United States Congress

WASHINGTON, DC 20515

November 30, 2023

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

Dear Commissioner Califf:

We write to express our concern about the ongoing national shortage of chemotherapy drugs which is making it harder for cancer patients to receive the treatments they need.

As you know, on August 24, 2023, several members of the Georgia congressional delegation wrote a letter to inquire about (1) the safety of imported chemotherapy drugs, (2) plans to resolve the shortage, and (3) ways that future shortages can be prevented.

Since sending the August 24, 2023, letter, we have continued to hear from patients and providers about how shortages of chemotherapy drugs present a significant challenge for Georgians. Many have had to consider alternative treatment programs or delay treatment. Unlike other medications, chemotherapy drugs are not interchangeable; many are only effective for specific cancers, and using alternative chemotherapy drugs can substantially reduce the success of the treatment. This shortage has placed a burden on both physicians and caregivers and has put the health of patients at risk.

Our primary goal is ensuring that Georgians can safely obtain the chemotherapy medications they need while also guaranteeing the safety of these drugs. Therefore, we respectfully request that you respond promptly to the following questions:

- 1. What is the current status of the chemotherapy drug shortage in the United States?
- 2. What efforts is the FDA undertaking to evaluate the safety of imported drugs from Qilu Pharmaceutical?
- 3. What is the FDA doing to ensure that any chemotherapy drugs imported to the U.S. meet U.S. drug safety standards?
- 4. What measures are the FDA undertaking to ensure that the agency is better equipped to respond to shortages of critical drugs in the future?

We look forward to working with the FDA to ensure that Georgia cancer patients and their doctors have access to the best medications and treatments without concern about the availability and safety of drugs.

Sincerely,

United States Senator

Nikema Williams Member of Congress

Henry C. "Hank" Johnson, Jr.

Member of Congress

Raphael Warnock United States Senator

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Member of Congress

Rich McCormick, MD, MBA Member of Congress