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

October 24, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Kennedy:

The Senate Special Committee on Aging is examining how vulnerable pharmaceutical supply chains present a risk to supply chain security. The Department of Health and Human Services (HHS) plays the principal role in identifying and responding to drug shortages in the United States, coordinating key agencies and activities to ensure every American can access the lifesaving medicines they need. Given this essential responsibility, we write to request information regarding HHS's efforts to address existing supply chain vulnerabilities to bolster the nation's public health preparedness and national security.

The United States extensively relies on the import of key starting materials (KSM), active pharmaceutical ingredients (API), and finished dosage form (FDF) generic drug products. With an estimated 91 percent of prescriptions filled as generic drugs each year in the U.S., it is clear that many Americans, including our seniors, depend on generic drugs to treat a wide range of medical conditions, underscoring the importance of a secure generics supply chain.[1] China and India, in particular, play a dominant role in producing the KSM and API crucial to domestic generic drug manufacturing. The U.S.'s limited operational oversight and control over foreign sourcing and manufacturing of these foundational materials represents vulnerability in the supply chain, which in the event of a crisis, may pose potential public health and national security risks.

Recent reporting details how, in order to prevent and mitigate shortages, the Food and Drug Administration (FDA) has granted exemptions to import bans for certain drugs or ingredients from foreign factories found to operate under substandard manufacturing conditions. [2] These reports highlight that many of these exemptions are for factories in China and India and identify more than 150 drugs and ingredients that

[1] https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2022-annual-report
[2] https://www.propublica.org/article/fda-drugs-banned-foreign-factories-list

have received exemptions since 2013.[3] While many factories ultimately make the necessary changes to be removed from FDA's import alert list, these exemptions can pose a threat to drug safety for American consumers.

Moreover, recent instability in geopolitics and global trade demonstrate an additional threat to the stability of our supply chain, particularly the KSM, API, and generic drugs imported from key manufacturing hubs like China and India. A recent trade dispute with China exemplifies this dynamic. Despite reaching a bilateral trade agreement on rare earth elements in April, just recently China imposed a new set of export restrictions demonstrating its willingness to use vital trade commodities as leverage against the U.S.[4] This raises the unsettling possibility that China could similarly restrict exports of pharmaceutical products in future diplomatic or trade disputes. Given that China is one of the world's largest suppliers of API and KSM, any disruptions in this supply chain could have profound ramifications for the availability of medications in the U.S., impeding the nation's ability to respond to future public health emergencies, potentially threatening military readiness and national security.

Furthermore, approximately 40 percent of generic medications are produced by only one FDA-approved manufacturer.[5] This is a clear vulnerability in our generic supply chain as drugs produced without multiple manufacturers face much greater risk of going into shortage due to disruption, jeopardizing patient access to essential treatments. Addressing this vulnerability requires a comprehensive and coordinated approach driven by HHS and its subagencies, including the Administration for Strategic Preparedness and Response (ASPR), which manages the Strategic National Stockpile (SNS) and administers the *Defense Production Act*.

In addition, in response to the weaknesses in the global drug supply chain highlighted by the COVID-19 pandemic, in 2020, the first Trump administration created the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR). Given the U.S.'s extreme reliance on foreign-produced API, President Trump's August 13, 2025, Executive Order (EO) to stock the SAPIR with API for the most critical medicines represents a strong first step toward addressing this vulnerability in the supply chain.

[3] https://www.propublica.org/article/fda-drugs-banned-foreign-factories-list
[4] https://www.reuters.com/world/china-hits-back-us-tariffs-with-rare-earth-export-controls-2025-04-04/
[5] https://www.nber.org/papers/w23640

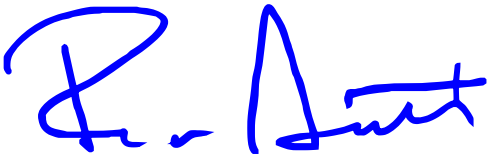
As we work together to secure the U.S. generic drug supply chain as a priority for national health and security, we request the following information by November 30, 2025.

1. A briefing from HHS on the present condition and capacity of the SNS and SAPIR.
2. A full inventory of medicines, medical countermeasures, and critical inputs in the SNS and SAPIR, including drug types, dosage forms, and amounts of each.
3. An update on ASPR's progress in fulfilling its directive under EO 14336 to:
    a. Develop a new list of 26 critical drugs
    b. Determine existing and available funds to finance the preparation and opening of the SAPIR repository
    c. Prepare the existing SAPIR repository to receive and maintain APIs
    d. Obtain a six-month supply of APIs required to manufacture the critical drugs on the list
4. A breakdown of the initial cost to fully fund stocking the SAPIR with API and a breakdown of the annual cost to staff, stock, and maintain the SAPIR facility over the next five fiscal years starting in FY26.
5. How is SAPIR developing its capacity to release API to manufacturers?
    a. Under what conditions and according to what protocol would SAPIR release API from its stockpile?
    b. Would SAPIR release API from its stockpile to a U.S. manufacturer experiencing interruptions in its supply chain? What if it is the sole manufacturer of a critical generic drug in the U.S. market?
    c. How would SAPIR handle the replenishment of API nearing the end of its shelf life? Would it be distributed or sold to domestic generics manufacturers producing the critical drugs?
6. How can HHS facilitate greater coordination among its agencies in identifying and responding to drug shortages?
    a. What staff does HHS have in place to coordinate department-wide responses and strategies for addressing drug shortages? Which current or planned offices and positions within HHS will oversee these department-wide responses?
7. What steps is HHS taking to incentivize U.S. manufacturers to adopt more resilient KSM and API procurement practices?
8. If supply chains of drugs from China are disrupted:
    a. Which essential medicines are at risk of shortage?
    b. What quantity of these medicines are in the federal stockpile?
    c. How many Americans use these medicines daily?
    d. How long will the current federal stockpile of these medicines be able to meet domestic need?

9. If supply chains from India are disrupted:
    a. Which essential medicines are at risk of shortage?
    b. What quantity of these medicines are in the federal stockpile?
    c. How many Americans use these medicines daily?
    d. How long will the current federal stockpile of these medicines be able to meet domestic need?
10. If China or India were to, without warning, stop exports of KSM, API, or generic drugs, to the U.S. or to other foreign companies that sell to the U.S., how many days of drug inventory do you estimate that the United States has of various generic drugs before it would run out?
    a. To what extent would this impact civilians?
    b. What risks would this pose to our national security?
    c. Is America prepared for this potential threat?
11. Any available information on supply chain gaps and challenges that may affect readiness to respond to a national crisis.
12. Are there plans to enhance the SNS?
    a. If so, please describe them in detail.
13. Is ASPR adequately staffed to carry out the agency's responsibilities under statute?
14. If China or India were to, without warning, stop exports of KSM, API, or generic drugs, to the U.S. or to other foreign companies that sell to the U.S., how many days of drug inventory do you estimate that the United States has of various generic drugs before it would run out?
    a. To what extent would this impact civilians?
    b. What risks would this pose to our national security?
    c. Is America prepared for this potential threat?
15. Any available information on supply chain gaps and challenges that may affect readiness to respond to a national crisis.
16. Are there plans to enhance the SNS?
    a. If so, please describe them in detail.

As chairman and ranking member of the Senate Special Committee on Aging, the health and safety of Americans, especially our seniors, is our top priority. We must work to address existing supply chain vulnerabilities, including our nation's extreme reliance on foreign generic drugs. Inaction to address these supply chain concerns could be catastrophic. We stand ready to support HHS in bolstering the nation's public health preparedness and national security.

Sincerely,



Rick Scott
Chairman
Senate Special Committee on Aging

Kirsten E. Gillibrand
Ranking Member
Senate Special Committee on Aging