Date : 18th July 2023

To

Deputy Director (AV)

Directorate General of Health Services (AV Section)

Ministry of Health & Family Welfare

For the kind attention of Shri Arindam Banerjee

Subject: Complaint against Dr.S.Eswara Reddy, Joint Drugs Controller. Your letter dated 10th July 2023.

Dear Sir,

1. **An aggrieved senior citizen has been oppressed and tortured for 9 long years seeking justice in untimely, unnatural and merciless death of his wife.**

   Attached is my ID Proof (Aadhaar Card and PAN Card), pages 804-805).

2. Matter pertains to homicide of my wife, late Smt Kamini Barkur; The doctors watched her sinking for 5 days at a stretch & later abandoned her to her fate which was death.

   This was just to protect Cipla drug Rokfos causing Serious Fatal Adverse Drug Reactions (ADRs).

3. The doctors were in nexus with Cipla Ltd conducting "Illegal Trials" on innocent patients. Cipla Ltd is playing with lives protected by Drug Controllers in the Health Ministry. Full evidence is before the Health Ministry. The same is sent to you herewith for stringent action against Dr.Eswara Reddy, Dr.P.B.N.Prasad and pharmaceutical company Cipla Ltd.

4. **Role of Dr.S.Eswara Reddy to protect Cipla Ltd by conspiring/organizing** a "Fake Joint Investigation" along with FDA (Gr Mumbai and Goa) is explained in detail subsequently under **paragraph 10 (Evidence documents pages 282-292) is attached.**

   - Cipla Ltd should have been prosecuted in 2018 itself but for Dr.S.Eswara Reddy abandoning his duty, legal and moral responsibility.

- Letter issued to Cipla Ltd dated 03/21/2018 that no action is taken against them should be withdrawn and instead letter should be issued cancelling Licence of Cipla Ltd.

5. For reference and proof of massive cover up of this inhuman crime by Cipla Ltd and doctors, I am enclosing two documents:

   a) Entire episode is submitted as a "Document" titled **"SAVE HINDU RASHTRA".**

   b) Foul Play by Public Health Departments of Maharashtra viz Dean of Sir J.J.Group of Hospitals, Navghar police, Mumbai & lokayukta of Maharashtra. This is titled **"PUBLIC HEALTH DEPARTMENTS OF MAHARASHTRA, LOKAYUKTA OF MAHARASHTRA & NAVGHAR POLICE, MUMBAI.**

6. Around 800 pages of evidence documents have been submitted to Navghar Police, Mulund, Mumbai.

7. Human Rights Violation in its worst form in the largest democracy in the world by bribing & corrupting every authority in India by **Cipla Limited. "INHUMAN".**

8. Crime (homicide) is proved as explained below:

   a) Order in Civil Suit before Maharashtra Medical Council; Committee of 10 experienced doctors. They have implicated serious ADRs of injection Rokfos manufactured by Cipla Ltd.

   The Order is reproduced below:

   Charges framed by the Medical Council were as follows:

   * Respondents had administered "Rokfoszoledronic" acid without blood investigation of patient.

   * Consent for administering "Rokfos injection" was not taken by respondents.

   * Proper documentation not maintained by respondents.

   * Treatment was not provided as per severity of disease.

   * Required investigation of patient was not done.

* After complication, respondents had failed to detect the reason & treat the patient.

* Dose of methotrexate medicine was not mentioned on paper provided before committee in spite of advising and prescribing the same.

Executive Committee resolution dated 09/01/2021 is reproduced as under :

After detailed discussion & deliberations, the committee observed that,

On the next day of admission, the patient's platelets and WBC dropped down rapidly. The platelets had dropped from 143,000 to 20,000 and WBC from 20,080 to 200.

However, RMP ignored and transferred the patient for surgery to another hospital which was scheduled on the 16/06/2014.

In spite of adverse reaction RMP had not taken action.

RMP was alleged to have given methotrexate to the patient as supported by prescription, bills, treatment sheet.

Discharge card was not filled properly when patient was transferred to another hospital for surgery.

Therefore, the Council has passed sentence *to remove the Registration No.2001031433 of Dr.Mihirgiri Goswami (Respondent1) for a period of 3 months from the Register of the Council.*

b) Order in Civil Suit before Maharashtra State Consumer Disputes Redressal Commission; They too have implicated serious ADRs of Cipla injection Rokfos.

Order is reproduced below:

OP1 & OP2 (Treating doctor, Dr.Mihirgiri Goswami and Maruti Nursing Home) :

- Were negligent in prescribing and administering injection Rokfos.
- On the day of admission in the evening, she was given injection Rokfos.
- Without ascertaining indications as per special literature provided by manufacturer Cipla company, this injection was given.

- At Maruti Nursing Home, blood was checked daily and reports were available. From the date of admission on 9th June 2014 to 14th June 2014, there was progressive reduction in the values of white blood cells, platelets and haemoglobin. These values were not reviewed in time by the treating doctors which later on surfaced as pancytopenia due to bone marrow failure and led to Aplastic Anaemia.
- OP1 & 2 failed to diagnose bone marrow failure in time with subsequent Aplastic Anaemia.
- Maruti Nursing Home purchased medicines and sold to the patient when it was not having valid license to hold stock of medicine.
- Maruti Nursing Home did not hold pharmacy licence to procure and sell medicines.
- We are of the opinion that Rokfos was prescribed Ad Hoc and was given to the patient without looking into the indications for the injection.
- There were manipulations in record as the later on submitted medical record was different from the one that was handed over by the sister in the ward.

Opposite Party No.3 (Dr.Aafaque Dolare)

- Dr.Dolare examined deceased patient on 12th June 2014 and gave fitness for surgery provided advised investigation CRP report comes normal.
- OP3 did not review the blood reports and thus failed to consider diagnosis of bone marrow failure.

Opposite Party No.4 (Dr.Satyen Mehta).

- Dr.Satyen Mehta, the neurosurgeon, who was supposed to operate upon the patient in Platinum Hospital examined the patient and advised investigations and medical fitness.
- Dr.Satyen Mehta clinically diagnosed that patient was in septicaemia.
- Since OP No.4 was the treating neurosurgeon, he should have reviewed the patient and should have informed the nature and seriousness of the disease. There is no document supporting his role in this regard.

Opposite Party No.5 (Platinum Hospitals).

- OP No.5 failed to deliver the Indoor case records in time and also manipulated the medical records.
- At Platinum Hospitals, the initial admission process on 14th June 2014 was not as per protocol. Discharge card from Maruti Nursing Home did not mention the serious nature of the disease.
- For the copy of medical records Platinum Hospital was requested by complainant through application. He did not receive the same for more than a week period. He had to apply again.
- There was incompleteness of medical record and also manipulation. The admission paper is incomplete, no plan of treatment mentioned, no documentation of serious condition of the patient informed to relatives, no documentation support that the patient was admitted in ICU of Platinum Hospital.
- There is failure to maintain good record that is helpful in knowing the condition of the patient in the hospital, treatment planned and given, proper information given to the patient relatives and condition at the time of discharge, may it be against medical advice found lacking.

Opposite Party No.6 (Jupiter Hospital).

- There was no act of commission or omission, deficiency in service or medical negligence by OP No.6.

Proof of crime (homicide) contd...

c) There is no difference in Order by Maharashtra State Commission and Order by Maharashtra Medical Council.

- That injection Rokfos was the cause of the disaster.

d) **False Cause of Death in Death Certificate** and how the serious ADRs were hushed up by around two dozen doctors at three hospitals; Maruti Nursing Home, Platinum Hospitals and Jupiter Hospital.

- Bone Marrow biopsy report says 'aplastic bone marrow' **[Evidence document page 88] attached.**
- Cause of death given by Jupiter Hospital was septic shock with multi-organ failure **[Evidence document page 89] attached.**
- Death Summary – Aplastic Anaemia was not included in death summary by Jupiter Hospital. Death Summary lists the immediate and antecedent

causes of death **[Evidence document page 90] attached.** ADRs which were responsible for death of my wife were also conveniently excluded in in-patient records of Jupiter Hospital as well as in death summary.

- The weapon (meaning ADRs of injection Rokfos) that caused death of my wife was hidden by around two dozen doctors at three hospitals and by Cipla Limited in collusion with FDA authorities.
- Email from treating doctor, Dr.Mihirgiri Goswami dated 01/08/2014 to the Complainant **[Evidence documents pages 91-93] attached.**
- The first line says "We are aware of the sad demise of Mrs Kamini Barkur at Jupiter ICU following diagnosis of Aplastic Anaemia leading to complications" **[Evidence document page 91].**
- Diagnosis of Aplastic Anaemia was in bone marrow biopsy report. Sample for bone marrow was taken on 16/06/2014 i.e. next day after shifting the patient from Platinum Hospitals on the night of 15/06/2014 to Jupiter Hospital at 10.30 p.m.

e) Written submissions are before Maharashtra Medical Council by treating doctor, Dr.Mihirgiri Goswami that the drug did not suit the complainant's wife and that he immediately discontinued it **(evidence document page 791) attached.**

Discontinuing the drug is a bizarre statement as the injection was infused within 15 minutes and reactions started after 20 hours. How could he discontinue it?

f) Reply to RTI Query by IPC (Indian Pharmacopoeia Commission) that Cipla Ltd has finally reported the ADRs to DCG(I), IPC (PVPI) and FDA **(evidence documents pages 252-254) attached.**

g) There was no need to hide known side-effects of an injection unless "Foul Play" was involved in manufacture or trial conducted on innocent patients.

h) **Adulterated drugs manufactured at Cipla Goa Plant** is exposed in USFDA warning to Cipla Ltd dated 25-02-2020 **(evidence documents pages 243-251) attached.**

There were more warnings by USFDA subsequently which means that Cipla Ltd is a perennial offender playing with lives by manufacturing adulterated drugs.

i) Trial on my wife is in the statements of doctors at Maruti Nursing Home in a meeting held on 22nd August 2014 to discuss how the death was caused. **(evidence documents pages 549-673) submitted in my police complaints, and before the State Commission and Maharashtra Medical Council)**
The meeting lasted for two hours and forty-three minutes and was recorded by me without the doctors' knowledge. Present were relatives of the deceased, Dr.Mihirgiri Goswami, Dr.Aafaque Dolare and Maruti Nursing Home 'Accounts Officer', Dr.Dubey. Dr.Satyen Mehta after agreeing to attend the meeting skipped it as also family doctor, Dr.S.L.Korgaonkar. Dr.Dubey was an ayurvedic doctor working for TPA Health Services involved in mediclaim business. He was also involved in selling Rokfos to other doctors and orthopaedics. The doctors admitted to the serious ADRs of injection Zoledronic acid never seen before.

Crucial points to decipher nexus between Cipla Limited and Maruti Nursing Home in transcripts of the meeting are the following :

- The doctors admitted that Zobone was their regular brand of Zoledronic acid and Rokfos was their new brand which caused the disaster **(evidence document page 586) attached.**
- The treating doctor said that it had been given to his mother also. That safe it is in all cases. It will turn out to be like this, who will understand? **(evidence document page 588) attached.**
- Further said that he will never give now. That he will not give anyone. It has been given to his mother also, you can understand why he should be so much worried about giving it? **(evidence document page 588) attached.**
- When questioned why did he give the drug, said that he planned for one day admission - Give today and discharge tomorrow. MRI was also not planned. Hence there was no MRI on admission. **(evidence document page 606) attached.**
- Mediclaim doctor, Dr.Dubey said that he goes to 25 hospitals and three-four orthopaedics and gives Rokfos with full responsibility. His target was to ensure that there is no problem to treating doctor as well as the patient. That he had to balance both **(evidence document pages 640) attached.**

- Further said that, for bone support, this is a yearly injection and is commonly given but he never realized that this can cause such dramatic allergy or reaction. That he had never seen such serious adverse drug reactions of Rokfos ever before **(evidence document page 642) attached.**

Proof of crime (homicide) contd..

j) Cipla Ltd has admitted to the serious ADRs in written statements to FDA Goa Director **(evidence documents pages 17-20 of "Document" SAVE HINDU RASHTRA).**

- Ignorance of law **(evidence document page 139 para 3) attached.**
- Linking imaginary diseases to the deceased prior to drug Rokfos being administered to her **[Evidence documents pages 141-142].**
- Unknown to Ongoing - Concurrent condition - Tuberculosis of spine (Bone tuberculosis).
- Unknown to Ongoing - Concurrent condition – Arm paralysis (Monoplegia).
- The patient's medical history and concomitant medications were not reported. The patient's concurrent conditions included spinal tuberculosis, cervical spondylitis, arthralgia and one paralytic arm.

  Note : Arthralgia occurred after injection Rokfos and is a known side effect of the drug.

- When a senior editor of a leading newspaper had asked the PR of Cipla with a questionnaire on the above statements by Cipla, he had told him that he will fix an appointment with the doctors at Maruti Nursing Home. Subsequently, succeeded in silencing the journalist.
- Linking Imaginary treatment for the imaginary diseases **[Evidence documents pages 142-144].**
- On an unknown date, the patient received one shot of steroids for tuberculosis treatment.
- The unknown steroid which was administered on unknown date could also be the cause of aplastic anaemia.
- The above false, imaginary diseases and statements to deceive FDA Goa Director was exposed by in-patient record noting of physician,

Dr.Aafaque Dolare who had certified Complainant's wife as 'Fit for Surgery'.

He had noted that she was "Pre-morbidly healthy" "No known allergies" "No addictions" "No major illness in the past" **[Evidence document page 177], attached.**

- Cipla's Lies on admitting to following statutory guidelines; Schedule 'M' and reporting to DCG(I), PVPI and FDA Goa **[Evidence documents pages 173-175], attached.**

"The Company denies that it did not carry out any investigation. In fact, immediately after receiving information from Dr.Mihirgiri Goswami, Company representatives followed a procedure in speaking on telephone with the treating doctor, Dr.Mihirgiri Goswami who informed that the late Smt.Kamini Barkur was suffering from spinal tuberculosis and that her one arm was paralytic; annotated in the telephone record form ("TRF") on August 7, 2014. Later following pharmacovigilance guidelines six CIOMS forms were submitted on August 20, 2014, Sept. 08, 2014, July 21, 2016, May 2, 2017, March 7, 2018 and May 22, 2018 to the DCGI. Therefore, your allegations on attempts to suppress material whether of the alleged adverse drug reactions or otherwise is clearly devoid of any merit and denied **[Evidence documents page 173].**

"As stated earlier, the Company had immediately informed the appropriate licensing authority of the adverse event. Similarly, the explanations given to the FDA Goa on non-compliance of Schedule 'M' has no relevance to the issue at hand. In any event, our explanation has been accepted by the FDA, Goa and has been adequately dealt with" **[Evidence documents page 174].**

"Applicable provision of Schedule M of Drugs and Cosmetics Rules (referred by you) relates to reporting to the licensing authority, which the Company has complied with in having informed the DCGI (the appropriate licensing authority), the Pharmacovigilance Program of India and later FDA, Goa". **[Evidence document page 175].**

Copies of this explanation were sent to FDA Maharashtra, FDA Goa, Directorate of Public Grievances, Government of Goa, Directorate of Health Services, Mantralaya, Government of Maharashtra.

- Cipla's lies on reporting of the ADRs were exposed as follows :

  Reply to RTI Query of the Complainant from FDA Goa dated 17/01/2018 stating that they had not received any report of serious adverse drug reactions of IV Rokfos from Cipla. As per records available at Cipla Goa no any drugs recalled is conducted **[Evidence document page 178], attached.**

- Reply to RTI Query of the Complainant from Indian Pharmacopoeia Commission; The National Coordination Centre for Pharmacovigilance Programme of India does not have record of the adverse event of Rokfos - IV Infusion manufactured by Cipla. Indian Pharmacopoeia Commission does not possess any other information in this regard. **[Evidence document page 179], attached.**

- Letter from ADC(I), CDSCO dated 15/02/2018; Public Grievance; in relation to conduct investigation for alleged nexus between M/s Cipla Ltd. and M/s Maruti Nursing Home's, Mulund, Mumbai in sale of sub-standard drugs Rokfos i.v.; reg. **[Evidence documents pages 180-181], attached.**

  Note : If Cipla had followed statutory guidelines, investigated their drug Rokfos and reported the serious ADRs, there was no reason to conduct an investigation.

- Letter dated 26.06.2018 from Cipla Authorised Representative stating that they will comply with the directions of the authorities as and when received. **[Evidence documents pages 212-213], attached.**

k) Cipla has finally reported to FDA, DCG(I) and PVPI. This was conveyed to me by Indian Pharmacopoeia Commission (Pharmacovigilance Program of India) in reply to my RTI query **(evidence documents pages 252-254) attached.**

l) **There is nothing left for Navghar Police Station, Mumbai except to arrest the killers** and their supporters in regulatory and law enforcement agencies viz CDSCO, FDA and Public Health Departments of Maharashtra.

9. This is an extensive case:

a) Crime was committed in Mumbai.

b) Cipla Ltd bribed and corrupted authorities from Mumbai to Goa to Delhi to Ghaziabad.

c) An aggrieved senior citizen was forced to Investigate homicide of his wife on his own.

d) I have been oppressed and tortured for 9 years seeking justice in homicide of my wife by killer pharma company Cipla Ltd, Public Health Departments of Maharashtra, regulatory and law enforcement authorities viz Food and Drugs Administration (State licensing authority for drugs) and CDSCO (National regulatory authority for drugs).

e) It is a disgrace for the largest democracy that an aggrieved senior citizen was left to fend for himself.

f) I have managed to investigate all of their anti-national acts.

g) I have got favourable Orders in "Civil Suits".

10. ROLE OF DR.S.ESWARA REDDY WHO WAS DCG(I) FOR A TEMPORARY PERIOD

a) **Joint Drugs Controller, Dr.S.Eswara Reddy** was arrested by the CBI in Biocon Biologics bribery case – as per Media Reports.

b) **Dr.S.Eswara Reddy (who was DCGI for a temporary period) was involved in this case also; against Cipla Limited.**

"Fake Joint Investigation" was organised by Dr.S.Eswara Reddy, Dr.P.B.N.Prasad (CDSCO), along with FDA Gr Mumbai & FDA Goa Director to silence an aggrieved senior citizen seeking justice in untimely, unnatural & merciless death of his wife. **(Refer evidence documents pages 282-292) attached.**

c) **Joint Investigation was proved as "FAKE" (Refer pages 25-44 of Document "SAVE HINDU RASHTRA") enclosed.**

KEY POINTS & LIES IN JOINT INVESTIGATION REPORT (evidence documents pages 282-292) :

- Background of the report:

Complaint dated 23rd July 2018 made by Shri Umeshchandra Barkur to CDSCO, WZ, Mumbai regarding death of his wife (Late Smt. Kamini Barkur) from serious adverse drug reactions of sub-standard drug IV Rokfos, manufactured by M/s Cipla Limited and administered at Maruti Nursing Home, Mulund to Smt.Kamini Barkur.

This report was prepared based on Complaint to CDSCO, WZ, Mumbai dated 23.07.2018 and also emails from CDSCO (HQ) to CDSCO, WZ, Mumbai. That my written complaint was dated 23.07.2018 to DDC(I), WZ, Mumbai and I had submitted photograph of carton of drug Rokfos produced by treating doctor in in-patient record of my wife **[Evidence document page 286].**

Note: Complainant's wife died in June 2014. Complaint was made to Cipla Ltd on 16.08.2014 and to FDA Gr Mumbai on 28.04.2015.

Note: There was no investigation conducted by either Cipla Ltd or FDA Gr Mumbai in August 2014 as per statutory guidelines; Schedule 'M' of Drugs and Cosmetics Rules.

Pages 1-4 of the report [Evidence documents pages 284-287].

- That only single dose of drug Zoledronic acid was administered on 09/06/2014 and the said drug was not administered to her again.

Note: There were no allegations of injection Rokfos being administered again during her hospitalisation at Maruti Nursing Home.

Note: The report is silent on treating doctor's in-patient record noting of ADRs of injection Zoledronic acid "Post Zobone Arthralgia" meaning joint pains after injection Zoledronic acid.

- Drug Inspector, FDA Maharashtra has filed a case against Dr.Mihirgiri Goswami and Smt. Ashwini Kallapa Kamble, receptionist cum salesman at M/s Maruti Nursing Home in the Court of Hon'ble Metropolitan Magistrate's 15th Mazgaon Court, at Sewree, Mumbai for contravention of section 18 (c), Section 18-A and section 22 (1) (cca) of Drugs and Cosmetics Act, 1940.

Note: Case is not filed for serious ADRs of injection Rokfos till date which was not questioned by the Joint Investigation Team

Note: Joint Investigation Team did not deem it fit to question manufacturer of injection Rokfos, Cipla Limited and what action was taken on my complaint dated 16/08/2014.

Cipla had acknowledged my complaint, offered condolences on death of my wife, sent me indications of use but had not followed statutory guidelines of Schedule 'M' of Drugs and Cosmetics Rules.

They had deliberately not investigated their drug Rokfos.

The drug batch was manufactured in February 2014 and there would have been plenty of stock available when my complaint was made.

Drug Inspector Mr.P.D.Thorat, Drugs Inspector at CDSCO (WZ), Mumbai should be aware of Schedule 'M' guidelines of Drugs and Cosmetics Rules 1945. He did not question FDA Maharashtra, Mumbai Drug Inspector also.

Note: The matter is sub-judice since six years even for illegal sale of drugs due to deliberate non-submission of evidence by the Drug Inspector of FDA Maharashtra.

Note: Open collusion by FDA Gr Mumbai officials and CDSCO officials with both Cipla Ltd as well as Maruti Nursing Home.

Pages 5-9 of the report

- Complainant made complaint dated 14th May 2018 to Joint Commissioner FDA, Greater Mumbai Division, Maharashtra w.r.t death of his wife from serious adverse drug reactions of injection IV Rokfos manufactured by Cipla Limited.

  Note: Complainant did not make complaint dated 14th May 2018 to Joint Commissioner FDA, Greater Mumbai Division, Maharashtra w.r.t death of his wife.

  Note: Complainant's wife died in 2014 and complaint was registered on 16.08.2014 with Cipla and with FDA Maharashtra on 28.04.2015 along with copy of complaint to Cipla Limited.

  Note: Drugs Inspector of CDSCO (West Zone) should have questioned the Drug Inspector of FDA Maharashtra regarding objective for sending a sample four years after the adverse event and more than two years after the shelf life of the drug batch of February 2014 in question was over.

Note: What forbade Cipla Limited from sending one sample for testing from the batch in 2014 after my reporting to them on 16.08.2014.

Note: Why did FDA Maharashtra, Mumbai not send one sample of the batch for testing when the complaint was made in April 2015? or from the remaining four injections purchased by Maruti Nursing Home?

Sale invoices were not produced during the raid by FDA and neither was drug Rokfos in stock as per list of drugs seized during the panchnama.

- It was observed that Smt.Kamini Barkur w/o Sh. Umeshchandra Barkur was hospitalised in M/s Maruti Nursing Home, Mulund, Mumbai for treatment of Cervical-Spondylitis & Stiff Neck and it is not a case of clinical trial as defined under Rule 122-DAA of Drugs and Cosmetics.

  Note: That is exactly the point. Why was Zoledronic acid administered on the day of admission for curing stiff neck? Stiff neck is not in the indications of use of Rokfos.

- In view of inadequate information available with respect to patient history, other drugs administered & the sequence of events occurred after discharge of patient from Maruti Nursing Home, Mulund, clinical investigation reports as well as the exact cause of death (Post Mortem findings, if done); it is difficult to comment on whether there was lapse in the standard of care administered. Opinion of the concerned speciality expert's i.e. Rheumatologist, Intensivists, TB – Chest specialist etc. may be sought to ascertain this.

  Note: There was voluminous, abundant and adequate information available with respect to patient history at Maruti Nursing Home.

  There were two complaints; 1) with Maharashtra Medical Council and 2) with Maharashtra State Commission.

  Note: In-patient record noting of physician, Dr.Aafaque Dolare who certified complainant's wife as 'Fit for Surgery' was available. He had noted that she was "Pre-morbidly healthy" "No known allergies" "No addictions" **"No major illness in the past" [Evidence document page 177].**

  Note: The patient was certified as 'Fit for surgery' subject to **CRP (quantitative)** test being normal. Professor in Joint Investigation Team

did not bother to check with treating doctor whether he had conducted this test.

Note: Other drugs administered were available in Maruti Nursing Home in-patient records. Drug Rokfos was administered within seven hours of admission of my wife to Maruti Nursing Home.

Note: ADRs occurred within twenty hours and were noted by treating doctor as "Post Zobone Arthralgia" meaning "Joint pains after injection Zoledronic acid". She was bed-ridden till her death two weeks later.

Note: Drug Inspectors of both FDA Maharashtra as well as CDSCO (WZ) should be aware of section 27 (a) and drug causing "Grievous Hurt" within the meaning of section 320 of the Indian Penal Code.

Note: Blood investigations were available from 9th June 2014 till 14th June 2014 at Maruti Nursing Home. Pancytopenia is a typical side effect of drug Zoledronic acid.

Chart of complete blood counts (CBC) is reproduced below to prove that bone marrow had failed at Maruti Nursing Home itself.

Chart of CBC is given by the treating doctors themselves in their submission before the Maharashtra Medical Council :

Sr.No	Date	HB	WBC Count	Platelets
1	09/06/2014	10.1	13,900	74,000
2	11/06/2014	10.5	20,080	142,000
3 SRL	**12/06/2014**	**9.5**	**2,300**	**95,000**
	PATIENT WAS	**IN**	**PANCYTOPENIA**	
4	13/06/2014	9.2	2,800	59,000

After shifting the patient in a critical condition, bed-ridden, unable to swallow even saliva, petechial rashes on her arms and legs and pancytopenia since 12th June 2014, results of first CBC taken at Platinum Hospitals were :

	Date	HB	WBC Count	Platelets
	14/06/2014	**7.6**	**200**	**20,000**

After blood and blood products administered after 11.30 p.m. on the night of 14th June 2014 and during the day on 15th June 2014 blood counts were as follows :

	Date	HB	WBC Count	Platelets
	15/06/2014	**8.1**	**150**	**12,000**

It is very clear that there was no effect of blood transfusions and blood products administered. Bone marrow had failed at Maruti Nursing Home itself. Pancytopenia was not treated for three days from 12th June 2014 till 14th June 2014. Pancytopenia was not informed to Platinum Hospital.

Note: Blood disorders is listed first in the list of side effects of Rokfos as per indications of use.

Note: Google search will give side effects of Rokfos (Zoledronic acid). Petechial Rash and Pancytopenia are typical side effects.

Note: Rash was noted in in-patient records.

Note: Pancytopenia was revealed in blood test reports as proved above.

Note: Side effects of Rokfos in Cipla booklet were available at Maruti Nursing Home. It lists blood disorders, arthralgia, myalgia, bone pain, back pain, rash, blood creatinine increase and blood calcium decrease. All these side effects had occurred in death of the patient.

Note: The expert doctor and Professor from L.T. Hospital did not deem fit to investigate Rokfos indications of use.

Note: Creatinine clearance test is a Contra-indication. The Professor in Joint Investigation Team did not look into this.

Note: Sequence of events that occurred after discharge of patient from Maruti Nursing Home, Mulund, was available at Maruti Nursing Home in Complaint file with Maharashtra State Consumer Disputes Redressal Commission as well as Maharashtra Medical Council.

Note: Exact cause of death was Aplastic Anaemia as per bone marrow biopsy report **[Evidence document page 88].**

There was no need of Post Mortem findings. These reports were all there at Maruti Nursing Home.

Note: Consumer Court had held the treating doctors and Maruti Nursing Home 'Guilty' vide Order dated 21/02/2019. These facts must have been informed by DCG(I) under CDSCO (HQ) to CDSCO (WZ) DDC(I).

- The Joint Investigation Team says that It was difficult to comment on whether there was lapse in the standard of care administered. Opinion of the concerned speciality expert's i.e. Rheumatologist, Intensivists, TB – Chest specialist etc. may be sought to ascertain this.

  Note: There were lapses not only by the treating doctors but also by the Joint Investigation Team whose only objective was to absolve both Maruti Nursing Home as well as injection Rokfos manufactured by multi-national company Cipla Limited.

  Note: Lapses in standard of care is proved in Order of the Executive Committee of Maharashtra Medical Council by removing the name of treating delinquent doctor, Dr. Mihirgiri Goswami from their Register.

  Note: There was no need for TB Chest specialist as MRI report was available at Maruti Nursing Home which suggested clinical diagnosis and follow up for Koch's. The Joint Investigation Team did not deem it proper to question treating doctor why this was not followed.

  Note: TB was never proved as surgery was never performed.

  Note: Subject Expert Committee (SEC) at CDSCO (HQ) had deliberated on Rheumatism and had opined that the reported adverse reactions like arthralgia, myalgia, bone pain, etc. were known side effects of Zoledronic acid.

  Note: SEC did not deem it fit or proper to deliberate on other known side effects of Zoledronic acid which occurred in this case; pancytopenia, petechial rashes, dysphagia, serum calcium decrease, serum creatinine increase that occurred in quick succession in three days.

  Note: Petechial rash and pancytopenia are typical symptoms and characteristic features of Aplastic Anaemia as per standard medical

textbooks on Aplastic Anaemia produced by the complainant in his criminal complaints. The Complainant's wife died of Aplastic Anaemia.

Remarks of the Joint Investigation Team :

a) As per in-patient records available with M/s Maruti Nursing Home, Mulund, Mumbai it was observed that only single dose of drug Zoledronic Acid IV was administered to Smt.Kamini Barkur on 09/06/2014 and said drug was not administered to her again during her hospitalisation at M/s Maruti Nursing Home till 14/06/2014.

Note: As stated earlier, Zoledronic acid 5mg/100ml has to be administered only once in a year. There is no need to protect the treating doctor by the Investigation Team by this remark of 'Single dose' repeatedly.

- There were no allegations that another dose was administered.

b) It is observed that Smt.Kamini Barkur w/o Sh.Umeshchandra Barkur was hospitalised in M/s Maruti Nursing Home, Mulund, Mumbai for treatment of Cervical Spondylitis & Stiff Neck and it is not a case of clinical trial as defined under Rule 122-DAA of Drugs and Cosmetics Rules 1945.

Note: There was no need to repeat this again and again. As explained in details of meeting on 22nd August 2014, explained above, this was an unauthorised 'Clinical Trial' to cure 'Stiff Neck' in a single day. Not in indications of use and hence not investigated by manufacturer Cipla Ltd.

c) As complaint is related to adverse drug reaction, opinion of National Coordination Centre, Pharmacovigilance Programme of India, IPC, Ghaziabad may be obtained to take necessary action in the matter.

Note: Secretary-cum-Scientific Director of IPC, Ghaziabad has given his opinion to the complainant on 10th January 2019 **[Evidence document page 304].** That Indian Pharmacopoeia Commission is not the Regulatory Authority to oversee and regulate matters related to manufacturing, sales and Clinical Trials induced adverse drug reactions/death. As such the grievance is not pertaining to IPC. Matters relating to clinical trials and adverse drug reactions/death in this country are regulated by CDSCO

under DGHS, MOHFW, Govt. of India headed by DCG(I). That the matter stands clarified from their end.

d) Also opinion of the concerned speciality expert's i.e. Rheumatologist, Intensivists, TB – Chest specialist etc. may be sought to ascertain lapses in the standard of care administered, if any?

Note: This has been clarified above under Subject Expert Committee by CDSCO. SEC did not deem fit to investigate petechial rashes and pancytopenia, dysphagia, serum calcium decrease and serum creatinine increase. All these side effects occurred, one by one in three days' time.

Note: As per indications of use of Zoledronic acid, my wife was not admitted for any of the indications. As per Orders by both Maharashtra Medical Council and Maharashtra State Commission, ADRs of injection Rokfos was responsible for pancytopenia and subsequently bone marrow failure.

Note: Statements made by the doctors at the meeting held on August 22nd 2014 and inferences drawn from the statements explained above proves nexus between Maruti Nursing Home and Cipla Limited for trials conducted to treat minor bone problems like joint pains, bone pain, etc which are not there in indications of use of Zoledronic acid.

e) That only single dose was administered.

- Who had alleged that double dose was administered? What about indications of use ignored by the Professor? What about Zoledronic acid for stiff neck?
- What about precautions?

Note: The same pattern instructed by the DCG(I) was followed. Place the matter in Orbit so that the aggrieved will be forced to abort seeking justice. Inhuman Professors and Regulatory authorities.

Note: From the facts explained in detail above by the Complainant, it is evident that the Joint Investigation Report was a farce conducted by CDSCO (WZ) in collusion with CDSCO (HQ) and FDA Maharashtra as well as FDA Goa Director to absolve both doctors at Maruti Nursing Home as well as Cipla Limited for hushing up side effects of drug Rokfos causing death of the Complainant's wife.

Note: To which authorities was this Joint Investigation Report submitted. The Complainant was sending reminders and RTI queries to all concerned authorities viz CDSCO and FDA Maharashtra.

Note: The DCG(I) under CDSCO (HQ) and DDC(I) under CDSCO (WZ), Mumbai had a limited agenda to the Joint Investigation team :

- To declare that it was not a 'Clinical Trial'.
- Keep the matter in Orbit on the ADRs.
- Pass the buck to PVPI. (PVPI had already given their opinion).
- Finally say that the matter is sub-judice.
- But in this case, the conspirators will be answerable to the Nation.
- FDA Maharashtra is exposed after Status of case at Mazgaon Court was produced by the Complainant.

f) The Joint Investigation Team as well as FDA Maharashtra, FDA Goa, CDSCO (WZ) and CDSCO (HQ) are answerable for colluding with criminal offenders, gross dereliction of duty, abetment to crimes against humanity and taking a senior citizen for a ride for more than six and half years seeking justice in the untimely, unnatural and merciless death of his wife.

g) Officials in CDSCO (HQ), DCG(I), FDA Maharashtra and FDA Goa Director have to be booked for playing with lives of citizens and colluding in pharma-doctor nexus. These are very serious anti-national acts along with foreign promoters,

h) **Indications of use of Zoledronic acid sent by DGHS** to the Complainant is for the following :

- Paget's disease of bone.
- Prevention and treatment of postmenopausal osteoporosis.
- For the treatment of osteoporosis in postmenopausal women and in men who are at risk of fracture, including those with a trauma of hip fracture.
- Bone metastasis and multiple myeloma.
- Treatment of hypercalcaemia of malignancy.

i) Rokfos booklet on indications of use runs into 15 pages. Cervical spondylitis and stiff neck are not there in indications of use. There are

multiple precautions to be followed. None were followed. Creatinine clearance test which is a contra-indication was also not performed.

j) My wife was not admitted for any of the above-mentioned diseases nor is there any mention of the above-mentioned diseases in in-patient records of Maruti Nursing Home or in the in-patient records of Platinum Hospitals or Jupiter Hospital.

k) Joint Investigation Team and especially Drugs Inspector of CDSCO (WZ) and Expert on Pharmacology did not deem it necessary to question the treating doctor at Maruti Nursing Home on his faulty treatment.

l) There were no conclusive actions after this investigation and in Remarks of the Investigating team **(20th March 2019)** except the following which is junked and proved as protecting the killers of my wife.

m) Very next day **(i.e. 21st March 2019)** after "Fake Investigation Report" report**, letter was issued by FDA Goa Director to Cipla Limited that no action is taken against the company (evidence document page 306) attached.**

n) Investigation was regarding homicide of my wife but Report was not sent to the aggrieved complainant.

o) Report was leaked to the complainant after two years by Public Health Departments of Maharashtra after they themselves were trapped destroying "Expert Committee Report" in Lokayukta hearings.

p) Investigation was regarding drug Rokfos manufactured by Cipla Ltd but Cipla Ltd was not involved.

q) **Date of Investigation : 29-01-2019 & 01-02-2019**

r) **Date of Report : 20 March 2019**

s) Cipla Head Global Pharmacovigilance, Dr.Avinash Kakade's explanation in Show Cause to FDA Goa Director was **dated 26.03.2018**

t) Dr.Eswara Reddy did not consider Cipla's written submissions a year ago on 26.03.2018. **This proves Dr.S.Eswara Reddy as a fraudster.**

u) Corrections to dates in both the letters is obvious **(evidence document pages 283 and 306).** This proves that it was a **coordinated conspiracy between CDSCO and FDA authorities of Gr Mumbai and Directorate of Food & Drugs Administration, Govt. of Goa.**

v) This was one year after FDA Goa Director had warned Cipla Limited of Legal Action **(evidence document page 766-767) attached.** Obviously, bribing was the reason for the sudden U-Turn by Director of Food and Drugs Administration, Government of Goa.

w) After false explanations by Cipla Ltd, FDA Goa Director had passed the matter to DCG(I) for action from his side **(evidence document page 305) attached.**

x) Instead of legal action against Cipla Ltd, DCG(I) Dr.S.Eswara Reddy passed the matter to Secretary-cum-Scientific Director of Indian Pharmacopoeia Commission, Dr.G.N.Singh four times in five months **(Evidence documents pages 768-774) attached.**

y) 10th January 2019 - Letter to the complainant from Dr.G.N.Singh (Secretary-cum-Scientific Director, IPC) **[Evidence document page 304] attached** stating the following :

Indian Pharmacopoeia (IPC) is not the Regulatory Authority to oversee and regulate matters related to manufacturing, sales and Clinical Trials induced adverse drug reactions/death. As such, the grievance is not pertaining to IPC. Matters related to clinical trials and adverse drug reactions/death in this country are regulated by the Central Drugs Standards Control Organisation (CDSCO) under DGHS, Ministry of Health and Family Welfare, Government of India **headed by Drugs Controller General (India).** I hope that with the above information, the matter stands clarified from our end.

z) Dr.S.Eswara Reddy was forced to take legal action against Cipla Ltd.

aa) **However, Dr.S.Eswara Reddy abandoned his duty, moral and legal responsibility and conspired to protect an unscrupulous international pharmaceutical company playing with lives of 141 crore citizens.**

bb) Cipla Ltd should have been prosecuted in 2018 itself but for this criminal conspiracy engineered by Dr.S.Eswara Reddy.

11.COMPLAINT TO CABINET SECRETARIAT:

a. Complainant addressed the matter to the **Cabinet Secretariat.** The Cabinet Secretary and his team of around 6-7 deputies went through the entire story (around 250 pages) and asked the Health Secretary for action in 'CIPLA DRUG TRIAL'. This was at end-July 2020.
b. Health Secretary did not convey to Cabinet Secretary that Joint Investigation has already been conducted and Report was dated 20th March 2019. He was very much aware that it was a Fraud.
c. Conspiracy and foul play by CDSCO officials DCG(I) ADC(I), DDC(I) (WZ), Mumbai has been exposed above under Joint Investigation Report.
d. Health Secretary has not taken any action as officials in CDSCO were involved or it leaves a doubt in my mind as to a larger conspiracy in MOHFW in protection given to Cipla Limited.

12.I received an Email from cpgrams-darpg@nic dated **25th March 2019** regarding my grievance with registration No. PMOPG/E/2018/0214210 for providing my feedback on resolution on my grievance. This was immediately after FDA Goa Director issued letter **dated 21/03/2019** to Cipla Ltd that no action is taken against them.

I wrote to Dr.S.Eswara Reddy **(evidence documents pages 801-803)** that it was he who has to order immediate cancellation of Cipla licence for playing with lives of citizens of India. Nexus with doctors/private hospitals in conducting clinical trials on unsuspecting patients, deceiving FDA authorities, taking consumers for a ride and fooling the world with fake public claims.

There was no response by DCG(I) Dr.Eswara Reddy who abandoned his duty towards the citizens for whom he was appointed.

13. Money power of Cipla Ltd coerced officials in regulatory and law enforcing agencies to collude with the criminal offenders and protect them from prosecution since nine years.

14. An aggrieved senior citizen had to investigate his wife's murder himself as all regulatory and law enforcing authorities failed him.

15. **"Right to Life"** of my wife was cut short by Cipla Limited in nexus with doctors. Illegal Trial conducted with Cancer injection (to be given only once in a year even to bone cancer patients) administered for curing "Stiff Neck" in one day.

16. **"Right to Justice"** denied by Cipla Limited to an aggrieved senior citizen by bribing and corrupting each and every regulatory and law enforcement authority viz FDA, CDSCO, Public Health Departments, Deans & Professors of Medical colleges.

17. **Fake Science,** Fake Chemistry and Fake Medical Theses used extensively to silence an aggrieved senior citizen.

18. **"Anti-corruption Ombudsmen"** (Lokpal of India & Lokayukta of Maharashtra) at Federal & State levels are past Judges of High Courts & Supreme Court. Their conduct has tarnished the image of Judiciary in our country.

19. **Role of pharma firms in allegedly bribing CDSCO officials is under CBI scanner.** Alleged involvement of several pharmaceutical companies in bribing officials of Central Drugs Standard Control Organisation (CDSCO) through a conduit to get their files "processed favourably" has come under scanner of CBI, people aware of the matter told **ET. Dr.S.Eswara Reddy was arrested by the CBI and later suspended by the Health Ministry.**

20. **Lokpal of India** - Complaint was made by me against **Dr.S.Eswara Reddy, Dr.P.B.N.Prasad (Joint Drugs Controller), Shri Somnath Basu (Asst Drugs Controller), Shri Rajesh Bhushan (Health Secretary) & DCG(I), Dr.V.G.Somani** with Anti-corruption Ombudsman, Lokpal of India. Lokpal of India (Full Bench) disposed of my complaint without looking into it & multiple lies in their Order.

21. **Lokayukta of Maharashtra -** The same Fake Joint Investigation was explained threadbare to Lokayukta of Maharashtra, Justice V.M.Kanade who preferred to disregard it, thus favouring FDA Gr Mumbai officials & criminal offenders.

There were only two points for action against public servants in government of Maharashtra by the Lokayukta, Justice V.M.Kanade:

1) FIR in police complaint for culpable homicide against Cipla Ltd, doctors and hospitals. Statement for arrest warrant was taken from me in 2017.
2) Case (under Drugs & Cosmetics Act) was filed by Drug Inspector in Magistrate Court in 2015 but was not followed up by the Drug Inspector of FDA Gr Mumbai. Matter had to be pursued and guilty parties arrested.

Firstly, Lokayukta, Justice V.M.Kanade protected all public servants in Directorate of Health Services, Government of Maharashtra, Department of Medical Education & Drugs, Government of Maharashtra, Dean & doctors of Sir J.J.Group of Hospitals after **Expert Committee Report** submitted in **September 2018** was destroyed by the Dean.

Secondly, Lokayukta of Maharashtra did not question FDA Gr Mumbai joint Commissioner why case filed before Mazgaon Court, Mumbai by FDA Gr Mumbai Drug Inspector in 2015 was not pursued since seven years.

Thirdly, the Lokayukta did not question FDA Gr Mumbai joint Commissioner on Fake Joint Investigation along with CDSCO.

Lokayukta colluded with Public Servants (and indirectly with criminal offenders) and disposed of my complaint illegally without submitting minutes of the last hearing.

Order to dispose of my complaint on his own volition was abandoning his duty towards the citizens for which he was appointed. He has to face charges of "criminal conspiracy", cheating the citizen, among other charges.

22. As is evident, this is the biggest pharma-doctor malpractice; investigated and caught with fool proof evidence.

23. Damage to the nation cannot be imagined or evaluated.

24. Charges against doctors and Cipla have been listed in both the documents submitted.

25. First and foremost Cipla Ltd licence has to be cancelled and directors arrested.

26. There is no way that Dr.S.Eswara Reddy can escape stringent punishment. CBI should be entrusted with the task of investigating disproportionate assets of Dr.S.Eswara Reddy.

I request you to please send a message on my cell on receipt of my document.

In case you need any further clarification, please let me know.

Thanking you,

Yours Sincerely,

Umeshchandra Barkur

A-15, Neeta Apartments, Chaphekar Bandhu Marg, Mulund East, Mumbai 400081. Email: barkurumesh4@gmail.com Cell: 98201 17923