressing the fact that the prime supplier was Ganesh Chemicals.

6. (*a*) In the matter of reports made to Government FDA deliberately failed to reveal to Government the true facts of the investigation it was doing.

(*b*) Vital information was suppressed in an attempt to misinform and mislead Government from knowing the true state of affairs.

(*c*) Vital facts were deliberately not stated, for instance to name a few, (*i*) the receipt by FDA of Chem Med's report which revealed or should have revealed to the FDA that Chem Med had falsely certified Batch No. 27 to be of standard quality, (*ii*) H. M. Chemicals' vital letter dated 3rd February 1986 clearly establishing the purchase by them from the original supplier Ganesh Chemicals (Jethalal Soni) sale thereafter to Kailash and Co. (Kasat brothers), whereby was revealed the link between Alpana Pharma and its prime and intermediary suppliers; (*iii*) that Asstt. Commissioner Kamble had given information as far back as 30th January

1986 identifying Kailash & Co. as the immediate supplier of Alpana Pharma. Instead deliberate diversionary tactics were used to focus attention on Bake well (India) who had not supplied the killer glycerol to Alpana Pharma.

(*d*) An impression was sought to be created in Government's mind that on a thorough inquiry by FDA, glycerine was not the cause of the deaths in the J. J. Hospital.

(*e*) Obvious steps in the investigation were deliberately ignored, which if taken would, for instance, have led FDA straight to Chem Med and the other links would have been revealed.

(*f*) Government was misled as FDA deliberately took no steps against Chem Med by way of a prosecution.

(*g*) No mention was made that as early as 7th February 1986, Dr. Sane had discovered the presence of diethylene glycol. On the contrary, Dr. Sane's achievement was belittled and suspicion was sought to be cast on it to the extent of slapping a show cause notice on the laboratory regarding matters which had nothing to do with the vital discovery by Dr. Sane of the presence of diethylene glycol.

(*h*) FDA tried to take credit for the discovery of diethylene glycol and shielded Dr. Pilankar's lethargy and lapse in not discovering its presence till June 1986 after the present Commission started its sittings.

(*i*) Instead of appreciating Dr. Sane's discovery of the presence of diethylene glycol, which should have been done by the FDA, and not belatedly in June 1986, as a face saving devise after the Commission started its sittings, FDA tried to shrug away Dr. Sane's discovery on the specious ground that it was not an official test and even slapped a show cause notice on the laboratory, as stated earlier.

(*j*) The Reports were merely a ruse to hide from Government the deliberate and premeditated scuttling of FDA investigation in the right channels and diverting it into wrong channels, as FDA had decided whom to protect (viz. Kasats) and who was to be made scapegoats (viz. Backwell India and Dr. Sane.).

(*k*) The Reports contradicted themselves. On the one hand FDA sought to implicate Alpana Pharma as having mixed a contaminant, yet at the same time advanced the proposition that there was no diethylene glycol in Batch No. 27, and all in a patent attempt to protect Kasats and their concern Kailash & Co. who were the immediate suppliers to Alpana Pharma.

(*l*) Jt. Commissioner Dolas misled and misguided Government not only regarding the investigation but also to lull Government into a sense of false security by playing down the gravity of the entire incident.

(*m*) Out of inefficiency, indolence or fear of Jt. Commissioner Dolas or all three, Commissioner Bhirud allowed himself to be manipulated by Dolas and merely signed the Reports on the dotted line. Thereby Commissioner Bhirud abdicated his power, position and authority in favour of Joint Commissioner Dolas.

V

Grant of Licence to Alpana Pharma

1. In the matter of grant of licence to Alpana Pharma, FDA overlooked the provisions of law and improperly granted the licence and that too expeditiously. This was by reason of the influence of Ramanlal Karwa with the FDA officers such as Drugs Inspector Babne, Asstt. Commissioner Kamble, Asstt. Commissioner S. G. Jadhav and Jt. Commissioner V. D. Deshmukh. Ramanlal Karwa was interested in influencing and did influence FDA officials as for all practical purposes Alpana Pharma belonged to the family of Karwa and O. P. Ladda was a mere dummy.

2. To the knowledge of the FDA, Alpana Pharma had neither the intention nor the capacity to carry out the undertakings given to the FDA in the matter of having a quality control laboratory in its own premises and the undertakings given on behalf of Alpana Pharma were to the knowledge of the FDA given only with a view to circumvent the legal requirements in respect of the grant of the drug repacking licence to Alpana Pharma.

VI

Alpana Pharma as Repacker

1. O. P. Ladda was ingnorant about repacking procedure nor had he any experience of the same.

2. O. P. Ladda was grossly negligent in repacking glycerol, Batch No. 27 without testing either the raw material or the final produce, despite the warning in bold letters on the drums supplied to Alpana Pharma that the contents were not for medicinal use. Even so, he supplied it as a repacked drug.

VII

Chem Med Laboratories

1. Chem Med Laboratories issued test certificate in respect of Alpana Pharma's glycerol, Batch No. 27 without actually carrying out the tests. In any event, the test certificate issued by them was false to their own knowledge as admitted in evidence.

2. Even on earlier occasions, Chem Med was found guilty several times of gross irregularities in the matter of analysis of drugs and/or issuance of test reports without actually carrying out the tests and had accepted and suffered the punishments in respect thereof.

VIII

Apex Laboratories

1. Apex Laboratories had falsely certified that Trans India's mannitol had passed the pyrogen test without actually carrying out the test.

2. On their own showing Apex Laboratories were habituated to issuing false test certificates without actually carrying out the tests and that in respect thereof, their own Assistant Chemists had in the years 1984 and 1986 complained to the FDA, without FDA taking any action against Apex Laboratories.

3. There was interaction between Apex on the one hand and Dolas, N. D. Kulkarni and Bijamwar on the other, for extraneous considerations.

IX

Health Ministers

(i) *Mr. Bhai Sawant*

1. A. K. Chavan's allegation regarding Health Minister Bhai Sawant is a canard. The evidence does not disclose that Mr. Bhai Sawant had any hand in the granting of the rate contract to Alpana Pharma either for a donation or otherwise.

2. The evidence does not disclose any nexus between Rural Upliftment Organisation or Mr. Bhai Sawant on the one hand, and Alpana Pharma on the other. Mr. Bhai Sawant is entitled to be exonerated from this charge of corruption levelled against him by A. K. Chavan.

3. However, Mr. Bhai Sawant has given false evidence in order to dissociate himself in the matter of making collections from pharmaceutical concerns through FDA and from others for the Rural Upliftment Organisation.

4. Mr. Bhai Sawant acted arbitrarily and mala fide in the matter of transfer to Bombay of S. D. Patil, Mali and P. R. Deshpande, which order had to be set aside by the the High Court in a Writ Petition.

5. Mr. Bhai Sawant showed undue favour to S. M. Dolas in the matter of his transfer to Bombay and appointing him as the person holding charge of the office of Joint Commissioner and Licensing Authority from 29th November 1985 and thereby superseding the claims of 4 officers senior to him. Mr. Bhai Sawant is guilty of extraneous considerations in this matter and of using the weapon of transfer to confer promotion and favour on S. M. Dolas.

6. Mr. Bhai Sawant was motivated by extraneous considerations in the matter of deciding the appeal of Cyma Pharma and permitting them to manufacture life-saving drugs even though they were found guilty of manufacturing sub-standard drugs.

7. Mr. Bhai Sawant misused his ministerial power and authority by ordering Assistant Commissioner Raykar and through him Dr. R. D. Kulkarni, the granting of rate contracts to Samarth Pharmaceuticals and Welcome Laboratories.

8. Mr. Bhai Sawant attempted to exert pressure on Commissioner Bhirud and Assistant Commissioner Raykar and thereby misused his ministerial office, so as to prevail upon them into giving evidence favourable to him.

9. In spite of being made aware of the vested interest of Joint Commissioner Dolas in the drugs industry, and despite his giving an assurance to the Commission to remove him from the sphere of influence, Mr. Bhai Sawant not only failed and neglected to carry out his assurance, but in an attempt to hoodwink the Commission resorted to the expedient of merely transferring Dolas from the Drugs to the Food Department in the same building on the same floor.

10. Mr. Bhai Sawant devalued the office of the Commissioner and thereby demoralised the Commissioner and other officers of the FDA.

11. Mr. Bhai Sawant is guilty of corruption, misuse of ministerial power and authority and dereliction of duty.

(*ii*) *Dr. Baliram Hiray*

1. Dr. Baliram Hiray was guilty of gross ministerial interference and of passing orders for extraneous considerations in the matter of—

(*a*) Transfer of V. D. Deshmukh from Pune to Bombay.

(*b*) Diluting the proposed action by the Upa-Lokayukta against V. D. Deshmukh and N. D. Kulkarni, and

(*c*) In the matter of appointment of V. C. Sane as the Commissioner of FDA, contrary to the strong secretarial notings and views of the Commissioner and in spite of having gone through his confidential records.

2. Dr. Baliram Hiray is guilty of improperly passing, and that too without sanction of the Home Department, the order for withdrawal of prosecution against Tolia of Atul Pharmaceuticals for extraneous considerations. To that end Dr. Hiray procured a false, untenable and tailor-made report from the then Acting Commissioner V. C. Sane and in spite of Dr. Hiray's knowledge that two earlier attempts by Tolia in that direction had failed.

3. Dr. Baliram Hiray is guilty of misuse of ministerial office and official position in the matter of collection of funds and donations for a Charitable Trust, namely Bhau Saheb Hiray Smaranika Samity Trust of which he was the President. This indicates a course conduct on Dr. Hiray's part in misuse of his ministerial position.

(*iii*) *G. S. Sarnayak*

Health Minister G. S. Sarnayak is guilty of gross ministerial interference and extraneous considerations in the matter of withdrawal of complaint against Naval Medico Distributors and Sakarchand Shah of Naval Medico Agency and in the matter of Novaigin tablets.

(*iv*) *K. M. Bapu-Patil*

Health Minister K. M. Bapu-Patil is guilty of ministerial interference in the case of withdrawal of prosecution against Naval Medico Distributors.

(*v*) *Dr. (Mrs.) Pramila Tople*

1. Health Minister Dr. (Mrs.) Pramila Tople is guilty of ministerial interference in the matter of transfer of Assistant Commissioner B. K. Bijamwar and two Drugs Inspectors.

2. Dr. (Mrs.) Pramila Tople is guilty of having succumbed to extraneous pressure in the matter of repatriating Venkatachalam from his post as Commissioner to his parent department, though not urgently required there, and even though she was satisfied with his work in the F.D.A. and found nothing against him. This was done to facilitate the appointment of V. C. Sane in the place of Venkatachalam.

(vi) Health Ministers in general

None of the Health Ministers *viz.* G. S. Sarnayak, Dr. (Mrs.) Tople, Dr. Baliram Hiray and Mr. Bhai Sawant were interested in having an upright, independent and efficient officer at the helm of the FDA, nor have they demonstrated any will or desire to curb corruption rampant in the FDA. On the contrary by their acts aforesaid, they encouraged corruption in the FDA.

X

FDA Officers

Commissioner Bhirud

1. The evidence of S. D. Bhirud makes pathetic reading, bespeaks as it does of inefficiency, laziness, indifference, weakness and abdication of authority in favour of Jt. Commissioner Dolas whom he should have controlled but could not.

2. Bhirud is guilty of dereliction of duty and conferring favours for extraneous considerations as summarised earlier.

XI

Jt. Commissioner Dolas

1. Jt. Commissioner Dolas was thoroughly inefficient, rarely did his work, flaunted his political patronage and encouraged corrupt practices and indulged in them himself.

2. His appointment to hold charge as Joint Commissioner and Licensing Authority demoralised the FDA officers senior and junior to him, as it signified his strong political patronage which he took full advantage of. Thereby he managed to improperly get favourable transfer orders and/or promotions over-ruling claims of officers senior to him. He also managed to get himself posted at Bombay for 20 years, and near Bombay (Thane) for 3 years out of his 28 years of service. To that end he made use of his political connections and exploited M. Ps., M.L.As., and ministers.

3. Jt. Commissioner Dolas has vested interest in the drugs industry and had no compunction in attending to and granting orders in concerns where his daughters are partners. He thereby misused his office.

4. Jt. Commissioner Dolas scuttled the departmental enquiry against him by winning over witnesses of the department against him, including N. D. Kulkarni who had made an adverse report against him and upon which that departmental enquiry had been ordered. S. M. Dolas also suppressed material facts from the Enquiry Officer, *inter alia* to wit, that he was habituated to signing blank licence forms.

5. It is not improbable that Jt. Commissioner Dolas helped Health Minister Bhai Sawant in collecting advertisements and donations for Rural Upliftment Organisation.

6. In spite of 582 drugs (several of them life-saving) having been found sub-standard between 1st January 1986 and 30th September 1986, Jt. Commissioner Dolas failed and neglected to take any effective action in spite of his attention having been drawn by the Commission to the same by an order dated 12th March 1987 or to render a satisfactory explanation for his failure. Evidence discloses that even in cases of grossest violations, a mere warning has been given. This, to say the least, is dereliction of duty and unmistakably points to extraneous considerations.

XII

Asstt. Commissioner Kochar

1. Asstt. Commissioner Kochar is guilty of intentionally giving false evidence and his evidence is also otherwise unreliable.

2. P. K. Kochar has sought to falsely implicate Mr. Bhai Sawant in the case of Goddama Laboratories and Talreja Brothers.

3. He is guilty of intentional dereliction of duty in the investigation of the J. J. Hospital tragedy with a view to protect the interest of Kasats for extraneous considerations.

4. Asstt. Commissioner Kochar was also guilty of several acts of malfeasance, misfeasance and non-feasance which amount to dereliction of duty as summarised earlier for extraneous considerations.

XIII

V. D. Deshmukh

V. D. Deshmukh is guilty of corruption and getting himself improperly appointed to the coveted post of Jt. Commissioner and Licensing Authority and dereliction of duty in the discharge of his duties as Jt. Commissioner and/or Commissioner of the FDA, to such an extent that an outsider Mr. Venkatachalam had to be brought in to improve the working of the FDA. His acts of omission and commission amounting to dereliction of duty have already been summarised above.

XIV

N. D. Kulkarni

N. D. Kulkarni was guilty of corruption and dereliction of his duty and of improperly passing several orders in the last days of his office prior to his retirement as discussed earlier.

XV

V. C. Sane

1. V. C. Sane was instrumental in the repatriation of Commissioner Vankatachalam to his parent department (Police) and several acts of corruption and dereliction of duty. Several complaints were made against him in this behalf and the matter was investigated by the Anti-corruption Bureau and an adverse report made against him.

2. V. C. Sane was instrumental in getting prosecution against Tolia (whom he closely knew) withdrawn for extraneous considerations and for that matter obliged Dr. Baliram Hiray by preparing false, untenable and tailor-made report.

XVI

N. C. Venkatachalam

1. N. C. Venkatachalam was the only honest and upright Commissioner which the FDA had and he did all he could in an attempt to improve the working of the FDA during his brief stint as Commissioner.

2. For Venkatachalam's downfall in the FDA the entire system under which the Government and the FDA work was responsible.

3. The Health Ministers and the FDA officers were responsible for undoing whatever good Venkatachalam had done in the matter for improving the FDA.

CHAPTER XIX

RECOMMENDATIONS

PART I

If I could have it my way, several would be candidates for instantaneous dismissal from service and certain others for permanent cancellation of their licences. However, the rule of law must prevail. Hence,

(A) Departmental and other actions

Immediate departmental action is recommended to be forthwith initiated and vigorously pursued against (1) Dean Dr. R. S. Chandrikapure, (2) Superintendent Dr. V. G. Deshmukh, (3) Professor of Pharmacology Dr. S. V. Shaligram, (4) Pharmacist A. K. Jamadagni (all of J. J. Hospital), (5) Assistant Director of Industries S. B. Satalkar, (6) Joint Director of Industries N. D. Dharap, (7) Industries Officer P. K. Torvi (all of Industries Department), (8) Joint Commissioner S. M. Dolas, (9) Assistant Commissioner P. K. Kochar (both of FDA) and (10) Assistant Commissioner B. K. Bijamwar.

In order to prevent recurrence of similar conduct on their part hereafter, it is pre-eminently desirable that all the above should be placed forthwith under suspension pending departmental inquiry against them.

Against Assistant Director of Industries S. B. Satalkar, Joint Director of Industries N. D. Dharap, Industries Officer P. K. Torvi, Joint Commissioner S. M. Dolas, Assistant Commissioner P. K. Kochar and Assistant Commissioner B. K. Bijamwar inquiries should also be ordered to be initiated forthwith by the Anti-Corruption Bureau and/or such other competent and appropriate investigating authority, and further necessary steps be taken thereafter in accordance with the law.

(B) Prosecutions and other actions

1. Prosecutions should forthwith be launched and vigorously pursued against Mahendra Doshi and Girish Doshi of H. M. Chemicals, Girdhar Kasat and Bharat Kasat of Haresh Chemicals and Kailash and Co. and O. P. Ladda of Alpana Pharma under Section 27(*a*) of the Drugs and Cosmetics Act, 1940, as also under Section 304-A of the Indian Penal Code.

2. If after inquiry Government finds that as result of the ingestion of this glycerol other deaths or injuries have been caused to other persons, the same provisions of the Drugs and Cosmetics Act, 1940, be resorted to, as also to Section 304-A I. P. C where other deaths have resulted, or to Section 338 I. P. C. where grievous hurt has been caused.

3. Public analytical laboratories like Chem Med and Apex are a public hazard. Government must intervene and issue show cause notices forthwith why their licences should not be cancelled and as an interim measure must suspend their licences.

4. Immediate prosecutions must also be launched and vigorously pursued against Chem Med Analytical Laboratories and Apex Analytical Laboratores under the appropriate sections of the Drugs and Cosmetics Act, 1940.

5. Health Minister Bhai Sawant, former Health Minister Baliram Waman Hiray, Dr. R. D. Kulkarni, V. C. Sane, S. D. Bhirud, V. D. Deshmukh and N. D. Kulkarni, are liable to be proceeded against for charges of corruption after appropriate enquiries are made by the Anti-Corruption Bureau and/or such other competent and appropriate investigating authority in that behalf.

PART II

J. J. HOSPITAL

Several doctors of the J. J. Hospital have in their evidence given illustrative instances of several deficiencies and inadequacies, *inter alia*, lack or non-functioning of apparatus, shortage of staff, uncomfortable working conditions, lack of storage facilities,

lack of laboratory for testing suspect drugs, lack of refrigeration in the floor pharmacies, difficulty of inter-communication in such a vast complex, lack of proper ambulances and transportation from one department in one building to another department in another building, and have suggested various improvements. I have no doubt as to the immediate necessity for carrying out such improvements in the J. J. Hospital.

However within the scope of the present Commission as envisaged by the questions which this Commission is called upon to answer, the Commission is not called upon to make an in-depth study of the facilities or lack of them in the entire hospital but is required to restrict itself only to such improvements as are germane to the present Inquiry as emphasised by question (J). (" ..... to suggest remedial measures to avoid such incident in future ").

Administratively, the J. J. Hospital, at one time reputedly the best-run Government Hospital in all-Asia, is today in shambles. Evidence reveals total lack of administrative or medical control or supervision by the Dean and Superintendent. If there had been, I have no doubt this ghastly incident could have been averted. The J. J. Hospital is a gigantic complex. Hence it must be managed administratively and medically on the footing of an industry, and in its present state of shambles, must be resuscitated on a war footing. In the present set up, the Dean, even with the best of intentions, (which however were lacking here), cannot possibly hope to cope up both with administrative and medical problems single-handed. Put a professional in administrative charge and give him a free hand with clearly laid down parameters.

The Dean's functions should therefore, be bifurcated by having 2 Deans, one to look after the administrative side and the other to look after the medical side.

I recommended—

(1) Two Deans for the J. J. Hospital, viz. (*i*) " Dean (Administrative) " and (*ii*) " Dean (Medical) ". The former need not be a medical person but must be a person assertive and of proven administrative ability, preferably drawn from the IAS, IPS or the Defence Services. The letter must be a medical person of proven ability, who will look after only the medical problems of the Hospital. Of course, their inter-action and co-relationship would be a minor matter of mutual adjustment.

2. A reasonable tenure must be assured to the Deans so as to ensure their involvement and commitment to the Institution. This would prevent Deans considering themselves merely as birds of passage and would also obviate their having an eye to aggrandisement by way of promotion, or preventing their transfers, to which end, ministers, bureaucrats and politicians must be pandered to and time wasted in the Mantralaya rather than in performance of their duties in the J. J. Hospital.

3. The Deans must not hold more than one charge so as to enable them to concentrate on their functions in the J. J. Hospital itself.

4. The Deans must be persons of independence and not compromise on principles or be subservient to ministers, politicians and bureaucrats in the discharge of their duties or in order to survive.

5. The Deans must be given more power to operate within the budget for local purchases instead of having to run to " higher authority " every time for the purpose.

6. There must be a Board of Governors comprising the Deans, the Superintendent and Heads of Departments, Director of Medical Education and Research, the Health Secretary and a representative of the resident doctors, whose recommendations to Government for implementation of steps and measures to rectify the deficiencies and effecting improvements shall be acted upon by Government without red-tapism and ado.

7. Ambulances in working condition with requisite emergency oxygen supply and first-aid measures.

8. An analytical laboratory in the premises for random testing of the drugs received by the hospital. I am informed that at least in Bombay, hospitals do not

have this facility. That however is no ground for the J. J. Hospital not to make a start in that direction and give a lead to others.

9. Medical Store must be managed by a person trained in hospital management.

10. Expansion space-wise of Medical Store and floor pharmacies and suitable refrigeration in each floor pharmacy.

11. Suitable increase of posts of pharmacists and compounders. Compounders must have a minimum qualification of D. Pharm. and the Chief Pharmacist must be an M. Pharm.

12. Bin Cards must mention the batch number of the drugs and supplies made to a particular ward from day to day, and must be contemporaneously maintained.

13. There must be intercom telephone facility connecting all wards to Medical Store and floor pharmacies.

14. Withdrawal of drugs must be effected by Medical Store by personally taking charge of such drugs forthwith from the wards and departments and not merely by the expedient of circulars.

15. To avoid accumulation, pilferage and wastage of drugs in the wards, direct indenting by the wards on the Medical Store should be discontinued. Drugs should be indented from floor pharmacies everyday on " unit dose " basis of that ward.

16. The nursing staff is at present totally inadequate, hopelessly over-worked, extremely under-staffed and grossly underpaid. Government must do all in its power to ameliorate their lot.

17. In order to properly account for the supply of drugs received and consumed, it is imperative to introduce the system of audit. This will not only ensure maintenance of correct and proper requisite records but will also act as a check on pilferage and wastage of drugs.

18. Living conditions of the doctors must be improved so as to make them hygienic and comfortable. This will assure towards morale and efficiency.

The success of any system must ultimately depend on the integrity and efficiency of those manning it. If these attributes are to be found at the top they must percolate downwards. It is here where the system has utterly failed. The result is the tragedy of the kind which struck the J. J. Hospital.

PART III

GENERAL STORES PURCHASE ORGANISATION
INDUSTRIES DEPARTMENT

1. Reservation given to backward areas in the matter of rate contracts for drugs and medicines must be abolished.

2. The rate contract system for supply of drugs to hospitals must be abolished and a system devised whereby Government hospitals are able to purchase drugs and medicines on direct sale basis from reputed manufacturers so as to ensure good quality.

3. While entertaining the tenders and awarding rate contract to drug manufacturers/repackers, the Industries Department must ensure the strictest possible compliance with the terms and conditions of the tender as also the requirements of the Drugs and Cosmetics Act.

4. In the matters of rate contracts, FDA must furnish to the Industries Department an up-to-date bio-data of the manufacturer/repacker for the past not less than 7 years together with a performance certificate indicating that the tenderer has not been found guilty of breaches of the terms and conditions of licence or of manufacturing substandard drugs. If any action in that direction (be it even a warning) is found to have been taken against the manufacturer/repacker, or has been convicted

for manufacturing/repacking a substandard drug in the past 7 years, his tender for such drug or any drug should not be entertained and no contract should be given to him.

5. The agenda and brief particulars of the tenderers must be circulated to the Rate Contract Committee members well in advance to enable them to make proper enquiries about the tenderers.

6. Every member of the Rate Contract Committee must be asked to make a a declaration in writing that he has no interest directly or indirectly in any of the tenderers. In the event of his having any such interest, he must disclose the same and must refrain from participating and voting regarding such tenderer.

7. No rate revision should be granted to any tenderer save and except in strict compliance with the provisions of the tender conditions. The Industries Officer shall furnish to the Committee members the prevailing market rates of such contracts at the time when the rate revision is being asked for.

8. True and complete minutes of the meetings must be maintained.

9. Least priced drugs are not necessarily of the best quality. Hence it must be the endeavour of the Industries Department to obtain the best quality drugs on competitive basis.

PART IV

FDA AND GOVERNMENT ANALYTICAL LABORATORY

The Drugs and Cosmetics Act, 1940, and the Rules *are comprehensive and contain requisite provisions and safeguards to ensure public health and safety.* Unfortunately, by reason of the *rampant corruption, nepotism and total lack of accountability prevailing* in the FDA, and ministerial interference, *the provisions of the Act and Rules are observed more in their breach than in their compliance.*

Hence it is absolutely imperative that—

1. *The provisions of the Act and Rules be scrupulously followed and implemented by the FDA officers without fear and without favour.*

2. The FDA must be headed by an assertive Commissioner of proven administrative ability, preferably drawn from the IAS, IPS or the Defence Services. It is not at all necessary to have a technical person as the Commissioner, as he can always draw for assistance on technically qualified persons under him.

3. He must withstand ministerial, bureaucratic and political pressure and not compromise on principles or be subservient to anyone in the discharge of his duties or in order to survive.

4. There must be no ministerial meddling, which must not be confused with general overseeing setting right a manifest wrong or patent injustice.

5. FDA officers must periodically be made to go through a refresher course with a view to acquaint themselves fully with the provisions of the Act and the Rules and the procedure thereunder.

6. The present procedure for inspection only by Inspectors must be discontinued. (i) Inspectors must be accompanied by higher officers; (ii) frequency of inspections must be increased; (iii) inspection reports must be made in accordance with a format laid down in that behalf; (iv) a separate register must be maintained of inspection and action taken thereon.

7. To keep a check on the movements of Inspectors the system of daily diary must be revived and strictly enforced.

8. In order to ensure adequate check and control by Assistant Commissioners over the Inspectors, the system of weekly diaries must be re-introduced.

9. There must be a time-bound programme for taking expeditious action against erring licence holders. Showcause notice must be decided expeditiously within a particular time and prompt action implemented within a fixed time thereafter.

10. As the present system of maintaining files and papers is hopelessly defective, there must be only one file in respect of each manufacturer/repacker, duly paged and indexed, wherein all necessary particulars about that particular manufacturer/repacker can be available at a glance. This file must also contain the previous history of the manufacturer/repacker, *inter alia*, to wit, previous show cause notices and actions, if any, taken thereon, prior convictions and so forth.

11. The procedure for sampling must be standardised with a view to ensure proper and correct analysis. A standard container containing sample, whether it be liquid or powder, must be provided by the FDA with code numbers so as to keep the name of the manufacturer secret from the analytical laboratory.

12. The powers of the Joint Commissioner and Licensing Authority must be decentralised. The powers of the Licensing Authority must be given to every Joint Commissioner in charge of a particular division.

13. FDA must take speedy and effective action against erring public analytical laboratories by way of suspension/cancellation of licences and prosecutions.

14. Public analytical laboratories proved to have given or habituated to giving false or misleading analytical reports must forthwith be de-recognised permanently and prosecutions must be forthwith launched and vigorously pursued against them. Norms for suspension or withdrawal of approval granted by FDA to public analytical laboratories must be prescribed.

15. (*a*) Wide publicity must be given in the media to acquaint the medical profession and those connected with it and the general public of any drug proved to be substandard, giving particulars, to wit, the name of the manufacturer/repacker, the name, batch number and date of manufacture/repacking of the drug, the nature of defect, the name of the analytical laboratory, the result of prosecution initiated, and other relevant particulars.

(*b*) FDA must come down with a heavy hand on misleading advertisements concerning drugs and medicines and wide media publicity must be given.

(*c*) The cost of such media coverage must be made recoverable from the party or parties concerned as arrears of land revenue.

16. As records maintained by the Government Analytical Laboratory do not inspire confidence, proper records must be maintained and updated.

17. Analysis must be carried out far more expeditiously than is done at present and within a timebound programme. The laboratory must be well equipped and totally adequate even to carry out sophisticated tests with sophisticated equipments. To that end, a larger laboratory, a larger staff and sophisticated instruments must be given prority on a war footing. Speed and accuracy must be of the essence.

18. The Government Analytical Laboratory must be delinked from the FDA and made a separate department directly under the Government, so as to ensure its working independent of the FDA.

19. Instead of an appeal lying to the Government as at present under the Act, it would be preferable if such appeals lay before the ordinary Civil Courts. Further, penalties should be suitably increased, culminating in the extreme penalty where death has taken place due to a substandard drug. To these ends the State Government may make suitable recommendations to the Centre for the amendment of the Act and Rules.

Once again the success of any system must ultimately depend on the integrity, independence and efficiency of those manning it. Once again, if these attributes, are to be found at the top, they must percolate downwards. Ministrial meddling, uncalled for interference in appointments and transfers, extraneous considerations, want of independence to withstand pressures, inefficiency and total lack of integrity

must take their toll of any system as indeed they have with the FDA. It is here that the FDA has monumentally and lamentably failed. The result is the known and unnecessary tragedy of the kind which struck the J. J. Hospital.

The controversy as to the propriety, feasibility or necessity of having an in-house laboratory and certain other topics do not come within the purview of the questions I am invited to answer. Hence no recommendations to that end are necessary in this Report.

PART V

THE NEXT-OF-KIN

The present amount of Rs. 10,00 paid to the next-of-kin of each of the 14 patients who needlessly died is far too inadequate. I recommend that Government do pay to the next-of-kin of each of them an additional amount of Rs. 20,000 as compensation as expeditiously as possible.

It is also the legal and moral duty of Government, with the machinery at its command, to search for other patients who had ingested Alpana Pharma's Batch No. 27 and pay them adequate compensation for the damage or injury suffered by them, and in case of death to pay to the next-of-kin Rs. 30,000.

Receipt of those amounts shall not preclude the parties or the next-of-kin as the case may be from claiming additional compensation from Kasats and/or Doshi and/or O. P. Ladda and/or Chem Med, as they may be advised.

Dated this 30th day of November 1987.

(sd.) B. LENTIN

Commission of Inquiry.

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