RICHARD J. DURBIN
ILLINOIS
MAJORITY WHIP

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY

United States Senate
WASHINGTON, DC 20510-1304

June 1, 2023

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

Dear Commissioner Califf:

"*My mother in law has stage four cancer and is in desperate need of the chemo drug Carboplatin in order to stay alive. She has tried a number of other drugs, and although they worked for short periods of time, her oncologist has moved her to this one, which is the one thing that has the potential to save her at this point. The drug, however, is in short supply and her doctor cannot get it … She is in a holding pattern, and we are not ready to lose her*."

This heart-breaking note from one of my constituents is an example of the desperation that patients, family members, and health care providers are experiencing as a result of the nationwide shortage of life-saving cancer drugs—including carboplatin and cisplatin. Given the Biden Administration's longstanding focus on accelerating the rate of progress against cancer, I urge the Food and Drug Administration (FDA) to use every authority at its disposal to immediately address the ongoing critical shortage of cancer drugs that are threatening the lives of patients nationwide.

As you know, carboplatin and cisplatin are front-line drugs that are used to successfully treat hundreds of thousands of cancer patients each year in the United States. However, stemming from a fragile supply chain, limited market competition, and following an inspection and the identification of quality issues at a single manufacturing facility in India, both drugs have been difficult, if not impossible, for patients and providers to obtain over the last few months.

As a result of these shortages, providers have struggled to obtain even a limited supply of these medications and have had to ration care only for their sickest patients—denying or delaying care for others. These delays in treatment have life or death consequences, with a 2020 study in The BMJ finding that every month delayed in cancer treatment can raise the risk of death by approximately 10 percent. We have come too far in our fight against cancer to take such a dramatic—and preventable—step backward.

Another unfortunate side-effect of any drug shortage is the toll it takes on important medical research and ongoing clinical trials. For example, last month, a major breakthrough out of Northwestern Medicine was achieved after researchers were able to open the blood-brain barrier to more effectively deliver chemotherapy to brain tumors. This breakthrough holds great promise for the treatment of glioblastoma and other neurological diseases and conditions. However, one of the chemotherapy drugs used in this research was carboplatin, which is now facing a shortage. Imagine if the researchers involved in this effort had not been able to access carboplatin during the course of their work. The best-case scenario is that the breakthrough

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would have been delayed by months or years. The worst-case scenario is that the breakthrough never would have been achieved at all.

To be certain, there are widespread and inherent problems with the drug and medical supply chain that must be addressed in the long-term, and which Congress has sought to tackle through enhanced supply chain monitoring, visibility, and authorities for FDA. I am committed to addressing such structural deficiencies, including through the passage of my *Commission on America's Medical Security Act* in 2020, and other efforts to build domestic manufacturing capacity and supply chain resiliency.

But in the short-term, I urge FDA to take immediate action to alleviate the burden on patients and providers caused by shortages of critical cancer drugs. The agency should use its authority to allow for the safe importation of these drugs from other countries, work with manufacturers to extend expiration dates—if safe and appropriate—on existing supplies of the drugs, regularly provide clear and timely updates to providers on expected timelines for additional supply, and ensure expedited inspections and reviews to assist in resolving this shortage. I know that FDA is working hard to address this shortage, and I welcome any suggestions you might have for how Congress can assist in these efforts.

Receiving a cancer diagnosis is distressing enough. Receiving a cancer diagnosis and then being told that there is a drug that can save you, but that you cannot get it because of a shortage, is simply unacceptable. And yet, that is exactly what is happening to cancer patients nationwide. Thank you for your immediate and ongoing attention to this critical issue.

Sincerely,

Richard J. Durbin
United States Senator