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Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
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February 21, 2024

Mr. Richard Francis
President and Chief Executive Officer
Teva Pharmaceuticals USA, Inc.
400 Interpace Parkway, Suite A1
Parsippany, NJ 07054-1119

Dear Mr. Francis:

We are concerned that a prolonged shortage of Adderall and other stimulant medications has left patients struggling to treat conditions such as attention deficit/hyperactivity disorder (ADD/ADHD), binge-eating disorder, and narcolepsy for well over a year.[1] The Food and Drug Administration (FDA) formally announced a shortage on October 12, 2022, and since then, patients have struggled to obtain Adderall and its generic equivalents.[2] An estimated 41 million ADHD patients rely on Adderall or its equivalents to treat ADD/ADHD.[3] Patients who rely on Adderall and other stimulant medications to stay focused, reduce impulsive behavior, and increase alertness face uncertainty as to if and when they will be able to access the medication they rely on.

Our constituents share story after story detailing how hard it is to fill prescriptions for Adderall and that the shortage affects every element of their lives. For example, previously capable students are now barely able to get passing grades, and adults are forced to contact every local pharmacy in an attempt to obtain a medication that may be the difference between being productive and focused in the workplace, or losing their livelihoods. According to a recent survey of caregivers and adults with ADHD, approximately 38% of patients reported trouble locating and filling their prescription medication over the last year, and 21% reported suffering

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[1] *One Year Later, Where's All the Adderall?*, TIME (Oct. 17, 2023) (online at https://time.com/6324717/one-year-later-wheres-all-the-adderall/); Letter from Robert M. Califf, M.D. Commissioner of Food and Drugs, Food and Drug Administration, and Administrator Anne M. Milgram, Drug Enforcement Administration (Aug. 1, 2023) (online at www.fda.gov/media/170736/download).

[2] *Teva Is Facing Adderall Supply Disruptions as Demand for ADHD Drug Soars,* Bloomberg (Aug. 2, 2023) (online at www.bloomberg.com/news/articles/2022-08-02/teva-facing-adderall-supply-disruptions-as-demand-soars); Food and Drug Administration, *Current and Resolved Drug Shortages and Discontinuations Reported to FDA* (accessed Feb. 15, 2024) (online at www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Amphetamine+Aspartate%3B+Amphetamine+Sulfate%3B+Dextroamphetamine+Saccharate%3B+Dextroamphetamine+Sulfate+Tablets&st=c&tab=tabs-4&panels=0).

[3] *One Year Later, Where's All the Adderall?*, TIME (Oct. 17, 2023) (online at https://time.com/6324717/one-year-later-wheres-all-the-adderall/).

from disruptions in treatment.[4] Independent pharmacy owners and managers and even hospitals have reported struggling to obtain Adderall. For example, 94% of independent pharmacy owners and managers surveyed by the National Community Pharmacists Association reported shortages of Adderall or generics.[5]

Some forms of Adderall are now listed as "available;" however, the FDA's drug shortage database still lists certain generic forms of Adderall as "unavailable" or "limited supply available."[6] For all forms of Adderall and generic equivalents listed on the FDA's drug shortage database, including for those listed as "available," FDA attributes "demand increase for the drug" as the reason for the shortage.[7] However, when FDA formally announced the Adderall shortage, the agency noted it was caused in part by Teva's ongoing intermittent manufacturing delays and that while other manufacturers continued to produce generic equivalents, there was not sufficient supply to meet U.S. market demand without Teva producing at full capacity.[8]

In August 2023, FDA and the Drug Enforcement Administration (DEA) issued a joint letter that explained that although the manufacturing delay that initiated the Adderall shortage was resolved, the effects of the shortage persist. FDA also noted "record-high prescription rates of stimulant medications."[9] FDA and DEA indicated that in 2022, manufacturers did not produce the full allotment of amphetamines DEA permitted them to produce under existing controlled substance regulations. DEA estimated that manufacturers could have produced approximately 1 billion more doses in 2022. FDA and DEA also said that data for 2023 showed a similar trend of a mismatch between the amount produced and the amount DEA permitted manufacturers to produce.[10] In fall 2023, Teva stated that production facilities were running at full capacity and increasing production would require new facilities.[11] Yet, Adderall and generic equivalents are still facing shortages. Absent critical information as to the root causes of the shortage, important questions remain as to Teva's failure to consistently produce the full allotment of Adderall and

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[4] *"A Daily Nightmare:" One Year into the ADHD Stimulant Shortage*, Attitude (Sept. 26, 2023) (online at www.additudemag.com/adhd-medication-shortage-adderall-vyvanse/).

[5] National Community Pharmacists Association, *Report for September 2023 Survey of Independent Pharmacy Owners/Managers* (online at https://ncpa.org/sites/default/files/2023-09/9.28.2023-NCPA_sept_survey.pdf); *An Adderall Shortage Has Not Let Up. Here is Why*., Washington Post (Mar. 30, 2023) (online at www.washingtonpost.com/business/2023/03/14/adderall-shortage-telehealth-prescriptions/).

[6] Mixed amphetamine salts are a generic form of Adderall comprised of Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, Amphetamine Sulfate. Food and Drug Administration, *Current and Resolved Drug Shortages Reported to the FDA* (online at www.accessdata.fda.gov/scripts/drugshortages) (accessed Jan. 2, 2024).

[7] *Id*.

[8] Food and Drug Administration, *FDA Announces Shortage of Adderall* (Oct. 12, 2022) (online at www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall).

[9] Letter from Robert M. Califf, M.D. Commissioner of Food and Drugs, Food and Drug Administration, and Administrator Anne M. Milgram, Drug Enforcement Administration (Aug. 1, 2023) (online at www.fda.gov/media/170736/download).

[10] *Id.*

[11] *ADHD Drug Shortages Worsen as Makers Say Production Is Maxed Out*, Bloomberg (Sept. 12, 2023) (online at www.bloomberg.com/news/articles/2023-09-12/adhd-drug-shortages-worsen-as-teva-novarti-takeda-say-production-is-maxed-out).

generic equivalents it is lawfully permitted, as well as convey to the public the cause for the manufacturing delays and subsequent shortages.[12]

To better understand the ongoing shortage of Adderall and other generic equivalents, including root causes and practical solutions needed to remedy it, we request written responses to the following questions, as well as a staff briefing on these topics, by March 6, 2024.

1. When did Teva first become aware of a potential shortage of Adderall and its generic equivalents?

2. What steps has Teva taken to increase the supply of Adderall and its generic equivalents to meet demand, and what steps is Teva taking going forward?

    a. Please explain why Teva produced less Adderall and generic equivalents than the allotted DEA quota in 2022.

    b. What percentage of DEA's allotted Adderall and generic equivalent quota did Teva produce in 2023?

    c. If Teva produced less Adderall and generic equivalents than the allotted DEA quota in 2023, please explain why.

    d. What percentage of DEA's allotted Adderall and generic equivalent quota does Teva plan to produce in 2024?

    e. If Teva plans to produce less Adderall and generic equivalent medications than DEA's quota in 2024, please explain why.

3. What steps is Teva taking to increase consumer access to Adderall?

4. What steps is Teva taking to prevent price gouging and otherwise increase consumer access to Adderall and its generic equivalents?

5. How is Teva working with the FDA to rectify this shortage and prevent future ones?

6. When does Teva expect to have sufficient supply to meet consumer demand?

7. Please identify all issues relating to the production of Adderall and its generic equivalents, including but not limited to supply chain, quality assurance, availability of raw materials, availability of labor, and availability of facilities, affecting production and distribution of these medications.

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[12] *One Year Later, Where's All the Adderall?,* TIME (Oct. 17, 2023) (online at https://time.com/6324717/one-year-later-wheres-all-the-adderall/).

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
Member of Congress
Ranking Member, Committee on Oversight and Accountability

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

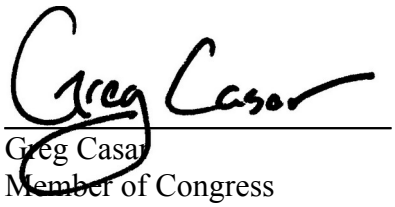
Cori Bush
Member of Congress

Melanie Stansbury
Member of Congress

Robert Garcia
Member of Congress

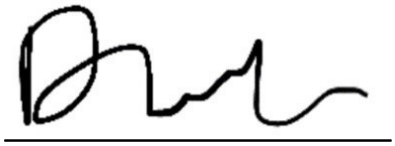
Maxwell Alejandro Frost
Member of Congress

Summer Lee
Member of Congress

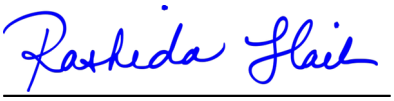


Greg Casar
Member of Congress

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.