Date : 28th July 2022

Hon'ble President of India,

Madam Droupadi Murmu,

Rashtrapati Bhavan, New Delhi 110004.

Respected Madam,

Greetings on being appointed the President of India.

It is definitely an historic event for all of us - the common man.

I am a frustrated senior citizen seeking your appointment in person.

You have assured all the countrymen that their interests will be paramount to you. Here is a matter which affects interests of all the citizens of the country and not only seeking justice in homicide of my wife for the past eight years.

Matter in National interest – Health and lives of the citizens.

Subject : Homicide of my wife, Late Smt Kamini Barkur; untimely, unnatural and merciless death. 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).

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"**

[**Joint Drugs Controller, Dr.S.Eswara Reddy** was arrested by the CBI in Biocon Biologics bribery case**]**

[Dr.S.Eswara Reddy is involved in my wife's case also; against Cipla Limited. "Fake Joint Investigation" was organised by Dr.S.Eswara Reddy, Dr.P.B.N.Prasad (CDSCO), Mr.Somnath Basu (CDSCO) along with FDA Gr Mumbai & FDA Goa to silence an aggrieved senior citizen (myself) seeking justice in untimely, unnatural & merciless death of his wife.

Very next day after "Fake Investigation Report", letter was issued by FDA Goa Director to Cipla Limited that no action is taken against the company. This was one year after FDA Goa Director had warned Cipla Limited of Legal Action. Obviously, bribing was the reason for the sudden U-Turn by Director of Food and Drugs Administration, Government of Goa.

1. The following facts in death of my wife sacrificed as a guinea pig in an illegal drug trial by doctors & hospitals in nexus with pharmaceutical company, Cipla Limited is before all regulatory & law enforcement agencies in the country. Besides, all concerned Ministries both at Federal & State levels of Maharashtra & Goa.

   a) Cipla Drug Trial (facts of the case).

   b) Evidence documents.

   c) Memorandum of parties.

   d) List of documents relied upon by the complainant.

2. **"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.

3. **“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.

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

5. **“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.

6. **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 has since been suspended by the Health Ministry.**

7. **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.

8. **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.

9. **Police Complaint -** My Statement as complainant was taken in 2017 by Navghar Police, Mulund, Mumbai for effecting "Arrest Warrant". Lokayukta has further delayed the matter which is a criminal offence. As former Judge of

Bombay High Court, Justice V.M.Kanade should know that FIR has to be registered & that too in a Homicide matter.

10. **Cipla cared a damn** for life lost from their drug, violated statutory guidelines, took the aggrieved for a ride for four years. Later deceived FDA by linking imaginary diseases on the deceased and imaginary treatment for the same.

Subsequently, bribed and corrupted FDA, CDSCO, Public Health Departments, Deans & Professors of Government Medical Colleges.

After Fake injection, used Fake Science, Fake Chemistry and Fake Medical Theses to suppress homicide of an innocent.

11. **Two Acts** were abused due to bribing and corrupting by Cipla Limited.

    1) Drugs & Cosmetics Act, 1940 and
    2) Lokpal & Lokayuktas Act

Where is Safety for the Citizens of Bharat Mata?

CDSCO is the National regulatory body for drugs in India. Drugs are approved by Drug Controllers working in CDSCO. FDA is the State Licensing Authority. If both FDA-CDSCO are in nexus with pharma companies, where is the safety for the citizens? Since I had determined to persevere death of my wife, I could reach this stage with documentary evidence implicating all authorities.

12. **NHRC** (National Human Rights Commission) has been provided with full details of bribing and corrupting in every authority by Cipla Limited.

13. **United Nations Human Rights Council –** Since Pharma companies export their drugs to several countries across the world, I have tried to complain to UNHRC.

14. **Media -** Cipla Limited silenced journalists in the media investigating “Cipla Drug Trial”. I have emails and WhatsApp Chats from six of them.

15. **All evidence** is before all authorities including two Orders in Civil Suits **(Maharashtra Medical Council and Maharashtra State Commission)** implicating Cipla drug Rokfos causing serious ADRs leading to death.

16. **CDSCO letter dated 17/01/2022 from Drugs Controller General of India** to FDA Goa Director to take action against Cipla Limited is proof that Cipla should have been prosecuted in **2018 itself.**

17. **Criminal offenders** viz Cipla Ltd, doctors and hospitals as well as civil servants involved in colluding with them including Lokayukta of Maharashtra, Justice V.M.Kanade as also Lokpal of India **should be arrested by the Central Bureau of Investigation (CBI).**

They have to face charges of "criminal conspiracy, cheating, to influence a public servant by corrupt or illegal means & bribery" among other charges. Serious anti-national criminal activities amounting to Sedition deserving imprisonment for Life.

- **Cipla Limited has destroyed the social fabric of our society.**

18. **Sequence of events** (Succinct summary for quick understanding) in this homicide is reproduced under **(Pages 6-22)** culminating in **CDSCO letter dated 17/01/2022 from Drugs Controller General of India to FDA Goa Director to take action against Cipla Limited.**

Thanking you for your co-operation & hoping for an appointment soon,

Yours Sincerely,

Umeshchandra Barkur

A-15, Neeta Apartments, Chaphekar Bandhu Marg, Mulund (E), Mumbai 400081.
Cell : 98201 17923 Email: umeshchandrabarkur@hotmail.com

Note:

1. Health is wealth. We have to save the citizens from this dangerous network; Pharma-Doctors-CDSCO-FDA playing with lives of innocents followed with bribing and corrupting authorities.
2. Central Bureau of Investigation has undertaken an historic step to save citizens from consuming sub-standard, adulterated drugs.
3. In addition to CDSCO, FDA authorities have to be overhauled as is evident in Cipla Drug Trial episode.

Sequence of events in homicide of my wife, Late Smt Kamini Barkur

Succinct Summary exposing the Massive Cover up from Mumbai to Goa to New Delhi to Ghaziabad (Indian Pharmacopoeia Commission)

Worst form of Human Rights Abuse. The doctors watched her sinking for five days at a stretch and later abandoned her to her destiny which was death.

MARUTI NURSING HOME/PLATINUM HOSPITALS/JUPITER HOSPITAL

1. **June 9th, 2014** – Patient was admitted to Maruti Nursing Home for Stiff Neck & Cervical Spondylitis at 12.15 p.m. Cancer injection Rokfos was administered within seven hours for curing stiff neck in a single day without patient's or relatives' consent.

2. **June 10th, 2014** – Patient was sent for MRI in the morning. After returning, side-effects (Adverse Drug Reactions) to this injection occurred i.e. within 20 hours of administering the injection; arthralgia (joint pains), myalgia (muscle pain), bone pain & back pain. She was bed-ridden till her death 2 weeks later.

3. **June 11th, 2014** – Spine surgeon, Dr.Satyen Mehta advised surgery for cord compression (cause of stiff neck revealed in MRI Scan) at Platinum Hospitals on 16th June 2014, subject to Surgical Fitness. Patient was to be shifted on 15th June 2014.

Patient had dysphagia (difficulty in swallowing) and could not swallow even saliva after 5 days. She had petechial rashes (bleeding from under the skin).

4. **June 12th, 2014** – Patient was certified "Fit for Surgery" by physician for cord compression (cause of stiff neck). Repeat blood counts were advised which revealed pancytopenia (drop in all three blood counts). WBC fell from 20,080 to 2,300 & platelets from 143,000 to 95,000. It was a dire emergency.

Treating doctor, Dr.Mihirgiri Goswami, physician, Dr.Aafaque Dolare who certified patient as fit for surgery & Spine Surgeon, Dr.Satyen Mehta decided to postpone surgery scheduled for 16th June 2014.

This was not revealed to the patient or her relatives.

5. **June 13th, 2014** – There was no treatment of the patient. Blood was collected three times. Patient & relatives were waiting for surgery on 16th June 2014.

6. **June 14th, 2014** – Treating doctor, Dr.Mihirgiri Goswami told the complainant to shift the patient to Platinum Hospitals. When questioned as to "Why shift a day earlier" and pay more bed charges at the Multi-specialty hospital, he replied that bed charges were included in "Surgery Package".

Ambulance was called for by Dr.Mihirgiri Goswami and patient was dumped on her relatives with nothing mentioned in "Discharge Card" except "Shift to Platinum for Surgery".

Platinum hospitals admitted the patient in the absence of a properly filled Discharge Card. She was admitted in a ward. Within one hour, she was shifted to the ICU. **Relatives were stunned beyond belief.**

Blood counts on admitting to Platinum Hospitals were; WBC 200 & platelets 20,000. From 20,080 to 200 (WBC) & platelets 143,000 to 20,000 the doctors watched the patient sink to her death for three days.

I insisted that Dr.Satyen Mehta be called as it was under his consultancy that patient was admitted and that he cannot absolve himself of his responsibility. Upon his arrival, Dr.Satyen Mehta instead of telling the truth that patient was in "Pancytopenia" since three days, deceived the relatives that patient was in "Septicaemia". He said that surgery is postponed and disappeared from the scene altogether. Did not respond to letters & emails subsequently.

7. **June 15th, 2014** – Dr.Mihirgiri Goswami arrived at Platinum Hospitals in the morning. When questioned on the sudden turn of events, replied "How do I know? Ask Dr.Agarwal from Dadar and disappeared from the scene altogether.

In the evening, platelets count was 12,000 & WBC 150. Bone marrow had failed at Maruti Nursing Home itself.

In a desperate attempt to save her life, I shifted my wife to Jupiter Hospital and she was admitted at 10.30 p.m. in the night.

8. **June 16th, 2014** – Sample for bone marrow biopsy was taken which subsequently revealed "Aplastic Bone Marrow" **[Evidence document page 88].**

9. **June 16th to June 24, 2014** – All attempts to revive the patient's bone marrow failed and she succumbed to her death on 24th June 2014.

Cause of death given by Jupiter Hospital was "Septic Shock with Multi-organ Failure" instead of "Aplastic Anaemia" **[Evidence document page 89].**

Death Summary gives the immediate & antecedent causes of death. Aplastic Anaemia was omitted to suppress the serious ADRs of injection Rokfos **[Evidence document page 90].**

MAHARASHTRA STATE CONSUMER DISPUTES REDRESSAL COMMISSION

CIVIL SUIT FOR DEFICIENCY IN SERVICE & MEDICAL NEGLIGENCE

10. **21st February 2019** - Order by Maharashtra State Commission (Consumer Court) dated 21st February 2019 holding doctors and hospitals guilty of causing death of my wife from serious ADRs of injection Rokfos manufactured by Cipla Limited **[Pages 68-87 of Evidence documents].**

INVESTIGATION BY THE AGGRIEVED COMPLAINANT

WITH DOCTORS INVOLVED

11. **July 2nd, 2014** - Complainant started his investigation into death of his wife by writing to treating doctor, Dr.Mihirgiri Goswami.

Reply was received vide email dated 01 August 2014 that they were aware of my wife's death following diagnosis of Aplastic Anaemia **[Evidence documents pages 91-93].**

22nd August 2014 - Subsequently, upon my insistence, Dr.Mihirgiri Goswami arranged for a meeting with relatives of the deceased to reveal causes leading to death of my wife**.**

The meeting was recorded on my mobile without the doctors' knowledge wherein the doctors revealed the truth that injection Rokfos caused serious ADRs never seen before with Zoledronic acid, the ingredient of the injection **[Pages 549-673 of Evidence documents].**

12. **July 28th, 2014** – Complainant wrote to family doctor, Dr.Korgaonkar seeking answers who replied that he did not advise injection Rokfos and that his responsibility regarding treatment of the patient ceased the moment she was accepted by Dr.Mihirgiri Goswami as his patient and started her treatment.

13. **July 28th/July 31st/August 2nd 2014** – Complainant wrote to Spine Surgeon supposed to perform surgery and referred to by treating doctor on 11th June 2014. Dr.Satyen Mehta did not respond to my letters & emails which proves his guilt in suppressing the ADRs and not informing the relatives that patient had become critical.

14. **July 28th/August 9th 2014** – Complainant wrote to Dr.Aafaque Dolare the physician who certified the patient as fit for surgery. These letters were not responded.

15. Failure to even respond to simple questions in death of the patient by the doctors involved proves their Guilt.

CIPLA LIMITED – INFORMATION ON SERIOUS FATAL ADRs

16. **Schedule M of Drugs & Cosmetics Rules –** Protocol to be followed by drug companies in case of serious Adverse Drug Reactions **[Evidence documents pages 94-95].**

As per Schedule M of Drugs & Cosmetics Rules, all complaints regarding product quality, shall be carefully reviewed and recorded according to written procedures by the manufacturing companies. Each complaint shall be investigated/evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained. There shall be written procedures describing the action to be taken, recall to be made of the defective product. Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority.

Note: Cipla cared a damn for life lost. Did not follow statutory guidelines, lied to FDA Goa Director & the complainant that they had followed statutory guidelines. FDA Goa Director did not ask for proof of compliance. Complainant has produced letters from FDA Goa, PVPI & DCGI.

August 16th, 2014 till April 18th 2017 – Complainant wrote to Cipla Limited on August 16th, 2014 to investigate their drug **[Evidence documents pages 96-98].**

Subsequently followed up with emails & letters to Cipla Drugs Safety upto Cipla Global CEO & M.D. Shri Umang Vohra.

There were only terse replies like “Thank you for notification” “We acknowledge receipt of your email” “We will take appropriate action” **[Pages 96-136 of Evidence documents].**

August 7th, 2014 - Cipla Limited was already informed by the treating doctor of the serious fatal ADRs **[Pages 173-174 of Evidence documents].**

Proof of Non-reporting of serious Fatal ADRs by Cipla Limited:

24th November, 2017 – Reply to RTI Query by Indian Pharmacopoeia Commission that the National Coordination Centre for Pharmacovigilance Programme of India does not have record of the adverse event of Rokfos – IV Infusion manufactured by Cipla **[Page 179 of Evidence documents].**

17th October 2019 - Reply to RTI Query (Whether the serious adverse drug reactions of injection Rokfos been finally reported by Cipla Limited to FDA authorities, IPC (PVPI) and DCGI). Reply by Indian Pharmacopoeia Commission. Reply was a categoric **“Yes”. [Pages 252-254 of Evidence documents].**

18th January 2018 - Reply to RTI Query by Directorate of Food & Drugs Administration that they have not received any report of serious adverse drug reactions of IV Rokfos from Cipla Limited. As per records available at Cipla Goa no drugs recalled is conducted **[Page 178 of Evidence documents].**

26th March 2018 - Explanation to Show Cause Notice by FDA Goa Director was submitted by Cipla Head, Global Pharmacovigilance. This was full of blatant lies and imaginary statements **[Pages 138-150 of Evidence documents].**

- Ignorance of Law **[Page 139 of Evidence documents].**
- Linking imaginary diseases to the deceased prior to drug Rokfos being administered to her and imaginary treatment for the same **[Pages 141-144 of Evidence documents].**

Unknown to ongoing – Concurrent condition – Tuberculosis of spine, bone tuberculosis, Arm paralysis (monoplegia).

On an unknown date, the patient received one shot of steroids treatment for tuberculosis treatment. The unknown steroid which was administered on an unknown date could also be the cause of aplastic anaemia.

Note: Explanations were submitted from sheer imagination to deceive Director of Food & Drugs Administration, Government of Goa.

False explanation to FDA Goa on health condition of the patient prior to Rokfos being administered to her was exposed in in-patient record by physician, Dr.Aafaque Dolare who had certified the patient as "Fit for Surgery". He had noted "Pre-morbidly healthy" "No known allergies" "No addictions" "No major illness in the past" **[Page 177 of Evidence documents].**

Lies to the Complainant on admitting to following statutory guidelines, reporting to appropriate licensing authority, following applicable provisions of Schedule M of Drugs & Cosmetic Rules reporting to DCGI, PVPI & FDA Goa **[Pages 173-175 of Evidence documents].**

These lies have been exposed as stated above **[Pages 178-179 of Evidence documents].**

9th May 2018 - **Unconditional apology** demanded from Cipla Head Global Pharmacovigilance & Cipla Board of Directors **[Pages 153-157 of Evidence documents]** has not been received by the complainant since four years.

04th March 2019 – Letter to Shri Yusuf Hamied, Cipla Ltd Chairman for malpractices & criminal offences at Cipla claiming lives of innocents **[Pages 214-215 of Evidence documents].** There was no reply by the Chairman.

04th March 2019 – Letter to Shri Yusuf Hamied, Cipla Ltd Chairman for an Inspirational Science Programme & "Yusuf Hamied Quotes" VS "Reality at Cipla" **[Pages 216-241 of Evidence documents].**

26th June 2018 - After being cornered, Cipla agreed to comply with directions of the concerned authorities **[Pages 212-213 of Evidence documents].**

- CDSCO is the National Regulatory Authority for drugs in India.
- FDA is the State Licensing Authority.

FDA MAHARASHTRA, GREATER MUMBAI

17. **April 28th 2015** – Complainant filed complaint before FDA Gr Mumbai with copy of complaint addressed to Cipla Ltd for investigating the fatal drug.

July 22nd 2015 - FDA Gr Mumbai Drug Inspector raided Maruti Nursing Home & found out that they did not have a valid licence for selling or stocking of drugs. Case was filed before Magistrate Court, Mazgaon, Mumbai but my name as complainant was not given. Neither were drugs being sold above MRP and most importantly no mention of drug Rokfos causing serious ADRs resulting in death of my wife.

January 28th 2016 – Letter from Assistant Commissioner (Zone 4) that they had seized drugs worth Five lakhs & eight thousand at Maruti Nursing Home and action will soon be initiated at the earliest **[Page 262 of Evidence documents].**

September 14th 2016 – Media Report of Assistant Commissioner of FDA Gr Mumbai was caught accepting bribe of Rs.40,000. This was the same officer with whom my complaint against Maruti Nursing Home was registered **[Page 278 of Evidence documents].**

December 17 2019 – Media Report that Maharashtra tops list of drug samples failing FDA tests. Statement was made by MOS Health, Shri Ashwini Kumar Choubey in Parliament on December 13, 2019 **[Page 281 of Evidence documents].**

FDA Gr Mumbai Commissioners, Joint Commissioners & Assistant Commissioners took me for a ride with **false, misleading replies to my RTI queries; [Page 268 of Evidence documents].**

- That they had no jurisdiction as the drug was manufactured in Goa,
- That there is no report of sub-standard report in their records.
- That Drug Inspector had launched prosecution against Maruti Nursing Home & other concerned persons in the Court.

DIRECTORATE GENERAL OF HEALTH SERVICES

18. **20/12/2017** – Reply to RTI Query of complainant from Directorate General of Health Services regarding protocol to be followed by drug companies in case of serious ADRs; Schedule M of Drugs & Cosmetics Rules **[Pages 94-95 of Evidence documents].**

The link between the doctors' statements and violation by Cipla of legal provisions of the Act solved the secret behind the suppression of the fatal ADRs by Cipla Limited.

- The drug was sub-standard.
- It was specially manufactured for treating minor bone problems like stiff neck, joint pains, bone pain, etc.
- Maruti Nursing Home sold Rokfos injection to other doctors illegally i.e. without a valid license as required under Drugs & Cosmetics Act, 1940.
- The drug was administered as a Trial without precautions & contra-indication tests to cure stiff neck in a single day.

DIRECTORATE OF FOOD & DRUGS ADMINISTRATION, GOVT OF GOA

19.**01st January, 2018** - Since FDA Gr Mumbai refused to act on the serious ADRs & since DGHS advised me protocol to be followed by Drug companies, I filed my complaint before FDA Goa.

18/01/2018 – Warning & Show Cause was issued by FDA Goa Director to Cipla Ltd of Legal action for failing to follow statutory guidelines in case of serious ADRs. However gave an opportunity to Cipla to submit their explanation **[Pages 766-767 of Evidence documents].**

26/03/2018 – Cipla Head, Global Pharmacovigilance submitted his explanation full of blatant lies. Linked imaginary diseases including "Paralysis" on the innocent patient after their drug caused her death. Also linked imaginary treatment for imaginary diseases **[Pages 138-150 of Evidence documents].**

15/05/2018 - Instead of following up with the warning given, FDA Director sent the matter to DCGI for action from his end against Cipla Limited **[Page 305 of Evidence documents].**

DRUGS CONTROLLER GENERAL OF INDIA

20. Dr.S.Eswara Reddy held the DCGI post for a temporary period.

26/07/2018 – Letter from DCG(I), Dr.S.Eswara Reddy to National Coordination Centre, Pharmacovigilance Programme of India, Indian Pharmacopoeia

Commission to examine the matter relating to serious ADRs of Rokfos branded Zoledronic acid by Cipla **[Pages 768-769 of Evidence documents].**.

10/09/2018 – Letter from ADC(I), Shri Somnath Basu to National Coordination Centre, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission to examine the matter relating to serious ADRs of Rokfos branded Zoledronic acid by Cipla **[Pages 770-771 of Evidence documents].**.

30/11/2018 – Letter from DDC(I), Shri A.K.Pradhan to National Coordination Centre, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission to examine the matter relating to serious ADRs of Rokfos branded Zoledronic acid by Cipla **[Pages 772-773 of Evidence documents].**.

05/12/2018 – Letter from ADC(I), Shri Somnath Basu to National Coordination Centre, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission to examine the matter relating to serious ADRs of Rokfos branded Zoledronic acid by Cipla **[Page 774 of Evidence documents].**

INDIAN PHARMACOPOEIA COMMISSION

21. **10th January 2019 –** Secretary-cum-Scientific Director of IPC, Dr.G.N.Singh sent letter to complainant that "Matters related to clinical trials and adverse drug reactions/death are handled by CDSCO under DGHS, Ministry of Health & Family Welfare, Govt of India headed by Drugs Controller General (India)" **[Page 304 of Evidence documents].**

DCG(I), Dr.Eswara Reddy was cornered by both FDA Goa Director as well as Indian Pharmacopoeia Commission to take action against Cipla Ltd under Drugs & Cosmetics Act; Penalty as well as imprisonment for Life.

JOINT INVESTIGATION FRAUD

22. Dr.Eswara Reddy, Dr.P.B.N.Prasad, Shri Somnath Basu (Asst Drugs Controller) hatched a conspiracy to give letter of pardon to Cipla Limited by organizing a "Fake Joint Investigation" along with FDA Gr Mumbai & Professor & Head of Pharmacology, Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai (Expert) **[Pages 282-292 of Evidence documents].**.

- This investigation was based on complaints from Shri Umeshchandra Barkur regarding death of his wife Smt Kamini Barkur from sub-standard drug Rokfos manufactured by Cipla Limited **[Page 283 of Evidence documents].**
- Complainant was not informed of the investigation nor was the report sent to him.
- Report was regarding sub-standard drug Rokfos but drug maker Cipla was not included in the investigation nor was Cipla Limited questioned by the investigation team.
- Cipla had already submitted their explanation to FDA Goa Director on **26th March 2018** which was exposed as fraudulent and apology was sought from each and every director and Cipla Global Head Pharmacovigilance **[Pages 153-157 of Evidence documents].**

DCG(I) was aware of this.

- **26th June 2018** – After being cornered from all sides, Cipla had pleaded to comply with directions of the authorities as and when it comes **[Pages 212-213 of Evidence documents].** Authorities, CDSCO & FDA protected Cipla with "Fake Joint Investigation" explained & exposed in detail in my detailed complaint document "**Cipla Drug Tria**l" **[Pages 27-44 of Document on Cipla Drug Trial].**
- **October 2018 -** Maharashtra State Commission had held doctors & hospitals guilty for causing death of my wife & implicating drug Rokfos causing serious ADRs. Order was pronounced on **21st February 2019.**
- **29/01/2019 & 01/02/2019** – Joint investigation was conducted and report was dated **20th March 2019.** Very next day, FDA Goa Director issued a letter dated **21st March 2019** that no action has been taken against Cipla Limited.

23. Aggrieved Complainant and senior citizen was taken for a ride from **June 2018 till February 2021** when this Fraud was leaked to him by Medical Education & Drugs Department, Government of Maharashtra during Lokayukta Hearings. It was sent vide Speed Post on **16th February 2021** prior to the next hearing wherein FDA Gr Mumbai Commissioner was summoned.

24. **Reason for leaking this Report to the Complainant:**

Public Health Departments of government of Maharashtra were trapped in three hearings after Dean of Sir J.J. Group of Hospitals destroyed **"Expert Committee Report"** to be submitted to Navghar Police, Mulund, Mumbai for registering FIR in my police complaint after my statement was taken in 2017 for effecting "Arrest Warrant".

Complainant was discretely informed that cover up was from Ministry of Health and Family Welfare viz CDSCO.

POLICE COMPLAINT WITH NAVGHAR POLICE, MULUND, MUMBAI

25. **10th April 2017** – My Complaint was made on 10th April 2017. Navghar police took my statement for effecting arrest warrant**.** But did not register it.

Upon my complaint to DCP Shri Sachin Patil, he directed that the matter be sent to Directorate of Health Services, Public Health Department, Government of Maharashtra.

DIRECTORATE OF HEALTH SERVICES, PUBLIC HEALTH DEPARTMENT, GOVERNMENT OF MAHARASHTRA

26. **24th July, 2018** - Directorate of Health Services kept the matter with them for 7 months and then sent it back to Navghar police station saying that matter falls under section 304-A and that it should be forwarded to Dean of Sir J.J.Group of Hospitals **[Page 345 of Evidence documents].**

DEAN, SIR J.J.GROUP OF HOSPITALS

27. **29th August 2018 –** Dean of Sir J.J.Group of Hospitals appointed a panel of three doctors (Expert Committee) to adjudicate criminality in death of my wife on "Tatkal" basis i.e. within a week **[Page 347 of Evidence documents].** This was by Acting Dean, Dr.Tayde.

07th September 2018 – Reply to RTI query by Navghar Police Station regarding Expert Committee Report; Information will be given after receipt of details from the Dean of Sir J.J.Group of Hospitals **[Page 348 of Evidence documents].**

23rd October 2019 – Reply to RTI query from PIO of Sir J.J.Group of Hospitals; That the report is confidential and cannot be given to the complainant. Further, they have no authority to give details to police station for framing charges against the accused and register an FIR **[Page 349 of Evidence documents].**

01st January 2021 – Complaint to Commissioner of Police, Mumbai informing him of destruction of evidence and attempt to tamper with evidence **[Pages 467-468 of Evidence documents].**

07th April 2022 - Complaint to Commissioner of Police, Mumbai informing him regarding Foul Play by the Lokayukta of Maharashtra, Justice V.M.Kanade disposing my case without minutes of the last hearing and with multiple lies in his Solo Order. This was an illegal order and collusion with Public servants and criminal offenders **[Pages 674-678 of Evidence documents].**

MAHARASHTRA MEDICAL COUNCIL

28.**29TH January 2021 –** Order by Maharashtra Medical Council holding treating doctor, Dr.Mihirgiri Goswami guilty of causing death of my wife from serious ADRs of injection Rokfos manufactured by Cipla Limited **[Pages 61-67 of Evidence documents].**

This Order corroborates Order by Maharashtra State Commission; that injection Rokfos caused death of my wife.

LOKAYUKTA OF MAHARASHTRA

29.**31.10.2019 –** Online complaint was sent to Hon'ble Lokayukta of Maharashtra.

12th March 2020 – First hearing before Justice Tahiliyani. On being shown reply from Office of Dean, Sir J.J.Group of Hospitals **[Page 349 of Evidence documents]** he said "How can the report not be given to the complainant". Asked me to tell the Dean that if the report is not given to the complainant, he will summon the Dean himself.

Dean's office said that the report is not ready as information has to be received from the police station. Subsequently they said that they required X-Ray & MRI films.

Note: Full information was submitted in police complaint as given in Civil suit before Maharashtra State Commission. **X-Ray & MRI Reports were there.** Why were the films needed as patient had died and there was no question of Surgery.

24th March 2020 – Hearing with FDA Gr Mumbai was cancelled due to lockdown. Justice Tahiliyani retired and next hearing was on 24th November 2020.

24 November 2020 – The hon'ble Lokayukta, Dr.Shailesh Kumar Sharma summoned the Dean, Dr.Ranjit Mankeshwar. Dr.Abdul Hannan, Chairman of the Expert Committee submitted that the report was not ready as they required X-Ray & MRI films.

On being told by me that the Expert Committee Report has been submitted, he told me to fax it. However, I sent a detailed report on the hearing.

30th December, 2020 – Hearing was held by the hon'ble Upa-Lokayukta, Shri Sanjay Bhatia who asked Dr.Abdul Hannan if he has considered the Complainant's points on ADRs of injection Rokfos. Dr.Hannan replied in the affirmative. The meeting ended abruptly.

03.01.2021 – Complainant sent email to Lokayukta explaining destruction and tampering of evidence by the Dean & Expert Committee Chairman, Dr.Abdul Hannan **[Pages 428-432 of Evidence documents].**

15.01.2021 – Email to hon'ble Lokayukta/Upa-Lokayukta was for full evidence for action; now that both the law enforcement authorities against whom they were supposed to follow up for action are themselves the accused for colluding with criminal offenders **[Pages 433-450 of Evidence documents].**.

20.10.2021 – First hearing was held by newly appointed Lokayukta, Justice V.M.Kanade. Joint Commissioner of FDA Gr Mumbai was also summoned **[Pages 63-64 of Document on Cipla Drug Trial].**

Vide letter dated 27th October 2021, I explained what transpired in previous three hearings **[Pages 679-701 of Evidence documents].**

Vide letter dated 27th October 2021, I sent to the Lokayukta Memorandum of parties i.e. departments answerable for public servants who colluded with the accused in my criminal complaints with Navghar Police and FDA Maharashtra, Gr Mumbai **[Page 702-716 of Evidence documents].**

Vide letter dated 27th October 2021, I sent to the Lokayukta my response to the Joint Investigation Report **[Pages 717-742 of Evidence documents].**

06.01.2022 - Second & Final hearing with Dean & Expert Committee doctors, FDA Gr Mumbai Joint Commissioner, Police Inspector of Navghar Police Station, Mulund, Mumbai.

Shocking! Lokayukta of Maharashtra had come prepared to dispose of my complaint. He spoke on behalf of the civil servants in spite of my detailed explanation of previous three hearings. Department-wise gross dereliction of duty by civil servants were given as per his request.

Justice V.M.Kanade facilitated in protecting criminal offenders Cipla Limited, doctors & hospitals in illegal drug trial.

Protected destruction of Expert Committee Report submitted to Dean of Sir J.J.Group of Hospitals in September 2018. Protected officers in FDA Gr Mumbai for their collusion with the said criminal offenders. Protected Drug Inspector, Commissioners & Assistant Commissioners for not taking action after complaint was registered in 2015.

12th January 2022 – I sent letter to the Lokayukta, copy endorsed to the hon'ble Governor of Maharashtra **[Pages 743-761 of Evidence documents].** I said that I am shocked and perturbed. **Also refer to Pages 65-68 of Document on Cipla Drug Trial.**

Since journalists investigating Cipla Drug Trial were silenced by Cipla Limited, I had to rely on Social Media Twitter and Facebook (Meta).

I posted Justice V.M.Kanade's cowardly act to abandon responsibility & Sacred office for the common man **[Pages 68-69 of Document on Cipla Drug Trial].**

GOVERNOR OF MAHARASHTRA

30.**23.03.2022 –** Letter to Hon'ble Governor of Maharashtra, Shri Bhagat Singh Koshyari.

Subject : Demand for Dismissal of Lokayukta of Maharashtra, Justice V.M.Kanade for colluding with civil servants in Public Health Departments of Mantralaya, Government of Maharashtra, FDA Gr.Mumbai & Navghar police to dismiss homicide of my wife with false statements in his order dated 22.02.2022. Justice V.M.Kanade should be made an accessory to homicide.

LOKPAL OF INDIA

31.**25th May 2021 –** Complaint before Lokpal of India – Foul Play in protecting CDSCO & MOHFW officials in Corruption Complaint against Dr.S.Eswara Reddy,

Dr.P.B.N.Prasad (Joint Drugs Controller), Shri Somnath Basu (Asst Drugs Controller), Dr.V.G.Somani (DCGI) & Health Secretary, Shri Rajesh Bhushan.

Order was dated 24.08.2021. This order was issued without going into my complaint seriously & with multiple lies in the Order **[Pages 69-70 of Document on Cipla Drug Trial].**

INTERFERING IN FREEDOM OF THE PRESS

32. Journalists were keen on investigating CIPLA DRUG TRIAL. Their voices were silenced. I have emails & WhatsApp Chats from six of them.

WORLD HEALTH ORGANISATION - OFFICE OF REPRESENTATIVE TO INDIA

33. **July 9th 2019 –** Complainant sent letter dated 9th July 2019 to WHO representative to India, Dr.Henk Bekedam on serious ADRs of injection Rokfos **[Evidence documents pages 501-506].** This letter was not responded by the WHO representative to India.

October 8th 2019 – Complainant sent letter dated 09th March 2020 to WHO Director, Dr.Tedros Adhanom requesting him whether the Adverse Event from Cipla Limited drug Rokfos (ingredient Zoledronic acid) has been reported to WHO **[Evidence documents page 507].** There was no reply.

9th March 2020 - Complainant sent letter dated 09th March 2020 October 2019 to WHO Chief Scientist, Dr.Soumya Swaminathan requesting the same information on serious ADRs of Rokfos **[Evidence documents pages 508-509].** Book on CIPLA DRUG TRIAL was also sent to her. Upon delivery of the book to WHO office in Geneva, complainant got a call immediately from the office of WHO representative to India who said that they were not aware of my letters. The caller refused to reveal his name & sent a reply to get information from PVPI (Pharmacovigilance Programme of India).

Note: Information sought was whether the ADRs were reported to WHO which **went unanswered.** It is very clear that even staff in WHO office in India were compromised.

USFDA WARNING TO CIPLA LIMITED

34. **February 25th 2020** – Letter stated that the warning summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals.

Because your methods, facilities, or controls for manufacturing, processing, packing or holding do not conform to CGMP, your drug products are adulterated **[Evidence documents pages 243-251].**

February 27, 2020 – Media Report of USFDA Warning to Cipla **[Evidence document page 242].**

CABINET SECRETARIAT

35. **End-July 2020 –** Cabinet Secretary and his team of deputies went through the entire story and asked the Health Secretary for action in "CIPLA DRUG TRIAL" **[Evidence documents pages 510-512].**

HEALTH SECRETARY IN MINISTRY OF HEALTH & FAMILY WELFARE

36. There has been no action whatsoever by the Health Secretary on Cabinet Secretariat's order for two years which itself is disrespect to the Cabinet Secretariat & not expected of the Health Secretary.

Health Secretary should have submitted **"Fake Joint Investigation" Report** dated 20th March 2019. Did not do so as he was aware that it was a **"FRAUD".**

NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION

37. NCDRC President, Justice R.K.Agrawal joined the fray of INHUMAN characters at top-most positions in the country in silencing the aggrieved senior citizen and dragged the matter needlessly in Appeal filed by the doctors and hospitals **[Refer Pages 71-72 of document on Cipla Drug Trial].**

COMPETITION COMMISSION OF INDIA

38. Complaint against Cipla does not fit exactly under CCI Mandate. However, I have requested the officers concerned to advise the government of malpractices in the "Pharmaceutical Sector" and bring out a revised document on Pharmaceutical Sector in India. Also refer to **Pages 72-74 of document on Cipla Drug Trial.**

MINISTRY FOR CONSUMER AFFAIRS

39. **01st July 2021** – Consumer grievance against FDA & CDSCO officers was made to Shri Piyush Goyal, hon'ble Minister for Consumer Affairs; **Pages 81-82 of document on Cipla Drug Trial.**

MINISTRY OF CORPORATE AFFAIRS

40. **12th October 2020 –** Complaint was made to Registrar of Companies. Ministry of Corporate Affairs had warned of action against Cipla; **Pages 81-82 of document on Cipla Drug Trial.**

DEPARTMENT OF PHARMACEUTICALS

41. Pharma Policy (2015) had been proposed which called for stringent actions. A marketing ban of one year and confiscation of stock. After exposure of Cipla Drug Trial and multitude malpractices, it is required that the same Draft Pharma Policy be implemented.

DCGI LETTER TO DIRECTOR OF FDA GOA

42. **04th February 2022 –** Letter from FDA Goa Director to Drugs Controller General (India) – DCG(I) regarding action against Cipla Limited **[Evidence documents pages 782-783].**