Congress of the United States
Washington, DC 20515

August 24, 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 request information on the U.S. Food and Drug Administration's (FDA) response to the ongoing shortage of chemotherapy drugs, including measures the agency is taking to ensure the safety of imported replacement drugs.

On December 2, 2022, the FDA released a report documenting severe deficiencies at the Intas Pharmaceuticals production plant in Ahmedabad, India. These failures include issues with procedures for preventing microbiological contamination and reports of trucks inappropriately disposing of shredded documents intended to ensure product safety.[1] Following this report, Intas willingly halted production and distribution of its chemotherapy drugs, which include cisplatin, carboplatin, and methotrexate. The facility has reportedly now halted production for eight months. The closure of this production plant, which is responsible for about 50 percent of the U.S. supply of cisplatin, has led to ongoing shortages.[2] Moreover, the closure of the Intas production plant has started a chain reaction, with higher demand for alternative chemotherapy drugs, creating additional shortages.

We have heard from cancer patients and doctors across Georgia who are confronting these shortages. Providers at cancer centers have started to alter treatment programs and delay preferred therapies due to limited drug availability. Cancer hospitals in Georgia are currently tracking several drugs other than cisplatin as limited in supply, including carboplatin, fludarabine, fluorouracil, methotrexate, dacarbazine, idarubicin and Bacillus Calmette-Guérin (BCG). Georgia cancer patients and their doctors deserve to choose treatment based on best evidence and what works for the patient without the additional burden of worrying about the availability and safety of drugs.

We are glad that the FDA is taking actions to mitigate these drug shortages. This includes working with additional manufacturers to increase supplies of these drugs.[3] However, we are concerned by the lack of transparency from the FDA about these suppliers, especially since the FDA has begun importing cisplatin injections from Qilu Pharmaceutical, which is not FDA-approved and manufactures the injections in China. We are also alarmed by the lack of timeline

[1] Ed Silverman, *'A Cascade of Failures': FDA Cites Indian drugmaker for Numerous Quality Control Problems*. STAT News (January 19, 2023), https://www.statnews.com/pharmalot/2023/01/19/fda-indian-drugmaker-intas-pharmaceuticals.
[2] Daniel Gilbert, *How Troubles at a Factory in India Led to a U.S. Cancer-Drug Shortage*, Wash. Post (June 27, 2023), https://www.washingtonpost.com/business/2023/06/27/cancer-drug-shortage-generics.
[3] Berkeley Lovelace, Jr., *To Ease Cancer Drug Shortage, FDA Will Allow Imports from China*, NBC News (June 5, 2023), https://www.nbcnews.com/health/cancer/cancer-drug-shortage-fda-will-allow-imports-cisplatin-china-rcna87751.

and detail on when any new, safe imports of carboplatin will begin and from where they will be imported.

The FDA must work quickly to assist in resolving shortages of chemotherapy drugs and ensure that the United States is better equipped to address drug shortages in the future.

In light of these concerns, we respectfully request that the FDA respond to the following questions by September 18, 2023:

1. How is the FDA working with Intas Pharmaceuticals and its subsidiary, Accord Healthcare, to quickly and safely reopen the production plant in Ahmedabad, India? Is there a timeline for when Intas Pharmaceuticals will resume production?
2. What is the status of the FDA's engagement with additional drugmakers outside of Qilu Pharmaceuticals regarding importing chemotherapy drugs?
3. How is the FDA ensuring that any chemotherapy drugs that are imported to the U.S. meet U.S. drug safety standards?
4. What is the FDA doing to resolve shortages of other chemotherapy drugs outside of carboplatin and cisplatin?
5. How can Congress address the root causes of drug shortages, particularly those affecting chemotherapy drugs so that in the future, the closure of one manufacturing plant will not affect half of the U.S. supply of a critical drug?

We look forward to receiving your response. We are committed to working with the FDA to address the chemotherapy drug shortages so that cancer patients in Georgia and around the country can access the treatment they need.

Sincerely,

Raphael Warnock
United States Senator

Earl L. "Buddy" Carter
Member of Congress

Henry C. "Hank" Johnson, Jr.
Member of Congress

Lucy McBath
Member of Congress

Rick W. Allen
Member of Congress

Sanford D. Bishop, Jr.
Member of Congress

Rich McCormick, MD, MBA
Member of Congress

Austin Scott
Member of Congress

Barry Loudermilk
Member of Congress