# Congress of the United States

## Washington, DC 20515

June 8, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Becerra and Commissioner Califf:

Thank you for your leadership in addressing ongoing drug shortages and ensuring Americans have access to the medications and devices they need. We especially appreciate the FDA's recent actions to address current shortages of key oncology drugs. We are writing to you today expressing our concerns with the impact these shortages have on patients, particularly in cancer care. We'd like to request additional information about how the U.S. Food and Drug Administration (FDA) is working to resolve these issues and ways in which Congress can assist in these efforts.

For years, the medical community has experienced shortages of critical drugs that are used to treat a variety of conditions. These shortages are caused by a multitude of factors, including but not limited to quality issues, manufacturer business decisions, disruptions to active pharmaceutical ingredients (APIs) and excipient supplies, natural disasters, and other emergencies that take place in countries that house critical drug manufacturing facilities. In recent years, the United States has experienced shortages in broadly used essential products, as well as to products critical to smaller patient populations.

Within the oncology pharmaceutical supply chain, patients and providers continue to face shortages of potentially curative treatments. A recent survey of U.S. Oncology Pharmacists found that oncology drug shortages occurred frequently in 2020 and led to delays in chemotherapy and changes in treatment or omission, complicated clinical research, and increased risk of medication errors and adverse outcomes.[1] Of the 136 drugs currently in shortage, as reported by the FDA, 15 are oncology drugs.[2] Shortages of these 15 drugs, such as carboplatin and cisplatin, are causing care disruptions across the country. While we cannot quantify the direct impact to patients, estimates show that shortages in cisplatin[3] and fluorouracil[4] could impact 500,000 and 275,000 patients respectively. These drugs are used in the treatment of multiple common cancers, including lung, breast, ovarian, testicular, head and neck cancer, endometrial cancer, and many types of cancers impacting children.

Drug shortages also place children at risk across the United States. Drugs affected by shortage are often critical for treatment, and there are limited or no alternatives. Many childhood cancers are highly treatable, often curable, but in many cases certain drugs are essential for cure. In both adult and pediatric settings, some community cancer centers are unable to treat patients due to shortages in carboplatin and cisplatin, while some large academic cancer centers have reported having less than two weeks supply of the drugs on hand. As a result, doctors are forced to choose

between inferior or potentially ineffective therapies to protect their patients. Health providers may also be forced to make treatment decisions that prioritize the most curable patients, rather than administering these drugs to all who need them. Ultimately, shortages of critical drugs lead to worse health outcomes.

The FDA has existing authority to monitor and collect data on current and potential drug shortages, including Section 510(j)(3) of the Federal Food, Drug, and Cosmetics Act (FD&C Act) which requires registrants of drug establishments to report on numbers of drugs manufactured for commercial distribution. FDA has pursued these drug shortage mitigation goals and issued guidance requiring manufacturers to notify the FDA of discontinuances or interruptions in drug manufacturing, create risk management plans for drugs, and report quantities of drugs manufactured.[5] It is our understanding, however, that many manufacturers are currently non-compliant with these guidelines. We also understand that neither the federal government nor industry has end-to-end visibility into the pharmaceutical supply chain. Together, we believe these factors may limit the federal government's ability to proactively identify and mitigate drug shortages.

Given this, we request responses to the following inquiries:

1. In the past two years, the FDA has helped prevent over 500 shortages due to early notifications and intervention. In instances where manufacturers have been compliant with FDA reporting guidelines, how has that data allowed the agency to work with manufacturers to mitigate drug shortages? How could this existing required reporting be strengthened?
2. What steps is FDA taking to ensure manufacturers not in compliance with existing guidelines become compliant? What challenges exist in FDA's ability to leverage its oversight authorities?
3. Does FDA have sufficient transparency and visibility into the supply chain necessary to identify potential shortages, including visibility into root suppliers for raw materials used in API manufacture and other suppliers more than one step removed from finished-product manufacture?
4. Could FDA benefit from additional manufacturer reporting requirements, such as, when a manufacturer identifies increased demand for their specific product(s)?
5. The device shortage reporting requirements ended with the end of the COVID-19 Public Health Emergency (PHE) on May 11, 2023 (section 506J of the Federal Food, Drug and Cosmetic Act (FD&C Act); mandatory reporting during a PHE). FDA no longer has the statutory authority to require companies responsible for manufacturing devices that are critical for health to notify the FDA of supply disruptions. Are there ways Congress can strengthen the ability of FDA to mitigate potential device supply shortages whether with data collection or other tools?
6. Beyond increased visibility into the drug supply chain, are there other policy recommendations for how Congress can help mitigate drug shortages? Does the FDA have the necessary statutory authority to assist in mitigating drug shortages? If not, how can the agency's current authority be strengthened to secure the pharmaceutical supply chain?

7. How can the FDA improve communications with healthcare stakeholders such as hospitals, providers, and pharmacies, in the short-term to help address drug shortages?

Patients, physicians, and pharmacists are often the last to know when an essential drug will no longer be available, yet, are affected by these shortages the most. We strive to ensure patients, physicians, and pharmacists never have to experience shortages of essential medications, but when shortages do occur it is vital that these individuals are made aware as quickly as possible so that they can better prepare.

We appreciate the actions FDA has already taken to address the ongoing cancer drug shortage and encourage you to take all appropriate steps to protect this vulnerable population. We stand ready to assist you in any way possible.

Thank you very much for your attention to this important issue.

Sincerely,

Ami Bera, M.D.
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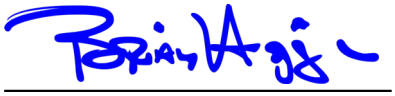

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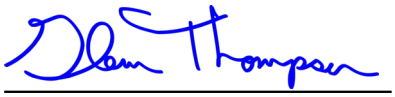

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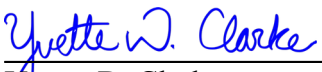

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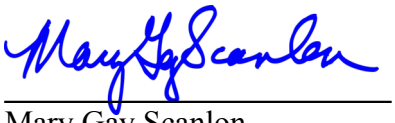

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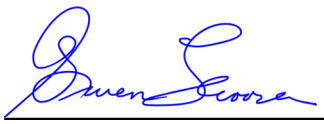

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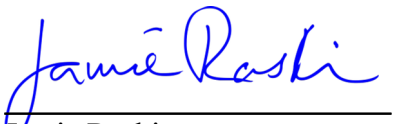

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