Congress of the United States

Washington, DC 20515

October 7, 2024

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

Dear Commissioner Califf:

Drug shortages not only impact patients and the care they receive, they pose a threat to the nation's economy and national security. As Congress considers whether to give the U.S. Food & Drug Administration (FDA) new authorities to combat drug shortages, we call on the Agency to use its current authority to empower existing pharmacy stakeholders, like 503B drug compounding outsourcing facilities, to partner with the federal government to avert and mitigate drug shortages.

Congress established the 503B category in the 2013 *Drug Quality and Security Act* (P.L. 113-54) to ensure patient safety through uniform and stringent compounding standards (current Good Manufacturing Practices [CGMP]) and direct FDA oversight. Inspection issues with 503Bs led the Agency to establish the Compounding Quality Center of Excellence in December 2019 to improve 503B performance. However, the Agency's inconsistent and sometimes burdensome regulatory oversight has limited this sector from more effectively contributing to the nation's supply of drug therapies.

Nevertheless, the 503B sector presents the Agency with an opportunity to mitigate the adverse effects of drug shortages while also strengthening the standing of outsourcing facilities. We are aware of the FDA's existing authority over outsourcing facilities, and we urge you to use this authority to establish regulatory mechanisms that foster increased confidential communication between the Agency and outsourcing facilities whenever drug manufacturers alert the Agency of product shortages, increased demand, discontinuances, manufacturing issues, recalls or supply chain interruptions. Confidentially sharing drug shortage information with outsourcing facilities would allow the 503B sector to temporarily fill supply gaps until manufacturing is back online. This would help ensure hospital outpatient departments and other healthcare providers can effectively treat patients without interruption, leading to better patient outcomes while conserving scarce hospital resources.

Additionally, we urge the FDA to take steps to improve the drug shortage list, including better utilization of drug shortage information provided to the agency by health care providers, including both 503B outsourcing facilities and 503A state licensed compounding pharmacies, which are also authorized to compound drugs on the FDA shortage list pursuant to final guidance from the agency. FDA should be considering more than just information submitted by drug manufacturers in establishing the list, and should consider information about how the drug is prepared and dispensed, including API, dosage form and route of administration.

We respectfully request that you explore all the ways the Agency can use its existing authority to more effectively use FDA-registered 503B outsourcing facilities and 503A state-licensed compounding pharmacies to avert and mitigate drug shortages.

Thank you for your attention to this important matter.

Sincerely,

Diana Harshbarger, Pharm.D.
Member of Congress

Gus M. Bilirakis
Member of Congress

Debbie Lesko
Member of Congress

H. Morgan Griffith
Member of Congress