May 7, 2018

To,

Shri Narendra Modi,
Prime Minister,
Prime Minister's Office
South Block, Raisina Hill
New Delhi-110011
Phone No: +91-11-23012312

**Sub: Petition requesting for appointment of a Commission of Inquiry under the Commissions of Inquiry Act, 1952 to investigate the illegal approval of drugs by the Central Drug Standards Control Organization**

Dear Mr. Prime Minister,

Sir, by way of introduction, I am an Overseas Citizen of India (OCI) and was the Whistleblower in the Ranbaxy case. In 2016, I filed a Public Interest Litigation (PIL) before the Supreme Court requesting action on certain issues pertaining to the sorry state of drug regulation in India. While the court was disinclined to interfere in the matter, it granted me liberty to petition the government.

I am petitioning you today seeking your intervention with regard to the failure of the Ministry of Health to investigate the manner in which the Drug Controller General of India (DCGI) granted approval for medicines for treating certain diseases despite an absence of any clinical data to justify these approvals. Previous administrations had made a written commitment to Parliament to investigate the manner in which these drugs were approved for sale in India but never did so. To make matters worse, these questionable drugs continue to be sold in India putting patients at serious risk.

More specifically, I would like to direct your attention to comments made in the 59th and 66th Reports of the Hon'ble Parliamentary Standing Committee on Health & Family Welfare. The Hon'ble Committee had identified four questionable approvals granted by the DCGI.

**Buclizine:** This drug is an antihistamine that was first approved to treat nausea and vomiting. In 2006, the DCGI mysteriously approved the drug for an additional indication – appetite stimulation in children. As noted by the Hon'ble Standing Committee in its 59th report, there is absolutely no clinical data to justify the use of the drug for appetite stimulation. The Hon'ble Committee also pointed that the drug was discontinued in Brazil, South Korea, Malaysia etc. My research indicates that the drug has been discontinued even in the United States. In its 59th report, the Hon'ble Standing Committee stated that "responsibility needs to be fixed for unlawfully approving Buclizine, a drug of hardly any consequence to public health in India, more so since it is being administered to babies/children."

In its Action Taken Report, the Ministry had promised the Committee that the "DCGI will constitute an enquiry committee to investigate into the issue". In its 66th Report, tabled in 2013, the Hon'ble Standing Committee once again reviewed the status of the drug and harshly reprimanded the Ministry. The Committee took "serious umbrage over these more than apparent dilatory tactics being adopted by the Ministry to somehow delay action against the wrongdoers." and reiterated "its Recommendation that responsibility be fixed in this case without any further loss of time and the approvals granted be reviewed in the light of latest scientific evidence regulatory states in developed countries, particularly in Belgium, the country of its origin…."

Till date, the Ministry of Health has not moved a finger to either order an inquiry into the manner in which Buclizine was approved or to ban the prescription of this drug for the additional indication. This despite the fact that in 2016, the Drug Technical Advisory Board (DTAB) made a recommendation to the Ministry of Health to use its powers under Section 26A of the Drugs & Cosmetics Act, 1940 to ban the use of Buclizine as an appetite stimulant.

**Deanxit:** This drug is a fixed dose combination (FDC) of Flupentixol and Melitracen, which is approved in India to treat depression and anxiety. As pointed out by the Hon'ble Standing Committee in its 59th report, the manufacturers of this drug were focussed on selling this drug only in developing countries like India, Bangladesh, Pakistan and not in developed countries like the United States, Canada, Japan or Australia. Suspiciously, the Ministry lost the approval file of the drug and was unable to provide the necessary documents to the Committee to jusitify its approval. In its subsequent 66th report, tabled in 2013, the Hon'ble Committee after reviewing the Ministry's Action Taken Report on Deanxit commented that "the case of Deanxit conveys a strong whiff or collusion and cover up". The Hon'ble Committee concluded by saying that "In the opinion of the Committee, it is an open and shut case that needs immediate action, not a promise of prolonged fruitless deliberation designed to delay action. Why should the people of India consume a questionable drug approved in a questionable manner even for a day longer…".

Since 2013, the Ministry of Health has banned the drug twice using its powers under Section 26A and on both occasions, the Karnataka High Court quashed the ministry's orders. In my opinion, in both instances, the government counsel in the Karnataka High Court provided ineffective legal representation and the Ministry failed to appeal the court orders. As a result, the drug itself continues to be sold in India. The Ministry of Health is yet to conduct an inquiry into the manner in which the drug was approved by the DCGI to begin with.

**Letrozole:** This drug was originally approved in 1997 in the United States for the purpose of treating breast cancer in women. Since 2003, there have been allegations that some Indian companies were marketing generic versions of the drug for the treatment of infertility in women. In 2007, the Drug Controller General of India (DCGI) approved the drug for the additional indication of treating infertility. The DCGI's decision provoked outrage amongst the Indian medical community for two reasons. Firstly, scientific studies had suggested that Letrozole may cause deformities in newborns. Second, that none of the developed countries like the United States had granted approval for this additional indication. While the Ministry eventually exercised its power under Section 26A to ban the drug for this additional indication, via a gazette notification dated 2.02.2011, it came under scathing criticism from the Hon'ble Standing Committee in its 59th report.

Listing a series of lapses in the approval process, the Hon'ble Standing Committee had remarked that there was a "serious lapse on the part of the CDSCO" and that it expected the DCGI to "take action against those CDSCO functionaries who colluded with private interests and got the drug approved in violation of law". In response to the Committee's scathing criticism, the Ministry constituted a three-member committee to look into the issue. This committee recommended that the government institute an inquiry committee to investigate into the issue. The Ministry made a written commitment to the Hon'ble Standing Committee that the DCGI would be ordered to setup an inquiry committee. The Hon'ble Committee expressed its strong disapproval with the Ministry's handling of the issue, remarking in its subsequent 66th report that it was "deeply" perturbed by the lack of lack of action on behalf of the Ministry "in this very open and shut case of impropriety and criminal lapse though more than six months have elapsed" and reiterated its demand for "immediate and exemplary action against officials of CDSCO who colluded with private interest and got the drug approved in violation of laws". Far from instituting an inquiry into the matter, the Ministry of Health in an unprecedented move issued an order on 17.02.2017 rescinding its earlier order dated 2.02.2011 to ban the drug for infertility treatment and allowed the drug to be marketed once again for the treatment of infertility. The ministry claims that the DTAB, after reviewing an ICMR study, recommended the use of the drug for the treatment of infertility. This drug is however still not approved in jurisdictions like the United States for the treatment of infertility. Why then is the Ministry of Health expressing such an uncharateristic haste, going as far as to rescind its own orders?

**The fixed dose combination (FDC) of Aceclofenac + Drotaverine:** The Hon'ble Standing Committee reserved its most critical comments for the manner in which the CDSCO approved this particular FDC. As per the Hon'ble Committee, this drug is not approved anywhere in North America, Europe of Australasia and commented that the manner in which the drug was approved for clinical trials was "outrageous" and that there was "sufficient evidence on record to conclude that there is conclusive nexus between drug manufacturers, some functionaries of CDSCO and some medical experts". Once again, the Ministry promised an inquiry which never took place. In its 66th Report, the Hon'ble Standing Committee remarked that it was "aghast to note the paralytic inertia gripping the Ministry which is preventing it from taking action against guilty official(s) of CDSCO and others involved in proven cases of delinquency and illegality".

**The approval of thousands of illegal FDCs:** As your office must be aware, the Indian market is flooded with thousands of illegal and irrational fixed dose combinations (FDCs). These FDCs have been the subject of much concern amongst the medical community. Only two years ago, in March 2016, the Ministry of Health had to step in order to ban 344 FDCs under Section 26A, thousands more still remain on the market. Till date, the Ministry of Health has not provided an official explanation as to the manner in which these FDCs were approved to be marketed to patients in the first place. There have only been whispers and rumors about different state authorities granting illegal approvals in contravention of the Drugs & Cosmetics Act, 1940. The fact that these drugs keep making their way into the market is indicative of a larger problem with India's drug regulatory framework.

**Prayer**

The cases described herein are merely symptomatic of a much larger problem that extends to hundreds of illegal and irrational fixed dose combinations. When written commitments to Parliament to conduct investigations are not being honored and when the government regularly loses legal proceedings before the courts, it is clear that the problem is systemic and deep-rooted and can be fixed only by the intervention of the PMO.

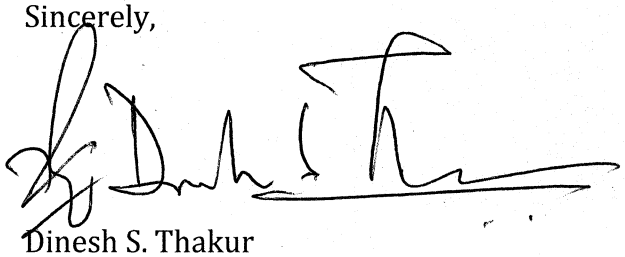
In specific, I request your intervention on two counts:

(i) Direct the Minister of Health to appoint a Commission of Inquiry under the Commission of Inquiry Act, 1952 to investigate the manner in which the DCGI and State Authorities have granted so many illegal approvals. The Commission should be headed by a judge or public figures of integrity and repute;

(ii) Direct Niti Ayog to propose a new law to replace the Drugs & Cosmetics Act, 1940 as the present framework dates back to the colonial era of 1940s and is ineffective to securely and transparently support your vision of Ayushman Bharat. The biggest problem today with the regulatory process is that it vests tremendous discretionary powers in the hands of the DCGI, with no specific binding rules and procedures on how drug approvals are to be granted. After the 59th Report of the Hon'ble Standing Committee, the Ministry has been creating new committees with a dizzying speed. The range of committees include New Drug Advisory Committees (NDACs), Subject Expert Committee (SECs), Apex Committees, Technical Committees etc. These committees are being setup under various office memorandum and circulars and the legal framework regulating these committees is not clear. Surely, such an important component of India's drug regulatory framework cannot be handled in such an arbitrary and capricious manner. An additional issue is the fact that the regulators lack the appropriate tools to penalize pharmaceutical companies for violating the law. For example, if a company sells FDCs without proper approvals, fairness and equity would demand that the company be forced to disgorge the profits that it made by selling the drug. Under the current law, this is not possible.

I thank you for your attention to this pressing public health issue. I hope suitable action can be taken with your intervention in this regard failing which I will be have to approach the Supreme Court once again, this time with evidence that I have petitioned the government to no avail.

Sincerely,



Dinesh S. Thakur

dinesh.thakur@gmail.com

**ITEM NO.13 COURT NO.1 SECTION PIL(W)**

**S U P R E M E C O U R T O F I N D I A**
**RECORD OF PROCEEDINGS**

**Writ Petition(s)(Civil) No(s). 137/2016**

**DINESH S. THAKUR Petitioner(s)**

**VERSUS**

**UNION OF INDIA Respondent(s)**
**(With I.A. No. 1 (Appln. For permission to file addl. documents)**

**WITH**
**W.P.(C) No. 140/2016**
**(With appln.(s) for permission to file additional documents and Office Report)**

**Date : 11/03/2016 These petitions were called on for hearing today.**

**CORAM :**
**HON'BLE THE CHIEF JUSTICE**
**HON'BLE MR. JUSTICE UDAY UMESH LALIT**

**For Petitioner(s) Mr. Raju Ramachandran, Sr. Adv.**
**Ms. Anitha Shenoy,Adv.**
**Mr. Prashant Reddy, Adv.**
**MS. Maitreyee Mishra, Adv.**

**For Respondent(s)**

**UPON hearing the counsel the Court made the following**
**O R D E R**

**Mr. Raju Ramachandran, learnd senior counsel for the petitioner seeks leave to withdraw these petitions reserving liberty for the petitioner to seek such redress as may be otherwise open to him in law in appropriate proceedings before an appropriate Forum. The writ petitions are dismissed as withdrawn with liberty prayed for.**

**(Shashi Sareen) (Veena Khera)**
**AR-cum-PS Court Master**