

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074
MINORITY (202) 225-5051

<https://oversight.house.gov>

February 21, 2024

Ms. Keren Haruvi
President North America
Sandoz Inc. U.S.
100 College Road West
Princeton, NJ 08540

Dear Ms. Haruvi:

We write concerning the prolonged shortage of powder amoxicillin. For more than a year, patients, hospitals, and healthcare providers have struggled to find powder amoxicillin, a critical, life-saving antibiotic. Sandoz, a subsidiary of Novartis until October 2023, is one of the top manufacturers of powder amoxicillin within the U.S. market and manufactures popular biosimilar and generic antibiotics, including Augmentin.¹ Parents, pediatricians, and children depend on amoxicillin to treat a variety of childhood illnesses, from the routine to life-threatening, and antibiotics like amoxicillin are 42% more likely to experience shortages than other prescription medications.²

Children under three and people who have difficulty swallowing pills depend on powder amoxicillin, which is a core component to produce the liquid version of the drug. Recent seasonal influxes of respiratory illnesses lead more people to require antibiotics, making the shortage even more acute.³ Strep throat, a common pediatric bacterial infection increased by almost 400% in some parts of the country, and aggressive cases of the illness appear to be on the rise.⁴ Shortages of amoxicillin may make strep throat more difficult to treat and left untreated may have serious consequences, such as increased risk of organ damage.⁵

According to the Food and Drug Administration (FDA), powder amoxicillin has been in short supply since October 2022. FDA's drug shortage database lists seven out of the twelve

¹ Sandoz, *Products* (Sept. 27, 2023) (online at www.us.sandoz.com/patients-customers/products).

² *A New Season of Infections is Here, But the Shortage of a Common Kids' Antibiotic Never Ended*, CNN (Sept. 22, 2023) (online at www.cnn.com/2023/09/22/health/amoxicillin-drug-shortage/index.html).

³ *400% Surge of Strep Throat Cases Complicated by Antibiotic Shortage*, The Messenger (Oct. 31, 2023) (online at <https://themessenger.com/health/strep-throat-cases-surging-cdc-antibiotic-shortage-amoxicillin-powder>).

⁴ *Id.*; *Aggressive, Sometimes Deadly Strep Infections on the Rise, Experts Warn*, The Messenger (Jan. 19, 2024) (online at <https://themessenger.com/health/invasive-group-a-strep-infections-canada-us-cdc-who>).

⁵ *Id.*

powder amoxicillin products manufactured by Sandoz with “limited availability.”⁶ We are concerned that despite several consecutive quarters of sales growth, Sandoz has failed to address the amoxicillin shortage and ensure that prescribers, hospitals, and retail pharmacies have appropriate access to powder amoxicillin that is critical to treat the ongoing surge of pediatric respiratory illnesses.

In September 2023, Sandoz issued a public statement attributing the amoxicillin shortage to the marketplace and stating that the low price point for amoxicillin was causing manufacturers to exit the market.⁷ As families struggle to afford prescription medications, it is critical that companies do not exit the market because of lower profits, in particular for essential pediatric medications like powder amoxicillin.⁸

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 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.⁹

It is important that pharmaceutical companies such as Sandoz continue to produce sufficient amoxicillin to meet seasonal demand even amidst lower financial incentives. To better understand the amoxicillin drug shortage, including its root causes and practical solutions we can take to remedy it, we request information regarding the steps your company is taking to respond to ongoing shortages of powder amoxicillin. 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 Sandoz become aware of a potential shortage of powder amoxicillin?
2. What steps has Sandoz taken to increase the supply of powder amoxicillin to meet demand, and what steps is Sandoz taking going forward?

⁶ Food and Drug Administration, *Current and Resolved Drug Shortages and Discontinuations Reported to FDA, Amoxicillin Powder, For Suspension* (online at www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Amoxicillin%20Powder,%20For%20Suspension&st=c&tab=tabs-) (accessed Nov. 28, 2023).

⁷ *A New Season of Infections is Here, But the Shortage of a Common Kids' Antibiotic Never Ended*, CNN (Sept. 22, 2023) (online at www.cnn.com/2023/09/22/health/amoxicillin-drug-shortage/index.html).

⁸ World Health Organization, *WHO Model List of Essential Medicines for Children—9th List 2023* (July 26, 2023) (online at www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.03).

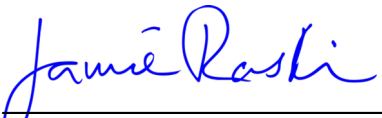
⁹ Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Impact of Drug Shortages on Consumer Costs* (May 2023) (<https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf>).

3. What steps is Sandoz taking to increase consumer access to powder amoxicillin and ensure its affordability?
4. When does Sandoz expect to have sufficient supply to meet consumer demand?
5. Is Sandoz planning to increase the quantity of powder amoxicillin it manufactures to meet demand, in light of other manufacturers exiting the market in recent years? Please explain why or why not.
6. How is Sandoz working with the FDA to rectify this shortage and prevent future ones?
7. Please identify all issues relating to the supply chain, quality assurance, availability of raw materials, and availability of labor affecting the production and distribution of powder amoxicillin.

The Committee on Oversight and Accountability is the principal oversight committee of the House of Representatives and has 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,



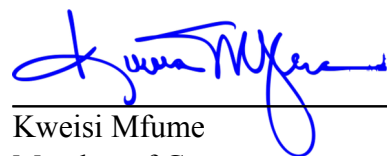
Jamie Raskin
Ranking Member



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



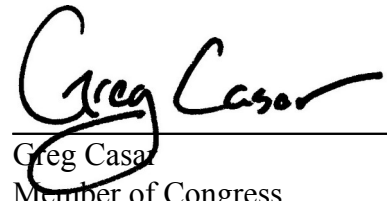
Robert Garcia
Member of Congress



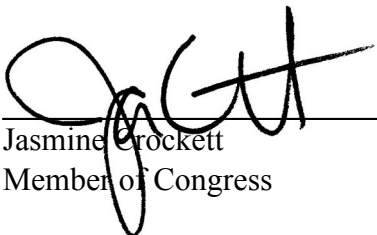
Maxwell Alejandro Frost
Member of Congress



Summer Lee
Member of Congress



Greg Casar
Member of Congress



Jasmine Crockett
Member of Congress



Dan Goldman
Member of Congress



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.