United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

June 22, 2023

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Califf:

As Ranking Member and members of the of the U.S. Senate Special Committee on Aging, we ask you to work with us to better understand, mitigate, and eliminate growing drug shortages that are especially devastating to older Americans. From gold standard chemotherapies to local anesthetics and basic hospital drugs, drug shortages are growing increasingly prevalent. As Congress works towards the reauthorization of the Pandemic All-Hazards Preparedness Act (PAHPA) this year, we look forward to ensuring we finally solve the longstanding problem of drug shortages.

Not having enough medicine to meet demands has led to rationing, which hurts older Americans the most. Among drugs in dire shortage are standard of care chemotherapy drugs including cisplatin, carboplatin, pluvicto, and methotrexate.[1] Without these vital products, patients will continue to face damaging delays in treatment and higher mortality rates, as every month of delaying cancer treatment increases their risk of death by ten percent.[2] Hospitals and medical societies are now establishing guidelines that give priority to patients with curative intent while denying this treatment to others who would benefit, putting older Americans at a disadvantage and rolling dice with life.

We were shocked to see the Food and Drug Administration (FDA) announce via a tweet that the Administration has "taken steps for temporary importation of certain foreign-approved versions of cisplatin products" – meaning from China - without otherwise informing American oncologists.[3] The FDA published a "Dear Healthcare Professional" letter written by the Chinese manufacturer, which explained the doses will not carry U.S. labels, and that the barcodes may not register accurately on American scanning systems.[4]

[1] Massey M (April 12, 2023). Nationwide Shortage Impacts Cancer Treating Drugs. Baltimore, MD: CBS News Baltimore; https://www.cbsnews.com/baltimore/news/nationwide-shortage-impacts-cancer-treating-drugs/.
[2] Hanna TP, King WD, Thibodeau S (2020). Mortality due to cancer treatment delay: Systematic review and meta-analysis. *BMJ*, 371:m4087; https://doi.org/10.1136/bmj m4087.
[33] Califf RM [@DrCaliff_FDA] (June 2, 2023). Today, we've taken steps for temporary importation of certain foreign-approved versions of cisplatin products; https://twitter.com/DrCaliff_FDA/status/1664786511680643072.
[4] Qilu Pharmaceutical Co., Ltd. (May 24, 2023). Dear Health Professional - Subject: Temporary Importation of CISplatin Injection with non-U.S. Labeling to Address Drug Shortage; https://www.fda.gov/media/169001/download.

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This use of a Chinese-approved product without adequate vetting, labeling or communication may cause frustration among healthcare providers and patients and is especially inappropriate while we are still discovering the truth about China's role in the COVID-19 pandemic. America is still waiting for President Biden to declassify all intelligence related to any link between the Wuhan Institute of Virology and the COVID-19 virus, as required by law.

Your agency should be especially sensitive to this link, as the FDA highlights the COVID-19 pandemic as a source of the current disruption.[5] However, the COVID-19 Public Health Emergency ended on May 11, 2023. Emergencies amplify, but do not cause, drug shortages. Drug shortages are a longstanding problem. In 2014, the Government Accountability Office (GAO) reported the number of active drug shortages increased significantly from 154 drugs in 2007 to 361 in the first six months of 2013.[6] The 2012 Food Drug and Drug Administration Safety and Innovation Act (FDASIA) and the 2020 Coronavirus Relief and Coronavirus Aid, Relief, and Economic Security Act (CARES Act) increased the FDA's authority to require manufacturers to inform the FDA of forthcoming shortages when they are caused by an anticipated disruption in supply to manufacturers.

In its most recent annual report to Congress on drug shortages, the FDA credits these laws with enabling the agency to reduce the number of new drug shortages per calendar year from a high of 250 in 2011 to 41 in 2021.[7] The report also includes estimates of how many shortages the FDA prevented because of these authorities, from 282 in 2012 to 3317 in 2021. While this is welcome, it has not solved the problem of chronic, ongoing drug shortages. When the drug shortage crisis previously peaked in 2013, the FDA listed 97 drugs experiencing ongoing shortage. This number improved quickly to 41 in 2017 but then slipped back quickly to 86 in 2020 and 83 in 2021.

Nor have these increased authorities prevented the continuing offshoring of manufacturing to India and China. U.S. Pharmacopeia, an independent nonprofit designated under federal law to set quality standards for medicines marketed in the U.S., reports 62% of Drug Master Files (DMFs, which the FDA requires when manufacturers supply Active Pharmaceutical Ingredients to other manufacturers) are filed from India, up from 20% in 2000. DMFs from China increased from 4% to 23%, while DMFs from the U.S. dropped from 15% to 7%.[8] We cannot imagine a greater threat to our nation's drug supply during emergencies than increasing dependence on China. Instead of responding to drug shortages by accelerating imports of cancer medicines from China, the FDA should focus on re-shoring production to the United States.

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[5] Food and Drug Administration (April 5, 2023). Drug Shortages; https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.
[6] Government Accountability Office (2014). GAO-14-194 Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability; https://www.gao.gov/products/gao-14-194.
[7] Food and Drug Administration (2022). Report to Congress: Drugs Shortages for Calendar Year 2021 (Required by Section 506C-1 of the Federal Food, Drug, and Cosmetic Act); https://www fda.gov/media/159302/download.
[8] U.S. Pharmacopeia (May 18, 2022). Geographic Concentration of Pharmaceutical Manufacturing: USP Medicine Supply Map Analysis; https://qualitymatters.usp.org/geographic-concentration-pharmaceutical-manufacturing.

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As we work with you to address these issues, we ask you to update us by July 21 on how the FDA is addressing the needs of older adults who are impacted by drug shortages today, and how to ensure they will have better access to critical treatments when emergencies arise. If you have any questions, please contact [redacted].

Sincerely,

Mike Braun
United States Senator
Ranking Member, Special Committee on Aging

Rick Scott
United States Senator
Special Committee on Aging

JD Vance
Unites States Senator
Special Committee on Aging