Fw: SEEKING YOUR HELP - DEATH OF MY WIFE FROM SUB-STANDARD DRUG - NEXUS BETWEEN PHARMA COMPANY AND DOCTORS/HOSPITALS

Attachments :

CONSUMER COURT ORDER

CIPLA SUB-STANDARD DRUG EXPOSE (3)

QUESTIONNAIRE CIPLA

EVIDENCE DOCUMENTS 1

EVIDENCE DOCUMENTS 2

CORRUPTION IN FDA PROOF

From: Umeshchandra Barkur

Sent: Thursday, October 31, 2019 10:42 AM

To: lokayukta@maharashtra.gov.in <lokayukta@maharashtra.gov.in>; upalokayukta@maharashtra.gov.in <upalokayukta@maharashtra.gov.in>; ar1.lokayukta@maharashtra.gov.in <ar1.lokayukta@maharashtra.gov.in>; ar2.lokayukta@maharashtra.gov.in <ar2.lokayukta@maharashtra.gov.in>; ar3.lokayukta@maharashtra.gov.in <ar3.lokayukta@maharashtra.gov.in>; ar4.lokayukta@maharashtra.gov.in <ar4.lokayukta@maharashtra.gov.in>

Subject: SEEKING YOUR HELP - DEATH OF MY WIFE FROM SUB-STANDARD DRUG - NEXUS BETWEEN PHARMA COMPANY AND DOCTORS/HOSPITALS

Hon'ble, Respected Sirs ,

I am not sure if i am following the protocol.

I have no option but to try various authorities as i have been seeking Justice since more than five years.

This letter is basically a request to look into nexus between FDA authorities with pharma companies and doctors/hospitals. Please request FDA Maharashtra Commissioner to take action against doctors/hospitals in illegal sale of drug Rokfos in nexus with Cipla Limited causing death of my wife.

1. Maharashtra State Commission (Consumer Court) Order in Civil case for medical negligence and deficiency in services has held doctors and two hospitals "Guilty" in causing death of my wife. False death certificate given by Jupiter Hospital is also proved by the order of the court.

2. Also, please refer to file attached on open display of corruption in FDA, Maharashtra, Mumbai. It is shocking that FDA, Maharashtra Commissioner is in support of this broad daylight death. It is more than five years now.

3. I am constrained to send full details of the case along with evidence documents.

4. Are multinational pharma company, Cipla Limited and Multi-speciality hospitals above the law of the land ?

Please find attached the following :

1) Order from Consumer Court holding the doctors and hospitals Guilty in causing death of my wife. The Consumer Court has held that cause of death was Aplastic Anaemia. However Jupiter Hospital has given cause of death as Septic Shock with Multi-organ Failure (Page 71 of evidence documents No.1). Death Summary also does not mention Aplastic Anaemia (Page 73 of evidence documents).

2) Expose - Nexus between Cipla and doctors/hospitals.

3) Questionnaire to Cipla.

4) Scanned copies of evidence documents in two pdf files. You have to just scroll down to the page number in the questionnaire to Cipla Limited.

5) File on Corruption in FDA, Maharashtra, Mumbai exposed.

Explanation by Cipla Limited to FDA-Goa Director was sent to me (pages 116-127 of evidence documents).

Cipla's correspondence with me is reproduced under (pages 107-112).

My repeated appeals to Cipla Drugs Safety, Product queries, Global CEO and M.D. are reproduced under pages 139-160.

The following points need to be answered by Cipla :

1) As per Cipla, they had received information from treating physician on 7th August 2014 and they had complied with all statutory procedures. That they had immediately informed the appropriate licensing authority of the adverse event. Applicable provisions of Schedule M of Drugs and Cosmetics Rules relates to reporting to the licensing authority which the company has complied with in having informed the DCGI (the appropriate licensing authority) the Pharmacovigilance Program of India and later FDA, Goa. (Pages 109-111 highlighted portions).

2) As per Cipla explanation to FDA Goa Director (page 116) they were unaware that "Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority".

3) On the one hand Cipla is feigning ignorance of the laws and rules and on the other hand they say that they have complied with all statutory procedures and reported to three authorities.

4) Page 106 is letter from FDA-Goa that Cipla had not reported the ADRs. That no drugs were recalled.

5) Page 113 is letter from Pharmacovigilance Commission that Cipla had not reported the ADRs.

6) Pages 114-115 is letter from DCGI office asking for investigation into the nexus from Chairman, Medical Council of India, FDA Maharashtra Commissioner and Director, Health Services, Govt. of Maharashtra.

7) Pages 92,93 gives Protocol to be followed in case of serious ADRs received by me from DGHS which revealed the mystery behind the silence by Cipla to my repeated appeals to investigate drug Rokfos in the interest of medical science.

8) The physician who had certified my wife as fit for surgery (Page 132) had said that she was pre-morbidly healthy, no known allergies, no addictions, no major illness in the past.

9) In contrast, Cipla projected my wife as being paralytic in one arm, having spinal tuberculosis, bone tuberculosis, arthralgia (Pages 118, 119). All of this was stated without a shred of evidence.

10) Cipla also deceived FDA-Goa Director that my wife had received one shot of steroid for tuberculosis (page 119). The unknown steroid given on an unknown date could also be the cause of Aplastic Anaemia (page 121). Cipla's falsehood is alarming. Cipla invented steroid treatment for tuberculosis and linked imaginary diseases just to deceive FDA-Goa Director that Rokfos was not the cause of death.

11) Page 191 is Cipla's last letter to me. Please read last line where it says that they will comply with the directions of the authorities as and when received. Is this acceptance of guilt ?

12) Pages 192 to 202 is correspondence with DCGI/CDSCO/PGCELL. They had asked for my feedback on resolution of the grievance. What does this indicate ?

13) Pages 179, 203-204 is from FDA Goa Director. She had refused to take action after i proved to her that Cipla's explanation was totally false. She put the onus on DCGI.

14) After the Consumer Court order in May 2019, implicating Cipla drug Rokfos for causing death of my wife, they are now trying to dilute serious criminal charges of manufacturing sub-standard drug rokfos. That there were no adverse remarks as to quality of the drug batch.

I have responded by saying that i had repeatedly appealed to Cipla Drugs Safety and others to investigate in the interest of medical science as this drug is used by millions across the world by cancer patients. Cipla did not investigate, did not recall the drug (mandatorily required as per Sch 'M' of Drugs and Cosmetics Rules) and did not report to drug control authorities for obvious reasons. After 4 years gave false statements in their defense.

These statements cannot be retracted now as they are on record.

Hence Cipla could not respond to the journalists' and editor's questionnaire.

Criminal complaint with Mumbai Police under section 304(1) of the IPC (culpable homicide) is yet to be adjudicated. The Dean of Sir J.J. Group of Hospitals had appointed a panel of three doctors to give their report within a week (Pages 206-209). They must have done so, but the Police have yet to get the charges from the Director, Health Services, Public Health Department, Government of Maharashtra. It is more than a year now.

Full evidence is before FDA-Maharashtra, Mumbai, CDSCO under DCG(I), FDA-Goa Director (the drug was manufactured in Goa), and Mumbai Police/Director Health Services, Public Health Department, Govt. of Maharashtra.

It is FDA, Maharashtra who has to take action. How can FDA-Goa take action against Mumbai doctors selling drugs illegally causing death of my wife ?

I request all concerned to do whatever is needed to punish the guilty. Please advise me the best course of action.

It was an unnatural, untimely and merciless death in pursuit of unethical monetary rewards and to get filthy rich even at the cost of people's lives.

Thanking you,

Yours Sincerely

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