Date : 4th March, 2019

Shri Yusuf Hamied,

Chairman, Cipla Limited

Dear Sir,

Subject : Appeal for an Inspirational Science Program on PHARMACOVIGILANCE.

I read a newspaper item in 'Hindustan Times' of 1st March, 2019 – 'Another Feather in His Cap' (Yusuf Hamied) **(Page 26).**

The Royal Society of Chemistry will celebrate the successful completion of Yusuf Hamied Inspirational Chemistry Program with the launch of the next phase of the RSC-Yusuf Hamied Inspirational Science Program where Shri Yusuf Hamied will be felicitated.

I congratulate you on the successful completion of your Inspirational Chemistry Program and the launch of the next phase of the RSC-Yusuf Hamied Inspirational Science Program.

However, I would like you to respond to the reality at your company, Cipla Limited into malpractices and criminal offences that was responsible for the untimely, unnatural and merciless death of my wife.

An Inspirational Science Pharmacovigilance Program will serve the cause of saving innocent lives. It will be but Apt that this program be conducted firstly at Cipla.

I have once again reproduced before Cipla Management how your company was responsible for the death under the heading "Cipla Limited in nexus with doctors/private hospitals causing death of an innocent" **(Pages 7-25).**

The doctors of Maruti Nursing Home who were in nexus with Cipla Limited into sale of sub-standard drug Rokfos as well as spine surgeon, Dr.Satyen Mehta and Platinum Hospitals have been held guilty of 'Medical Negligence' and 'Deficiency in Services' in the Consumer Court (Before the Maharashtra State Consumer Disputes Redressal Commission) on **21st February 2019.** Cipla Limited and Jupiter Hospital along with Maruti Nursing Home and other doctors are accused in my police complaint with Navghar, Mulund, Mumbai police. Jupiter Hospital have to explain concealing the most vital piece of evidence in this homicide case which is cause of death. They have given a False Death Certificate to Thane Municipal Corporation. Cipla Limited will be answerable in this police complaint under

section 304 of the IPC (culpable homicide). Also under the Drugs and Cosmetics Act, 1940 which complaint is with CDSCO.

However, the objective of this letter to you was driven by reading the famous **'Top Quotes by Yusuf Hamied'** wherein I found a totally contradictory thinking of Cipla Management vis-à-vis your quotes into healthcare in India, prices of Cipla drugs, sub-standard drugs by Cipla, violation of Drugs and Cosmetics Act, 1940 by Cipla Limited and finally Cipla Anti-pharmacovigilance following death of my wife.

You have said the following :

1. **"Anybody manufacturing products for healthcare cannot regard it truly as 100 percent business : It is business plus a humanitarian approach to society because you are saving lives. You are playing with people's lives".**

   My response to this famous Quote :

   Drug Rokfos was sub-standard to cause such serious adverse drug reactions never seen before with Zoledronic acid, the ingredient of that injection. Manufacturing sub-standard drugs cannot be a humanitarian approach but pure business for unethical monetary rewards. My allegation of the drug being sub-standard is based on the following premises :

   a) *The three private multi-speciality hospitals suppressed the serious ADRs of Rokfos and watched the patient sinking to her death. They protected the sub-standard drug from being exposed.*

   b) *Rokfos was administered as a 'Clinical trial' to cure Stiff Neck in a single day even before diagnosing the cause of stiff neck. The doctors in nexus with Cipla played with the lives of the citizens used as 'Guinea Pigs' for experimentation.*

   c) *Cipla Limited suppressed the ADRs even after my appeal to investigate the drug in the interest of medical science. Cipla violated the legal provisions of Schedule 'M' of Drugs and Cosmetics Rules. They were aware that the drug would fail the 'Standard Quality' test. Did not recall the drugs (mandatorily required as per law). The fine would have been huge. The drug was manufactured just six months back and there would have been a large quantity of Rokfos in stock.*

d) *Where was the need for an international drug company to suppress known adverse reactions of their drug unless* ***FOUL PLAY*** *was involved.*

e) *Where was the need for Cipla Global Head Pharmacovigilance to indulge in blatant falsehood to portray the patient as a critically ill patient (Paralytic ?) just to deceive FDA-Goa Director that Rokfos was not the cause of her death. It was like rubbing salt to injury. My wife was a hale and hearty person with no major illness in her past. Her life was destroyed within twenty hours of this sub-standard drug administered to her. I have yet to get an unconditional apology from Cipla Management and Board of Directors for the false, derogatory, defamatory and disgusting remarks on my wife's health condition and all the more since Cipla drug Rokfos was the cause of her death.*

2. "Alleviation of suffering is your fundamental principle".

The above facts prove that the drug was not administered to alleviate the suffering of the patient but administered as a 'clinical trial' in nexus with Cipla.

3. "Reducing the price of cancer drugs is a humanitarian approach".

"Patients are becoming aware that they're being taken for a ride by big pharma companies. They charge high prices and have never cared for India's healthcare. There are 23 million cases of cancer every year and India has a fair share of that".

Drug Rokfos is a cancer drug. MRP was Rs.2,950.00. It was purchased by the doctors for Rs.2,205.00. It was sold to the patient for Rs.3,500.00. Margin of Rs.745.00 to wholesaler + similar margins to stockist and manufacturer will mean that the patient paid more than 500 percent of cost.

Subsequent events (after being informed of the serious ADRs of drug Rokfos) prove that Cipla cares a damn for India's healthcare. They care a damn on their drugs causing deaths.

Cipla cares a damn for pharmacovigilance. Cipla Pharmacovigilance and Drugs Safety Department is purely to deceive the Regulator, FDA (Food and Drugs Administration). Cipla pharmacovigilance head created a thesis on "Aplastic

Anaemia" vis-à-vis Antitubercular drugs and deceived the FDA-Goa Director that Rokfos was not the cause of her death.

It was all the more pertinent and in the interest of medical science to investigate the serious ADRs of Zoledronic acid especially since as per Yusuf Hamied there are 23 million cases of cancer in India every year. Shri Yusuf Hamied should put his house in order on pharmacovigilance in Cipla Limited.

4. **"Unfortunately, the mechanism for doing philanthropy in a structured way isn't yet in place in India. I already do a fair bit and support various causes such as education, sanitation, health. But selling costly drugs at affordable prices is philanthropy in itself ".**

My experience with Cipla drug Rokfos was extremely painful in all respects. The drug was sub-standard, sold expensively, administered as a clinical trial, sold illegally by Maruti Nursing Home doctors to other doctors and hospitals, caused serious ADRs, patient was left untreated for five days leading to her death. Besides the aggrieved party was taken for a ride by Cipla drugs safety department as well as Cipla pharmacovigilance department.

This is not PHILANTHROPY. Profits from sub-standard and costly drugs would have raked in crores of rupees and philanthropy would have been only a small fraction of the unethical profits. Besides this philanthropy is stained with the blood of innocents.

5. **"Cipla has a strong professional management team and we take team decisions"**

If the promoters are themselves involved in decisions with respect to the malpractices of producing sub-standard drugs, drugs to be given as clinical trials, criminal offences and violation of Drugs and Cosmetics Act, 1940, deceiving FDA authorities, etc. it could be a professional management team for Shri Yusuf Hamied but this professionalism transcends all moral norms and against the interests of consumers and definitely against humanity itself.

6. **"I want it to be said when I leave this world that 'he was not just a money-making machine".**

Shri Yusuf Hamied owes it to the citizens of India to explain all the malpractices at Cipla Limited into this unnatural, untimely and merciless death.

I have every right and reason to believe that it was "Money at whatever Cost" at Cipla Limited since a very very long time which was exposed by this one incident caught red-handed.

The benefit of doubt to Shri Yusuf Hamied not being part of the malpractices and criminal offences can be given only if :

a) *He punishes the persons responsible for causing this death.*

b) *Cipla has to accept punishment as per section 27 of the Drugs and Cosmetics Act, 1940 (CDSCO has confirmed in reply to my RTI query).*

c) *Shri Yusuf Hamied has to offer an unconditional apology to the aggrieved party on defamation of the deceased patient's health condition.*

d) *Shri Yusuf Hamied is on record through his famous quote that* ***"Patients are becoming aware that they're being taken for a ride by big pharma companies. They charge high prices and have never cared for India's healthcare.***

In view of the above admission by Shri Yusuf Hamied, he should take the lead and ask the government to bring in the "Proposed Amendments" by CDSCO to Drugs and Cosmetics Act, 1940.

e) *Shri Yusuf Hamied should ask the government to bring in the "Draft Pharma Policy" by Department of Pharmaceuticals as a stringent law.*

7. **Matter currently stands for action against Cipla Limited for violation of Drugs and Cosmetics Act, 1940 with the Drugs Controller General (India) under Ministry of Health and Family Welfare. Also with FDA-Maharashtra.**

Navghar, Mulund, Mumbai police has to take action under section 304 of the IPC (Culpable homicide) :

a) Letter from Director of FDA-Goa to DCG(I) that action has to be taken at his end **(Page 27).**

b) Letter from Secretary-cum-Scientific Director that action has to be taken by DCG(I) under DGHS, Ministry of Health and Family Welfare **(Page 28).**

c) Reply to RTI query from CDSCO – Penalty under Section 27 of Drugs and Cosmetics Act, 1940 **(Pages 29-31).**

d) Section 27 of Drugs and Cosmetics Act, 1940 **(Page 32).**

e) Letter from DCG(I) to IPC for judgement and compensation **(Page 33-34).**

f) Letter from ADC(I) to IPC for judgement and compensation **(Page 35-36).**

g) Cipla Letter to the complainant that they will comply with the directions of the authorities as and when received **(Page 37).**

h) Letter from PMO that my suggestion for amendments to laws is well taken and noted **(Page 38).**

i) Letter by Dean of Sir J.J. Group of Hospitals appointing a panel of three doctors to adjudicate in this homicide case **(Page 39).** It is six months now and a Writ Petition will be required to be filed at the Bombay High Court.

j) A Public Interest Litigation will also be filed with the Supreme Court of India as this matter is in public interest – To save human lives – Cipla Limited in nexus with doctors/private hospitals into sale of sub-standard drug causing death of an innocent. Citizens of India cannot be used as 'Guinea Pigs' for experimentation by multinational drug companies in nexus with doctors.

Finally, as a philanthropist, scientist, humanitarian with concern for healthcare of the citizens of India, I request you to at least respond to my letter. Else, it will be understood that you do not stand by what you profess in real life.

Umeshchandra Barkur

A-15, Neeta Apartments, Chaphekar Bandhu Marg, Mulund (E), Mumbai 400081.

Cell : 98201 17923

Cc : Cipla Management.

Cc: Drugs Controller General (India) – For immediate action in the matter.

Cc: Shri J.P.Nadda, Union Minister - Ministry of Health and Family Welfare.

Cc: The Editor, HT Media Limited.

How the nexus between Maruti Nursing Home and Cipla Limited was exposed :

1. Meeting called by treating doctor, Dr.Mihirgiri Goswami with relatives of the deceased to explain the causes leading to death of the patient :

   a) A meeting was arranged with the relatives of the deceased Late Smt.Kamini Barkur by Dr.Mihirgiri Goswami to explain the reasons and causes that resulted in death of the patient. The meeting was held on 22nd August 2014 as per e-mails exchanged between Dr.Mihirgiri Goswami and the complainant fixing and confirming the meeting. The doctors admitted that drug Rokfos from pharmaceutical company Cipla Ltd. administered to the patient on 9th June 2014 caused severe adverse reactions never seen by them ever before. The doctors of Maruti Nursing Home were not aware that the meeting was recorded by the relatives of the deceased in a mobile and hence to defend themselves put the onus on adverse drug reactions and that they were not responsible. On the contrary, they had suppressed the adverse drug reactions in their in-patient records as well as in their discharge card. They had sent the patient for surgery to Platinum Hospitals and not for treatment of the serious ADRs.

   b) If drug Rokfos was the cause of the disaster, there was no reason for suppressing the same. Rather than watching the patient sinking to her death, Dr.Mihirgiri Goswami should have taken remedial action immediately since 10th June 2014 itself.

   c) The recording of the meeting on my mobile was downloaded on to a CD which has been given to the Accused Parties. The entire transcript of the meeting has been produced to all the accused.

2. **Proof of "Clinical Trial"** conducted on the patient to cure "Stiff Neck" in a single day without even diagnosing the cause of stiff neck :

   a) A booklet on Zoledronic acid from Cipla Ltd. (manufacturer of drug Rokfos) was handed over by Dr.Mihirgiri Goswami to the complainant at the said meeting on 22nd August 2014.

   b) Dr.Mihirgiri Goswami had also produced the bill for Rokfos in the name of Dr.Meghal Goswami (co-owner of Maruti Nursing Home) and given to the complainant showing purchase price as rupees 2,100 + Vat 5%. Total purchase price = rupees 2,205.00. MRP was rupees 2,950.00. This drug was sold for rupees 3,500.00.

c) The complainant had checked and enquired from DGHS (Directorate General of Health Services), New Delhi for indications of use of Zoledronic acid. DGHS had given approval for Zoledronic acid in India for the following indications as given below. Information was obtained by the complainant vide RTI query from DGHS - letter dated 05-05-2015.

- Paget's disease of bone.
- Prevention and treatment of osteoporosis in post menopausal women and in men who are at increased risk of fracture including those with a recent low trauma hip fracture.
- Treatment and prevention of glucocorticoid osteoporosis.
- Prevention of clinical fracture after hip fracture in women.
- Bone metastasis and multiple myeloma.
- Treatment of hypercalcaemia of malignancy.
- For treatment of tumour induced hypercalcaemia post menopausal osteoporosis.

d) The patient was not admitted for any of the above-mentioned diseases nor is there any mention of the same in the in-patient records of the patient at Maruti Nursing Home.

e) There were no test reports like bone density tests for determining osteoporosis, tests for hypercalcaemia of malignancy, tests for Paget's disease of bone, bone metastasis or multiple myeloma nor did the patient have hip fracture. There was no diagnosis of any of the above diseases in the in-patient records of the patient at Maruti Nursing Home.

f) Osteoporosis is diagnosed by the following tests :

- High-Resolution Magnetic Resonance Imaging.
- Bone density testing using a device called densitometer.
- Dual Energy X-Ray Absorptiometry (DXA).
- Quantitative Computerised Tomography (QCT).
- 3-D Imaging.

g) Contra-indications and precautions to be taken before treatment with Zoledronic acid are as follows :

- Zoledronic acid is contra-indicated in patients with creatinine clearance <35 mL/min. Creatinine clearance should be calculated based on actual

body weight, using Cockcroft-Gault formula before each Zoledronic acid dose. There is no mention of this crucial test in in-patient records of the patient.

- Patients must be appropriately hydrated prior to administration of Zoledronic acid. The intravenous infusion should be followed by a 10 mL normal saline flush of the intravenous line.
- For osteoporosis treatment and to reduce the risk of hypocalcaemia, patients must be adequately supplemented with calcium and vitamin D if dietary intake is not sufficient. An average of at least 1,200 mg of calcium and 800-1,000 IU of vitamin D daily is recommended.
- Zoledronic acid can cause hypocalcaemia. To reduce the risk of hypocalcaemia, all patients should receive 1,500 mg of elemental calcium daily in divided doses, particularly in the two weeks following Zoledronic acid administration. Besides there are other precautions also as mentioned in the booklet sent by Cipla Ltd., manufacturer of drug Rokfos.
- None of the precautions were taken before administering drug Rokfos.

h) Side effects of Zoledronic acid that occurred in this case were as follows :

- Blood disorders (thrombocytopenia, pancytopenia).
- Arthralgia, myalgia, bone pain, back pain.
- Metabolism and nutrition disorders (hypocalcaemia).
- Dysphagia.
- Petechial Rashes.
- Blood creatinine increase.
- Blood calcium decrease.

Besides, there are other side-effects also. Only those side-effects that occurred in the case of the patient are listed above.

Serum creatinine on 9th June 2014 was **1.55 (High)** (Normal values 0.4 – 1.2 mgs/dl) and on 11th June it was **1.82 (High).**

Serum calcium was normal **(9.2)** (Normal range 8.8 – 10.2 mgs/dl) on 9th June 2014. On 11th June 2014, serum calcium dropped to **7.97 (Low)** after treatment with Zoledronic acid.

3. **Detailed Analysis of Cipla's explanation to FDA-Goa** and detailed Analysis of Cipla's letters to the complainant.

Detailed Analysis of Cipla's explanation to FDA-Goa dated 26.03.2018 is produced by the complainant in his letter dated 29th June 2018 addressed to the below-mentioned authorities. Detailed Analysis of Cipla's letters to the complainant dated 18.05.2018, 31.05.2018 and 26.06.2018 are also produced by the complainant in the same letter dated 29th June 2018.

a) Cipla Management (Board of Directors).

b) Food and Drugs Administration, Maharashtra, Mumbai.

c) Directorate of Food and Drugs Administration, Government of Goa.

d) Directorate of Public Grievances, Government of Goa.

e) Directorate of Health Services, Mantralaya, Government of Maharashtra.

f) Office of the Drugs Controller General of India.

A. Violation of the Drugs and Cosmetics Act, 1940 and Schedule M of Drugs and Cosmetics Rules.

1. As per Cipla authorised representative, the treating doctor, Dr.Mihirgiri Goswami had informed them of the serious adverse drug reactions on 7th August 2014 and they had immediately informed FDA-Goa, PVPI and DCGI. This is as per Cipla letter dated 31st May, 2018 to the complainant.
2. As per Schedule M of the Drugs and Cosmetics Rules, all complaints thereof concerning product quality shall be carefully reviewed and recorded according to written procedures by the manufacturing companies. Each complaint shall be investigated/evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained. There shall be written procedures describing the action to be taken, recall to be made of the defective product. Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority.
3. The above information was provided to me vide letter dated 20/12/2017 by Directorate General of Health Services, Office of DCG (I), RTI Cell **(Page 40).**
4. They had further asked me to contact FDA, Maharashtra for the requisite information under RTI Act, 2005.
5. Subsequently, the office of the Drugs Controller General of India had asked for investigation into alleged nexus between Cipla Ltd and Maruti Nursing Home

into sale of sub-standard drug IV Rokfos that was the cause of untimely and unnatural death of my wife. They had asked the matter to be investigated by FDA-Maharashtra, Medical Council of India, Directorate of Health Services, Public Health Department, Mantralaya, Government of Maharashtra and Dy. Drugs Controller, CDSCO (WZ) **(Pages 41-42).**

6. Cipla violated the legal provisions of Drugs and Cosmetics Rules, Schedule 'M'. Cipla's assertion that they had, on information received on their drug Rokfos' serious ADRs reported the same to FDA-Goa, PVPI and DCGI is proved as blatantly false. I have produced letters from both FDA, Goa and IPC (Indian Pharmacopoeia Commission) that they have not received any information of the serious adverse drug reactions of Rokfos **(Pages 43,44).**

B. Follow up with Cipla Limited by the complainant on the serious adverse drug reactions for pursuing his case against the doctors as well as in the interest of medical science :

1. The complainant wrote several letters and sent several e-mails to the Manager (Product Queries), Drugs Safety Division and finally to Global CEO and M.D. of Cipla Ltd. Shri Umang Vohra.
2. Further to information received by Cipla from Maruti Nursing Home of the ADRs on 7th August 2014, the complainant had also informed Cipla Drugs Safety Department of the ADRs on 16th August 2014 giving them batch number, manufactured date, expiry date and that the death of his wife was drug-induced (e-mail by complainant). The hard copy was sent through courier. The complainant had raised the following issues with Cipla.
   - That his wife was no more but he needed to investigate the causes leading to her death which was due to "Aplastic Anaemia", reason being drug-induced.
   - That he needed all information about their product ROKFOS (concise info, dosage, Adverse Drug Reactions, etc).
   - That he needed to know how this drug reached Maruti Nursing Home. Whether it was sold or given as sample or through distributor or pharmacy.
3. Subsequently the complainant received a telephone call from Dr.Akhtar of Cipla Ltd. who promised him an official reply quickly.

4. Meanwhile, a meeting was convened by Dr.Mihirgiri Goswami with relatives of the deceased on 22nd August 2014 to explain the causes that led to the disaster, meaning death of my wife.
5. Confirmation of the meeting is as per e-mails exchanged with Dr.Mihirgiri Goswami.
6. The treating doctor, Dr.Mihirgiri Goswami handed over "Indications of use of drug Rokfos" to the complainant at the start of the meeting. This booklet was sent by Cipla Limited to be handed over to me.
7. This goes to prove that upon receiving information of the serious adverse drug reactions leading to death of the patient from Maruti Nursing Home, Cipla took cognizance of the ADRs and sent Rokfos booklet which shows the side effects. All side effects that occurred in the case of my wife are listed in the booklet. Cipla did not contest the ADRs with their customer, Maruti Nursing Home. Petechial rashes and pancytopenia are typical symptoms and characteristic features of Aplastic Anaemia. Cause of death is proved from Bone Marrow Biopsy Report which says "Aplastic Bone Marrow". There is no need for further proof that Rokfos caused Aplastic Anaemia.
8. The meeting was recorded on my mobile without the doctors' knowledge. Transcript of the entire meeting is available.
9. The doctors elaborately explained their customer-vendor relationship with Cipla Limited.

Statements by doctors on the adverse drug reactions and sale of Rokfos by them to other hospitals and orthopaedics :

- The doctors explained that Zobone was their regular brand of Zoledronic acid and Rokfos was their new brand which caused the disaster.
- The treating doctor said that It had been given to his mother also. That safe it is in all cases. It will turn out to be like this who will understand.
- Further said that he is afraid to give now. That he will not give anyone. It has been given to his mother also, you can understand, so why should he be so much worried about it.
- When questioned what steps do they take on the severe side effects, the treating doctor said that they have to send it as a report to the company.

That he had told the fellow who comes to meet him. That was the reason why he came up with this article (meaning Rokfos booklet).

- Further said that they (Cipla) have to report it as adverse reaction and they have to take steps.
- When asked whether this was a unique case, treating doctor says that this was definitely one very rare reaction with Zoledronic acid. That they are also shocked.
- He added that companies get these reports of adverse reactions and ultimately they put a ban on the drug.
- Treating doctor said **"From a simple neck pain,** why we wanted to keep quiet" ???.
- When questioned why did he give the drug, says that he planned for one day admission – Give today and discharge tomorrow, MRI was also not planned, hence there was no MRI on admission.
- Mediclaim doctor, Dr.Dubey who is an ayurvedic doctor said that he goes to 25 places and three orthopaedics and gives Rokfos with full responsibility. His target was to ensure that there is no problem to treating doctor as well as the patient. That he had to balance both.
- Further says that, for bone support, this is a yearly injection and is commonly given but he never realised that this can cause such dramatic allergy or reaction. That he had never seen such serious adverse drug reactions of Rokfos ever before.

Inferences gathered from the doctors' statements :

- It is clear that Cipla induced Maruti Nursing Home to switch to their brand of Zoledronic acid Rokfos, while their regular brand was Zobone. The treating doctor said that he will never give anyone again. Why should he be worried about giving it ? which proves that Cipla was instrumental for Maruti Nursing Home administering this drug Rokfos for minor bone problems like stiff neck, joint pains and bone pain.
- That Rokfos was given as a one-day admission to treat stiff neck.
- Obviously, this drug was given as a **clinical trial** to cure stiff neck in one day.

  Stiff neck is not in the indications of use of Rokfos.

- Since the ADRs were so serious and never seen before, it mandated Cipla to investigate Rokfos all the more seriously rather than suppress the Adverse Drug Reactions. Cipla violated the legal provisions of Schedule 'M' of Drugs and Cosmetics Rules. They were aware that Rokfos batch was sub-standard.
- Who was Dr.Dubey to take responsibility of a drug manufactured by International company Cipla ? What did he mean when he said that it was his target and responsibility that neither the patient nor the doctor had any problem ? What did he mean by saying that he had to balance both ?
- Obviously these were specially manufactured batches for patients admitted to Maruti Nursing Home as well as for onward sales to other hospitals and orthopaedics. These were given for treating minor bone problems like stiff neck, joint pains, bone pain, etc. and given as clinical trials. It was Cipla who gave responsibility to these doctors. This proves the excellent vendor-customer relationship between Maruti Nursing Home and Cipla Limited.

10. Since no reply was received from Dr.Akhtar of Cipla for more than a week, I again reminded him vide e-mail dated 26th August 2014.
    - I told him that I had a meeting with Dr.Goswami who has produced the purchase invoice for IV Rokfos.
    - I also stated the Dr.Goswami says that it is the first time that this drug has caused such severe reactions. Since Dr.Goswami says it is the rarest of rare cases, it needed to be further investigated in the interest of medical science.
    - I gave brief details of the case and also offered to meet Dr.Akhtar personally to sort out my queries.
11. Cipla Drugs Safety Department sent me indications of use vide their e-mail dated 27/08/2014 as also FAQs on Rokfos.
    - They offered their condolences for the loss of my wife.
    - Cipla did not contest the ADRs.
    - In fact they are on record that they had immediately reported to the drug control authorities.
12. Since there was no explanation given to me by Cipla on the ADRs, I again sent my concern on the ADRs on 07/07/2016 and attached a file giving status of my enquiry regarding ADRs in the case of death of my wife.

- The file showed the sequence of events on ADRs reporting to various drug control authorities in New Delhi (CDSCO, National Pharmacovigilance Centre, Drugs Controller General, Directorate General of Health Services).
- I also said that DGHS has sent indications of use of Zoledronic acid to me.
- Further I gave a chronological list of my follow up with Dr.Mihirgiri Goswami seeking information on reasons for the sudden turn of events at Maruti Nursing Home ultimately resulting in death of my wife.
- I further gave statements made by the doctors, Dr.Mihirgiri Goswami and Dr.Dubey that they had never seen such dramatic reactions before. Dr.Mihirgiri Goswami had also stated that he will stop giving Rokfos now and when I asked Dr.Goswami what is the procedure on adverse reaction Dr.Mihirgiri Goswami had replied "We have to report it" and hence he got the indications for use of Rokfos from Cipla.
- Dr.Dubey (TPA Health Services Mediclaim doctor) further said that he supplied drugs to 25 hospitals and three orthopaedics with full responsibility but had never seen such dramatic reactions before.
- Further I requested CIPLA – Whether Dr.Goswami has reported the ADRs to them or to National Pharmacovigilance Centre or to Drug Controllers and as such he would like to meet Cipla officials to get full clarity about ROKFOS.
- I further stated that there is no record of these drugs in in-patient records of both Platinum Hospitals as well as Jupiter Hospital, whereas Dr.Goswami says that he was in touch with the doctors at both Platinum and Jupiter hospitals.
- Finally I asked Cipla the procedure for following up with ADR reported by patients.
- The only reply received by me from Drugs Safety division of Cipla Limited to this e-mail was **"Thank you information".**

13. I sent a letter dated 18th April, 2017 to Cipla Managing Director and Global CEO, Shri Umang Vohra on the ADRs. I followed it up with an e-mail dated 18th April, 2017 to Cipla Drugs Safety. The complainant sought the following information from the Managing Director of Cipla :

- At the outset, the complainant is not accusing Cipla in any manner.

- What is the reason that Cipla did not investigate into their drug Rokfos causing severe adverse reactions ultimately leading to patient's death.
- Why did Cipla not inform FDA or CDSCO about these rare disorders.
- Was it because of bad publicity or to protect Dr.Goswami who failed to take action as the drugs were sold illegally.
- Or was the drug really sub-standard ?
- That there was no information forthcoming from Cipla, FDA, Maruti Nursing Home as also other hospitals involved in the treatment of the patient. That the complainant needed to put the information to the Prime Minister's Office and Central and State Health Ministers.

- Cipla Drugs Safety division in their reply to me on 19th April 2017 by e-mail have said **"Thank you for notification" "We acknowledge receipt of this e-mail" "We will take appropriate action".**

14. Since the drug IV Rokfos caused serious and dramatic adverse reactions never seen before as admitted by doctors of Maruti Nursing Home and since Dr.Mihirgiri Goswami had informed the medical advisor of Cipla, it was incumbent upon Cipla Drugs Safety division to check the batch sold to Maruti Nursing Home immediately. Product recall system as per Schedule M of Drugs and Cosmetics Rules should have been put into action within the shortest period to all concerned stockists, wholesalers, suppliers up to the retail level. The invoice for IV Rokfos produced by Dr.Mihirgiri Goswami and Dr.Dubey was for five quantities of the injection. The purchase date was 25-04-2014. The drug was administered to the patient on 9th June 2014 i.e. within a period of one and a half months. The batch should have been sent to Cipla Ltd and onwards to FDA, Maharashtra who would have sent them to Govt. Analyst, Drug Control Laboratory, M.S., Mumbai for the purpose of test and analysis. Precious lives were at risk if the batch did not meet the Standard Quality. Cipla could have also tested the injections as they had received the information from Dr.Mihirgiri Goswami on 7th August 2014 as also from the complainant regarding adverse reactions as early as 16th August 2014 i.e. less than two months after the drug caused serious and rare adverse effects never seen with this drug before. There would have been sizeable stock of Rokfos with the company as the manufacturing month was February 2014. There could be no

logical reason to suppress this information from the complainant unless there was foul play involved.

15. My curiosity on the silence of an international drug company, Cipla on their drug causing death made me restless. Under an RTI query to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, I sought answers on ADRs and the protocol to be followed by pharmaceutical companies in case of Adverse Drug Reactions of their injection. I had also given facts of the case regarding death of my wife due to unfair selling practices of pharmaceutical companies (in this case Cipla ltd) pushing doctors to promote their products by offering lucrative margins. Also Adverse Drug Reactions of their drug IV Rokfos which was suppressed by all doctors involved. The RTI query was transferred to CDSCO (Central Drug Standards Control Organisation) which is a subordinate office of Directorate General of Health Services, under Ministry of Health and Family Welfare, Government of India. This was on 23rd November 2017. I received a reply dated 20/12/2017 from Directorate General of Health Services – Office of DCG (I) (RTI Cell).

    The mystery into silence by Cipla on the ADRs was solved upon receipt of information from the Directorate General of Health Services regarding Schedule M of the Drugs and Cosmetics Rules as explained above **(Page 40).**

16. The link between the doctors' statements and violation by Cipla of legal provisions of the Drugs and Cosmetics Act, 1940 and Schedule M of the Drugs and Cosmetics Rules solved the secret behind the suppression of the serious ADRs by international drug company, Cipla Limited.

- The drug was sub-standard.
- The drug was specially manufactured for Maruti Nursing Home doctors for treating minor bone problems like stiff neck, joint pains, bone pain, etc.
- Maruti Nursing Home doctors sold Rokfos to other doctors and hospitals. The sales were done illegally i.e. without a valid license as required under the Drugs and Cosmetics Act, 1940.
- The drug was administered as a clinical trial (without precautions and contra-indication tests) to cure stiff neck in a single day.

Profit Margin on drug Rokfos sold to the complainant.

a) There were 5 injections of Rokfos purchased by Maruti Nursing Home.

b) Purchase price of Rokfos was Rs.2,100.00 + Vat 5%. Total cost = Rs.2,205.00

c) MRP was Rs.2,950.00

d) This injection was sold to the patient for Rs.3,500.00 (IV charges, Ward charges and Nursing charges were charged separately)

e) The margin of profit between MRP and purchase price was Rs.745.00.

f) Assuming same margins for wholesaler, stockist and drug manufacturer (Rs.745.00), the cost of Rokfos works out to (Rs.2,950.00 less Rs.745.00 x 4) i.e. -Rs.30.00.

g) If wholesaler is eliminated then cost price works out to Rs.715.00.

h) Rokfos was sold to the end-consumer (patient) at 500% of cost.

This requires that the draft pharmaceutical policy drawn by the Department of Pharmaceuticals, capping Trade Margins be passed as a law urgently.

Directorate, Department of Public Grievances, Government of Goa :

On coming across a website of the Government of Goa for Public Grievances, I registered my complaint with them. The PG cell forwarded my complaint to the Director, Directorate of Food & Drugs Administration, Government of Goa.

Directorate of Food and Drugs Administration, Government of Goa :

Since FDA, Mumbai refused to take action on the serious adverse drug reactions even though they were aware that it had caused a death and even in spite of the fact that drugs were sold illegally at Maruti Nursing Home, I wrote to FDA, Goa on the serious adverse reactions and whether Cipla had followed the mandatory provisions of Schedule 'M'. Rokfos was manufactured at Cipla's Goa manufacturing Plant.

- Cipla, Goa replied to me that complaints on serious adverse drug reactions were handled at Cipla, Mumbai and not at Goa. That there were no report of the ADRs of Rokfos and no drugs were recalled **(Page 43).**

Cipla explanation to Director of FDA Goa :

FDA, Goa sent a Show Cause Notice to Cipla, Goa. Cipla Head-Global Pharmacovigilance completely deceived the Director of FDA, Goa with totally false and baseless statements.

It was not expected that a company which prides itself as a Pharmaceutical Major would stoop to such low morals to defend their sub-standard drug

Rokfos such as to defame a patient who was the victim of their malpractices. It was like rubbing salt to injury. The patient was a hale and hearty person with no history of illness of any sort. Her life was destroyed in less than a day (within twenty hours) after sub-standard drug Rokfos was administered to her. The following were his explanations :

False statements on the health condition of the patient to portray her as critically ill and that Rokfos was not the cause of her death :

a) That the patient was paralytic in one arm.

b) That she had bone tuberculosis.

c) That she had spinal tuberculosis.

d) That on an unknown date, she had received one shot of steroid for bone tuberculosis.

e) That she had arthralgia (joint pains).

All of the above false condition of the patient was given without any shred of evidence and just to deceive FDA-Goa by portraying the patient as paralytic and being critically ill and that Rokfos was not the cause of her death.

Protecting the doctors on their faulty treatment as well as precautions taken before administering Rokfos :

a) That the treating doctor had administered Rokfos for treatment of osteoporosis.

b) That the patient was properly hydrated before giving Rokfos.

- The patient was not admitted for treatment for osteoporosis. There is no mention of osteoporosis in in-patient records or even in the doctors' submissions before the Hon'ble Maharashtra State Consumer Disputes Redressal Commission. As per e-mail from Dr.Mihirgiri Goswami, he says that he administered Rokfos for multiple joint pains and bone pain. In direct contrast, he says that joint pains occurred after injection Zoledronic acid. This proves that Foul Play was involved in administering Rokfos.

c) Zoledronic acid has been approved by DGHS for the following indications of use sent to the complainant by DGHS :

- Hypercalcaemia of malignancy (cancer).
- Multiple myeloma (cancer).
- Paget's disease of bone.

- Treatment for osteoporosis (brittle-bone disease).

d) There is no mention of osteoporosis or any other disease for which this strong drug (which has to be given only once in a year) was administered to the patient in her in-patient records.

e) There were no precautions followed. Rokfos booklet runs into 15 pages and none of the indications of use were followed.

f) There were no contra-indication tests followed as per in-patient records.

g) Creatinine clearance test which was crucial was not conducted.

- The gravest criminal offences by the doctors were :

- Keeping quiet for five days at a stretch knowingly that Rokfos had caused serious adverse drug reactions.
- Watching the patient sinking to hear death for three days after pancytopenia (drop in all three blood counts).
- Conspiring and planning for surgery even after pancytopenia since three days.
- Sending her clandestinely by deceiving the relatives that she was fit for surgery and then abandoning her.

Deceit by Cipla Head Pharmacovigilance to Director of FDA-Goa :

a) After the above explanation on patient's history of bone tuberculosis, paralysis and steroids to the Director of FDA, Goa, Cipla representative followed up his deceit by producing past instances of Aplastic Anaemia in cases of treatment with anti-tuberculosis drugs and antitubercular therapy.

b) Cipla Head – Global Pharmacovigilance created a Thesis on T.B. vis-a-vis Aplastic Anaemia just to deceive the Director of FDA-Goa and suppress their malpractices of manufacturing sub-standard drugs for clinical trials.

c) If as per Cipla Head Global Pharmacovigilance, Aplastic Anaemia was rare with Zoledronic acid, it was all the more a serious matter and should have been investigated immediately. This shows the farce of Cipla's Global Pharmacovigilance or to rightly put it "Anti-Pharmacovigilance". The side effects were known side effects as per Rokfos booklet. Petechial rashes and pancytopenia are typical symptoms and characteristic features of Aplastic Anaemia or bone marrow failure. These side effects were responsible for death of the patient who was administered Rokfos faultily as a clinical trial.

d) There was no treatment for T.B. and no antitubercular therapy was given.

e) Even after MRI report suggested clinical correlation for suspected T.B. this was not followed. Surgery for cord compression could not be performed as bone marrow had failed at Maruti Nursing Home itself.

f) T.B. or whatever the infective etiology was, could never be established.

Cipla explanation that they did conduct investigation of the batch V40056 is devoid of any merit. That the complaint batch had already expired in January 2016 having shelf life of 24 months.

a) Cipla cannot defend that the shelf life was over as information on the serious adverse drug reactions of the Complaint batch was given on 7th August 2014. The batch was manufactured in February 2014.

b) Cipla never investigated the said batch as they were aware of its sub-standard quality. The investigation required testing the sample from the batch at a Government laboratory for standard quality. The batch would have failed the test to determine its standard quality.

c) Cipla would have revealed the result of investigation to concerned authorities FDA and PVPI. Also to the aggrieved party who had been following and appealing to investigate in the interest of medical science.

d) It was all the more imperative that Cipla shared the information of the serious ADRs with PVPI and with other manufacturers across the world as Zoledronic acid is used by millions across the globe.

e) Obviously, Foul Play was involved in the manufacture and sale of sub-standard drug Rokfos in nexus with Maruti Nursing Home.

f) Cipla Limited violated Schedule 'M' of Drugs and Cosmetics Rules, a serious violation as such (**Page 45),** provisions of Schedule M of Drugs and Cosmetics Rules.

g) Cipla had to recall drug Rokfos from Stockist to Wholesaler to Retailer level. The batch in question was specially manufactured for sale by Maruti Nursing Home doctors to their patients as well as to other hospitals and orthopaedic doctors. This was the reason why Maruti Nursing Home withdrew the remaining injections from their stock. This is proved in the case at 15th Court, Mazgaon, Mumbai against the treating doctor, Dr.Mihirgiri Goswami for sale without a valid license as required under the Drugs and Cosmetics Act, 1940.

h) Penalty for sub-standard drug causing "Grievous Hurt" within the meaning of section 320 of the IPC is imprisonment – minimum ten years and which can extend upto Life. Also fine three times the value of drugs confiscated. MRP was rupees 2,950.00. The drug was manufactured just six months before the disaster occurred. There would have been plenty of stock available and fine would have been very huge. Hence Cipla did not follow mandatory provisions of Drugs and Cosmetics Rules to avoid the huge fine.

Ignorance of the Law relating to Schedule M of Drugs and Cosmetics Rules :

a) On the one hand Cipla claims that they followed pharmacovigilance guidelines and reported the ADRs to FDA, Goa, PVPI and DCGI.

b) In sharp contrast Cipla authorised representative feigns ignorance of the Law relating to Schedule 'M' of Drugs and Cosmetics Rules. Coming from an international drug company this is shocking.

c) Cipla says that they will conduct product quality investigation into cases of death due to Cipla drug in the future. That they will report ADRs in the future.

d) Is Cipla above the law of the land and decide to absolve themselves of malpractices and foul play leading to death of a consumer and a patient ?

e) Can Cipla Limited be pardoned for violating the provisions of Drugs and Cosmetics Act, 1940 and Schedule 'M' of Drugs and Cosmetics Rules ?

f) Are deaths by manufacture of sub-standard drugs and conducting clinical trials not amounting to culpable homicide and punished accordingly ?

- Cipla officials and Management have to be booked for criminal offences, causing death of an innocent patient and a consumer.

The might and power of the pharmaceutical industry in Food and Drugs Administration in India is on display.

a) Cipla's nexus with FDA, Maharashtra officials is proved by Cipla's explanation to me on my complaints to FDA-Maharashtra and FDA-Goa.

b) Cipla's authorised representative says that as Cipla's manufacturing unit of IV Rokfos is situated in Goa, apparently FDA, Maharashtra had forwarded my complaint to FDA, Goa.

c) My complaint was not made to FDA-Goa. I had only asked FDA-Goa through an RTI query dated 05/01/2018 on report of serious adverse drug reactions of IV Rokfos from Cipla Ltd.

d) FDA-Goa responded that they had not received any report of the ADRs of Rokfos from Cipla. Further said that handling of product complaint and complaint related to ADR are investigated by Drug Safety Department, Cipla, Mumbai and not at Cipla Goa location.

e) FDA-Maharashtra officials refused to act against Maruti Nursing Home since April 2015 on drug Rokfos causing serious ADRs and ultimately death.

f) FDA-Maharashtra officials also refused to act against Cipla even after I showed them letter from Directorate General of Health Services on Schedule M of Drugs and Cosmetics Rules. Assistant Commissioner (Zone 4) said that they have no jurisdiction in this matter which is on record **(Page 46).** This was the reason for my complaints against FDA, Maharashtra officials to PMO and CMO as well as the State FDA Minister.

g) My complaint regarding the serious ADRs were to Directorate of Public Grievances, Government of Goa who forwarded the same to FDA-Goa.

h) Cipla is trying to absolve itself of the following serious criminal charges by giving false, baseless, defamatory and disgusting information on the health condition of the deceased prior to being administered Rokfos and justify that Rokfos was not the cause of her death :

- **CRIMINAL CHARGES :**
- Manufacture of sub-standard drug Rokfos causing death of my wife.
- Suppression of the serious ADRs by violating the Drugs and Cosmetics Act, 1940 and Schedule M of Drugs and Cosmetics Rules.
- Nexus with Maruti Nursing Home doctors in sale of sub-standard drug Rokfos given as clinical trials to patients admitted there as well as onward sales to other hospitals and orthopaedics.
- The outdoor sales to other doctors were made illegally i.e. without a valid licence as required under Drugs and Cosmetics Act, 1940.
- Treachery and deceit to Director of FDA-Goa with total falsehood.

i) Cipla is trying to absolve FDA, Maharashtra officials for failing to take action on the serious ADRs against Maruti Nursing Home.

j) My complaints to PMO, CMO and CDSCO have not been acted upon by FDA, Maharashtra. It was FDA-Maharashtra who had to investigate nexus between Maruti Nursing Home and Cipla into sale of sub-standard drug Rokfos causing untimely and unnatural death of my wife. This investigation had to be done by FDA-Maharashtra and not by FDA-Goa.

k) Cipla cannot decide what action Food and Drugs Administration authorities both at Maharashtra and Goa have to take. Full evidence of Rokfos causing death (beyond any doubt) has been provided to all drug control authorities.

l) **Refer to page 27,** letter from the Director of FDA-Goa dated 15th May 2018 to Drugs Controller (India). It says :

- FDA-Goa received this complaint on 01/01/2018 via e-mail.
- That the said complaint was investigated by Investigating officer of FDA-Goa 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 Mumbai and subsequent follow up reports are submitted to Drugs Controller General (India) as per pharmacovigilance guidelines and the said adverse drug reaction was not reported to FDA-Goa.
- Further firm Cipla 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 is forwarded for information and necessary action at DCG(I) end.

m) Cipla's claims that this matter has been dealt with by FDA-Goa is again a blatantly false statement just to deceive and coerce the complainant that he cannot pursue the matter any further.

This shows Cipla's methods of bulldozing the consumer even after their drug has caused a death.

Cipla is flaunting its money power and nexus with FDA-Mumbai officials who as per the voluminous evidence, are ever willing to toe to the whims and fancies of a multi-national drug company.

- The doctors have admitted that they have never seen such drastic adverse reactions of Rokfos before.
- Cipla sent indications of use to the complainant showing the known side effects of Rokfos as was evidenced in death of my wife from the ADRs.
- Cipla itself has admitted that they were informed of the serious ADRs on 7th August 2014 by treating doctor.
- That they had also reported the adverse event immediately to PVPI, DCGI and FDA-Goa.

n) All my allegations are based on in-patient records, Rokfos booklet confirming the known side effects that occurred in the case of my wife, the doctors' statements on the ADRs as well as sales of Rokfos illegally to other hospitals and doctors by Maruti Nursing Home.

o) If all my allegations are false, Cipla rather than suppressing the ADRs and violating the Drugs and Cosmetics Act and Rules thereunder should have taken legal action against Maruti Nursing Home four years back. Rather they have admitted to reporting the ADRs to DCGI, PVPI and FDA-Goa.

p) They have supported Maruti Nursing Home doctors on their faulty treatment by false statements to FDA-Goa.

q) They have lied blatantly and deceived the Director of FDA-Goa by creating a thesis on Aplastic Anaemia vis-à-vis Anti-tubercular therapy.

r) The nexus between Cipla, Maruti Nursing Home and FDA, Maharashtra officials is evident with the voluminous evidence produced by me to all drug control authorities.

- What is left is stringent action against all the accused for causing death of my wife and violations under various acts, IPC as well as Drugs and Cosmetics Act, 1940 and Schedule M of the Drugs and Cosmetics Rules.
- FDA officials (Joint Commissioner Shri O.Sadhwani, Assistant Commissioner Shri J.B.Mantri and drug inspector Shri A.T. Rathod have to be charged for suppressing evidence in this heinous crime causing death of an innocent.

Date : 4th March, 2019

Shri J.P.Nadda,

Union Minister – Ministry of Health and Family Welfare

And

The Drugs Controller General (India)

Dear Sirs,

Attached, please find my letter to the Chairman of Cipla Limited, Shri Yusuf Hamied asking him to respond to the malpractices and criminal offences in sale of sub-standard drugs and violation of Drugs and Cosmetics Act, 1940 by Cipla Limited. Besides being in nexus with doctors/private hospitals and playing with the lives of the citizens of India.

As is evident from this letter as well as the numerous appeals by me to all the concerned government officials, concerned government authorities, concerned ministers besides the PMO and CM of Maharashtra, there has been no action on such a horrific death.

This matter is in public interest to save human lives. Is the government of the day insensitive to the common man ? Is the government of the day concerned about welfare and protection of only big businesses ?

Will your party in power (BJP) state in your manifesto that criminal offences against multinational drug companies and doctors/private hospitals will not be acted upon ?

In that case you do not have to spend money on PM-JAY. Health of the citizens will deteriorate at the hands of criminal drug companies and doctors/private hospitals. Ultimately, the tax-payers' money will go to the coffers of these criminals.

Can I have a response from the Minister of Health and Family Welfare ?

Can I have a response from the Drugs Controller General of India ?

Thanking you,

Yours Sincerely

Umeshchandra Barkur

A-15, Neeta Apartments, Chaphekar Bandhu Marg, Mulund (E), Mumbai 400081.

E-mail : umeshchandrabarkur@hotmail.com Cell : 98201 17923