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

September 18, 2025

The Honorable Martin Makary, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2356
Silver Spring, MD 20993

Dear Commissioner Makary:

Thank you for your service overseeing the safety of our nation's food, drugs, and cosmetic products. The Senate Special Committee on Aging is examining how vulnerable pharmaceutical supply chains present a risk to public health and national security. The Food and Drug Administration (FDA) plays a critical role in ensuring the products Americans buy are safe and effective, certifying that products made in and imported into the United States fully comply with all laws and regulations. Given this essential responsibility, we write to request information regarding exemptions made to import bans on pharmaceutical products.

The United States relies on the import of key starting materials, active pharmaceutical ingredients, and finished dosage form drug products to help ensure every American has access to the lifesaving medications they need. FDA holds a unique role in being charged with both ensuring the safety and efficacy of all drugs sold in the U.S. and preventing and mitigating supply disruptions and shortages of medically necessary drugs. This dual responsibility creates a unique tension between the FDA's Center for Drug Evaluation and Research (CDER) and the FDA's Office of Inspections and Investigations (OII).

Recent reporting and Aging Committee interviews with former FDA inspectors have detailed incidents of OII employees issuing a Form 483, where investigators note any observed conditions that may indicate violations of the *Food, Drug and Cosmetic Act* and related Acts, and recommending an import ban from the facility. However, decisions were made at CDER, or its Office of Drug Shortage, to exempt products from that facility or provide a carve-out from an import ban, potentially to help avoid a disruption in supply. The challenges at Sun Pharma, a major generic drug manufacturer in India, exemplifies this dynamic. In 2014, FDA found violations at their manufacturing facility for sterile injectables. In 2025, eleven years later, the FDA

continues to find impurities and dirty equipment, yet allows the facility to continue operations under an exemption.[1]

Another concern is the ongoing use of forced labor and genocide of the Uyghurs in China. Due to these crimes against humanity, Congress passed the *Uyghur Forced Labor Prevention Act of 2021* (Public Law No. 117-78) to ensure goods made in the Xinjiang region, presumably with forced labor, do not enter the United States. However, several Chinese companies operating in the Xinjiang region supply either active pharmaceutical ingredients or key starting materials to companies.[2] The importation of these drugs would be a violation of *the Uyghur Forced Labor Prevention Act*.

These exemptions undermine the goals of U.S. policy, threaten the safety of drugs, and place Americans' health at risk. As we work together to address these concerns and protect the health and safety of American families, we would like to request the following information by October 15, 2025:

1. How many classifications has CDER downgraded or reclassified from the FDA's Office of Inspections and Investigations recommendation? Please list this for each year from 2020 to 2025.
2. How many import alert exemptions or carve-outs have been issued by CDER since 2020?
    a. Please provide a complete list of products and their manufacturing companies that were provided exemptions or carve-outs.
3. How many regulatory meetings for Official Action Indicated (OAI) classified inspections has CDER held in lieu of issuing a warning letter or import alert since 2020?
4. How many drugs carved out or exempted from import bans since 2020 were in shortage or considered to be at risk of a shortage?
    a. What was the market share of the manufacturer's drug that was exempted/carved out?
5. What definition and metrics does CDER use to define a drug in shortage or at risk of being in shortage when making reclassification decisions?
6. What metrics does CDER reference when considering the implications of a potential shortage when issuing a downgrade, exemption from an import ban, or other reclassification?
7. How does CDER's Risk-Based Site Selection Model determine which facilities will be prioritized for surveillance inspections?

[1] https://www.propublica.org/article/fda-inspections-sun-pharma-drug-exemptions
[2] A Bitter Pill: Medicaid's Dangerous Dependence on China-Made Pharmaceuticals and Forced Labor. Exiger. March 2025.

   a. How many of the companies inspected since January 2024, as a total number and percentage of all companies inspected, were producing low-risk products?
8. Since 2010, how many companies have received an exemption for over five years and still have not passed or applied for reinspection?
   a. What is the longest a company has received an exemption without passing a reinspection?
9. The FDA has Mutual Recognition Agreements (MRA) in force with the European Union, Switzerland, and the United Kingdom. In these MRA countries, what is the longest amount of time the FDA has allowed a company to operate without a surveillance inspection? If over a decade, please explain why.
10. Is there a public-facing database for pharmacists, pharmacy benefit managers, group purchasing organizations, or patients to determine if a drug or company is imported under a waiver from an import ban or other safety-related actions?
11. Does the FDA report to U.S. Customs and Border Protection which pharmaceutical products contain or may contain parts, such as key starting material or active pharmaceutical ingredients, manufactured in the Xinjiang Uyghur Autonomous Region?
   a. Has the FDA investigated if Sinopharm, Zhejiang Shindai Chemical Group, Zhejiang Chemicals Export Corp, or other Chinese state-owned entities that have documented connections to forced labor are manufacturing pharmaceutical products that are imported into the United States?

We look forward to hearing from you and finding solutions to secure the United States pharmaceutical supply chain and protect the health of American families.

Sincerely,

Rick Scott
Chairman
Senate Special Committee on Aging

Kirsten Gillibrand
Ranking Member
U.S. Senate Special Committee on Aging