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Congress of the United States

House of Representatives

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May 13, 2024

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
700 Army Navy Dr.
Arlington, VA 22202

Dear Administrator Milgram:

The Committee on Oversight and Accountability is continuing to investigate the growing number of critical drug shortages impacting Americans' medical care.[1] We seek to understand how the Drug Enforcement Administration (DEA) is acting to support the pharmaceutical manufacturing industry in its efforts to respond to legitimate patient needs for controlled substances. Pursuant to Section 1005 of the Food and Drug Administration Safety and Innovation Act, DEA has authorities to evaluate production of controlled substances in shortage.[2] Therefore, we request documents and communications related to DEA's impact on and response to the prolonged shortages of Schedule II drugs like Adderall.

DEA sets aggregate production quotas (APQ) for pharmaceutical manufacturers to produce controlled substances, including Schedule II substances like amphetamine salts (name brand Adderall), that have medical value and high potential for abuse.[3] APQs set a maximum level of a controlled substance that can be produced each year. Adderall is a well-known stimulant treatment for Attention Deficit Hyperactivity Disorder (ADHD) and is medically necessary for serious conditions such as narcolepsy and binge eating disorder.[4] APQs are intended to cover the annual needs of a company to produce the drugs necessary to meet demand. Due to spiking demand, pharmaceutical manufacturers producing at full capacity—sometimes more—are unable to meet the demand for more prescriptions amid manufacturer exits. Additionally, in the last four years, there are fewer manufacturers of Adderall and generic alternatives. Despite increased demand and fewer manufacturers, DEA has not provided

[1] Letter from Hon. James Comer, Chairman, H. Comm. on Oversight and Accountability and Hon. Lisa McClain, Chairwoman, Subcomm. on Health Care and Fin. Servs. to Hon. Robert M. Califf, Comm'r, U. S. Food and Drug Admin. (Nov. 2, 2023).
[2] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-44, 126 Stat. 993, 1105 (2012).
[3] Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1236 (Oct. 27, 1970).
[4] Ike Swetlitlz, *Understanding why Adderall shortages are shrouded in mystery*, BLOOMBERG (Feb. 28, 2023).

manufacturers an increased APQ.[5] As a result, shortages of these drugs have remained for more than a year and a half.[6]

Two factors impacting the supply of Adderall are directly attributable to DEA regulatory decisions. First, mixed-ingredient pharmaceuticals like Adderall require unequal amounts of active pharmaceutical ingredients (API) that are also distributed via DEA quotas. However, DEA allocates the API in a 1:1 ratio. While the exact ratios used to create the finished drug are proprietary business information, DEA has the knowledge and ability to allocate APQ to reflect industry usage rather than distributing it in equal ratios. Additionally, DEA has the market visibility to detect the ratios used for common Adderall or similar drug formulations and monitor returned allocation. However, this does not appear to be the case and as a result, amphetamine manufacturers are not using API in equal amounts and are unable to utilize their full APQ because DEA continues to only provide equal ratios despite industry requests for change.

Second, DEA recently changed the application of its quota allocation systems.[7] Instead of proposing yearly quota allocations, manufacturers must submit quarterly requests to DEA.[8] This change was introduced as an attempt to increase visibility into drug production and reduce uncertainty in the market.[9] Instead, it had the opposite effect and making it more difficult for drug manufacturers to predict the next quarter's manufacturing plan. The quarterly allocation system exacerbated the challenge of allotment ratios between different finished goods by removing flexibilities allowed by an annual allocation. Since the quarterly system began, pharmaceutical manufacturers have been given little notice of their allocation before the next quarter begins. For example, manufacturers were alerted on December 29, 2023, of their 2024 Quarter One APQ, which began on January 1, 2024. Recognizing these issues, DEA has again altered the process for quota allocation, shifting it from quarterly to semi-annually. The change represents a welcome shift, though highlights the ongoing uncertainty for manufacturers which is likely to extend shortage concerns.

DEA's mishandling of the APQ system resulting in shortages is not a new problem. In a 2015 Government Accountability Office (GAO) report, DEA's quota process was found to be ineffectively administered, leading to drug shortages.[10] This report found that DEA consistently missed required time frames for establishing quotas for Schedule II substances and lacked performance measures to ensure quotas were adequate and meeting demand.[11] The systems

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[5] James D. Walsh, *The empty Adderall factory*, N. Y. MAG. (Feb. 19, 2024).
[6] U.S. Food & Drug Admin., FDA Announces Shortage of Adderall (Oct. 12, 2022), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall.
[7] Docket No. DEA-1228P, Notice, Proposed Aggregate Production Quotas for Schedule I and Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2024, 88 Fed. Reg. 75312 (Nov. 2, 2023);
[8] Letter from Hon. Anne Milgram, Adm'r, Drug Enforcement Admin. (Nov. 1, 2023).
[9] *Id.*
[10] U. S. GOV'T ACCOUNTABILITY OFF., GAO-15-202, DRUG SHORTAGES: BETTER MANAGEMENT OF THE QUOTA PROCESS FOR CONTROLLED SUBSTANCES NEEDED: COORDINATION BETWEEN DEA AND FDA SHOULD BE IMPROVED (Feb. 2015).
[11] *Id.* at 29.

established in response to this report may need re-evaluation and updating amid today's current pharmaceutical supply chain challenges.

The committee recognizes the potential for abuse of these medicines and DEA's intention to ensure they only go to individuals who need them. It is critical that DEA work with pharmaceutical manufacturers, not against them, to provide regulatory support that reduces drug shortages and prevents abuse. DEA has a duty to promulgate rules that reflect an understanding of the industry it regulates. Shortages of controlled substances are even more challenging due to the constrained nature of the market. Therefore, to assist our investigation of this matter, please provide the following documents and as soon as possible, but not later than May 27, 2024:

1) All processes and procedures related to the determination of the total amount of APQ;

2) All processes and procedures related to the determination of the allocation ratio of d-amphetamine to l-amphetamine;

3) A complete list of d-amphetamine and l-amphetamine APQ allocations and the amount of allocation returned; and

4) All documents and communications related to the DEA's response to shortages of controlled substances, in particular Adderall, Vyvanse, and related generics.

To schedule the briefing or ask any related follow-up questions, please contact Committee on Oversight and Accountability Majority Staff at (202) 225-5074. The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you for your attention to this matter.

Sincerely,

James Comer
Chairman
Committee on Oversight and Accountability

Lisa McClain
Chairwoman
Subcommittee on Health Care and Financial Services

cc: The Honorable Jamie Raskin, Ranking Member
Committee on Oversight and Accountability

The Honorable Katie Porter, Ranking Member
Subcommittee on Health Care and Financial Services