

Date : 10th September 2021.

To:

Shri Arvind Mishra

Deputy Registrar

Lokpal of India.

Plot No-6, Phase II, Institutional Area,

Vasant Kunj, New Delhi – 110070.

Dear Sir

Complaint No.48/2021 - Order dated 24.08.2021 of the Hon'ble Bench of Lokpal of India - Complaint against five public servants serving in Departments under the Union Ministry of Health and Family Welfare.

I am aggrieved by the Order of the Hon'ble Bench of Lokpal of India and am responding accordingly, point by point to the said Order.

1. As per Lokpal Order;

Allegation of the complainant that public servants named are indulging in corruption and gross dereliction of duty and, by colluding with unscrupulous pharmaceutical (pharma) companies are turning a blind eye to the violation of statutory guidelines to be followed by such companies and are hushing up the results that follow.

Complainant has annexed

- a) A spiral bound booklet titled "Facts of the Matter" and
- b) Book written by complainant titled "Cipla Drug Trial"
- c) Complainant states that this complaint is not been motivated only by personal considerations but is being made in the interest of all citizens of the country who may be prejudicially affected as there is a dangerous network between pharma companies, doctors and hospitals, which is supported by the Food and Drug Administration (FDA) of the States and CDSCO, the National Regulatory Body for Drugs.

Complainant's response to point 1 above :

- a) At the outset, my complaint is basically against officers of Ministry of Health and Family Welfare indulging in corruption, gross dereliction of duty by colluding with unscrupulous pharma company Cipla Limited who have violated statutory guidelines on serious fatal adverse drug reactions; Schedule 'M' of drugs and Cosmetics Rules.

- There was no need to hide known side effects of a drug unless **Foul Play** was involved in manufacture and Trials conducted on innocent patients.
- The said corrupted officers are trying to silence the aggrieved senior citizen to abandon seeking justice after indulging in corruption.
- **Joint Investigation Report had only one purpose which was to issue a letter to Cipla Limited by FDA Goa director that no action is taken against them and is explained subsequently in detail below.**
- This letter was required by Cipla to show to media journalists and others questioning death of my wife and after false explanations given by Cipla Limited to FDA Goa director & the aggrieved complainant had exposed their role in this homicide in nexus with doctors.

Journalists investigating 'Cipla Drug Trial' were silenced by higher ups. I have emails and WhatsApp chats from several leading journalists.

- b) 'Spiral bound booklet' is evidence and proof of foul play. It has been given to prove my allegations but it seems that the learned hon'ble Bench of Lokpal of India has not given full consideration to the same.
- c) Book written on 'Cipla Drug Trial' shows the desperation of the aggrieved senior citizen, when each and every regulatory and law enforcement agency were being compromised.
- I had preserved each and every correspondence and evidence document to prove Foul Play involved in death of my wife by doctors, hospitals and drug manufacturer, Cipla Limited.
- The book represents only facts (in written statements by the criminal offenders themselves) with evidence produced in 'Spiral bound Booklet'.
- d) Human Rights have been violated.
- e) Complainant investigated the crime for seeking justice in unnatural, untimely and merciless death of his wife and soon comprehended that there was a "Sinister Dangerous Network" between doctors, pharma companies and Food and Drugs Administration of the States, fully supported by CDSCO, the National Regulatory Body for Drugs in India.
- f) Why did the learned hon'ble Bench not look into the voluminous evidence in "Spiral bound booklet" titled "Facts of the Matter" ?

- g) Is there no value for life of a citizen killed by criminal offenders? I am being made to look as if I have submitted facts which have no value.
- h) The network has been proved in **FRAUDULENT JOINT INVESTIGATION REPORT** which forms the basis and **CRUX** of my complaint against Central Government Officers.

Unfortunately, just like MOHFW, CDSCO, FDA, PMO, DARPG, MINISTRIES, responsible persons from the President, Prime Minister down the line have maintained a discreet silence into this killing.

I have addressed this matter with full evidence multiple times for four long years with all concerned with Governance of the Nation.

- i) Interest of all citizens of the country are prejudicially affected by this network. This is not a one-off case. It is continuous manufacture of sub-standard drugs for amassing unethical profits with government support. FDA and CDSCO protecting Cipla Limited in this homicide caught red-handed is proof of sub-standard drugs manufactured on a regular basis.
- j) Citizens are not aware of the efficacy and effectiveness of drugs they are consuming as drug manufacturers are protected by FDA authorities which has been exposed in investigation in death of my wife. CDSCO support is evident by evidence placed before the Lokpal of India.
- k) Evidence of sub-standard drugs manufactured by Cipla at their Goa Plant has been submitted [**Evidence documents pages 242-251**].
- Warning was issued by USFDA to Cipla for Goa facility. That there were 12 serious violations as a result of which their drugs were sub-standard.
 - Drug which caused death of my wife was manufactured at Goa facility.
 - Ironically, during the same period, FDA Goa did not find a single violation in spite of a specific complaint of drug causing death.
 - After false explanation by Cipla Head, Global Pharmacovigilance, FDA Goa director asked DCG(I) for action at his end. That as per Cipla Policy, all complaints related to adverse drug reaction are investigated at Drug Safety Department of Cipla at Mumbai and subsequent follow up reports are submitted to Drugs Controller General (India) as per pharmacovigilance guidelines and the said adverse drug reaction case was not reported to the Directorate.

- What could be examined, inspected and investigated four years after the serious ADRs were hushed up by the criminal offenders including doctors, hospitals and drug manufacturer, Cipla Limited?
 - DCG(I) heading CDSCO under DGHS under MOHFW, ADC(I), DDC(I), WZ, Mumbai have indulged in gross dereliction of duty and colluded with criminal offenders.
- l) Evidence of Maharashtra State topping sub-standard drugs is in Media report - Statement by MOS Health on December 13, 2019 in Parliament [**Evidence document page 281**]. Sub-standard drugs manufactured is due to pathetic state of affairs in FDA Maharashtra.
- m) Proof of corruption in FDA Maharashtra is in **Evidence document page 278** wherein FDA Assistant Commissioner was caught red-handed accepting bribe in his office itself.
- This was the same Assistant Commissioner with whom my Complaint dated 28.04.2015 against Maruti Nursing Home was submitted along with my Complaint to Cipla Limited dated 16.08.2014 [**Evidence document pages 96-98**] to investigate drug Rokfos which caused death of my wife.
 - I had given batch number, manufacturing date, expiry date, etc in my complaint [**Evidence document pages 257-261**].
- n) Both Cipla and FDA Maharashtra violated statutory guidelines and did not investigate the drug causing fatal adverse reactions.
- Schedule 'M' of Drugs and Cosmetics Rules [**Evidence documents pages 94-95**] had to be followed.
 - The drug batch had to be recalled, investigated and records of investigation maintained.
 - Simultaneously, the ADRs had to be informed forthwith to the concerned licensing authority which was FDA. Also to PVPI and DCG(I).

2. As per Lokpal Order;

Order states that the complainant has already approached the Medical Council of Maharashtra.

Complainant's response to point 2 above :

Surprisingly, the learned Bench did not consider Order of Maharashtra Medical Council in 'Facts of the Matter'.

- This is on Page 1 itself supported by copy of the Order [**Evidence documents pages 61-67**].
- Treating doctor's name has been removed from the register of Maharashtra Medical Council.

3. As per Lokpal Order;

From the documents submitted by the complainant, it further appears that he has filed a case before the Additional Metropolitan Magistrate, Mazgaon, Mumbai.

Complainant's response to point 3 above :

The learned bench did not deem it necessary to look seriously into my submissions in such a serious matter involving healthcare of the citizens, bribing and corruption involved by officers in FDA and CDSCO.

- Case before Additional Metropolitan Magistrate, Mazgaon, Mumbai was not filed by the complainant but by Drug Inspector of FDA Maharashtra, Mumbai. This was based on my complaint dated 28.04.2015 to FDA Maharashtra.
- Status of case as of December 2020 [**Evidence documents pages 279-280**] proves that there has been no follow-up on the case for five years. This proves corruption involved and consequently dangerous network.
- These facts have been submitted to the Lokpal of India not for action against FDA authorities but to prove **FRAUDULENT JOINT INVESTIGATION REPORT** by CDSCO Drug Controllers under MOHFW in nexus with FDA Maharashtra officials.
- **This forms the basis and CRUX of my complaint against officers in Ministry of Health and Family Welfare.**

4. As per Lokpal Order;

His complaint to the Ministry of Health and Family Welfare, Government of India has resulted in an investigation into the matter and a Joint Investigation Report with a covering letter dated 20th March, 2019 is on record.

Complainant's response to point 4 above :

As explained above, Joint Investigation Report dated 20th March, 2019 was a **FRAUD**. This forms the crux of my complaint. This has been stated by me on **page 26** of my complaint and I am reproducing the same below :

Note : All letters by DCG(I), ADC(I), FDA Goa, CPGRAMS were immediately after the conspiracy resulting in fraudulent Joint investigation.

- a) From May 2018 till January 2019, DCG(I) & ADC(I) were only passing the grievance 'TO and FRO' to Secretary-cum-Scientific Director of Indian Pharmacopoeia Commission and taking the aggrieved senior citizen for a ride, explained under **pages 11 to 28** of my complaint to the Lokpal of India.
- b) FDA Goa Director had refused to take action against Cipla Limited telling DCG(I) that action has to be taken from his side [**Evidence document 305 dated 15/05/2018**]
- c) **10th January 2019** – After several attempts by DCG(I) and ADC(I), Secretary-cum-Scientific Director of Indian Pharmacopoeia Commission sent his letter dated 10th January 2019 to the complainant emphatically stating that action against Cipla had to be taken by Drugs Controller General (India) [**Evidence document page 304**].
- d) This paved the way for the Fraudulent Joint Investigation Report.
- e) After refusing to take action against Cipla for nearly a year, FDA Goa Director succumbed to corruption along with DCG(I) and rather than questioning the false explanation and taking action against the criminal offender, Cipla Limited, they did exactly the reverse;
 - FDA Goa Director gave a letter to Cipla that no action was taken against them. The bizarre and crude manner by which the joint investigation was conducted and letter was given to criminal offender Cipla Limited is explained in **pages 11 to 28** of my complaint before the Lokpal of India.
 - **This is disgraceful to our democracy, our Administrative Services and Governance of our Nation.**
- f) This was a direct favour to a criminal pharma company, Cipla Limited playing with lives of citizens by manufacturing sub-standard drugs and conducting trials on innocent patients in nexus with unethical doctors. This very clearly spooks of corruption.

- g) The fraud has been comprehensively explained under Joint Investigation Report pages 23 to 39 of my petition to Hon'ble Minister for Consumer Affairs, Shri Piyush Goyal, copy enclosed for your reference.
- h) I am reiterating that my complaint to Lokpal of India is exclusively against officers under MOHFW ONLY for gross dereliction of duty and responsibility and direct involvement in letter & favour given to a criminal offender, Cipla Limited.
- This deserves stringent punishment to all officers in MOHFW named in my complaint before the Lokpal of India.

5. As per Lokpal Order;

To investigate the complaint of the complainant dated 20th April, 2015, officials from the FDA, Maharashtra raided the premises of M/s Maruti Nursing Home on 22.7.2015 along with two witnesses and found that the hospital is involved in sale of drugs without holding a requisite license. Accordingly, a case has been filed against the proprietor of the said nursing home.

Complainant's response to point 5 above :

This is covered under my response to point 3. That there was no case filed by me in civil court.

- a) Case before Additional Metropolitan Magistrate, Mazgaon, Mumbai was not filed by the complainant but by Drug Inspector of FDA Maharashtra, Mumbai. This was based on my complaint dated 28.04.2015 and complaint to Cipla dated 16.08.2014.
- b) My name is not there as complainant.
- c) My complaint was manipulated as a complaint received from a confidential source. My complaint was not for illegal sale of drugs but death of my wife and drugs sold above MRP.
- d) Case was filed for illegal sale of drugs without a valid licence as required under Drugs and Cosmetics Act, 1940.
- e) 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 temperature below 25* C.
- f) Only three samples of drugs (other than Rokfos) were sent to the government laboratory for testing.
- g) There was nothing about drugs sold above MRP.

- h) There is nothing regarding ADRs of injection Rokfos.
- i) Purchase bill for Rokfos should have been produced. I had provided the same in my complaint dated 28.04.2015.
- j) 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 my continued pressure on the Assistant Commissioner of FDA Maharashtra.
- k) Licence was issued to Maruti Nursing Home eight months later and that too for a different location.
- l) Status of case shows 'Evidence before charge' [**Evidence documents pages 279-280**]. No evidence has been submitted since five years. Sale invoices should have been produced.
- m) Even on illegal sale of drugs, there has been no action by FDA Maharashtra.
- n) This proves the dangerous network between doctors, pharma companies and FDA officials fully supported by CDSCO.
- o) **FRAUDULENT JOINT INVESTIGATION REPORT** was signed by the Drug Inspector of FDA Maharashtra and after not following up on the case for five years, himself says that the matter is sub-judice.

6. As per Lokpal Order;

Insofar as the death of the complainant's wife is concerned, the report states that there is inadequate information available in relation to the patient's health history, other drugs administered and the sequence of events that occurred after discharge of the patient from M/s Maruti Nursing Home, clinical investigation reports as well as the cause of death. Therefore it is difficult to comment on whether there was a lapse in the standard of care administered.

Complainant's response to point 6 above :

Why the Joint Investigation Report was a fraud and an "Unpardonable Sin" committed on the citizens of the country is explained below :

- a) As per the report, there was inadequate information available in relation to the patient's history.
 - Investigation was conducted at Maruti Nursing Home wherein all in-patient records were maintained.

- Proprietor and other doctors of Maruti Nursing Home involved in treatment of the deceased would have been informed in advance of the investigation.
 - Investigation was on drug Rokfos causing death of my wife and the drug manufacturer's presence was essential along with his written false explanations to FDA Goa director in Show Cause.
 - Final hearing at Maharashtra State Commission was over and part order was shown to the complainant & advocate for the treating doctors and hospital, Maruti Nursing Home. That the doctors and hospitals were held 'Guilty' and had to pay compensation.
Final Order was dated 21st February, 2019.
 - There were two complaints; one before Maharashtra Medical Council and another before Maharashtra State Commission. There were nearly 1,500 pages of submissions by all parties, affidavits, evidence documents including attested in-patient records at all three hospitals including Platinum Hospitals and Jupiter Hospital where the patient finally succumbed to her death.
- b) Patient's health history was noted by Physician Dr.Aafaque Dolare who had certified the patient as "**Fit for Surgery**" for cord compression, the cause of stiff neck.
- He had noted; "Pre-morbidly Healthy" "No Major illness in the past" "No Addictions" "No know allergies" [**Evidence document page 177**].
- c) All drugs administered were in in-patient records of Maruti Nursing Home. Patient was admitted at 12.15 p.m.
- Drug Pidimol (pain killer) was administered at 1.00 p.m.
 - Drug Rokfos was administered at 7.00 p.m. This was a cancer drug administered for curing "Stiff Neck" in a single day. This drug has to be given only once in a year even for treating bone cancer. This was given without the patient's or relatives' consent.
 - Side effects (ADRs) started within 20 hours after this injection was infused. This injection caused patient to be bed-ridden till her death two weeks later. Noted by physician in in-patient records as "**Post Zobone**

Arthralgia" [Evidence document page 298] meaning joint pains after injection Zoledronic acid.

- Next day, she was in dysphagia (difficulty in swallowing) and could not swallow even her saliva after four days.
 - She had petechial rashes (bleeding from under the skin).
 - Next day she was in pancytopenia (drop in all three blood counts); WBC fell from 20,080 to 2,300 and platelets from 1,43,000 to 95,000 in a single day. This was a dire emergency.
 - The doctors watched the patient sinking to her death for three days and in a panic sent her to Platinum Hospitals for surgery with no details in Discharge Card except "Shift to Plat for surgery" (Plat meaning Platinum Hospitals). "Plat" was later converted to "Platelets" which was manipulation of in-patient records.
 - The very first drug administered as a Trial (Cipla drug Rokfos) had caused serious adverse reactions, ultimately leading to the patient's death.
 - All efforts were only to hush up the ADRs and in the process an innocent life was sacrificed.
- d) Clinical investigation reports were in Complaint file. These were suppressed from receiving hospitals by sending a blank discharge card. There were around a dozen blood tests suppressed. No Transfer Summary was given. Transfer Summary should state the brief history of illness, tests conducted & diagnosis and condition of the patient at that particular moment of time before sending the patient to the receiving hospital.
- e) Sequence of events were in in-patient records of Platinum Hospitals submitted in Complaint file. Every detail was in complaint file :
- Admission record of 14th June 2014 says "Unable to walk" "Restriction of movement". This was due to the side effects of injection Rokfos (Arthralgia, myalgia, bone pain, back pain).
 - Discharge card of 15th June 2014 says "Mild petechial present". This was also side effect of injection Rokfos.
 - First blood counts taken at Platinum Hospitals were WBC 200 (Normal range 4,000 to 11,000) and Platelets 20,000 (Normal range 150,000 to 450,000).

- WBC dropped from 20,080 to 200 and platelets from 143,000 to 20,000 in three days and the doctors at Maruti Nursing Home watched the patient sinking to her death for three days.
 - After blood and blood products given at Platinum Hospitals in the night of 14th June 2014 and next day, blood counts were; WBC 150 and Platelets 12,000.
 - There was no improvement in blood counts. Bone marrow had failed at Maruti Nursing Home itself.
- f) Sequence of events at Jupiter Hospital :
- Patient was shifted to Jupiter Hospital in the night on 15th June 2014 and admitted at 10.30 p.m.
 - In-patient records of Jupiter Hospital were available in Complaint file with Maruti Nursing Home.
 - Admission records noted "inability to swallow (even saliva)" "pancytopenia" "ecchymosis" (petechial rashes) on both hands.
 - Bone marrow biopsy was conducted very next day which revealed "Aplastic Bone Marrow". This was the actual cause of death.
 - This report (bone marrow biopsy) was in complaint file with Maruti Nursing Home. Refer **[Evidence document page 88]** of my complaint before Lokpal of India.
- g) Cause of death was "Aplastic Anaemia", falsely given as "Septic Shock with Multi-organ failure" **[Evidence document page 89]**.
False Death Certificate was to hush up the serious fatal ADRs of Cipla injection Rokfos.
- h) Death Summary **[Evidence document page 90]** which shows the antecedent and immediate causes of death did not include Aplastic Anaemia and neither were ADRs of injection Rokfos. Such a massive cover up proves sub-standard drug given as trial.
- i) Not only Lapse of care. It was totally CRIMINAL acts by doctors and hospitals.
- j) Drug Inspector of FDA Maharashtra, Drug Inspector of CDSCO (WZ) along with doctor and Professor & Head of Pharmacology, L.T. Municipal Medical College and General Hospital, Mumbai (Expert) were involved in this

fraudulent investigation organised by CDSCO officers named in my complaint before the Lokpal of India.

Enclosed with my reply herewith is "Corruption Document" submitted to Hon'ble Minister for Consumer Affairs.

FRAUDULENT JOINT INVESTIGATION REPORT [Evidence document pages 282-292] is covered under pages 23-39 of my petition to the Minister for Consumer Affairs and is reproduced below.

- **Why this Joint Investigation Report was suppressed from the complainant since two years? and why was this leaked to the Complainant now ?**
- 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.
- The only possible relevant explanation why the report was leaked to the complainant two years later could be; That, after Civil Servants in the State of Maharashtra were 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 & Goa but also at the Central Government level and that the MOHFW and CDSCO were equally responsible for colluding with Cipla Limited.
- 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.

Joint Investigation Report [Extract from Corruption document, pages 23-39] submitted to Minister for Consumer Affairs, Shri Piyush Goyal dated 1st July 2021.

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
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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 to FDA Maharashtra.
- 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 as mentioned above, 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) What was enforced by DCG(I) under CDSCO Enforcement Division.

m) There are two judgements; by Maharashtra Medical Council and Maharashtra State Commission implicating Cipla drug Rokfos causing

serious ADRs leading to death of my wife. Both the Orders are identical "IN TOTO" exposing the farce of "Joint Investigation".

- n) 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.
- o) 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.

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.

7. As per Lokpal Order;

It further appears that the complainant has approached a number of authorities as also the Lokayukta of Maharashtra. The complaint has been actively pursued before the said authority. However, no copies of orders passed thereon have been annexed.

The complainant has also stated that the Maharashtra State Commission has passed orders against the concerned hospitals. However, copies of the orders to this effect have not been annexed.

Complainant's response to point 7 above :

- a) Authorities approached by the complainant are explained below.
- b) However, my complaint before the Lokpal of India is specific to "Corruption, gross dereliction of duty, colluding with criminal offenders and most importantly Fake and Fraudulent Joint Investigation Report" against officers in MOHFW.

- This was an **unpardonable Sin on the citizens of the country** and which has exposed freedom to manufacture sub-standard drugs for profit at the cost of precious lives of citizens of the country (Lok).
- c) Complainant had approached Maharashtra Medical Council and has got a favourable Order removing the name of treating doctor, Dr.Mihirgiri Goswami from its register.
- I have appealed to National Medical Commission for permanent removal of the doctor's name to save precious lives in the future.
- d) Complainant had approached the State Commission and got the right Order which was there in my complaint.
- It is very surprising that the bench says no copies of State Commission orders are annexed. Order by the Maharashtra State Commission are in **evidence documents pages 68-87.**
 - The learned bench has not perused documents submitted in my complaint.
 - Appeal is pending before the National Commission wherein the President of NCDRC, Justice Mr.R.K.Agrawal indulged in mis-conduct.
 - After FDA & CDSCO it was the turn of Justice Mr.R.K.Agrawal to join the fray to protect Cipla drug Rokfos.
 - He has prolonged the mental agony of the aggrieved senior citizen and his daughter by further seven months by trying to protect Cipla.
 - I have complained to the Chief Justice of India, President of India, Prime Minister of India as well as Minister for Consumer Affairs, Shri Piyush Goyal explaining the foul play.
 - Attached is my letter to the PM dated 8th September 2021 wherein I have explained the role of NCDRC and especially Justice R.K.Agrawal in prolonging the mental agony of a senior citizen and his daughter after seven years have passed seeking justice.
- e) Complainant has approached Lokayukta of Maharashtra. Orders have to be passed for action in Police complaints and complaint before FDA Maharashtra.

- Misconduct by Maharashtra Government officers will be handled by the Lokayukta who has no jurisdiction to act against Central Government officers.
- Hence, this complaint before the Lokpal of India against Central Government officers in MOHFW.

8. As per Lokpal Order;

From the last document in the booklet titled "Facts of the Case", it appears that the complainant has also approached the Hon'ble Supreme Court of India, vide diary No.16068/SCI/PIL/2021, diary No.17119/SCI/PIL/2021 and diary No.6819/SCI/PIL/2020. However the status of the matter is not clear as no orders have been annexed.

Complainant's response to point 8 above :

- a) What has been placed before the Supreme Court of India is Writ Petition for directions to Regulatory and Law enforcement authorities to register FIRs.
- b) CDSCO is the National Regulatory Body for Drugs and have failed to take action in a drug causing death. Both the DCG(I), ADC(I), DDC(I), WZ, Mumbai have taken the aggrieved senior citizen for a ride, conducted fraudulent joint investigation by roping in FDA Maharashtra officials and facilitated FDA Goa director to give a letter to Cipla that no action is taken against them.
This was the only purpose of fraudulent joint investigation and report.
- c) Health Secretary is accountable on inaction to Order by Cabinet Secretary (India) for more than a year.
- d) Action against FDA Goa director has to be taken for colluding with criminal offenders and instead of taking action against Cipla, openly gave a letter of pardon upon their assurance that such lapses will not occur in the future.
What about life lost ? What about laws of the land ?
- e) Orders have to be passed by the Supreme Court of India and has nothing to do with Complaint before the Lokpal of India.

9. As per Lokpal Order;

The complainant has already had recourse to the appropriate forums i.e.Lokayukta of Maharashtra, Maharashtra State Commission and the Civil

Court, for the redressal of his grievance. Furthermore, he has also approached the Hon'ble Supreme Court of India. In these circumstances, the Full Bench of the Lokpal of India will not be able to take up this matter, since it is barred under Section 15 of the Lokpal and Lokayuktas Act, 2015.

Accordingly, the complaint is disposed of.

Complainant's response to point 9 above :

- a) Recourse to each and every appropriate forum has been explained above.
- b) Complaint before Lokpal is against the CDSCO AND MOHFW OFFICERS under Prevention of Corruption Act and colluding with criminal offenders.
- c) This complaint cannot be disposed off.
- d) Lokpal is "Protector of people" and cannot be protector of corrupted.

10. Why the complaint cannot be disposed off. Rather immediate action is requested from the Lokpal of India :

- a) Lokpal is an Anti-corruption Ombudsman to look into complaints against public servants and my complaint is specifically this itself.
- b) I have enclosed letter to the Prime Minister of India, Shri Narendra Modi, copies to the President, Ministries and Ministers, Officers concerned in departments who were involved in the cover up.
- c) That this government will go down in history as having sided with killers of an innocent citizen, supported corrupted public servants and used all its might bestowed by the electorate to silence an aggrieved senior citizen.
- d) Cipla silenced journalists and interfered with freedom of the press.
- e) Right to life has been violated by Cipla Limited, doctors and hospitals.
- f) Fundamental rights essential for human existence in a civilised society has been denied by corrupted public servants and the Government.
- g) The social fabric of our society has been destroyed in this one case by Cipla promoters and directors deserving immediate arrest.
- h) My rights as a citizen in the largest democracy in the world has been denied.
- i) Power wielded and used against innocent law-abiding citizens of the country by corrupted civil servants at the behest of an unscrupulous pharma company, Cipla Limited.
- j) Cipla Limited, FDA Officers and CDSCO officers have jointly played with lives of citizens and cheated millions of people over the years with sub-standard

drugs for ill-gotten profits. The officers stooped to lowest level of misconduct in line of public duty against the citizens whom they are supposed to protect.

- k) This could be the norm prevailing in the entire country and citizens are paying the price for corruption by public servants.
- l) The government supporting crimes and protecting criminals is an insult to our "Independence & Freedom" gained by our forefathers who sacrificed their lives for the country.
- m) Recent statements from the Supreme Court of India are reassuring to the common man. Whatever the top-most learned judges in our country have voiced is for the cause of the common man. And I am the common man who is facing the tyranny of corrupted public servants.

Reproduced below are reassuring words from our Supreme Temple of Justice. That Judicial System exists for "Common Man" is established by the following statements by the judges of our Supreme Court of India :

- "The judiciary cannot be controlled, directly or indirectly, by the legislature or the executive, or else the Rule of Law would become illusory," the CJI underscored.
- "All the three organs of the state -- the executive, legislature and judiciary are equal repositories of the constitutional trust", the Chief Justice of India said.
- "Now, it is the turn of those who are manning the key organs of the State to ponder if they are living up to the Constitutional mandate", Chief Justice Ramana said.
- "But I began to feel that this pandemic might yet be a mere curtain raiser to much larger crises in the decades to come".
- "Surely, we must at least begin the process of analysing what we did right and where we went wrong," the CJI said.
- "The CJI said the judiciary requires "complete freedom" to apply checks on governmental power and action".
- "A mere right to change ruler once every few years need not be a guarantee against tyranny".

- “The idea that the people are the ultimate sovereign is also to be found in notions of human dignity and autonomy”.
- “Reminding the judiciary that its role and the scope are limited, he said they only pertain to the facts placed before it (the judiciary). Its limitation calls for other organs to resume responsibilities of upholding constitutional values and ensuring justice in the first place, with the judiciary acting as an important check," he added.
- “Fundamental rights and freedom of Indian citizens that are essential for human existence in a civilised society”.
- “Guardians of the constitution can truly protect the fundamental rights of the citizen”.
- “Health is wealth because a healthy nation can be a wealthy nation. Any investment is justified to acquire this wealth”.
- “Rendering justice is not an act of charity or mercy. Protection of rights and freedom is both power and duty of court, and is not just discretion but an obligation of the judge.”
- “I feel proud of serving the supreme temple of justice with utmost satisfaction. During my tenure I have tried my best to render justice to the people of this country. I can say with conviction and pride that I have been true to my oath to discharge my duty without fear or favour, and that I have upheld the constitution and law” – retiring justice of SCI.
- “The supreme court which is the last court of appeal in India has a wide reach over its population, executive and lower courts and provides greater access to individuals by exercising not just its appellate jurisdiction but also its writ jurisdiction in protecting fundamental rights enshrined in the constitution”.
- “The common man should not feel that the Government is protecting crimes”.

Supreme Court has also said :

- Justice is accessible and will be delivered to the common man.
- It is not only a right but also a duty of citizens to talk truth to power.

n) If the Lokpal (Protector of people) also dismisses rights of aggrieved citizens, what is left for our nation?

- o) It demolishes the 'Anna Hazare Movement' resulting in the appointment of 'Lokpal' five years after the movement.
- p) Democracy of which every citizen of India is proud of will be protected by the citizens at whatever cost.
- q) All facts have been explained in this submission making the matter very clear and especially the Fraud Joint Investigation Report.
- r) The accused may be asked to respond to all the charges and my right to respond to their submissions be reserved.
- s) Citizens cannot be discarded by persons in power, be it the Lokpal of India.
- t) How will justice be delivered by placing facts on Social Media for citizens to understand corruption by Government officers?
- u) It will need a new movement by citizens against the powers that be silencing common citizens of our country.

Thanking you for your co-operation,

Sincerely Yours,

Umeshchandra Barkur

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