United States Senate

WASHINGTON, DC 20510

August 4, 2026

Acting Commissioner Kyle Diamantas, JD
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Room 2356
Silver Spring, MD 20993

Dear Acting Commissioner Diamantas,

We write to express concern regarding the escalating national shortage of the critical oncology medications ifosfamide, carboplatin, cisplatin, and oxaliplatin highlighted in recent reporting. The prospect of widespread clinical rationing of frontline chemotherapy presents a crisis for patients, particularly older Americans who disproportionately rely on these medications. Some health systems are already reportedly receiving only a fraction of their standard supply, forcing clinicians to space out doses, prioritize certain patients over others, or ration medications to manage shrinking supplies.[1]

The U.S. Department of Health and Human Services (HHS) has reported that the Food and Drug Administration (FDA) is actively working to alleviate these shortages and is considering temporarily allowing the importation of medications from overseas manufacturers that do not typically supply the United States market. Remedial action of this kind is not novel, as the FDA employed similar strategies in navigating the carboplatin and cisplatin shortage crisis in 2023, but it is essential to ensure the safety and efficacy of any medicine administered to an American patient.

We appreciate the FDA utilizing its regulatory flexibility to inject supply into a strained system, but the temporary introduction of foreign pharmaceuticals raises potential safety concerns that demand transparency. To provide clarity to Congress and ensure patient safety, we respectfully request a briefing from the FDA by September 4, 2026, to answer the following questions:

1. Which specific foreign manufacturers and facilities is the FDA currently evaluating, or has it authorized, for temporary importation of drugs in shortage?
    a. In which country are these manufacturers and facilities located?
    b. Have any of these manufacturers received a Form 483 or been classified as Official Action Indicated (OAI) or Voluntary Action Indicated (VAI), specifically with respect to the drugs in shortage?
2. What protocols, quality checks, and regulatory standards is the FDA applying to guarantee supplemental imports meet safety standards?

3. How will the FDA monitor imported chemotherapy drugs for contamination or sub-potency once they are in the U.S. market?
4. How will shortage staff work with the Office of Inspections and Investigations (OII) and relevant quality staff within the Center for Drug Evaluation and Research (CDER) to ensure that facility inspection history and drug quality are considered in shortage mitigation efforts?
5. Does the FDA anticipate that efforts to temporarily rectify the shortage will result in increased costs for hospital purchasers or individual patients?
6. The 2023 carboplatin and cisplatin shortage prompted conversations about a durable solution for the chemotherapy supply chain. What steps has the FDA taken to prepare for future shortages given the continued fragility of that supply chain?
7. What is the market share for the oncology drugs in shortage? How many FDA-approved alternatives exist for these drugs and what are their respective market shares?

Thank you for your attention to this request and ongoing work to protect patients. We look forward to your prompt response and working together to ensure older Americans maintain access to critical medications.

Sincerely,

Kirsten Gillibrand
United States Senator
Ranking Member, Special Committee on Aging

Rick Scott
United States Senator