

Date : 28<sup>th</sup> May 2018

To :

Cipla Management

Re: Threatening letter issued to me dated May 18, 2018 (attached) for defamation and legal proceedings against the aggrieved party from Cipla's Authorised Representative (not named).

Hence my response is to Cipla Management (Board of Directors).

1. It is very surprising and shocking that International Pharmaceutical Giant Cipla Ltd is threatening a common man (the aggrieved party) and a consumer who has lost his wife due to serious adverse drug reactions of Cipla drug IV Rokfos with defamation cases. This threat is issued to me for putting all facts into death of my wife before the concerned government authorities both at the Centre and in the States of Goa and Maharashtra.
  2. It was CDSCO and the office of the Drugs Controller General of India who, after scrutinizing facts put before them, advised me of Schedule M of the Drugs and Cosmetics Rules which mandated drug manufacturing companies to report complaints of serious adverse drug reactions forthwith to the concerned licensing authority. The office of DCGI have asked for investigation into this case of nexus between Cipla and Maruti Nursing Home in sale of sub-standard drug Rokfos which caused untimely and unnatural death of my wife.
  3. Cipla has also taken offence for seeking apology from Cipla Management for false, derogatory, defamatory, maligning and baseless statements made by its Global Head of Pharmacovigilance, Dr.Avinash Kakade on the health condition of my wife prior to administration of their drug Rokfos which caused serious adverse drug reactions leading to her death. The following statements have been given by the head of Cipla Global Pharmacovigilance without any shred of evidence to the Director, Food and Drugs Administration, Goa.
    - That my wife was paralytic in one arm.
    - That she had Spinal Tuberculosis.
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- That on an unknown date she had received one shot of steroid for tuberculosis.
- That she had Arthralgia on admission to Maruti Nursing Home.
- That the treating doctor had administered Rokfos for osteoporosis.
- Cipla Authorised Representative (name unknown) has not produced proof of the disgusting defamatory remarks by Dr.Avinash Kakade. Nor has he produced any proof of arthralgia before admission to Maruti Nursing Home. There is no proof from medical records that the treating doctor administered Rokfos for osteoporosis.
- My wife did not come with arthralgia. The treating doctor has noted "Post Zobone Arthralgia". After four years Cipla is defending themselves by saying that it was not Cipla drug but Zobone that caused arthralgia. It was me who had advised Cipla of the confusion between Zobone and Rokfos in in-patient records of my wife at Maruti Nursing Home.
- Four years ago it was Cipla along with Maruti Nursing Home doctors who had deceived the relatives of the deceased that it was the known side effects of Rokfos that caused her death. Cipla had sent the indications of use of their drug Rokfos through their medical representative to the treating doctor to be passed on to me. The doctors informed us that they had never seen such serious adverse reactions of Rokfos ever before. Cipla had also sent indications of use and FAQs on Rokfos vide an e-mail to me. They had told me at that time that the treating doctor was the right person to decide whether a drug has to be administered to a patient or not. Cipla did not contest the serious ADRs four years ago and that Zobone was not their product. Transcripts of the meeting between the treating doctors and the relatives of the deceased shows that Maruti Nursing Home had been induced by Cipla into selling their brand of zoledronic acid Rokfos. Zobone was their regular brand and Rokfos was their new brand, says the treating doctor. Also says "From a simple neck pain why he had to give?". That it was a one day admission "Give today, discharge tomorrow". Hence there was no MRI on admission. Further says that he will not give Rokfos anymore. Maruti Nursing Home doctors withdrew the remaining injections

purchased by them from their stock. Mediclaim doctor attached to Maruti Nursing Home said that he goes to 25 hospitals and three to four orthopaedics and gave Rokfos with full responsibility. He took care to see that neither the patient nor the doctor had any problem. That he had to balance both. This proves that specially manufactured batches of Rokfos were supplied to Maruti Nursing Home doctors to treat minor bone problems, spondylitis, stiff neck, etc. Else who is Dr.Dubey to take responsibility for a drug manufactured by pharmaceutical giant Cipla? What did Dr.Dubey mean when he said that he had to balance both the patient and the doctor?

- It is strange that Cipla is supporting the doctor for his wrong and faulty treatment with Rokfos by saying that he administered the drug zoledronic acid for osteoporosis. There is no mention of osteoporosis in in-patient records of my wife. In an e-mail the treating doctor has said that he administered Zoledronic acid for multiple joint pains in sharp contradiction to his noting in medical records "Post Zobone Arthralgia". Why does Cipla have to defend the doctor's faulty and wrong treatment unless it was their drug that caused the disaster.
4. It is shocking that Cipla has not filed a criminal defamation suit against Maruti Nursing Home since four years for falsely implicating their drug ROKFOS in serious adverse drug reactions causing death of my wife. I had given all the relevant information from in-patient records of my wife at Maruti Nursing Home as well as the doctors' statements on Rokfos.
- The deceased patient's relatives would go by the in-patient medical records. It was the responsibility of Cipla to investigate from their Client, a very valuable one at that, regarding complaint received on the serious adverse drug reactions of Rokfos from me.
  - As per CDSCO and the office of the Drugs Controller General of India, "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 taken, recall to be made of the defective product.
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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”.

- Cipla violated the legal provisions of Schedule M of the Drugs and Cosmetics Rules and colluded with the doctors of Maruti Nursing Home since four years in suppressing the serious adverse drug reactions. It is obvious that **FOUL PLAY** was involved. The drug was sub-standard and was manufactured specially to treat minor bone problems and given as clinical trials. This is a dangerous experimentation by drug companies and has to be tackled at the highest levels in the Government (CDSCO, DGHS, Ministry of Health and Family Welfare and Department of Pharmaceuticals). Lives of the citizens of India are precious and cannot be used as Guinea Pigs for experimentation.
5. The nexus between Cipla and Maruti Nursing Home is also in the form of threats of defamation. Maruti Nursing Home had also threatened me with defamation if I did not withdraw the civil and criminal complaints filed by me.
  6. The Government needs to look into the aspect of defamation for filing cases against doctors and pharmaceutical companies in the new Consumer Protection Bill, 2018 introduced in the Parliament. Consumer cases of Medical Negligence and drugs-related deaths needs to be supported by the Government by providing legal aid to the aggrieved parties. Else justice will never be served against the powerful pharmaceutical companies in nexus with doctors and hospitals. The consumers have every right to fight for their grievances and seek justice. It cannot be called defamation.
  7. It will be ideal for Cipla and Maruti Nursing Home to hold a joint “Press Conference” and reveal the defamation indulged in by me. This could be held at the BSE as Cipla has a large shareholding from the public. They must be made aware.
  8. There is nothing in the contents of my letter which **are contradictory to the facts on record**. Everything contained in my letter are **“PURE FACTS” on record which has been proved with documentary evidence**.
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9. Cipla could have got a confirmation from their customer, Maruti Nursing Home doctors if there was any falsehood involved in my correspondence with Cipla four years ago. They chose to keep quiet then. They have broken their silence after four long years on being questioned and interrogated by the Government Authorities. Transcripts of the meeting with Maruti Nursing Home doctors proves in no uncertain terms the nexus between Cipla and Maruti Nursing Home doctors in sale of sub-standard drug IV Rokfos. That this drug was given as a **clinical trial to cure stiff neck in a single day**.
10. If the doctors could not prove to Cipla then (four years ago) that Rokfos was given, Cipla had to just negate my information. I would have proceeded with my cases against the doctors accordingly. **There is no question of defamation by the aggrieved party**. He will go by what the doctors have said with proof of Rokfos in in-patient medical records. Why did Cipla not investigate four years ago when information was given to them by me to investigate in the interest of medical science and not as a complaint against their drug Rokfos ?
11. In fact a defamation suit should have been filed by Cipla against Maruti Nursing Home doctors four years ago when I had given them all information received from the doctors on the serious adverse drug reactions of Rokfos. My letter dated **18<sup>th</sup> April, 2017** was to find out the truth on "Adverse Drug Reactions of IV Rokfos". I had been pursuing this case with Cipla since three years of death of my wife. Several doctors had told me that such serious adverse drug reactions were never seen by them before. I had sent batch number, manufactured date and expiry date from the box of Rokfos attached to in-patient records of my wife. Besides the doctors of Maruti Nursing Home had produced Purchase Invoice for five injections of Rokfos. Cipla had also sent the treating doctor indications of use of drug Rokfos to be given to me. This proves that Cipla had accepted the serious adverse drug reactions. **These were known side effects of Rokfos as per their booklet**. This Final letter of 18<sup>th</sup> April 2017 was sent by me to the Managing Director and Global CEO of Cipla. Cipla Drugs Safety Division had not responded to my earlier e-mails on action taken by Cipla on my report of serious adverse drug reactions of Rokfos. **I had not accused Cipla till that time in any manner**. I only wanted to pursue my case against the doctors and had asked Cipla to let me know the truth of IV Rokfos
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sold to Maruti Nursing Home. Drugs Safety Division had responded by saying that they will take appropriate action. They never informed me about what action they had taken. Till the time I was informed about Schedule M from DCGI, there were two issues bothering me in my pursuit of justice.

- A.** Why the doctors at Maruti Nursing Home did not take action after the serious adverse drug reactions of Rokfos and watched my wife sinking to her death for five days at a stretch and then abandoned the patient without any details in their Discharge Card. They had ample time but did not act. They protected the drug from being exposed at the cost of an innocent life.
- B.** Why was Cipla not taking action on the serious adverse drug reactions ?

The mystery into the merciless death of my wife is at last solved with Cipla personnel and drug Rokfos being at the helm of the disaster.

12. It was the Office of Drugs Controller General of India, New Delhi who made me aware of Schedule M of the Drugs and Cosmetics Rules. This information given to me solved the mystery why Cipla chose to maintain a stoic silence on my repeated complaints. That they had to recall their drugs from Stockist to Wholesaler to Retail level and report the same to the concerned licensing authority. That these specially manufactured batches of Rokfos for Maruti Nursing Home doctors would have failed the standard quality test and the clinical trials would have been exposed. This also explains the reason why Maruti Nursing Home doctors withdrew the remaining four injections in their stock.

13. Cipla has accepted violation of the laws citing their ignorance of the law in their explanation to the Director of Food and Drugs Administration, Goa. This coming from a pharmaceutical giant is Shocking !! They have also accepted that in future Cipla will conduct product quality investigations into all death cases from the use of a Cipla drug. Will also submit reports of serious adverse drug reactions to the concerned licensing authority and also to DCGI and PVPI.

14. What about **DEATH CAUSED** due to serious adverse drug reactions of Rokfos and suppression of the same. **Cipla is not above the Law of the land.** Cipla has colluded with Maruti Nursing Home doctors in sale of sub-standard drug. **Where was the need for a multi-national drug company to violate the Drugs**

**and Cosmetics Rules ?** They just had to check one injection from the five injections purchased by Maruti Nursing Home. Else, there was plenty of stock left with the company to confirm standard quality.

15. **Cipla can get their customer Maruti Nursing Home to respond to their admissions on Rokfos serious adverse reactions never seen before by them.** Also that this drug was given by them for curing stiff neck in a single day. "Give today, Discharge tomorrow". As per the doctors' versions, Cipla had induced them to promote Rokfos to other hospitals and nursing homes through the Mediclaim doctor attached to Maruti Nursing Home.
  16. Further, **there were no exhaustive correspondence in this matter from Cipla side.** It was a **one-sided appeal from my side** to investigate. There was no response and action required from Cipla side. **There are no fresh contentions except that DCGI office advised me the laws required to be followed by drug manufacturing companies.** Cipla has been caught in an act of culpable homicide in nexus with Maruti Nursing Home.
  17. I have not **elected to write this letter after four years. My complaints have been since the last four years.** It was Cipla who maintained a stoic silence for obvious reasons and suppressed the serious adverse drug reactions for four years. They had to break their silence after four years as the State Government Authorities of Goa sought an explanation.
  18. I have to write to **Cipla Management only** who are in charge of the company and its operations. They are responsible to the enormous shareholders who have invested their hard earned money in Cipla shares. They should be aware of the company activities and the actions of Cipla personnel.
  19. Cipla has lied to the authorities viz. Directorate of Food and Drugs Administration, Government of Goa. It was Cipla personnel (Head – Global Pharmacovigilance) who gave false, fabricated and disgustingly maligning and defamatory remarks on the health condition of my wife prior to being administered drug IV Rokfos which was the cause of her death. Hence my demand for an unconditional apology for defamation of my wife's health condition. I have sent all details to the Office of Drugs Controller General of India and sought action.
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20. **Cipla is a well-known pharmaceutical corporation of repute in India** and across the world. Cipla Management is also responsible to the large number of its shareholders. **It was all the more important that they could not treat a report on death due to their drug in such a casual manner. The lives of the citizens are valuable and they are the consumers.** Cipla had to be responsible rather than **not offering any assistance to its consumer.** On the contrary they have supported and colluded with the irresponsible doctors in an act of culpable homicide. Cipla's representatives have accepted the serious adverse drug reactions by sending the indications of use to the treating doctor to be given to me. The doctors of Maruti Nursing Home have admitted to the serious adverse drug reactions. Cipla also sent me the FAQs on Rokfos.
21. As far as **Cipla supplying quality products at affordable prices,** it is completely the opposite in my case. **Firstly, product Rokfos was sub-standard and hence it caused such drastic adverse drug reactions. Secondly, the price which I paid for Rokfos was exorbitant.** Purchase price to Maruti Nursing Home was Rs.2,205.00. MRP was Rs.2,950.00. **It was sold to me for Rs.3,500.00.** If you consider margin for retailer (Maruti Nursing Home) from the Wholesaler it works out to Rs.745.00. If you assume same margin for the Wholesaler, Stockist and the Manufacturing company Cipla, what is the cost to Cipla ?  $Rs.2950.00 - 745.00 - 745.00 - 745.00 - 745.00 = -Rs.30.00$ . Assuming that Maruti Nursing Home was given the lion's share of unethical profits for indulging in clinical trials, even then, **the consumer paid more than 500% on cost to manufacturer.**
22. Cipla drugs safety division never imagined that a layman would come to know of the provisions of the Drugs and Cosmetics Rules. That he will accept the death of his wife as his destiny and fate. **That they could continue with their experimentation with gullible patients like my wife who could be exploited in their pursuit of CLINICAL TRIALS.** Who could challenge Cipla against their money power to indulge in false defamation cases. I could never imagine that Cipla would indulge in such malpractices in nexus with nursing home doctors.
23. It is none other than the Honourable Prime Minister Shri Narendra Modi who has expressed his concerns on nexus between doctors and pharma companies for unethical rewards. The PMO, Chief Minister of Maharashtra and the FDA



Minister have been apprised of this case. DCGI office has asked FDA, Maharashtra to investigate and take action.

24. My allegation that **Cipla had sponsored administration of IV Rokfos in clinical trial** is proved in my detailed proof sent to the Assistant Drugs Controller (India), Shri S.Basu. Copies have been sent to Cipla Management who have to respond in co-ordination with their valued customer, Maruti Nursing Home.
25. Cipla authorised representative says that they have at all times dealt with me with utmost courtesy and extended all assistance in respect of my queries and concerns. **That it is my motive to falsely implicate Cipla as being complicit in my wife's tragic death.** Cipla is also threatening a common man with legal proceedings and defamation at his sole risk. This after their drug was cause of his wife's death.
- 26. There is nothing defamatory in my allegations.** Cipla has to respond with proof. Cipla may bring this case before the Courts with the whole world watching the sinister and dangerous practices being adopted by pharmaceutical giant Cipla unaware to the world. It will also force the Government in bringing the New Pharmaceutical Policy as well as the proposals by CDSCO in place ASAP. This will be the right step to protect the consumers and the common man from the powerful pharmaceutical lobby who are playing with the lives of the ordinary citizens of the country. PM Modiji has been right when he has been emphasising the doctor-pharma co. nexus. That **"Consumer Protection is a must for the creation of a New India"**.
- a) Cipla has not extended any help and assistance against the doctors. On the contrary, they have colluded with their valued customer in suppressing the serious adverse drug reactions.
- b) Cipla has failed in acting as per Schedule M of the Drugs and Cosmetics Rules. It was a simple matter of checking with Maruti Nursing Home doctors whether Zobone was administered or Rokfos. Cipla did not contest the serious ADRs at that time. Rather they accepted the ADRs by sending indications of use with known side effects. Unless there was foul play involved, there was no need for Cipla to be silent for four years.
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- c) Cipla Management was aware of faulty manufacturing practices at their Goa Plants. US FDA have issued warnings and observations year after year.
- d) Cipla have broken their silence after four years and are going extra miles in protecting their sub-standard drug. By giving false statements to Director of Food and Drugs Administration, Goa they have exposed their unethical and immoral standards.
- e) There was no need for Cipla to indulge in such disgusting remarks unless it was to protect their sub-standard drug.
- f) All of the false statements by both treating doctor and Cipla Head of Pharmacovigilance in conjunction with each other proves the foul play involved in death of my wife and Rokfos was administered as a clinical trial only to cure stiff neck in a single day. Cipla is still in nexus and supporting Maruti Nursing Home on their treatment. **Rather, Cipla should have filed a defamation case against the doctors of Maruti Nursing Home. It is they who have admitted that Rokfos was administered for curing stiff neck in a single day.**
- g) A detailed explanation into this foul play has been sent by me to the office of the Drugs Controller General of India.

27. I may be a layman but I have produced only facts with concrete evidence as it happened. I had given the same to Cipla within seven weeks of death of my wife. It is left to Cipla to prove why they kept quiet and suppressed the adverse drug reactions in nexus with Maruti Nursing Home for four long years until the law caught up with them.

28. I can only seek assistance from pharmaceutical experts and consumer activists for their expert opinion on this case as I have put all facts before all concerned authorities.

**29. It is not defamation with malafide intention.** On the contrary, it was malpractices by Maruti Nursing Home doctors in nexus with Cipla for **monetary benefit at the cost of precious lives of the citizens of this country.** My rightful allegations are for seeking justice for the merciless, untimely and

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unnatural death of my wife. **I have to bring the culprits including Cipla personnel to book for culpable homicide.**

30. The false explanation given by Cipla to FDA, Goa is a desperate attempt to save themselves from criminal proceedings for colluding with the doctors in causing death of my wife as well as acting as accessories in suppressing the serious adverse drug reactions.

31. I am awaiting an unconditional apology from Cipla Management for false, defamatory, maligning and baseless information on the health condition of my wife prior to drug Rokfos being administered to my wife. This after drug Rokfos was responsible for her death.

Yours Sincerely,

Umeshchandra Barkur

A-15, Neeta Apartments, Chaphekar Bandhu Marg,  
Mulund East, Mumbai 400081. Cell : 98201 17923

Cc: Shri S.Basu - Office of Drugs Controller General of India, FDA Bhavan, Kotla  
Road, New Delhi-110002.

Cc: Director, Directorate of Food and Drugs Administration, Goa.

Cc: Joint Commissioner, Food and Drugs Administration, Greater Mumbai.