

Congress of the United States
House of Representatives
Washington, DC 20515

October 12, 2023

The Honorable Anne Milgram
Administrator
U.S Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Administrator Milgram and Commissioner Califf,

One year ago today, on October 12, 2022, the Food and Drug Administration (FDA) declared a shortage¹ of amphetamine mixed salts, commonly referred to by the brand name Adderall. We write to express our continued concern about the persisting shortage of medications used to treat attention deficit hyperactivity disorder (ADHD).

We are disappointed that a year later, we continue to hear from our constituents regarding their challenges accessing prescriptions. We know too well that drug shortages pose significant threats to public health by delaying care for patients, requiring frustrated providers to prescribe alternatives that may be less effective or pose additional risks to the patients, and exposing consumers to price gouging by manufacturers. We cannot allow this to be the continuing reality for Americans across the country.

We are especially concerned by ongoing shortages coinciding with this fall's return to school. Historically, there has been an uptick in the demand for ADHD medications at the start of the school year and we are hearing from parents caught in limbo trying to find medications for their children. Without the necessary medications, students struggle to learn and regulate their emotions, contributing to the mental health crisis facing children. This is unacceptable.

Twelve months ago, the FDA declared a shortage of Adderall due to ongoing manufacturing delays at Teva. Since then, the situation has only worsened. A September 2023 survey² from the National Community Pharmacists Association found that 94 percent of independent community pharmacies reported experiencing shortages of Adderall or generics. Likewise, a recent survey³ of 10,936 caregivers and adults with ADHD found that nearly 40 percent of patients had trouble filling their prescriptions in the last year. This illustrates the dire situation we have witnessed in our districts.

¹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall>

² https://ncpa.org/sites/default/files/2023-09/9.28.2023-NCPA_sept_survey.pdf

³ <https://www.additudemag.com/adhd-medication-shortage-adderall-vyvvanse/>

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We understand that the FDA and Drug Enforcement Administration (DEA) have made efforts to provide relief to patients in need of ADHD medications, by approving several generic versions of Vyvanse in August⁴ and increasing the aggregate production quota for methylphenidate (brand name Concerta) in October⁵. Yet, there continues to be a lack of action on amphetamine mixed salts.

On August 1, 2023, the FDA and the DEA released a joint letter⁶ calling on drug manufacturers to fill their allotted quotas on stimulant production. This letter cited that in 2022, manufacturers only sold 70 percent of their allotted quotas and 1 billion additional authorized doses were not produced or shipped, with experts expecting similar trends for 2023. While your efforts to remedy these shortages are appreciated, we must be committed to doing more. Manufacturers and agencies alike must work together to protect patients' access to essential medications.

Americans deserve swift action on these issues. As such, we are requesting answers to the following questions.

- I. The DEA increased the aggregate production quota for methylphenidate (brand name Concerta) on October 3, 2023. Is the DEA considering similar adjustments to the production quota of amphetamine mixed salts?
- II. Following the joint letter on August 1, 2023, how have the FDA and DEA worked with manufacturers of ADHD medications to address issues fulfilling quotas?
 - a. Have manufacturers committed to filling allotted quotas for 2023?
 - b. If manufacturers do not plan on fulfilling their allotted quotas for 2023, how is the DEA working with manufacturers to relinquish these quotas?
 - c. Will the DEA consider increasing quota allotments for willing manufacturers with the capacity to continue additional production of amphetamine mixed salt medications?
 - d. How will the FDA and DEA continue to work with manufacturers to address shortages around amphetamine medications?
- III. How will the DEA implement lessons from the COVID-19 public health emergency into updated telemedicine prescribing rules?
- IV. What additional steps are the FDA and DEA taking to address continuing shortages around ADHD medications and to provide necessary relief for patients across the country?
- V. What steps are the DEA and FDA taking to mitigate future shortages of ADHD medications?
- VI. Please describe actions that Congress should take to support the DEA and FDA in addressing and preventing these challenges.

We kindly ask that you respond to these questions no later than November 12, 2023. Thank you for your commitment to addressing this critical issue impacting pharmacists, caregivers, and patients.

⁴ <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-multiple-generics-adhd-and-bed-treatment>

⁵ <https://www.federalregister.gov/documents/2023/10/03/2023-22059/adjustment-to-the-aggregate-production-quota-for-methylphenidate-for-sale-for-2023>

⁶ <https://www.fda.gov/media/170736/download>

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Sincerely,

Abigail Spanberger
Member of Congress

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