

May 25, 2023

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-002

Dear Commissioner Califf,

We are deeply concerned with the worsening shortages of chemotherapy drugs, including carboplatin and cisplatin, and urge the Food and Drug Administration (FDA) to do everything in its power to alleviate the strain on patients and prevent delays in life-saving treatments. We recognize that this shortage—as with the majority of shortages involving generic drugs—is largely due to a broken economic system in the generic drug industry. While Congress is actively working on long-term solutions to this longstanding problem, we ask that in the short-term, FDA utilize all of its existing authorities to mitigate this dire shortage. We know FDA is acutely aware of this issue and appreciate the agency’s tireless work.

Cisplatin and carboplatin, two critical chemotherapy agents used to treat a wide range of cancers, have been on FDA’s shortage list since February and April of this year. The per-unit wholesale cost of these two drugs is generally less than a side of fries at McDonalds.¹ At least 50,000 Americans rely on cisplatin as part of their chemotherapy treatments, as the product is used in approximately 10 to 20 percent of chemotherapeutic regimens.² In 2022, over 100,000 Americans were diagnosed with ovarian, bladder, and testicular cancers, which may rely on either cisplatin or carboplatin for treatment.³ According to the Michigan Health and Hospital Association, these shortages are “forcing Michigan hospitals and health systems to find alternative treatments for patients, some of which may be less effective.”⁴ Further reports

¹ According to drugs.com, the per-unit cost of cisplatin (200 milliliters) is 17 cents and the per-unit cost of carboplatin (60 milliliters) is \$1.02. See Drugs.com, Cisplatin Prices, Coupons and Patient Assistant Programs (<https://www.drugs.com/price-guide/cisplatin>) and Carboplatin Prices, Coupons and Patient Assistant Programs (<https://www.drugs.com/price-guide/carboplatin>) (accessed May 23, 2023).

² National Institutes of Health, National Cancer Institute, The “Accidental” Cure—Platinum-based Treatment for Cancer: The Discovery of Cisplatin (<https://www.cancer.gov/research/progress/discovery/cisplatin>) (accessed May 23, 2023).

³ Association for Clinical Oncology Correspondence to Senate Committee on Homeland Security and Governmental Affairs (May 19, 2023) (noting this number does not account for off-label treatment, such as cisplatin/carboplatin for cervical, head and neck, esophageal/gastric, and lung cancers as well as some childhood cancers).

⁴ Michigan Health and Hospital Association, Patient Treatment Impacted by Shortage of Cancer Drugs (<https://www.mha.org/newsroom/patient-treatment-impacted-by-shortage-of-cancer-drugs/>) (accessed May 23, 2023).

indicate patients in some cases may have had to postpone life-saving treatments altogether.⁵ Even when health care providers can secure supplies, they are often at outrageously inflated prices; one health system reported to us that it has paid 50 times the usual price for a small supply of cisplatin.⁶ In addition, hospitals and health care professionals have expressed significant frustration because they have been unable to tell patients *why* they cannot access the drugs or *when* they can expect to receive additional supply.

Unfortunately, this situation appears to be a textbook drug shortage. We understand the shortage of cisplatin and carboplatin stemmed from a disruption in supply due to quality control issues at Intas Pharmaceuticals Limited, a manufacturer based in India that supplies product for Accord Healthcare to distribute to the U.S. market.⁷ When Accord Healthcare could not continue supplying these products, the remaining manufacturers were unable to keep pace with increased demand. FDA’s website, however, does not list the reason for Accord Healthcare’s shortage, nor does it list Intas Pharmaceuticals Limited as the manufacturer.⁸ Instead, FDA’s website states “other,” as the reason for the shortage and notes that cisplatin and carboplatin are “marketed by Accord Healthcare” and “current inventory is being allocated, further availability pending return to manufacturing.”⁹ While we understand that certain restrictions prevent FDA from sharing some information publicly, the cause of a drug shortage helps inform provider mitigation strategies and communication with patients.

Strengthening our pharmaceutical supply chain will take sustained effort and investments over time to address the broken economic system. It will also require increased transparency from manufacturers and FDA. Given the acute nature of this shortage and the severe impact a delay in receiving this medication could have on cancer patients, we ask that FDA continue to work as expeditiously as possible and use all existing authorities to increase supply of these critical drugs. Specifically, we urge you to do everything in your authority to increase the availability of supply, including initiating temporary importation of alternate products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act and expediting approvals of new manufacturing lines, facilities, or suppliers to alleviate this crisis.

⁵ *Amid cancer drug shortages, some Michigan doctors are forced to ration*, Bridge Michigan (May 19, 2023) (<https://www.bridgemi.com/michigan-health-watch/amid-cancer-drug-shortages-some-michigan-doctors-are-forced-ration>).

⁶ Sparrow Health System Correspondence to Office of Rep. Elissa Slotkin (May 17, 2023).

⁷ *See Drug shortages near an all-time high, leading to rationing*, New York Times (May 17, 2023) (<https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html>); National Library of Medicine, DailyMed, Cisplatin (<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b2b029f5-0d7e-4e7f-accb-b722aec34c68>) (accessed May 23, 2023); National Library of Medicine, DailyMed, Carboplatin (<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=48aa7ef3-9f44-2a08-e054-00144ff88e88>) (accessed May 23, 2023).

⁸ Food and Drug Administration, FDA Drug Shortages (https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cisplatin%20Injection&st=c; https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Carboplatin%20Injection&st=c) (accessed May 23, 2023).

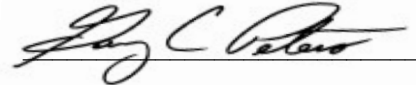
⁹ *Id.*

Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in blue ink that reads "Debbie Stabenow". The signature is written in a cursive style with a horizontal line underneath.

Debbie Stabenow
United States Senator

A handwritten signature in black ink that reads "Gary Peters". The signature is written in a cursive style with a horizontal line underneath.

Gary Peters
United States Senator

A handwritten signature in black ink that reads "Elissa Slotkin". The signature is written in a cursive style with a horizontal line underneath.

Elissa Slotkin
United States Representative