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United States Senate
WASHINGTON, DC 20510-0908

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June 20, 2023

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

Dear Commissioner Califf:

I write with regard to the U.S. Food and Drug Administration's (FDA) decision to temporarily authorize the importation of cisplatin, an important chemotherapy drug, from Qilu Pharmaceutical (Qilu) in the People's Republic of China (PRC). The shortage of critical pharmaceuticals in recent months has caused hospitals to begin rationing life-saving treatments, including those to treat aggressive cancers. As the FDA works to alleviate these shortages, it must carefully consider the health and safety consequences of foreign drugs it is allowing into the country. I am concerned that the FDA's solution to this problem, so far, is to import more drugs from the PRC, an adversary with a poor health and safety record.

The COVID-19 pandemic, which began in the PRC, took a drastic toll on our nation's drug supply and exposed significant gaps in our pharmaceutical pipeline. Three years later, the country is still grappling with shortages of commonly used, effective treatments, such as amoxicillin, Adderall, and multiple pain medications. Cancer patients have been among the hardest hit by these shortages. According to the FDA's shortage list, at least 12 medications indicated for oncology use are in short supply. At least some of these shortages began when Intas Pharmaceuticals, an India-based manufacturer responsible for producing a significant portion of cisplatin and carboplatin treatments to American hospitals, was forced to cease production after multiple quality violations from an FDA inspection at the end of 2022. As a result, multiple hospitals in Florida, and across the country, have had to limit their use of carboplatin, cisplatin, methotrexate, and other life-saving treatments. The National Cancer Institute cites that platinum-based drugs, including cisplatin and carboplatin, are provided to 10 to 20 percent of all cancer patients. Providers are increasingly concerned about their dwindling supplies and worry they will have to decrease or stop giving treatments to their patients.

On June 2, 2023, you announced that the FDA was taking steps to temporarily import "foreign-approved versions of cisplatin products from FDA-registered facilities." We later learned the FDA is working with Qilu Pharmaceutical to import a version of cisplatin that is marketed and manufactured in the PRC, but not approved by the FDA for use in the United States.

There are reasons to be concerned about the health and safety consequences of this decision. The U.S.-China Economic and Security Review Commission found that the PRC's

pharmaceutical industry has "serious health and safety deficiencies." According to the FDA's database, the last time the FDA inspected and gave Qilu a passing grade was December 2019—nearly four years ago, and before the pandemic. A separate review by the European Medicines Agency (EMA) found 30 deficiencies in Qilu's production of active pharmaceutical ingredients (APIs) for an antibiotic, resulting in the EMA implementing special measures to oversee production. Despite this previous incident, the FDA has given no indication what specific product quality measures Qilu will have to meet.

It is important that we address this shortage of life-saving drugs quickly, but it is imperative that the FDA prioritize the safety of the products prescribed in the United States and provide transparency about its approval processes so that patients can have full confidence in their treatments. I respectfully request that you provide answers to the following questions:

1. What criteria did the FDA use to evaluate Qilu Pharmaceutical as the best and safest manufacturer to import cisplatin to the United States?

2. When was the last time the FDA completed an inspection of Qilu Pharmaceutical facilities? Did they pass the FDA's criteria? Did Qilu resolve any concerns flagged by the FDA, if any were identified?

3. Why did the FDA decide to import cisplatin from a Chinese company instead of an allied country?

4. What other pharmaceutical manufacturers were considered in the FDA's search for an alternative foreign importer of cisplatin?

5. Does the FDA intend to request additional foreign manufacturers to temporarily supply the United States with cisplatin?

6. Does the FDA intend to import carboplatin and methotrexate, two other chemotherapy drugs experiencing a shortage, from Qilu Pharmaceutical or other Chinese manufacturers?

Thank you for your attention to this matter. I look forward to your prompt response.

Sincerely,

Marco Rubio
U.S. Senator