Date: 30th August 2022

Union Minister of India for Health & Family Welfare

Nirman Bhavan, New Delhi 110011.

Shri Mansukh Mandaviya

Hard copy of Email sent on 30th August 2022

Subject: "Fake Joint Investigation Report" by Drug Controllers in CDSCO to absolve pharma company, Cipla Limited of criminal offences.

Architect of this Fake Report, **Dr.S.Eswara Reddy** was arrested and Charge Sheeted by the CBI in another bribery case.

Lokpal of India (Full Bench) supported corrupted officers in the Health Ministry.

Cabinet Secretariat kept in the dark of this fake investigation by Health Secretary and Drugs Controller General of India, Dr.V.G.Somani.

Matter involves widespread ramifications for Healthcare/Lives of 140 Crore Citizens of the Nation.

Dear Sir,

- This matter must be handed over to the Criminal Bureau of Investigation at the
 earliest as attempt to tamper with evidence is being done by the Lokpal of
 India. This is explained in file attached LOKPAL REPLY TO LETTER DATED 11
 AUGUST 2022.
- Also attached is my reply to National Human Rights Commission NHRC REPLY TO DISPOSAL IN LIMINE.
- 3. Role of pharma firms in allegedly bribing CDSCO officials is under CBI scanner Besides S.Eswara Reddy, some unknown officials of CDSCO are also under the CBI scanner as per media reports.
- 4. Full facts of the matter, already investigated and exposed by the aggrieved complainant is before the CBI.
- 5. Attached, please find Cabinet Secretariat Order to Health Secretary [Evidence documents pages 510-512] regarding "Cipla Drug Trial". Around 250 pages of the matter was perused by around six deputies of top-most Bureaucrat in the

country, Shri Rajiv Gauba. Matter was sent to the Health Secretary for action. This was towards the **end of July 2020.**

"Joint Investigation Report" undertaken by CDSCO Drug Controllers, Dr.S.Eswara Reddy, Dr.P.B.N.Prasad along with FDA Gr Mumbai officials and a Professor of Government Medical college in Mumbai was already on record dated 20th March 2019 [Evidence documents pages 282-292].

This was suppressed from the Cabinet Secretariat by the Health Secretary and DCGI since more than two years as they are aware that it was a **FRAUD.**

- 6. Director of FDA Goa had issued warning to Cipla Limited (LEGAL ACTION) in Show Cause Notice dated 18/01/2018 [Evidence documents pages 766-767].
- 7. However after blatantly false explanations & multiple lies by Cipla Head, Global Pharmacovigilance, FDA Goa Director passed the matter to **DCG(I)** for action against Cipla Limited vide letter dated **15/05/2018** [Evidence document page 305].
- 8. DCG(I), Dr.S.Eswara Reddy & CDSCO Drug Controllers passed the matter to Indian Pharmacopoeia Commission four times in 5 months [Evidence documents pages 768-774].
- 9. Dr.G.N.Singh, Secretary-cum-scientific Director of IPC said that matters related to clinical trials and adverse drug reactions/death in this country are regulated by the Central Drugs Standards Control Organisation under DGHS, Ministry of Health & Family Welfare, Govt. of India headed by Drugs Controller General (India). I hope that with the above information, the matter stands clarified from our end. This was vide letter dated 10th January, 2019 [Evidence document page 304].
- 10.DCG(I) was cornered to take action. He organised "Fake Joint Investigation" which is an "Unpardonable Sin" committed on citizens of the Nation.
- 11. "Cipla Drug Trial", "Organised Fake Joint Investigation", "Protection by Lokpal of India (Full Bench)" resulted in "Attempt to cripple India's Healthcare" putting lives of 140 crore citizens of the Nation under perennial threat. Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022 regarding, The Drugs and Cosmetics Act, 1940. File attached CDSCO

PRESCRIPTION FOR DISASTER. This draft bill should be junked at the outset. Law makers in 17th Lok Sabha will write obituary of 140 crore citizens; If they pass this Bill.

12.If bribery of Rs.9 Lacs was a serious offence denying bail to Dr.Eswara Reddy & Associate Vice President of Biocon Biologics, what should be the punishment for the multiple criminal offences over the years by Cipla Limited; being tied up with CDSCO & FDA, regulatory and law enforcement authorities.

Cipla Executive Vice Chairperson, Samina Hamied is answerable before the Central Bureau of Investigation & the Citizens of India.

13. Cipla Limited Criminal Offences:

- a) Cipla played with innocent lives in nexus with doctors & hospitals.
- b) Cipla violated Statutory guidelines; Schedule M of Drugs & Cosmetics Rules.

 Did not investigate the fatal drug in spite of repeated appeals by the aggrieved complainant.
- c) Cipla cared a damn for life lost.
- d) US FDA warning to Cipla Limited exposed adulterated drugs manufactured at Goa facility where the fatal drug was manufactured.
- e) Cipla pleaded ignorance of the law relating to reporting of serious adverse drug reactions.
 - Ignorance of the law of the land is not an excuse in a homicide case punishable with Life imprisonment.
- f) Cipla deceived FDA Goa Director with false statements; **linked imaginary diseases** to the innocent victim including **bone tuberculosis** and one **paralytic arm.** Linked **imaginary treatment** for the imaginary diseases.
- g) Cipla lied to the complainant as well as FDA Goa Director that they had reported the serious ADRs to FDA, PVPI and DCG(I).
- h) Cipla Chairman hoodwinked the world with Fake Quotes and could not answer to multiple letters from the aggrieved complainant including demand for unconditional apology for false, baseless, defamatory & derogatory remarks on the victim's health prior to the fatal drug being administered to her and which caused her death;

- Physician who had certified her as Fit for Surgery had noted in in-patient records that she was "pre-morbidly healthy" "no addictions" "no known allergies" "no major illness in the past".
- i) **Cipla bribed & corrupted CDSCO & FDA** public servants comprehensively exposed in "Fake Joint Investigation" organised by CDSCO.
- j) Cipla destroyed the social fabric of our society.
- k) "Right to Life" of my wife was cut short by Cipla Limited in nexus with doctors. Illegal trial conducted with cancer injection (to be given only once in a year even to bone cancer patients) administered for curing Stiff Neck in a single day.
- "Right to Justice" denied by Cipla Limited to an aggrieved senior citizen by bribing & corrupting every regulatory and law enforcement authority viz FDA, CDSCO, Public Health Departments, Deans & Professors of Government Medical Colleges.
- m) Fake science, fake chemistry & fake medical theses used to silence the aggrieved complainant & senior citizen.
- n) Not only was my wife killed mercilessly but I was taken for a ride for more than eight years seeking justice.
- o) **Two acts were abused** due to bribing & corrupting by Cipla Limited.
 - a) Drugs & Cosmetics Act, 1940 and b) Lokpal & Lokayuktas Act, 2013. Where is safety for the citizens of Bharat Mata?
- 14.CDSCO is the National Regulatory body for drugs in India. Drugs are approved by Drug Controllers working in CDSCO. FDA is the State licensing authority. If both FDA-CDSCO are in nexus with pharma companies, where is safety for the citizens?
- 15.CDSCO letter dated 17/01/2022 [Evidence documents pages 782-783] from Drugs Controller General of India to FDA Goa Director to take action against Cipla Limited is proof that Cipla should have been prosecuted in 2018 itself after false written explanations were submitted to FDA Goa Director.

16.RTI Query to CDSCO dated 10th July 2022.

- a) Reason for not informing complainant of Joint Investigation Report.
- b) Action taken on Joint Investigation Report dated 20/03/2019.

- c) Reason for Health Secretary not informing Cabinet Secretary of Joint Investigation Report after his Order of July-end 2020 for action in "Cipla Drug Trial".
- d) Action against Cipla Ltd as per DCG(I) letter to FDA Goa Director dated 17/01/2022 and reply by FDA Goa Director to DCG(I) dated 04.02.2022.
- e) Penalty & punishment under Drugs & Cosmetics Act.

Reply by CPIO

Point no. a to d:

The matter was investigated, examined and inspected at various levels by this office and factual detail in the matter was forwarded to Ministry of Health and Family Welfare. After examination by the Ministry in consultation with CDSCO, the factual report in the matter was forwarded to the higher authority as on 25.02.2020. Further, license for manufacture, sale and distribution of drugs is granted by State Licensing Authorities appointed by respective State Governments under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. In view of above, you are requested to approach concern State Licensing Authority, Goa for requisite information.

Further, clarification/interpretation/opinions are not covered under Section 2(f) of RTI Act, 2005. Point no. e; You may refer Chapter IV of Drugs and Cosmetics Act 1940 which is available on the website of CDSCO i.e. www.cdsco.gov.in

Reply to RTI query proves that Joint Investigation Report was a FRAUD committed on an aggrieved senior citizen.

- Point a) is unanswered.
- Point b) Matter was forwarded on 25.02.2020 to which higher authority? & what happened since more than two years?
- Point c) is not answered. Health Secretary could not reply to Cabinet secretary on Joint Investigation report as he was aware that it was a FRAUD to silence the aggrieved senior citizen.
- Point d) FDA Goa Director wrote to DCG(I) on 04/02/2022. No answer to this point.

- 17. Lokayukta of Maharashtra, Justice V.M. Kanade has to be arrested by the CBI. Complaint is before the Governor of Maharashtra, Shri Bhagat Singh Koshyari for dismissal of the Lokayukta & arrest by the Central Bureau of Investigation. Public Health Departments of government of Maharashtra and Dean/doctors of Sir J.J. Group of Hospitals are answerable before the CBI for destruction of "Expert Committee Report" on criminality involved in homicide of my wife. Cipla, doctors and hospitals should be arrested at the earliest on multiple criminal charges including False Death Certificate to suppress ADRs of injection Rokfos manufactured by Cipla Limited.
- 18. Ranbaxy manufacturing malpractice VS Cipla Limited multiple criminal malpractices is brought out as a Poster (Evidence document page 96) on Twitter as journalists investigating Cipla Drug Trial were silenced. I have emails & WhatsApp chats from six of them. Ranbaxy had pleaded Guilty & paid US \$ 500 Million.
- 19. Cipla malpractices were criminal in every aspect and penalty should be value of Promoters' Shares in the company. Besides imprisonment for Life for those responsible including the Directors of Cipla Limited.

The Government of India has to recover ill-gotten wealth by playing with lives of the citizens over the years from Chairman, Yusuf Hamied hoodwinking the world with false claims in his "Quotes" down the line to Cipla Drugs Safety.

20.I once again request for the following immediately:

- a) Suspension of Dr.P.B.N.Prasad for his collusion in "Fake Joint Investigation".
- b) Suspension of Mr.Somnath Basu (Assistant Drugs Controller of India) for taking the aggrieved complainant for a ride for four years using Fake Investigation Report.
- c) Suspension of Dr.V.G.Somani and Mr.Rajesh Bhushan for failing to act on Fake Investigation Report as also Cabinet Secretariat Order to investigate Cipla Drug Trial.
- d) Notices be sent to Cipla Directors restraining their participation in Cipla activities.

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e) Notices should be sent by Cipla Company Secretary to all stakeholders

informing them of criminal complaints under Drugs & Cosmetics Act, 1940

and Rules thereof as well as under the IPC for culpable homicide.

f) Cipla licence should be suspended.

• Health is wealth. We have to save the citizens from this dangerous

network; Pharma-Doctors-CDSCO-FDA playing with lives of innocents

followed with bribing and corrupting authorities.

• Central Bureau of Investigation has undertaken an historic step to save

citizens from consuming sub-standard, adulterated drugs.

• In addition to CDSCO, FDA authorities have to be overhauled as is evident in

Cipla Drug Trial episode.

Thanking you for your co-operation,

Yours Sincerely,

Umeshchandra Barkur

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