PETITION BEFORE

Honourable Minister for Consumer Affairs,

Shri Piyush Goyal

INVESTIGATED AND EXPOSED

Food and Drug Administration in India
"Nexus with criminal pharma" "Nexus with unethical doctors"
Fully supported by Drug Controllers under
CDSCO
(Central Drug Standards Control Organisation)

Joint Investigation by CDSCO and FDA was a fraud and an unpardonable sin committed on the citizens which has exposed "Freedom to manufacture sub-standard drugs" and "Prescription for Trials"
This could be the norm prevailing in the entire country and Citizens are paying the price for corruption by Public Servants

REQUIRED IN THE INTEREST OF THE NATION
"Corruption be wiped out from the country"
"Consumer Protection, a must for the creation of New India"
"Nexus between pharma companies and doctors for unethical monetary rewards be broken"

"Stringent mandatory Pharma Policy"

"Amendments to Drugs and Cosmetics Act, 1940"

Date : 01st July 2021

Shri Piyush Goyal,

Honourable Minister of Consumer Affairs,

Department of Consumer Affairs,

Krishi Bhawan, New Delhi 110001.

Respected Sir,

Subject : Consumer Grievance against FDA officers and CDSCO officers

There are fundamentally two distressing and serious issues in this petition for the safety and rights of all the citizens of the country :

A. Nexus between pharma companies and doctors for unethical monetary rewards and malpractices in playing with lives of innocent, vulnerable patients by conducting trials with injections not containing prescribed ingredients.
B. Nexus between pharma companies and FDA authorities of the states fully supported by CDSCO Drug Controllers.

1. The above-mentioned nexus was thoroughly investigated by me for seven long years; firstly, it was my personal loss which propelled me to seek justice and punish the criminals for causing unnatural, untimely and merciless death of my wife and secondly, I explored deep into the matter and left no stone unturned, in the interest of the people of our country.

2. The matter has been conclusively proved in death of my wife from serious adverse drug reactions (ADRs) of injection Rokfos manufactured by Cipla Limited and the massive cover up of the ADRs by around two dozen doctors at three hospitals; Maruti Nursing Home, Platinum Hospitals and Jupiter Hospital.

3. There was no need for Cipla Limited or FDA authorities to hush up known side effects of their drug unless Foul Play was involved in manufacture and Trials conducted on innocent, vulnerable patients.

4. Any complaint on a drug causing serious ADRs resulting in death has to be addressed to :

   a) Drug manufacturer. In this case Cipla Limited. Treating doctor had informed Cipla of the serious ADRs.

      The complainant had registered his complaint. I had provided batch number, manufacturing date, expiry date, M.L. number for Veena Industrial Estate Goa. Also informed Cipla that I needed to investigate the causes leading to her death which was due to “Aplastic Bone Marrow” reason being drug induced.

   b) Law Enforcement Agency for drugs. In this case Food and Drug Administration (FDA). Accordingly, after several attempts, I finally managed to lodge my complaint with FDA Maharashtra, Mumbai.

5. Food and Drug Administration, Maharashtra :

ROLE OF FDA OFFICERS IN THIS HOMICIDE - Commissioners, Joint Commissioners, Assistant Commissioners and Drug Inspectors.

a) The aggrieved Complainant has been taken for a ride for more than six years by officials at the highest levels at FDA Maharashtra.

b) False, misleading, evasive replies by FDA Maharashtra, Mumbai to RTI queries has finally nailed the officers. Proof of Foul Play and collusion with both Maruti Nursing Home doctors as well as Cipla is on open display :

c) They told me that my RTI Queries were in Question & Answer Form.

Note : RTI queries were specific to death of my wife only, and not for general knowledge on Drugs and Cosmetics Act, 1940 and Rules thereof.

d) RTI Query & reply dated 16/10/2019.

Rokfos is manufactured by Cipla Limited which comes under the jurisdiction of FDA Goa**.**

Note : Whom will residents of Maharashtra address their grievance relating to a drug causing death in Mumbai, if not FDA Maharashtra, Mumbai?

e) RTI Query & reply dated 16/10/2019.

Drug Inspector of this administration has launched the prosecution against Maruti Nursing Home and other concerned persons in the Court.

Note : They have said that FDA has launched prosecution in Court.

Case filed at 15th Court, Mazgaon was for illegal sale of drugs without a valid licence as required under Drugs and Cosmetics Act, 1940.

Complaint was not for illegal sale of drugs but regarding death of my wife from ADRs of Rokfos as per complaint dated 16th August 2014 to Cipla Limited, copy of which was submitted to FDA Assistant Commissioner (Zone 4). Even on illegal sale of drugs, there has been no action for six years.

f) RTI Query and reply dated 16/10/2019.

There is no sub-standard drug report in the record available in this office.

Note : Is the aggrieved supposed to prove sub-standard drugs. What are FDA officials paid for, from tax-payers' money? Who will implement Drugs and Cosmetics Act, 1940 and Rules thereof?

Note : Schedule 'M' of Drugs and Cosmetics Rules should have been followed by both Cipla Limited as well as FDA Maharashtra.

g) Both drug manufacturer, Cipla Limited as well as FDA officials in collusion violated 'Statutory Guidelines' under Drugs and Cosmetics Rules**.** They did not investigate the said drug as they were aware that the drug would fail the 'standard quality' test.

h) Dr.Metekar at FDA Maharashtra had told me "Purchase was illegal" and "Sale was illegal". There could be no defence that the drug was of standard quality.

However, Joint Commissioner, Shri O.Sadhwani told the petitioner that the drug causing serious ADRs had to be proved in the Consumer Court.

The Joint Commissioner should be aware of Drugs and Cosmetics Act 1940 and Rules 1945.

This was how FDA Maharashtra officers protected Cipla Limited and Maruti Nursing Home doctors from prosecution.

i) Two Judgements (by Maharashtra Medical Council & by Consumer Court) have been delivered implicating Cipla injection Rokfos causing serious ADRs resulting in death. What is holding FDA Maharashtra Commissioner from launching prosecution against Cipla and Maruti Nursing Home doctors. Obviously, corruption is involved.

j) Order by Maharashtra Medical Council dated 29th January 2021 wherein the Executive Committee has removed the name of treating doctor from its register has established the following facts :

- 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 by respondents as per severity of disease.

- Required investigation of patient was not done.
- After complication, respondents had failed to detect the reason and treat the patient.
- Dose of Methotrexate medicine was not mentioned on paper provided before committee in spite of advising and prescribing the same.
- 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 20,000 to 200.
- However RMP ignored and transferred the patient for surgery to another hospital which was scheduled on 15/06/2014.
- 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.

k) **Order by Maharashtra State Consumer Disputes Redressal Commission (Consumer Court) dated 21st February 2019 :**

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.

l) Complaint dated 14th May 2018 to Joint Commissioner of FDA Maharashtra was for action against Cipla, Maruti Nursing Home and FDA officials.

Complainant had enclosed his letter to Cipla Management dated 9th May 2018 demanding an unconditional apology for false, baseless and defamatory information given to Director, Food and Drugs Administration, Goa on the health condition of his wife prior to being administered injection IV Rokfos for curing stiff neck in a single day and which caused her death. They had portrayed her as “Paralytic”.

- This complaint was also a reminder to the Joint Commissioner for actions taken by FDA Maharashtra, Mumbai against **A.** Maruti Nursing Home, **B.** Cipla Ltd. and **C.** FDA Maharashtra, Mumbai officials.

  That actions were requested by **A.** DCGI, **B.** PMO complaint forwarded by Drugs 2 Department, Mantralaya, **C.** Office of Minister for Food, Civil Supplies, Consumer Protection and FDA and **D.** Office of Chief Minister of Maharashtra.

- After the false explanation by Cipla Head Global Pharmacovigilance were exposed by the Complainant, it was the role of FDA Goa Director and FDA Maharashtra officials to protect pharma company, Cipla Limited with a conspiracy hatched by the DCG(I) in collusion with CDSCO (WZ), Mumbai.

- Instead of questioning Cipla officials based on my letter of 14th May, 2018, FDA Maharashtra, Mumbai officials did exactly the Opposite.

  They sent one sample to government laboratory in Mumbai in the year 2018, i.e. four years after the adverse event and told the complainant that the drug had passed 'Standard Quality' test.

- This same letter dated 14th May 2018 was quoted by the Joint Investigation Team who were fully aware that Complainant's wife had died in 2014 and not in 2018. They were fully aware of expiry date (January 2016) of drug Rokfos administered to my wife in the year 2014 and which caused her death.
- This unimaginable, unthinkable and crude conspiracy by persons at the helm of affairs in regulatory and law enforcement agencies **{**DCG(I) under CDSCO, DDC(I) under CDSCO (WZ), FDA Maharashtra Joint Commissioner and FDA Goa Director**}** disgraces our nation and is covered under Joint Investigation Report subsequently.

m) Proof of corruption in FDA Maharashtra was in Media report – Arrest of FDA Officer**.** This was the same Assistant Commissioner with whom my complaint was registered.

n) Status of case registered at 15th Court, Mazgaon, Mumbai - Even on illegal sale of drugs, there has been no action after case was filed in 2015 i.e. six years subsequently.

- My complaint was manipulated as a complaint received from a confidential source. My name is not there as the complainant.
- After panchnama by FDA Drug Inspector on 22/07/2015, drugs were not seized. Instead, the Drug Inspector took an undertaking from Dr.Mihirgiri Goswami that drugs will be stored at temperatures below 25*C.
- Only three samples of drugs (other than Rokfos) were sent to the government laboratory for testing.
- There was nothing about drugs sold above MRP. There was nothing regarding ADRs of injection Rokfos.

- Purchase bill for Rokfos should have been produced. I had provided the same in my complaint dated 28/04/2015.
- Status of case shows 'Evidence before charge'. No evidence has been submitted since six years.
- Sale invoices should have been produced.
- After raid on 22/07/2015, case was filed only in October 2016 i.e. after one year and three months. This was due to complainant's continued pressure on the Assistant Commissioner.
- License was issued to Maruti Nursing Home eight months later and that too for a different location.

o) **Maharashtra tops in sub-standard drugs** – MOS, Health's statement in Parliament on 13th December 2019**.**

- About 8% of the drug samples from Maharashtra tested by the FDA had chemicals other than the prescribed dose or were filled with contaminants such as corn starch, potato starch or chalk revealed Union Minister of State for Health and Family Welfare, Shri Ashwini Kumar Choubey on December 13, 2019.
- Between 2014-15 and 2018-19, samples tested in Maharashtra were found to be sub-standard making it the state with the highest rate of drug samples failing FDA test.
- This pathetic state of affairs is due to the pathetic administration at FDA Maharashtra as brought out in this one case caught red-handed.
- There may be thousands of such cases in nexus with unscrupulous pharma companies like Cipla Limited playing with lives of the citizens of our country.
- Drug Rokfos that killed the Complainant's wife had chemicals other than 5mg/100ml of Zoledronic acid. Hence, the drug was not tested by Cipla as well as FDA Maharashtra. It was a trial conducted on an innocent, vulnerable patient.

p) Joint Investigation Fraud in nexus with CDSCO (HQ), CDSCO (WZ), Mumbai and FDA Goa Director was a sin committed on the citizens of the country. This is explained in detail separately.

6. Since FDA Maharashtra had refused to file complaint on the serious ADRs saying that the drug was manufactured in Goa, complainant had lodged his complaint with Directorate of Food & Drugs Administration, Government of Goa vide Public Grievance Portal of Government of Goa in January 2018.

ROLE OF FDA GOA DIRECTOR IN THIS HOMICIDE

a) Online complaint to PG cell of Government of Goa was transferred to Food and Drugs Administration, Government of Goa.

b) Letter was sent to Complainant by FDA Goa Director dated 16.04.2018 stating that explanation submitted by Cipla is sent to him which was self-explanatory.

c) False explanation by Cipla Head, Global Pharmacovigilance. The following false statements have been exposed :

- Ignorance of law pertaining to reporting of serious ADRs; Schedule 'M' of Drugs & Cosmetics Rules. Cipla Head Global Pharmacovigilance said "We were unaware of the fact that Schedule M mandates that 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 : Ignorance of laws of the land cannot be an excuse in a homicide case punishable with life imprisonment.

- Linking imaginary diseases to the deceased prior to drug Rokfos being administered to her.
  - 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.

Note : 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. I have WhatsApp chats and emails from six leading media journalists, similarly silenced.

- Linking Imaginary treatment for the imaginary diseases.
  - 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.

Note : 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".

d) Cipla's Lies to the petitioner on following statutory guidelines; Schedule 'M' and reporting to DCG(I), PVPI and FDA Goa.

- "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.

- "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".
- "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".

e) Copies of the above explanations were sent by me to FDA Maharashtra, FDA Goa, Directorate of Public Grievances, Government of Goa, Directorate of Health Services, Mantralaya, Government of Maharashtra.

f) 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.
- 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.
- 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.

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

g) Vide letter dated 26.06.2018 by Cipla Authorised Representative to the complainant, they said that they will comply with the directions of the authorities as and when received.

h) Letter from FDA Goa Director dated 15/05/2018 was sent to DCG(I) for necessary action at his end. Copy was sent to Dy. Drugs Controller (India) CDSCO (WZ), Mumbai.

- After explanation by Cipla Head Global Pharmacovigilance was proved by complainant as totally fraudulent, FDA Goa Director told DCG(I) that the said complaint was investigated by Investigating Officer of their Directorate by visiting the premises and was reported that as per Cipla's policy,
  - All complaints related to adverse drug reaction are investigated at Drug Safety Department of Cipla at Mumbai.
  - Subsequent follow up reports are submitted to Drugs Controller General (India) as per pharmacovigilance guidelines.
  - The said adverse drug reaction case was not reported to their Directorate.
  - Further firm was served with show cause notice and was personally heard in the matter.
  - As it was a serious adverse drug reaction case, copy of complaint and submission from Cipla along with reply from Complainant on explanation submitted by Cipla was forwarded for information and necessary action at DCG(I) end.

i) For one year there was no action from FDA Goa or FDA Maharashtra or Drugs Controller General (India) or Assistant Drugs Controller (India) or Deputy Drugs Controller (India), WZ, Mumbai.

- Suddenly out of the blue, letter dated 03/21/2019 was sent to Cipla Limited by FDA Goa Director. The letter stated as follows :
  - That explanation submitted by Cipla was not satisfactory.
  - That Cipla had failed to intimate their Directorate of serious Adverse Drug Reaction as required under Sub Para (2) of Para 28, Schedule M of Drugs and Cosmetics Rules.
  - However, considering the assurance given by Cipla that such violation will not be repeated and on investigating the matter by the Inspecting Officer of their Directorate no adverse findings were

reported in respect of quality of the product no action was taken against Cipla.

- However, Cipla was warned on the matter that if such lapses are reported on their part in future, then strict action as per provision of law will be taken against Cipla.

Note : Submissions by the Complainant on the above letter by FDA Goa Director to Cipla Limited :

- This letter dated 03/21/19 arrived a year after Cipla was exposed for their fraudulent explanation vide Complainant's letter dated 21.04.2018 to FDA Goa Director.
- Correction to date of the letter is obvious and visible.
- Coincidence is to be noted seriously. This letter came exactly a day i.e. 21/03/2019, after the fraudulent Joint Investigation Report dated 20/03/2019 was submitted to the DCG(I) by CDSCO (WZ), Mumbai.
- The Joint Investigation Report has been proved as a farce by the Complainant as explained subsequently.
- Only Warning, Even after death was caused ?
- Only Warning, Even after 'Explanation was not Satisfactory' ?
- Only Warning, Even after 'Failing to report the serious ADRs' ?
- Inspecting Officer was investigating the accused and how did the Investigating Officer got satisfied with explanation of the accused criminal offender? Any documents to substantiate Cipla's claims?
- How could you determine lapses in quality of manufacturing four years after the death? And two years after shelf life of the concerned batch in question was over in January 2016.
- 'Clean Chit' W/O investigation? What about investigation as per Schedule 'M' of Drugs and Cosmetics Rules?
- What about life of innocent sacrificed?
- FDA Goa Director did not deem it fit to question why the drug was not investigated and why protocol of Schedule M was not followed.
- FDA Goa Director tells the killer drug manufacturer that "If you kill again, strict action will be taken as per provision of the law".

- Law regarding Drugs and Cosmetics Act, 1940 was in place and was applicable to all the states of India.
- Why was this law deferred by the Director, Directorate of Food and Drugs Administration, Government of Goa to an unscrupulous pharma company playing with lives of the citizens of India.
- What if a loved one of FDA Goa Director was the casualty? Would the killer still be pardoned till he commits the homicide again in the future?

j) Letter to Complainant by FDA Goa Director dated 15/05/2019.

- It says that the matter was investigated by the Inspecting Officers of their Directorate and it was reported that there are no lapses on the part of the firm as regards quality of the drug of batch in question.
- However the firm had failed to intimate their Directorate regards the serious adverse event.
- Hence firm was issued Show Cause notice and explanation was called.
- Thereafter warning was issued as they had failed to intimate the Directorate regarding serious Adverse Drug Reaction as per requirements of Drugs and Cosmetics Rules 1945 (Copy of warning enclosed).

Note : Submissions by the Complainant to the above letter by FDA Goa Director dated 15/05/2019 to the Complainant :

- FDA Goa Director trusted the words of the Inspecting Officer who in turn was investigating a homicide case and trusted the words of the accused even after being deceived by Cipla Head Global Pharmacovigilance with ‘Fake Chemistry’ and ‘Fake Medical Theses’.
- Warning was issued to the accused but what about lives of the survivors of the deceased?
- Both Cipla Board of Directors as well as regulatory authority, FDA Goa are one seditious family playing with lives of citizens and amassing ill-gotten wealth.

k) Letter to Complainant by Shri Somnath Basu, Assistant Drugs Controller (India) dated 23/05/2019.

- That the office had received Complainant's offline grievance as on 26.03.2019 vide letter Nil dated 14.01.2019 on subject matter; Public grievance; Adverse drug reaction following administration of "Rokfos" branded Zoledronic acid (5mg/100ml) for infusion Mfgd. by M/s Cipla Ltd., Goa-reg.

- Reference was made to office letter dated 20.03.2019.

- That the case was under examination and active consideration with this office and Director, Food & Drugs Admn., Goa. The reminder letter dated 17.05.2019 has been issued to the Director, Food & Drugs Admn., Goa to take necessary action in this matter under intimation to their office at the earliest.

Note : Submissions by the Complainant on the above letter :

- Petitioner's grievance was not made on 26.03.2019 but since the past six years with various regulatory and law enforcement authorities. Complainant's grievance was not initiated in March 2019.

- Which office letter dated 20.03.2019 was referenced. It was CDSCO (WZ) letter on Joint investigation report. Joint Investigation was a conspiracy hatched by CDSCO (HQ), CDSCO (WZ), FDA Goa Director and FDA Maharashtra, conclusively exposed.

- FDA Goa Director had already intimated Cipla vide letter dated 03/21/19 that no action was taken in spite of non-satisfactory explanation and not reporting the ADRs. This was sent to the Complainant vide letter dated 15/05/2019.

- Still the office of DCG(I) says that the case was under examination and active consideration with this office and Director, Food & Drugs Admn., Goa. That reminder letter dated 17.05.2019 has been issued to the Director, Food & Drugs Admn., Goa to take necessary action in this matter under intimation to their office at the earliest.

- Was this an offer for settling the matter with intermediaries, FDA Goa Director and CDSCO officials?

- Earlier offers were made by the DCG(I) under MOHFW. In both letters to the Secretary cum Scientific Director of IPC, the DCG(I) as well as the ADC(I) were stating that complainant is repeatedly asking for compensation.

- Office of DCG(I) were aware of penalty under section 27 (a) of the Drugs and Cosmetics Act, 1940.

l) Complainant wrote a letter dated 12th June 2019 to the Director, Directorate of Food and Drugs Administration, Government of Goa seeking information on their letter dated 21st March 2019 to Cipla Limited and their letter dated 15/05/2019 to the Complainant.

- It is two years and no reply has been submitted to the Complainant by FDA Goa Director.

- Clearly, the entire episode of death of his wife is a massive cover up by an unscrupulous pharma company in nexus with doctors, hospitals and top most civil servants in regulatory and law enforcement agencies of the country. This amounts to anti-national seditious acts.

m) Complaint was registered by the Complainant with the Chief Minister of Goa dated 21st December 2020 against FDA Goa Director and Inspection officers. Subject matter was as explained above.

- Complainant has not received any reply or acknowledgement for the complaint.

n) Complainant sent an RTI request dated 09th February 2021 for information from the Office of Chief Minister of Goa. Information requested was the following **:**

- Reason for not acknowledging my complaint.

- Action taken report in my complaint against the Director, Food and Drugs Administration, Government of Goa.

- Action taken against Cipla Limited for death caused from their drug Rokfos manufactured at their Goa facility.
- Action taken against Cipla Limited for violating statutory guidelines; Schedule 'M' of Drugs and Cosmetics Rules.
- Action taken against Cipla Limited for suppressing the serious ADRs of injection Rokfos which caused death of the Complainant's wife.

o) The RTI request was forwarded to the PIO of Directorate of Food & Drugs Administration, Bambolim, Goa.

- Note : Who in FDA Goa can take action against their own Director?
- There has been no reply to the RTI query which tells the story and admission of guilt.

7. **ROLE OF DRUG CONTROLLERS UNDER CDSCO IN THIS HOMICIDE**

a) Dr.S.Eswara Reddy as Drugs Controller General (India) and Shri Somnath Basu as Assistant Drugs Controller (India) were jointly handling this matter.

b) As Drugs Controller General (India) heading CDSCO, the National Regulatory Authority for Drugs in India, there was no action by Dr.S.Eswara Reddy against criminal offender, pharma company, Cipla Limited in death of my wife from serious adverse drug reactions (ADRs). He along with Shri Somnath Basu have failed in their duties and responsibilities towards the citizens of the country.

c) The drug was manufactured in Goa and 'Show Cause Notice' was issued to Cipla Limited by Director, Directorate of Food and Drugs Administration, Government of Goa.

d) False explanations submitted by Cipla Head, Global Pharmacovigilance were exposed by the complainant.

e) FDA Goa Director submitted complaint, explanation by Cipla and reply by the complainant to explanation by Cipla to DCG(I) for necessary action from his side. Leave alone action, both the DCG(I) and ADC(I) under CDSCO did not even question Cipla Limited on their false explanations regarding serious ADRs causing death of an innocent.

f) **Details of offences committed** by Cipla are as follows :

- In this homicide, Cipla indulged in playing with innocent lives by conducting trials in nexus with doctors.
- Manufacture of sub-standard drugs and caring a damn for lives lost by not following statutory guidelines.
- Cipla was aware of ingredient used for trials. Hence, in spite of repeated requests by the aggrieved, Cipla violated statutory guidelines and did not investigate their drug Rokfos.
- Cipla indulged in anti-pharmacovigilance and deceived FDA authorities with fake chemistry and fake medical theses.
- Future students of Chemistry and Medicine will follow 'Fake Chemistry' and 'Fake Medical Theories'.
- Cipla Chairman, Yusuf Hamied hoodwinked the world with false claims. Did not reply to multiple letters from aggrieved complainant for three years while professing ‘Caring for Life’ and proclaiming himself as a ‘Money-Making-Machine’.
- Cipla being a Public Listed Company kept stakeholders, external regulators and BSE in the dark regarding malpractices indulged by the personnel.
- Malpractices at Cipla has the tacit support of Cipla Management and Board of Directors. No replies to multiple letters by the aggrieved complainant for three years is acceptance of ‘GUILT’.
- Taking an aggrieved senior citizen for a ride for seven years shows the inhuman character of Cipla Foreign Promoters and Board of Directors deserving stringent punishment amounting to Life imprisonment to Cipla Directors.
- Damage caused to the nation by corrupting public servants cannot be estimated by any stretch of imagination.
- Like-wise, ill-gotten wealth by Cipla Limited over the years cannot be estimated.

g) DCG(I), Dr.S.Eswara Reddy and ADC(I) took the aggrieved senior citizen for a ride, tried to silence him into submission and openly favoured and protected criminal offender, Cipla Limited playing with lives of the citizens.

h) The matter has been kept moving from Pillar to Post for three years.

i) Reply to RTI query application no. DTGHS/R/2017/90070 dated 20.11.2017; Protocol to be followed by drug manufacturing companies in case of serious adverse drug reactions; Statutory guidelines were not followed by Cipla nor by FDA authorities of Maharashtra and Goa and neither did the DCG(I) question Cipla or the State Licensing Authorities.

j) CDSCO is the National Regulatory body for drugs and drug Rokfos (Zoledronic acid) had caused serious ADRs never seen before.

- Zoledronic acid is manufactured by several companies in the world and used by millions across the world.
- It was absolutely required to be investigated in the interest of 'Medical Science'.

k) 26th July 2018 - Letter from DCG(I), Dr.S.Eswara Reddy to Indian Pharmacopoeia Commission asking them to examine the whole issue under PvPI and to give their considered opinion so as to take further necessary action in the matter. That the complainant is repeatedly writing letters to their office and other parties asking for re-examination in the matter for judgement and due compensation.

Note : There was nothing to examine or re-examine. It was an open and shut case under both the IPC and Drugs and Cosmetics Act, 1940.

- Drug Rokfos had caused serious ADRs resulting in death of my wife.
- Statutory guidelines were violated by Cipla. They did not investigate their drug Rokfos as foul play was involved in manufacture and trials conducted in nexus with doctors at Maruti Nursing Home.
- As per Email from treating doctor, Dr.Mihirgiri Goswami, he had administered Zoledronic for joint pains.

  Ironically, in direct contrast, he had himself noted that joint pains occurred after infusion of Zoledronic acid**.**

- Transcripts of meeting with treating doctors proves nexus between Cipla and Maruti Nursing Home.

  Treating doctor, Dr.Mihirgiri Goswami said that he will never give Rokfos again. Mediclaim doctor, Dr.Dubey attached to Maruti Nursing Home

said that he goes to several orthopaedics and gives Rokfos with full responsibility. His target was to ensure that there was no problem to treating doctor as well as the patient. These statements (on record) prove that it was Cipla who gave responsibility to the doctors for trials with cancer drug Rokfos for joint pains, stiff neck, etc.

- **Note :** The Complainant did not ask for due compensation. The very fact that DCG(I) has mentioned 'due compensation' confirms that criminal offence has been committed necessitating penalty and punishment under Drugs and Cosmetics Act, 1940.
- DCG(I) did not deem it fit to question Cipla Limited but indulged in gross dereliction of duty. Besides, colluding with a criminal offender is a serious offence necessitating disciplinary, penal and criminal action.

l) 10th September 2018 - Letter from Assistant Drugs Controller (India), Shri Somnath Basu to Dr.G.N.Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission asking to examine the whole issue under PvPI and to give their considered opinion so as to take further necessary action in the matter. That the complainant is repeatedly writing letters to their office and other parties asking for re-examination in the matter for judgement and due compensation.

Note : After DCG(I), it was the turn of ADC(I) to pass the buck to IPC.

m) 30th November 2018 - Letter from Deputy Drugs Controller (India) Shri A.K.Pradhan to Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission stating that since the matter is related to alleged ADR reported with drug Rokfos (Zoledronic acid) for infusion and not related to any clinical trial, you are requested to examine the whole issue under PvPI and give your considered opinion so as to take further necessary action in the matter. All in CDSCO were involved in protection to criminal, Cipla Limited.

n) 05th December 2018 - Letter from Assistant Drugs Controller (India), Shri Somnath Basu to the complainant that since the alleged ADR related to Zoledronic acid for Infusion (manufactured by M/S Cipla Limited) is not related to clinical trial this office has once again requested Secretary-cum-

Scientific Director, IPC Ghaziabad to examine the whole matter under PvPI and to give his considered opinion in the matter.

Note :

- It was an unauthorised trial as revealed in transcripts of meeting between the doctors and relatives of deceased. Treating doctor, Dr.Mihirgiri Goswami has said that he planned for one-day admission; Give today, discharge tomorrow. Stiff neck is not in indications of use of Zoledronic acid sent to complainant by Directorate General of Health Services.
- There was no need for Cipla to suppress the serious ADRs unless FOUL PLAY was involved in manufacturing and trials conducted on innocent patients.
- Cipla officially reported the serious ADRs five years later after being comprehensively trapped. This information was given by IPC in reply to RTI Query.

  This confirms suppression of the serious ADRs by Cipla for five long years till law caught up with them. They had suppressed the adverse event from even WHO.

  The same CPIO of Indian Pharmacopoeia Commission, Sh.V.Kalaiselvan lied to WHO that the ADRs were suspected. My email to the Secretary-cum-Scientific Director and CPIO Shri Kalaiselvan regarding false information given to Uppsala Monitoring Centre (UMC) World Health Organisation Collaborating Centre for International Drug Monitoring Programme has not been answered.

  Copies of this letter were sent to the Health Minister, DCG(I) along with Order/Advise by Cabinet Secretariat, Shri Rajiv Gauba for action in CIPLA DRUG TRIAL case.

  I stated that the ADRs were "NOT SUSPECTED" but "REAL and HUSHED UP". I asked all concerned including Uppsala Monitoring Centre (UMC) World Health Organisation Collaborating Centre for International Drug Monitoring Programme for investigating and reporting.

There has been no reply from any of the authorities concerned.

- **Such a massive cover up.** What is the role of PvPI and IPC if ADRs are hushed up at W.H.O. level also? Such a hue and cry on Pharmacovigilance and an unscrupulous international pharma company, Cipla Limited having around 55 subsidiaries across the world is playing with lives of innocents.

All falsehood by the drug controllers by moving the matter to and fro was laid to rest by IPC as below :

o) **10th January 2019** - Letter to complainant by Dr.G.N.Singh (Secretary-cum-Scientific Director-IPC) 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.

Note : It is evident that DCG(I) and ADC(I) were trying to absolve themselves of their duties and responsibilities and passing the matter to Secretary-cum-Scientific Director of IPC. Simultaneously, they were protecting criminal offender, Cipla Limited from penalty and punishment.

p) Reply to RTI query dated 14/09/2019 by CDSCO. Subject Expert Committee (SEC) meeting on **11.04.2019** pertaining to Analgesic and Rheumatology deliberated on serious ADRs of injection Rokfos and said that the reported adverse reactions like arthralgia, myalgia, bone pain are known side effects of drug Rokfos.

Note : That is exactly the point; why were the serious ADRs suppressed? Apart from the above-mentioned side effects, more serious ADRs were petechial rashes and pancytopenia which were not deliberated upon at the said SEC meeting. Both are typical symptoms and characteristic features of Aplastic Anaemia and my wife died of Aplastic Anaemia.

Note : Joint Investigation Report was sent to CDSCO Drugs Controller General (India) on **20th March 2019.** SEC must be aware of investigation carried out. That a letter of pardon was given to Cipla which spooks of corruption on open display.

Stringent disciplinary, penal and criminal actions have to be taken against all the officers.

- CDSCO reply proves protection given to Cipla Limited for their drug causing death of my wife and to divert the matter to State Licensing Authority which was FDA Goa. All attempts were made to make the aggrieved senior citizen to get fed up and abandon seeking justice.
- Both the authorities (CDSCO and FDA Goa) were compromised. DCG(I) not even questioning Cipla Limited tells the story. We are hearing of DCGI's involvement in giving approvals to vaccines and other regulatory issues daily on the news channels. In spite of my repeated messages and emails, Dr.V.G.Somani, the current DCG(I) prefers to remain silent.

q) Complaint with CPGRAMS PMOPG/E/2018/0214210 was disposed off on 25/03/2019 with a request to view details and provide my feedback on resolution of my grievance. This confirms that my grievance was genuine. Grievance was death caused by Cipla drug ADRs which were hushed up.
   - Complainant had sent his feedback to the DCG(I) as this matter was under examination of Ministry of Health and Family Welfare and under the active consideration of CDSCO - Officer concerns - DCGI. I had asked for action against Cipla Limited.

r) Periodically the DCG(I) was hinting at compensation whereas complainant was claiming penalty and punishment as per section 27 of Drugs and Cosmetics Act, 1940. DCG(I) tried to act as intermediary along with FDA Goa Director.

s) There has been no action by the DCG(I) since, three years.

t) Replies by CDSCO/DCGI is clear evidence that the authorities have been taking a senior citizen for a ride seeking justice in death of his wife. Attempt to silence the aggrieved, so that he aborts seeking justice.

Joint Investigation Report :

A. I received letter dated 11/02/2020 from Department of Medical Education and Drugs, Mantralaya, Mumbai enclosing Joint Investigation Report **[Evidence documents Pages 282-292],** attached. The report was sent on 16.02.2021 by Medical Education and Drugs Department, Government of Maharashtra. Investigation was conducted by the following **:**

1. Dr.Sudhir Pawar, Professor and Head Dept. of Pharmacology, Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai (Expert).
2. Mr.P.D.Thorat, Drugs Inspector, CDSCO (West Zone), Mumbai.
3. Mr.Sanjay Rathod, Drugs Inspector, FDA Maharashtra, Greater Mumbai, Zone-4.

Joint Investigation Report dated 20/03/2019 was submitted by Dy.Drugs Controller (India) CDSCO (West Zone) Mumbai to the Drugs Controller General (India) CDSCO (HQ), FDA Bhawan, New Delhi and to the Joint Commissioner (Gr.Mumbai), FDA Maharashtra, Mumbai 400051.

a) Copy of this report was submitted to the Office of the Hon'ble Lokayukta by Department of Medical Education and Drugs, Mantralaya, Mumbai for the scheduled next hearing on 16/03/2021.

b) As per minutes of the previous hearing on 30.12.2020 sent to the Complainant by the Office of the Hon'ble Lokayukta/Upa-Lokayukta, Principal Secretary, Department of Medical Education and Drugs said that a committee has been constituted at the level of Maharashtra Medical Council, Mumbai to look into the matter.

c) A committee has been constituted at the level of the Government of India to make arrangements for sending the relevant documents to this office as well as to the complainant.

d) The questions to the Principal Secretary, Department of Medical Education and Drugs, Mantralaya, Mumbai are the following :

- Why was Mr.Sanjay Deshmukh, Registrar of Maharashtra Medical Council present at the hearing of the Hon'ble Upa-Lokayukta on 30th December 2020?
- At whose instance was he present and who invited him. The Hon'ble Lokayukta, Dr.Shailesh Kumar Sharma had not intimated the Complainant in the minutes of the hearing held on 24th November 2020.

- Only four parties were supposed to be present for the hearing viz. 1) Principal Secretary, Department of Medical Education and Drugs, Mantralaya, Mumbai, 2) Director, Directorate of Health Services, Mantralaya, Mumbai, 3) Dean of Sir J.J.Group of Hospitals and 4) Complainant.
- The role of Maharashtra Medical Council is to take action against delinquent Registered Medical Practitioners for violation of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002.

  The 'Executive Committee' is a regular affair at Maharashtra Medical Council.

  They had already framed Charges against the delinquent RMPs of Maruti Nursing Home.

- By inviting the Registrar of Maharashtra Medical Council, an attempt was made to alter the Charges already framed and the Principal Secretary, Department of Medical Education and Drugs is answerable before the Hon'ble Lokayukta.
- As per Complainant's email dated 03/01/2021 to the Hon'ble Lokayukta/Upa-Lokayukta, he has explained how evidence was destroyed by the Dean and Expert Committee at Sir J.J.Group of Hospitals.
- Complainant had sent a detailed letter dated 01/01/2021 by speed post. I had explained in detail with conclusive evidence how evidence was destroyed/hidden by the 'Acting Dean', Dr.Tayde who had appointed the panel of three doctors at Sir J.J.Group of Hospitals in August 2018. That Dr.Abdul Hannan during the hearing on 30/12/2020 was tampering with evidence on record which were Orders by the Consumer Court and Charges framed by Maharashtra Medical Council.
- Why was this Joint Investigation Report suppressed from the complainant since two years? and why was this leaked to the Complainant now ?

- Same pattern was followed; Report of 'Expert Committee' at Sir J.J.Group of Hospitals was submitted in September 2018. Subsequently, it was destroyed.
- The Joint Investigation Report was not by a committee constituted at the level of the Government of India.
- This report was a conspiracy hatched by CDSCO (HQ), DCG(I), ADC(I) in collusion with FDA Maharashtra, FDA Goa Director and CDSCO (WZ) DDC(I) to protect Maruti Nursing Home treating doctor, Dr.Mihirgiri Goswami and try to absolve drug Rokfos for the serious ADRs causing death of the Complainant's wife.
- Also, to pressurise the aggrieved and act as intermediaries to the settlement. Scam at the highest level involving billionaire scientists and foreign promoters playing with lives of the citizens.
- There is no relevance of the Joint Investigation report to the ongoing investigation before the Lokayukta/Upa-Lokayukta.

  Report of 'Expert Committee' was not dependent on Maharashtra Medical Council or Joint Investigation Report, secretly conducted by corrupted Civil Servants.

- The only possible relevant explanation could be, that, after Civil Servants in the State of Maharashtra have been implicated in a very serious homicide matter deserving stringent disciplinary and criminal charges, they were informing the Complainant that the cover up was not only at the State levels in Maharashtra and Goa but also at the Central Government level and that the MOHFW was equally responsible for colluding with Cipla Limited.

e) This report when analysed, shows the nexus between CDSCO (HQ) headed by DCG(I), FDA Maharashtra and FDA Goa in taking the aggrieved Complainant and a Senior Citizen for a ride for more than six and half years seeking justice in untimely, unnatural and merciless death of his wife.

f) It was a massive cover up not only by the doctors and hospitals in nexus with Cipla Limited but by one and all in the regulatory and law enforcement agencies of the country, both at the State and Central Government levels.

B. Letter from Dy.Drugs Controller (India) CDSCO (West Zone) Mumbai dated 20.03.2019 was addressed to the Drugs Controller General (India) CDSCO (HQ), FDA Bhawan, New Delhi.

a) That the matter was with reference to CDSCO (HQ) email dated 23/10/2018 and 13/11/2018 on the subject matter which was in connection with complaint regarding death of Smt.Kamini Barkur w/o Sh.Umeshchandra Barkur by sub-standard drug Rokfos manufactured by M/s Cipla Limited and also sold illegally at M/s Maruti Nursing Home, Mulund, Mumbai.

b) CDSCO (HQ) had asked CDSCO (West Zone) to conduct their investigation which they did on 29/01/2019 and 01/02/2019.

C. Background of the report.

a) 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.

b) 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. Complainant's written complaint was dated 23.07.2018 to DDC(I), WZ, Mumbai and he had submitted photograph of carton of drug Rokfos produced by treating doctor in in-patient record of his wife.

c) Details of drug as specified in photograph of carton were as below :

Name of Drug : Rokfos (Zoledronic Acid Solution for Infusion 5mg/100ml).

Batch No. V40056.

Mfg. FEB 14.

Exp. Jan 16.

d) Purchase invoice No.00788 dated 25/04/2014 received from AMI Agency was also submitted.

e) Maruti Nursing Home bill for Rokfos sold to Complainant @Rs.3,500/-

f) Copy of the Joint Investigation report was sent to CDSCO (HQ) vide their letter dated 20.03.2019.

- Copy of this report was deliberately not sent to the Complainant and the aggrieved party in spite of his complaints with both CDSCO (HQ) and CDSCO (WZ), Mumbai as the following facts to protect drug Rokfos which caused death of his wife would have been exposed by the Complainant.

D. Pages 1-4 of the report :

As per the Joint Investigation Report the following points were reported :

a) Documents verified were in-patient records of the deceased, Late Smt.Kamini Barkur at Maruti Nursing Home from date of Admission on 09/06/2014 till her discharge on 14/09/2014 and shifting to Platinum Hospitals for further treatment.

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

c) That Complainant made Complaint dated 28th April 2015 to Joint Commissioner FDA, Maharashtra that drugs are sold above MRP at Maruti Nursing Home.

d) In view of the above complaint, officials from FDA Maharashtra raided the premises of M/s Maruti Nursing Home on 22/07/2015 along with two witnesses. It was observed that hospital is involved in sale of drugs without holding requisite licence as per the provisions of Drugs and Cosmetics Act, 1940.

e) 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.

f) Said case is under court of law and matter is sub-judice.

E. Note : Complainant's submissions to the above points in pages 1-4 of the report by the Joint Investigation team :

a) Zoledronic acid has to be administered only once in a year even to bone cancer patients. There is no question of administering it twice in a year. There were no allegations by the Complainant that it was administered again to his wife during her hospitalisation at Maruti Nursing Home.

b) 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.

c) Petitioner's complaint was regarding drugs sold above MRP but he had also said that his wife after being admitted to Maruti Nursing Home on 9th June 2014 was shifted after six days in very critical condition and succumbed to her death on 24th June 2014. He had attached admission form, purchase bill for Rokfos and bill from Maruti Nursing Home.

d) He had given them copy of his complaint to Cipla dated 16/08/2014.

e) Case is not filed for serious ADRs of injection Rokfos till date which was not deliberated by the Joint Investigation Team.

f) The investigation was conducted in January 2019 and all evidence was with CDSCO (HQ) including false explanation by Cipla Head Global Pharmacovigilance, Dr.Avinash Kakade exposed by the complainant.

g) Joint Investigation Team did not deem it fit to question manufacturer of injection Rokfos, Cipla Limited and what action was taken on complaint dated 16/08/2014. Cipla had acknowledged the complaint, offered condolences on death of my wife, sent indications of use but had not followed statutory guidelines of Schedule 'M' of Drugs and Cosmetics Rules.

h) 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.

i) 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.

j) Open collusion by FDA Maharashtra officials with both Cipla as well as Maruti Nursing Home. 'Status of Case' - Evidence documents has not been submitted since six years.

F. Pages 5-9 of the report :

As per the Joint Investigation Report, the following points were reported :

a) 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.

b) To investigate the subject matter officials from FDA Maharashtra visited premises of M/s Novacare Drugs Specialities Pvt. Ltd.

c) Stock of drug Rokfos Injection IV Batch No. 40056 was not found in the premises of M/s Novacare Drugs Specialities Pvt.Ltd.

d) However other batches as described in Joint Investigation Report were available. One sample was taken for the purpose of test and analysis at Government Analyst, Food and Drugs Control Laboratory, Mumbai, Maharashtra.

e) The sampled drug was declared as of Standard Quality vide Govt. Analyst, Drugs Control Laboratory.

f) 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.

g) 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.

h) In this context, Drugs Controller General, India, has already written letter vide ref No.PG/90/ADR/Rokfos/2018/DCG(I) dated 26/07/2018 to National Coordination Centre, Pharmacovigilance Programme of India, IPC, Ghaziabad and requested to examine the issue under PvPI and give their opinion to take necessary action in the matter.

i) ADC(I), Public Grievance Cell CDSCO, HQ, New Delhi has also written a reminder letter vide ref No.PG/90/ADR/Rokfos/2018/DCG(I) dated 10/09/2018 to National Coordination Centre, Pharmacovigilance Programme of India, IPC, Ghaziabad and requested to examine the issue under PvPI and give their opinion to take necessary action in the matter.

G. Note : Complainant's submissions to the above points in pages 5-9 of the report by the Joint Investigation team :

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

j) How could Stock of drug Rokfos Injection IV Batch No. 40056 be available in the premises of M/s Novacare Drugs Specialities Pvt.Ltd. Shelf life of the batch was over in January 2016. Were they selling expired drugs also?

b) 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.

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

d) 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.

e) It was observed by the Joint Investigation Team 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.

- 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.

f) The Joint Investigation Team was formed not for impartial investigation but to absolve **both Cipla drug Rokfos** as well as **faulty treatment (Trial)** by Dr.Mihirgiri Goswami of Maruti Nursing Home.

g) This was precisely the reason for not intimating the aggrieved regarding this investigation even when the aggrieved was asking repeatedly for information through RTI queries.

h) The conspiracy is exposed, thanks to Department of Medical Education and Drugs, Government of Maharashtra for submitting this suppressed Joint Investigation Report before the Hon'ble Lokayukta and by sending the same to the aggrieved Complainant.

i) **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.

j) 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.

k) Patient 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.

l) 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.

m) 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.

n) 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"**.

o) 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.

p) 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.

q) 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.

r) 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.

s) 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 submissions 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.

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

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

v) Google search will give side effects of Zobone (Zoledronic acid). Petechial Rash and Pancytopenia are typical side effects.

w) Rash was noted in in-patient records.

x) Pancytopenia was revealed in blood test reports as proved above.

y) 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.

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

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

bb) 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.

cc) Exact cause of death was Aplastic Anaemia as per bone marrow biopsy report.

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

ee) 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).

ff) 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.

gg) 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.

hh) 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.

ii) 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.

jj) TB was never proved as surgery was never performed.

kk) 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.

ll) 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.

mm) 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.

H. 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.

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.

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.

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?

I. Complainant's submissions on Remarks of the Joint Investigation Team :

- RTI Query & reply dated 16/10/2019.
- Rokfos is manufactured by Cipla Limited which comes under the jurisdiction of FDA Goa**.**

a) Joint Investigation was conducted on 29/01/2019 and 01/02/2019. There was no mention of Joint Investigation to my RTI request ten months later?

b) 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.

c) 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.

- 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.

d) As per indications of use of Zoledronic acid, complainant's 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.

e) Statements made by the doctors at the meeting held on August 22nd 2014 and inferences drawn from the statements 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.

f) 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.

- Secretary-cum-Scientific Director of IPC, Ghaziabad had already given his opinion to the complainant on 10th January 2019. **This was three weeks prior to the Joint Investigation.**

  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.

- It was after IPC stated that action had to be taken by DCG(I), this conspiracy of fraudulent joint investigation was conceived by CDSCO.

g) 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?

- 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.

h) That only single dose was administered.

Note : 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?

i) 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.

j) 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.

k) To which authority was this Joint Investigation Report submitted by DCG(I). The Complainant was sending reminders and RTI queries to all concerned authorities viz CDSCO and FDA Maharashtra.

l) 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 before the Hon'ble PM, the Hon'ble Lokpal of India, the Hon'ble Lokayukta of Maharashtra and the Hon'ble Supreme Court of India.

m) 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.

Note : The extent of this crude conspiracy exposes the network between criminal pharma and officers under both FDA authorities in the states and Ministry of Health and Family Welfare.

8. There were multiple requests to Cipla Limited by the aggrieved Complainant to investigate their drug Rokfos causing serious fatal adverse reactions never seen before. Statutory guidelines were violated.

- CDSCO headed by DCG(I) and ADC(I) did not question Cipla on the fatal ADRs.
- DCG(I) and ADC(I) did not question FDA Maharashtra, Mumbai.
- DCG(I), ADC(I) and FDA Goa Director did not question Cipla Limited on their blatantly false explanations in Show Cause by FDA Goa Director.
- DCG(I), ADC(I) and FDA Goa Director did not question Cipla and ask proof of 'paralysis', arthralgia, bone tuberculosis, spinal tuberculosis, monoplegia.

- DCG(I), ADC(I) and FDA Goa Director did not question Cipla and ask proof of treatment with steroids and anti-tubercular therapy.
- As per Cipla, immediately on receiving information on the serious ADRs from the treating doctor, they had reported the serious ADRs to FDA Goa, PVPI and DCG(I).

  DCG(I), ADC(I) and FDA Goa Director did not deem it fit to question Cipla and ask for proof of reporting of the serious ADRs.
- On the contrary, FDA Goa Director did an open favour before the nation to the criminal offender, Cipla Limited by issuing a letter that no action was taken against them.
- Sh.Somnath Basu's explanation that this matter has been investigated, examined & inspected at various levels viz FDA Maharashtra, FDA Goa & CDSCO and action has been taken accordingly, is acceptance of the fact that all the officers were involved in the cover up to protect Cipla.
- As per letter dated 23rd May 2019 from Shri Somnath Basu, assurance has been given to the complainant that the matter is under examination and active consideration with CDSCO and FDA Goa.
- It is two years now and no action has been taken against Cipla.
- There are repeated mention of the word **"ACTION"** by one and all public servants; Action and justice has still eluded the aggrieved senior citizen for seven years. The criminals are roaming free even after sacrificing a life. It seems that lives do not matter for MOHFW.
- Money Power of a multi-national pharma company is on open display.

9. **Corruption at the highest levels in healthcare system of our nation** which will destroy future citizens of our country.
10. This deserves to be punished forthright by a **National Task Force** comprising of officials in the Lokpal, Lokayuktas, Cabinet Secretariat and Judges of the Supreme Court of India.
11. Strict laws on the lines of Proposed Pharma Policy of Department of Pharmaceuticals in 2015 needs to be implemented along with stringent action against officers in CDSCO, MOHFW and FDA authorities of the states.

12. Dr.V.G.Somani took over as DCG(I) from Dr.S.Eswara Reddy in August 2019. Subsequently all correspondence in death of my wife were addressed to Dr.V.G.Somani and Assistant Drugs Controller (India), Shri Somnath Basu. Dr.V.G.Somai has failed in his duty and responsibility towards the citizens.

13. As Deputy Drugs Controller (India), WZ, Mumbai, Dr.P.B.N.Prasad was involved in a fraudulent Joint Investigation with CDSCO DCG(I) Dr.S.Eswara Reddy and FDA Maharashtra Joint Commissioner in March 2019.
    a) The report is all about complaints by the aggrieved on various dates but the report was hidden from the complainant for more than two years.
    b) It was revealed by Medical Education and Drugs Department to prove that cover up in Cipla drug trial case was by CDSCO drug controllers both at the Centre as well as West Zone headed by Dr.P.B.N.Prasad.

14. Health Secretary, Shri Rajesh Bhushan :
    a) There has been no action whatsoever on Cabinet Secretariat's order of July-end 2020 by the Health Secretary for ten months, which in itself is disrespect to the Cabinet Secretariat and was not expected of the Health Secretary.
    b) Chapter on Joint Investigation Report explained proves that DCGI under CDSCO (HQ) under MOHFW is involved in FOUL PLAY along with CDSCO (WZ), Mumbai, FDA Maharashtra and FDA Goa Director.
    c) The Health Secretary has preferred to remain silent and a mute spectator as his own colleagues were involved in collusion with Cipla Limited.

       Or is he also a part of the massive scam with an unscrupulous multi-national pharma company playing with lives of the citizens?

15. This complaint exposes corruption in public life which has undermined democracy and the rule of law, violated human rights and compromised the quality of medicines manufactured in the country for the citizens.

16. Interests of all the citizens of the country are prejudicially affected by this complaint which exposes the dangerous network between pharma companies, doctors and hospitals fully supported by Food and Drugs Administration of the States and by CDSCO, the National Regulatory body for Drugs.

17. Vide letter dated 26th June 2018 to the complainant, Cipla Limited pleaded to comply with directions of the authorities as and when it comes.
18. Cipla finally reported the serious ADRs to FDA Goa, DCGI and Indian Pharmacopoeia Commission after suppressing it for five long years.
19. Unscrupulous foreign promoters and directors of this company had FDA and CDSCO public servants in their pockets as is exposed now before the Hon'ble Prime Minister, Hon'ble Lokayukta of Maharashtra, Hon'ble Lokpal of India and the Hon'ble Supreme Court of India.
20. Doctors & hospitals have been held 'Guilty' in civil cases before Maharashtra Medical Council & Maharashtra State Consumer Disputes Redressal Commission (Consumer Court) for causing death of my wife from serious ADRs of injection Rokfos administered Ad Hoc without ascertaining indications.
21. It is an organised crime and drug racket, playing with lives of people and threat to human security. An innocent life was sacrificed and protection to lives of the citizens deprived by regulators and law enforcing agencies.
    - Criminal complaints in this homicide case are being compromised by regulatory and law enforcement authorities in collusion with all the accused.
22. Respondents in my writ petition before the Hon'ble Supreme Court of India are the following regulatory and law enforcement agencies :
    a) Commissioner, Food and Drugs Administration (FDA), Maharashtra.
    b) Director, Directorate of Food and Drugs Administration Govt. of Goa.
    c) Director, Directorate of Health Services, Public Health Department, Mantralaya, Government of Maharashtra.
    d) Director, Directorate of Medical Education and Research, Mantralaya, Government of Maharashtra.
    e) Dean, Sir J.J.Group of Hospitals, Mumbai.
    f) Drugs Controller General (India) under CDSCO under DGHS, Ministry of Health and Family Welfare, Government of India.
    g) Secretary cum Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad.
    h) Health Secretary, Ministry of Health and Family Welfare, Government of India.

i) Commissioner of Police, Mumbai.

23. The state government authorities mentioned above have lied and tried to misguide the Hon'ble Lokayukta/Upa-Lokayukta of Maharashtra also.

a) After being cornered in three hearings, and after Maharashtra Medical Council passed their Order on 29th January 2021, they have placed before the Lokayukta, Joint Investigation Report conducted by CDSCO (HQ), CDSCO (WZ) and FDA Maharashtra.

b) Fraudulent Joint investigation exercise has exposed the fact that cover up of the ADRs and protection given to Cipla Limited was by CDSCO headed by the Drugs Controller General (India).

c) There was no action on the report by any of the three parties; FDA Maharashtra, CDSCO (WZ), Mumbai or CDSCO (HQ).

d) The report is all about the complainant's follow up in death of his wife but the report was not given to the complainant.

e) Immediately, the very next day after the date of the report i.e. 20th March 2019, FDA Goa Director issued a letter dated 21st March 2019 to Cipla Limited that no action is taken against them.

f) The reasons for 'No Action' itself exposes corruption and desperation by Cipla to get this letter from FDA as explained under FDA Goa above.

24. The level and extent of conspiring by all authorities to protect Cipla Limited is mind-boggling but it has also exposed corruption and dangerous network prevalent in the country between criminal pharma companies, CDSCO officers and FDA authorities.

Note : This could be the norm taking place in the entire country and the people are paying the price of corruption by topmost public servants.

25. Case against CDSCO and MOHFW officers has been filed by me with the Lokpal of India as they are central government officers.

26. Case against the criminal offenders is before the Hon'ble Lokayukta of Maharashtra wherein, Public servants in the Government of Maharashtra have been exposed for colluding with the criminal offenders.

27. The entire matter has been placed before the Hon'ble Supreme Court of India with fool-proof evidence running into 673 pages.

28. Public servants have to be punished for gross dereliction of duty and responsibility, corruption and colluding in crimes against humanity.
29. Criminal offenders have to be punished as per laws at the earliest.
30. The most crucial requirement is amendment to laws :
    a) Stringent Mandatory Pharma Policy as warned by Prime Minister Narendra Modiji himself.
    b) Amendments proposed by CDSCO to Drugs and Cosmetics Act, 1940. Compensation to consumers for damage caused by sub-standard drugs on account of drug manufacturers compromising quality to reap rich profits and to get 'Filthy Rich' at the expense of lives of citizens.
31. All citizens are vulnerable in this dangerous cartel of criminal pharma, unethical doctors, FDA and CDSCO. Consumer activists and organisations as well as Anti-corruption bodies and organisations have to take this matter aggressively to enable the Government to bring in necessary amendments to laws which have been proposed in Modi 01 by CDSCO for amendments to Drugs and Cosmetics Act, 1940 and by Department of Pharmaceuticals with a proposal for a stringent Pharma Policy.

I request the Hon'ble Minister for Consumer Affairs to take necessary action against public servants in FDA Maharashtra and Goa and in CDSCO under MOHFW for working against the interest of citizens of our country while protecting criminal offenders in a homicide case.

Thanking you for your co-operation,

Yours Sincerely,

Umeshchandra Barkur
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