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Poisoned Pills: The Human Cost of Dangerous Foreign Drugs

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Chairman Scott, Ranking Member Gillibrand and distinguished members of the Committee, I thank you for convening this hearing on a topic which impacts each and every one of us and for giving me the opportunity to appear before you today. My name is Dinesh Thakur, I am here to offer my testimony on the effectiveness of regulatory structure, its function and its impact on our drug supply and quality.

I am a Chemical Engineer by training. I obtained my Bachelor's degree from Osmania University in India in 1990 and my Master's degree from the University of New Hampshire in 1992. I have graduate training in Computer Engineering from Syracuse University. I was trained in drug development and manufacturing at Bristol-Myers Squibb Company for ten years in the US. In 2003, I had an opportunity to go and work in India at one of the largest generic drug manufacturing companies that sold in the US market. During my tenure at Ranbaxy Laboratories, I discovered that the company was selling adulterated drugs to patients in the United States. I reported this to the US FDA in 2005 and worked closely with them for eight years assisting in their investigation and prosecution of this company. In May 2013, Ranbaxy pled guilty to seven counts of criminal felony and agreed to pay penalties of $500 million to the US DOJ[1]. I was the whistleblower in that case. Since 2013, I have invested much of time in advocating for drug regulatory reform in India; a country from which the United States buys substantial volumes of medicine. Most recently, I co-authored a book, The Truth Pill – The Myth of Drug Regulation in India in 2022[2].

The Committee has heard testimony from prior witnesses[3] about the importance of generic drugs to our country, especially to seniors aged 65 and older who take at least one prescription medication, and more than

[1] https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false
[2] https://www.amazon.in/TRUTH-PILL-Dinesh-Singh-Thakur/dp/9392099177/ref=sr_1_1?crid=10GD9CZ8HBPPB&keywords=The+Truth+Pill&qid=1706805750&sprefix=the+truth+pill%2Caps%2C228&sr=8-1
[3] https://www.brookings.edu/articles/marta-wosinskas-testimony-before-the-senate-special-committee-on-aging/

half take four or more prescriptions on a regular basis. It is important to reiterate that over 90% of retail or mail pharmacy prescriptions dispensed in the United States are generic drugs.

Recent reporting [4,5,6] in the news documents how little has changed in the manufacturing facilities located overseas in terms of complying with our standards for drug manufacture Code of Federal Regulations CFR 211, commonly known as Good Manufacturing Practices. Inspectors from the US FDA document in their inspection reports, consistent and repeated violations of these standards which I saw during my employment over two decades earlier in India. I have reviewed the recent GAO reports documenting challenges with the Foreign Inspections Program at the US FDA and their recommendations to improve it. While I am sympathetic to the hurdles faced by the US FDA in implementing this program (since inspecting these manufacturing facilities thousands of miles away from the United States in a foreign country and a different culture is very hard); I am also dismayed at how little has changed. Many of the issues raised by the US FDA in recent warning letters to Indian pharmaceutical manufacturing companies are substantially similar to the issues raised in the case against Ranbaxy. Little seems to have changed since I first turned whistleblower 20 years ago and that should worry us.

For example, a Warning Letter issued to the manufacturer of medicine used to treat Cancer[7] based in India in November 2023[8] makes the following observation: "*your firm continued this egregious pattern of altering and recording defect counts*". This is a recurring observation in many of the findings of the US FDA inspectors when inspecting Indian manufacturing facilities. Fifteen years ago, in 2009, the US FDA had made a similar observation in a Warning Letter to Ranbaxy[9]: "*Your investigation into an out-of-specification assay result discarded the initial result…. You replaced the out-of-specification result with (another) result …*". This fraudulent behavior seems to repeat consistently in these foreign manufacturing facilities which supply medicines to patients in the US. Two years ago, we saw the true impact of such violations of our GMP code resulting in real harm to patients with contaminated eye drops[10]. Whatever regulatory actions the US FDA has taken between 2009 and 2024 do not seem to have their intended deterrent effect, thereby subjecting patients in the US to grossly substandard medicines.

[4] https://www.propublica.org/article/fda-generic-drug-equivalents-tacrolimus
[5] https://www.propublica.org/article/fda-generic-drug-testing
[6] https://www.pbs.org/video/generic-drugs-1768158997/
[7] https://www.nbcnews.com/specials/cisplatin-shortage-cancer-drug-chemotherapy-us/index.html
[8] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/intas-pharmaceuticals-limited-662868-11212023
[9] https://dineshthakur.com/wp-content/uploads/2013/05/2009.12.21-Warning-Letter.pdf
[10] https://www.bloomberg.com/news/features/2023-07-17/eyedrop-recall-2023-and-infections-were-result-of-lack-of-fda-regulation

The solution, in my opinion, is two-fold. The first is to strengthen the Foreign Inspection Programs on the lines suggested by the GAO in its recent report. The second is to start rethinking the American approach to foreign regulatory inspections. Let me expand on both these suggestions.

1. Strengthening the Foreign Inspection Program

There are two aspects of the Foreign Inspections Program that merit attention by this Committee. Its design and its staffing. In 2022, The Government Accountability Office[11], in its report to the US Congress on FDA's Foreign Inspection Program documented that the US FDA had not finalized the design of a pilot program as of September 2021 despite the US Congress' directive that the agency use $3.5 million of its fiscal 2021 appropriation to establish pilot programs to increase the agency's use of unannounced inspections and short-notice foreign inspections. The agency had suspended a similar program in 2015 in the aftermath of Ranbaxy pleading guilty and entering into a consent decree. This delay is concerning. In fact, in its report to the Congress in January 2025[12], the GAO found that the US FDA has not met its domestic and foreign inspection targets since fiscal year 2018. In July 2025, the US FDA informed the GAO that it was unable to provide an update on the recommendations made by the GAO in 2022 to address staffing at its foreign offices. The agency has not identified an appropriate annual target and communicated this information to Congress, as the GAO recommended in January 2015[13].

As far as challenges to staffing and retention are concerned, in my considered opinion, a model that assigns and stations inspectors to foreign offices is better than the alternative. The Covid pandemic showed us how ineffective the inspections program was when international travel was curtailed. The agency had offices in India as a pilot which were successful in uncovering fraud at manufacturing facilities in India in a substantial manner. As long as our drug supply is dependent on manufacturing facilities abroad, it is imperative that we have a reliable and sustained cadre of investigators who are able to respond quickly to enforcing our regulations and ensure a safe and effective drug supply for patients in the US. Congressional support to alleviate these concerns is sorely needed so that the US FDA can build and retain a trained and qualified investigator cadre in its foreign offices.

[11] https://www.gao.gov/products/gao-22-103611
[12] https://www.gao.gov/assets/gao-25-107571.pdf
[13] https://www.gao.gov/products/gao-15-183

In the absence of a fully staffed and functional inspectorate for conducting foreign inspections, it has been suggested that we can rely on other national regulators[14] (e.g., the MHRA, the EMA) who similarly source a large volumes of medicines for their respective countries and share the burden of inspections and compliance among such a group. While this is a good idea in principle, it does not adequately address the concerns of our drug supply for a variety of reasons. Two such reasons are as follows:

- Of the 60 inspection reports made publicly available by the EMA for Indian manufacturing facilities between 2009 and 2024, only 16 were registered with the US FDA. And none of these inspection reports cite violations for data integrity as has been consistently documented in Form 483 by US inspectors.

- Inspections often are focused on products made for a specific market in addition to reviewing the overall Quality Management Systems. If a particular formulation/strength is not sold in the US market, its manufacturing process is often not the subject of inspection by the US FDA inspectors. Likewise, a formulation/strength sold only in the US may not be the subject of an inspection by a PIC/s partner.

2. Rethinking the American approach towards regulating foreign manufacturing facilities

It has been over two decades since I turned a whistleblower in the Ranbaxy case, at which time it became clear that the US FDA's foreign inspection program had serious shortcomings - the fact that the GAO raised red flags about the program in 2022 and in 2025 is very worrisome. The solutions proposed by the GAO are going to take time to implement and even when implemented fully, there is no real guarantee of outcomes. It is high time to accept the fact that the American regulatory approach, which is largely an honors-based system toward foreign pharmaceutical facilities with very different corporate cultures is fundamentally flawed. In essence we are trying to force a square peg into a round hole. It is time to think out of the box.

With this as a backdrop, I have four recommendations for the Committee to consider:

A. **Criminal prosecution to introduce a deterrent effect:** First, is to investigate the US FDA's prosecution practices when its drug inspectors discover brazen criminality during foreign inspections. In the last two decades, in addition to Ranbaxy, I know of only one Indian pharmaceutical company being fined

[14] https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs4751/files/downloads/WorkingPapers/GW%20Reg%20Studies%20-%20Improving-Cooperation-FDA-EU%20-%20RLutter%20&%20DZorn.pdf

$50 million[15,16] for destroying critical quality related data - such data is at the heart of the GMP model of regulation adopted by the US to monitor quality manufacturing practices in the pharmaceutical industry. The US FDA has documented this behavior in multiple inspection findings (Form 483s and Warning Letters) indicating a frightening amount of data fraud. Destroying such data is the equivalent of a financial services company shredding all its paperwork related to its accounting practices. It always means there is a coverup.

Under Sarbanes-Oxley, the management of such a firm would be criminally prosecuted. There have been multiple such instances[17,18,19] reported in the media of mind-boggling data fraud that cross the threshold of criminality in foreign drug manufacturing facilities. In one instance, the media reported that an Indian manufacturing facility had a whole quality testing lab[20] that was off the books; where quality data was being cooked up. In another instance, when massive data fraud at a Clinical Research Organization (CRO)[20,21] in India (these generate data that the pharmaceutical manufacturers require for regulatory approvals) was revealed by a whistleblower (who was later jailed by the local government), the Europeans cancelled[22,23,24] the marketing authorization of over 700 generic drugs which were approved on the basis of data generated at that particular facility. The US FDA, to the best of my knowledge, took no action despite sending its inspectors to the facility[25]; only one Indian manufacturer withdrew its drug from the US market because the whistleblower had specifically alleged that the laboratory in question had fabricated data used in its approval. There are many such examples[26,27,28,29].

Congressional oversight demands that the US FDA ensure there are no shortage of drugs in the country. To address this mandate, the agency is flexible with its rules, especially for medically necessary drugs where the manufacturer has a history of violating our standards and also holds a

[15] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/indian-cancer-drug-manufacturer-pay-50-million-concealing-and-destroying-records-advance-fda
[16] https://www.bloomberg.com/news/features/2019-02-01/the-4-3-billion-deal-that-blew-up-over-shoddy-drug-production
[17] https://www.bloomberg.com/news/articles/2019-07-16/drugmaker-shredded-quality-documents-ahead-of-fda-inspection
[18] https://www.bloomberg.com/news/features/2019-01-31/culture-of-bending-rules-in-india-challenges-u-s-drug-agency
[19] https://www.bloomberg.com/news/articles/2023-05-31/us-finds-contaminated-drugs-further-lapses-in-india-pharma-factories-post-covid
[20] https://www.fiercepharma.com/regulatory/dr-reddy-s-blasted-warning-letter-for-hiding-existence-of-testing-lab-from-fda
[21] https://www.science.org/content/blog-post/india-s-gvk-accused-systematic-fraud
[22] https://www.fiercebiotech.com/r-d/india-s-gvk-biosciences-gets-harsh-accusations-from-ema-on-fake-generic-trials
[23] https://www.chemistryworld.com/news/eu-regulator-calls-for-generic-drug-suspensions-/8216.article
[24] https://www.raps.org/News-and-Articles/News-Articles/2015/1/EMA-Recommends-Suspending-Drugs-over-GVK-Data-Inte
[25] https://www.outsourcing-pharma.com/Article/2015/08/31/Europe-bans-drugs-tested-by-GVK-FDA-monitors-but-keeps-allowing-sales
[26] https://www.biospace.com/article/indian-cro-quality-questioned-as-quest-life-sciences-warned-by-who-for-hiv-trial-fraud-/
[27] https://www.fiercepharma.com/pharma-asia/india-s-alkem-to-respond-to-european-data-fraud-probe
[28] https://www.outsourcing-pharma.com/Article/2016/04/25/WHO-says-Semler-Research-manipulated-data-and-warns-repeat-studies-may-needed
[29] https://www.statnews.com/pharmalot/2016/04/25/fda-warn-clinical-trials-run-indian-company/

large market share. Propublica reported recently[30] that "*A secretive group inside the FDA exempted the medications from import bans, ostensibly to prevent drug shortages. With each pass, the agency dismissed warnings from its own inspectors about* dangerous breaches in drug quality on factory floors." Its analysis identified more than 600 complaints in the FDA's files about the exempted drugs at three factories, each flagging concerns in the months or years after the medications were excluded from import bans. The reports cite about 70 hospitalizations and nine deaths.

This undermines the deterrence of holding wrongdoers to account, and "enables" manufacturers to factor in cost of compliance if caught into the cost of doing business. Sadly, this approach over the last decade has provided a permission structure to the generic companies to operate with impunity.

Manufacturing quality issues are the leading cause of drug shortages; 56% in 2011[31], 62% between 2013 and 2017[32] and 46% in 2022[33].

To be clear, I am not advocating for a witch-hunt; not every GMP violation warrants a criminal prosecution; but brazen acts of data fabrication or destruction of records (of which they are plentiful examples) most certainly do in a US court. Perhaps foreign pharmaceutical companies would take the US FDA foreign inspection program more seriously if they knew it had teeth. Compliance data from over the last decade shows that it does not.

The European Union employs a model where a Qualified Person (QPPV)[34] needs to be the resident of the EU and be accountable for drug safety and is therefore amenable to prosecution if gross violations of EU laws are discovered. The Committee should consider such a model where an officer of the foreign manufacturing company needs to be a resident of the US and is therefore accountable for the quality of our drug supply and gross violations of the US regulatory code. I would request the Committee to summon data on criminal prosecutions from the US FDA specifically in relation to its foreign inspection program and make it public so that activists like me can review it for accountability.

[30] https://www.propublica.org/article/fda-drug-safety-foreign-manufacturers-takeaways
[31] https://pubmed.ncbi.nlm.nih.gov/23337525/
[32] https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions
[33] https://web.archive.org/web/20240314230016/https:/accessiblemeds.org/sites/default/files/2024-02/access-2024-Jacqueline-Corrigan-Curay-presentation.pdf
[34] https://www.gov.uk/guidance/guidance-on-qualified-person-responsible-for-pharmacovigilance-qppv-including-pharmacovigilance-system-master-files-psmf

B. **Mandatory end-user testing:** Second, is to consider a legal mandate, as contemplated by the Department of Defense[35], to put in place a mandatory testing program for all drugs entering the United States from countries where past inspections have demonstrated a consistent pattern of data fraud and GMP violations. Such testing can be limited to random statistical sampling or potentially risky drugs with known manufacturing issues, such as injectables. Such testing should be conducted by the purchaser, be it the Pentagon or the Pharmacy Benefit Managers. Inclusion in the formulary should ensure that the batch is of consistent quality and bioequivalent as approved by the US FDA through the ANDA process.

Yes, this will cost money; but there is simply no alternative at this stage when public confidence in the foreign inspection program appears to be at an all-time low - the data generated by these testing programs will provide us with an independent source of data to assess how effective the US FDA's foreign inspections program is. At the moment, we have no independent source of data to continue to believe that all generic formulations can be interchangeably prescribed; rather we have enough evidence to the contrary[36,37,38,39,40]. Patients in the US cannot wait another decade for the US FDA to fix its foreign inspection program. Such testing can end when we restore the confidence that the Quality Assurance process works as designed and envisioned in CFR 211.

However, creating different grades of generic drugs, by labeling them as “Red”, “Green” or “Yellow” in my opinion is counterproductive. For the last five decades, healthcare providers in the United States have relied on the assurance that once the US FDA approves a generic formulation, it can be used interchangeably with the innovator drug. Creating various grades of quality undermines the confidence in our regulator; the consequence of this approach will be to create confusion among patients who lack the power to select an appropriate substitute at the pharmacy because the formulary that decides which generic equivalents are available for them is not in their control. It’s the PBMs that decide which formulations are available.

Likewise, including Country of Origin on the label is a good idea in principle from the point of view of transparency, but it does nothing to empower the patient whose choices are dictated by the PBM.

[35] https://www.bloomberg.com/news/articles/2023-06-07/drug-safety-fears-spur-pentagon-plan-to-test-widely-used-meds
[36] https://www.statnews.com/2024/01/25/chemotherapy-asparaginase-cancer-drug-investigation/
[37] https://www.bloomberg.com/news/features/2023-07-17/eyedrop-recall-2023-and-infections-were-result-of-lack-of-fda-regulation?srnd=storythread-RYQRPADWX2PS01
[38] https://www.bloomberg.com/news/features/2023-08-01/abortion-pill-provider-buys-from-indian-manufacturer-with-bad-quality-record
[39] https://www.bloomberg.com/news/articles/2018-09-17/prices-soar-for-hospital-drugs-after-shortages-hit-study-finds
[40] https://www.bloomberg.com/news/articles/2023-06-15/quality-issues-grow-at-generic-drugmaker-causing-chemo-scarcity

C. **Incentivize manufacturers to make investments in quality management systems**:

Empirical data from the market confirms price pressure on the generic drug manufacturers from concentrated purchasing power of the Pharmacy Benefit Managers (PBMs) and Group Purchasing Organizations (GPOs). While most of the attention is focused on their opacity and coercive behavior on payers and providers, a less articulated issue is their impact on manufacturers. A 2023 study of the generic pharmaceutical industry[41] found that many top-selling generics cost pharmacies less than $1.50 for a 30-day supply. Another 2024 analysis[42] found year-over-year deflation in acquisition costs for generic solid oral dosage formulations as high as 25%. Analysis by United States Pharmacopeia[43] of drug shortages show that over 50% of sterile injectables and 66% of solid oral dosage forms in shortage were invoiced at the pharmacy for less than $5 and $3 respectively in 2024.

Leveraging threats of exclusion, PBMs demand higher and higher rebates from drug manufacturers in exchange for including their products in their restrictive formularies. They exert undue influence of Monopsony Power over purchasing decisions by conditioning preferential treatment on manufacturer rebates. They extract fees from drug manufacturers as a part of commercial rebate negotiations. In fact, the American Society of Hematology has strongly protested[44] the practice of switching patients to change medications for non-clinical reasons primarily driven by PBMs decisions to remove a particular drug from their formulary. Academic data from the USC Schaeffer Center showed that intense PBM and purchasing organization price compression drove generic injectable profits down so far that U.S. companies abandoned production in the US, leaving the entire U.S. healthcare system vulnerable to a single overseas factory shutting down[45].

Such coercive practices result in real harm to patients. For example, to what extent did extractive pricing contribute to the bankruptcy of Akorn Pharmaceuticals[46], which was already facing regulatory action for cGMP violations from the US FDA and which resulted in an acute shortage of albuterol sulfate inhalation solution for pediatric patients in the aftermath of the Covid-19 pandemic is not known because the operations of these purchasing organizations are not transparent.

[41] https://apicenter.org/wp-content/uploads/2023/07/US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf
[42] https://www.46brooklyn.com/news/46brooklyn-2024-midyear-drug-pricing-report
[43] https://www.usp.org/supply-chain/drug-shortages
[44] https://www.hematology.org/advocacy/testimony-and-correspondence/ash-comments-on-the-ftc-rfi-on-business-practices-of-pbms
[45] https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/
[46] https://www.contemporarypediatrics.com/view/what-you-need-to-know-about-the-albuterol-shortages

We cannot expect to sustain such pressure to cut costs for life saving medicine and at the same time expect supply chain resilience and uncompromising quality. Something has to give; and we see that it is compliance with our standards and therefore the quality of medicine for our patients.

This unique characteristics of demand planning, an unpredictable market, a fragmented supply chain for raw materials and rigorous regulatory compliance all create challenges for a business that is under constant cost pressure. Onshoring the manufacturing of these mature generic drugs, even with the introduction of new technology and process (e.g., continuous process manufacturing) will not alleviate these challenges. Only those products that have a high entry barrier (e.g., sterile injectables) are able to sustain reasonable price elasticity because of a large market share (e.g., carboplatin). IV fluids have been notoriously prone to drug shortages, but they are largely manufactured in the US. Ascribing the reason for shortages to overseas manufacturing and non-compliance alone is incorrect.

A policy recommendation on this issue is premature because no substantive research exists due to the opacity of the extractive nature of the PBMs and the GPOs. The Committee should consider asking the GAO or another appropriate organization to study this issue and make this data available for independent researchers as well.

D. **A bilateral solution:** Finally, there is simply no avoiding the politics of Indo-American diplomacy and its effect on the US FDA's approach to the Indian pharmaceutical industry. The Government of India is very protective of its pharmaceutical industry and bats for the industry on the international stage. When the Europeans cancelled the approvals of 700 drugs post the scandal at the aforementioned CRO in 2016, the Indian government responded by cancelling long pending trade talks with the European Union[47,48]. When the US DOJ prosecuted Ranbaxy in 2013, the highest levels of the Indian government responded by claiming that "vested interests"[49] were acting against the Indian pharmaceutical industry. I've personally been threatened by the Indian drug regulator[50] for criticizing its actions. I suspect the US FDA is alive to these pressures and is treading a fine line. The question for you is whether the health of US citizens should be held hostage to the domestic politics of a foreign country? It may be time to dramatically escalate this issue to a diplomatic level and negotiate a

[47] https://www.fiercepharma.com/regulatory/india-defers-eu-trade-talks-as-ban-on-gvk-tested-drugs-rankles
[48] https://www.outsourcing-pharma.com/Article/2015/08/06/Indian-government-suspends-EU-trade-talks-over-spat-with-GVK-Biosciences
[49] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-sees-us-lobbies-behind-fda-ban-on-ranbaxy-drugs/articleshow/3600276.cms
[50] https://x.com/d_s_thakur/status/1581846234490208256?s=20

bilateral diplomatic agreement with the Indian government on the issue of drug regulation to force India to amend its domestic laws to improve the quality of domestic drug regulation - a convergence in regulatory standards in both countries and better domestic inspections by Indian drug inspectors of their own manufacturing facilities will reduce the burden on the US FDA to conduct inspections half the world away. The US spends billions of dollars buying drugs from India every year. As a customer and a strategic ally, the United States is in a strong position to demand that it receive quality drugs from Indian manufacturing facilities.

As a proud American of Indian origin, who has grown up and studied in India, I would like to see a strong and mutually beneficial relationship between India and the United States but this should be a relationship based on mutual respect, not one where the health of US citizens is threatened at the altar of politics.