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Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
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WASHINGTON, DC 20515–6143
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https://oversight.house.gov

February 21, 2024

Mr. Albert Bourla
Chairman and Chief Executive Officer
Pfizer Inc.
66 Hudson Boulevard East
New York, NY 10001-2192

Dear Mr. Bourla:

We are concerned that the intermittent and repeated shortages of cancer medications are affecting patients across the United States. Hospitals and healthcare providers have struggled with the scarcity in supply of 15 different oncology drugs, including three commonly used generic cancer treatment drugs manufactured by Pfizer and its subsidiaries—carboplatin, cisplatin, and methotrexate. The current oncology drug shortage affects the clinical decision-making process, patient outcomes, and quality of life, and without crucial oncology drugs, cancer patients face severe gaps in their treatments and an increased risk of severe, life-threatening complications.[1]

Generic oncology drugs, including carboplatin, cisplatin, and methotrexate, are used to treat a wide range of cancers. The current shortage of these drugs could affect up to 500,000 adult patients.[2] While the United States has experienced oncology drug shortages before, this shortage has been particularly acute.[3] At certain points in 2023, up to 90% of hospital systems lacked consistent access to these medications, and in many instances, oncology practices were forced to ration doses or provide less desirable alternatives to a patient's recommended treatment.[4] One patient, for example, reported that they were forced to undergo an amputation to

[1] '*I'm Scared To Death.' Behind The Shortage Keeping Cancer Patients From Chemo Key Drugs Have Been In Scarce Supply, Revealing A Deep Crisis In The Generic Drug Industry*, New York Times (Dec. 19, 2023) (online at www.nytimes.com/2023/12/19/health/cancer-drug-shortage.html); Edgardo S. Santos, MD, FACP, Thomas K. Oliver, BA, Christina Lacchetti, MHS, Rachel Geisel, BS, Lalan S. Wilfong, MD, Amanda N. Fader, MD, and Cathy Eng, MD, FACP, *Drug Shortages in Oncology: ASCO Clinical Guidance for Alternative Treatments*, JCO Oncology Practice, Volume 20, No.1 (Nov. 14, 2023) (online at https://ascopubs.org/doi/full/10.1200/OP.23.00545).

[2] *Id.*

[3] Cancer Cytopathology, *Generic Cancer Drugs are Still in Short Supply* (Jan. 1, 2024) (online at https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncy.22788).

[4] Johns Hopkins, Bloomberg School of Public Health, *How Drug Shortages Are Affecting Cancer Treatments* (July18, 2023) (online at https://publichealth.jhu.edu/2023/drug-shortages-are-affecting-cancer-treatments) (accessed Jan. 22, 2024); '*I'm Scared To Death.' Behind The Shortage Keeping Cancer Patients From Chemo Key Drugs Have Been In Scarce Supply, Revealing A Deep Crisis In The Generic Drug Industry* , New York Times (Dec. 19, 2023) (online at www.nytimes.com/2023/12/19/health/cancer-drug-shortage.html); *Why There's a*

treat aggressive bone cancer when two of three necessary prescriptions were unavailable in 2023.[5] These medications are particularly critical for cancer patients because they offer patients the chance of full recovery, and without access to these drugs, the consequences are life-threatening for many.[6]

Pharmaceutical companies, including Pfizer, as well as the Food and Drug Administration (FDA) have made meaningful progress rectifying the oncology drug shortage, and we recognize that not all generic oncology medications manufactured by Pfizer are currently experiencing shortages. In a letter to customers, Pfizer addressed the cancer drug shortage and noted the company "has been working diligently and increasing output above our historical volumes amidst these competitive shortages."[7] Pfizer's recognition of the issue and commitment to rectifying the shortage is a step forward; however, the root cause is not yet resolved and carboplatin, cisplatin, and methotrexate continue to experience residual delays.[8] For example, FDA's drug shortage database lists carboplatin, which is manufactured by Pfizer's subsidiary Hospira, as "currently in shortage."[9] We remain deeply concerned about volatility in the oncology drug supply and that these drugs, including carboplatin, cisplatin, and methotrexate, may continue to experience shortages in the coming months.[10]

As the oncology drug shortage persists, there are reports of price gouging driving up the price of these medications. In many instances, smaller hospitals and oncology care centers are forced to turn to third-party suppliers that can charge up to ten times the usual price for generic oncology medications. This means providers can only get medications for a reduced number of patients or face financial ruin.[11]

A recent report by the Department of Health and Human Services found that drug shortages affect patients in a number of ways. Patients may need to pay more out of pocket to access a drug that is in shortage or use a more expensive alternative. Patients may also face higher premiums because of increased spending on medical care by health insurers forced to

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Serious Cancer Drug Shortage, and How to Fix It, Scientific American (Sept. 18, 2023) (online at www.scientificamerican.com/article/why-theres-a-serious-cancer-drug-shortage-and-how-to-fix-it/).

[5] *Id*.

[6] *Id.*; The White House, Office of Science and Technology Policy, *Strengthening the Supply Chain for Cancer Drugs* (Sept. 12, 2023) (online at www.whitehouse.gov/ostp/news-updates/2023/09/12/strengthening-the-supply-chain-for-cancer-drugs/).

[7] Letter from Pfizer Hospital U.S. Entitled: *Availability Update for Select Oncology Products* (May 9, 2023) (online at www.fda.gov/media/168209/download).

[8] *Id.*; Cancer Cytopathology, *Generic Cancer Drugs are Still in Short Supply* (Jan. 1, 2024) (online at https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncy.22788).

[9] Food and Drug Administration, *Current and Resolved Drug Shortages Reported to the FDA* (online at www.accessdata.fda.gov/scripts/drugshortages) (accessed Feb. 15, 2024).

[10] *Id.*; Cancer Cytopathology, *Generic Cancer Drugs are Still in Short Supply* (Jan. 1, 2024) (online at https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncy.22788).

[11] *Price Gouging of Cancer Drugs in Short Supply Hits Some Hospitals Hard*, NBC News (Aug. 17, 2023) (online at www.nbcnews.com/health/cancer/cancer-drug-shortage-price-gouging-chemo-drugs-hits-hospitals-hard-rcna98041).

cover more expensive alternatives. These cost increases disproportionately affect consumers who are uninsured or underinsured, including those on high deductible plans or whose plans require them to pay coinsurance. Patients may also face indirect costs, such as having to contact additional pharmacies and travel farther distances to obtain their medication.[12]

It is extremely concerning that pharmaceutical companies may not be motivated to produce generic drugs like carboplatin, cisplatin, and methotrexate, because they are not as lucrative as producing patented brand name drugs.[13] For instance, several generic cancer drug manufacturers have discontinued products over time for economic reasons, including the lack of profitability for generic drugs.[14] As a principal supplier of carboplatin, cisplatin, and methotrexate, it is critical that Pfizer continues to increase production of these life-sustaining cancer medications, even amidst potential lower profitability.

To better understand the oncology drug shortage, including its root causes and practical solutions needed to remedy it, we request information regarding the steps your company has and is currently taking to respond to ongoing shortages of generic oncology drugs and steps your company is taking to prevent future shortages. Given the urgent need to address this shortage, we request written responses to the following questions, as well as a staff briefing on these topics, by March 6, 2024.

1. When did Pfizer become aware of a potential shortage of generic oncology drugs?

2. When did Pfizer begin taking steps to increase the supply of generic oncology drugs to meet demand, and are these steps Pfizer will continue going forward?

3. Does Pfizer anticipate additional generic oncology drug shortages? Why or why not?

4. Does Pfizer plan to make additional manufacturing changes to prevent future oncology drug shortages?

5. What steps is Pfizer taking to prevent price gouging and otherwise increase consumer access to generic oncology drugs?

6. How is Pfizer working with the FDA to prevent future oncology drug shortages?

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[12] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation *Impact of Drug Shortages on Consumer Costs* (May 2023) (https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf).

[13] *Why There's a Serious Cancer Drug Shortage, and How to Fix It*, Scientific American (Sept. 18, 2023) (online at www.scientificamerican.com/article/why-theres-a-serious-cancer-drug-shortage-and-how-to-fix-it/).

[14] *Id*.; The White House, *Press Release: Strengthening the Supply Chain for Cancer Drugs* (Sept. 12, 2023) (online at www.whitehouse.gov/ostp/news-updates/2023/09/12/strengthening-the-supply-chain-for-cancer-drugs/).

7. Please identify all issues relating to the supply chain, quality assurance, availability of raw materials, and availability of labor effecting the production and distribution of Pfizer's generic oncology drugs.

The Committee on Oversight and Accountability is the principal oversight committee of the House of Representatives and has the broad authority to investigate "any matter" at "any time" under House Rule X.

An attachment to this letter provides additional instructions for responding to this request. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Sincerely,

Jamie Raskin
Ranking Member

Eleanor Holmes Norton
Member of Congress

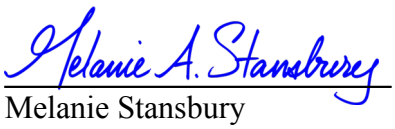
Stephen F. Lynch
Member of Congress

Kweisi Mfume
Member of Congress

Alexandria Ocasio-Cortez
Member of Congress

Katie Porter
Member of Congress

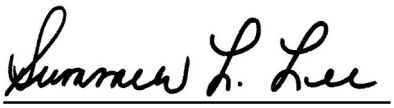
Cori Bush
Member of Congress



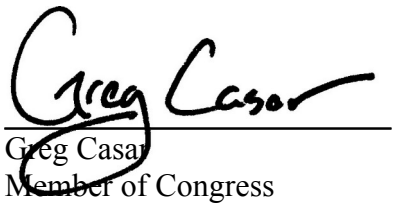
Melanie Stansbury
Member of Congress

Robert Garcia
Member of Congress

Maxwell Alejandro Frost
Member of Congress

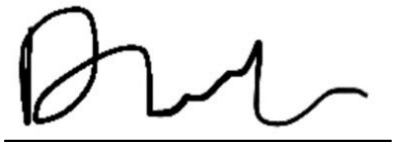


Summer Lee
Member of Congress

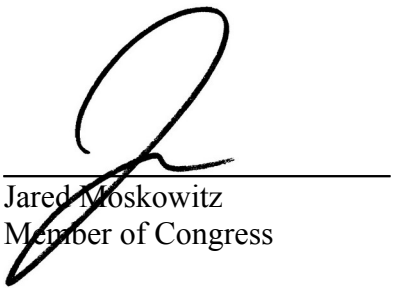


Greg Casar
Member of Congress

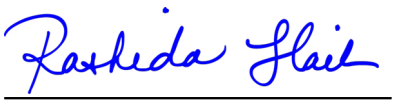
Jasmine Crockett
Member of Congress



Dan Goldman
Member of Congress



Jared Moskowitz
Member of Congress



Rashida Tlaib
Member of Congress

Enclosure

cc: The Honorable James Comer, Chairman

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.