United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

April 1, 2025

The Honorable Martin A. Makary, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Makary:

As members of the U.S. Senate Special Committee on Aging, we are committed to ensuring our seniors receive safe and high-quality medicines. The Food and Drug Administration (FDA) is widely considered to be the global standard for drug quality, however due to discrepancies with domestic and foreign inspections there are concerns with quality disparities between domestic and foreign drugs. We are especially concerned about the quality of drugs coming from foreign countries like China and India. We write today to get answers on what steps the FDA is taking to establish parity between domestic and foreign drug quality and how your agency is actively ensuring the medicines our seniors rely on are safe and of the highest quality.

More than 50% of drug manufacturers supplying the U.S. market are producing their products overseas.[1] Additionally, FDA estimates approximately 80% of Active Pharmaceutical Ingredients (API) are manufactured overseas.[2] Our nation's current reliance on foreign-made drugs and pharmaceutical ingredients necessitates thorough quality assurance processes and routine inspections to ensure that American standards are being met for all products entering our country. Unfortunately, this is not the case for a number of products made by Chinese and Indian manufacturers. Drug and API manufacturers in China and India have received the most FDA warning letters for violations which include, but are not limited to, carcinogens in medicines, destroying or falsifying data, and non-sterile manufacturing.[3] Incidents involving poor drug quality have resulted in injury and even death, such as the three tragic deaths that occurred due to contaminated eye drops from an Indian manufacturer in 2023.[4]

[1] https://www.gao.gov/products/gao-24-107359
[2] https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000380.asp
[3] https://energycommerce.house.gov/posts/e-and-c-republicans-press-fda-over-inadequate-inspection-of-drug-manufacturing-in-india-and-china
[4] https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-eye-drops-several-major-brands-due-risk-eye

Violations of this nature present an unacceptable risk to the health and safety of Americans, especially our seniors who disproportionately rely on pharmaceutical products, including prescription and generic drugs, but also to U.S. national security. Any disruption to the supply chain or international contamination of medicines could seriously harm a significant number of Americans.

The previous administration took no significant action to mitigate the potential threats posed by foreign drug and API manufacturers. It is essential that the status quo of inaction and complacency does not continue. We urge the FDA to use its authority to ensure that foreign drugs that are FDA-approved meet and maintain the same quality standards of domestic drugs, and take action that strengthens the FDA's ability to hold foreign manufacturers to the same level of scrutiny that it holds domestic manufacturers to with unannounced inspections.

Therefore, we ask that FDA answer the following questions:

1. What is the current status of FDA's efforts to conduct unannounced foreign inspections and utilize independent interpreters? Does FDA have any data on the efficacy of these programs?
2. What plans does FDA have to restore foreign inspections to, at minimum, pre-pandemic levels?
3. In the case of the cisplatin shortage, did the FDA under the Biden administration make any attempts to prioritize importing drugs from Trade Agreement Act (TAA) compliant countries?
    a. If not, what role did quality play in FDA's consideration to import this unapproved drug?
4. Are potential shortages considered when FDA makes an Official Action Indicated (OAI) following issues discovered during the inspection process?
5. Are there any differences in the level of testing scrutiny foreign drugs are subjected to compared to domestic drugs?
6. On average, how often does the FDA do unannounced inspections in the U.S. and how often does the FDA do unannounced inspections in India and China?
7. How much advance notice does FDA traditionally provide foreign facilities before inspectors arrive?
8. How many inspectors on staff does the FDA have for Chinese facilities, Indian facilities, and American facilities?
9. What auditing and analyses does the FDA conduct of foreign inspectors with respect to their rates of issuing NAI, VAI, or OAI? If an irregularity is identified, what steps are taken?
10. What are the current staffing levels at the FDA's China, India, Latin America, and Belgium offices? If there are vacancies, how does FDA plan to fill them?
11. Do FDA user fees cover inspectors' salaries?
12. How much money is allocated for inspectors? What is the average salary for a domestic inspector and a foreign inspector?

13. In May of 2024, the FDA issued a drug recall for all Glenmark potassium chloride medications. Why did it take FDA over four years to inspect this facility despite that facility having received seven recalls?
14. What training was required of a drug inspector in 2016 and how does that compare to today? Please provide information on the mechanism for providing the training, including whether it was/is virtual.
15. How many current inspectors who have conducted foreign inspections in India or China have not classified an inspection as OAI in 2022, 2023, and 2024, and how many sites did they visit during that year?

The FDA has found that manufacturer quality issues are the most common reason for drug shortages. Given that, it is of the utmost importance that the FDA prioritizes improving the foreign inspection process to identify potential shortages early and often.

We look forward to your prompt response and working together to ensure our seniors have access to safe, high-quality medicines without disruption.

Sincerely,

Rick Scott
Chairman
Senate Special Committee on Aging

Ashley Moody
United States Senator

James C. Justice
United States Senator