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

December 19, 2022

Anne Milgram
Acting Administrator
U.S. Drug Enforcement Agency
8701 Morrissette Drive
Springfield, VA 22152

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Administrator Milgram and Commissioner Califf,

I write to express my concern about shortages of Adderall and other medications needed to treat attention deficit hyperactivity disorder (ADHD). The ongoing shortage has made it difficult for patients to manage their ADHD and created especially acute challenges for parents of children with ADHD. As I continue hearing about the impact of these shortages on adults and children with ADHD who rely on their medication, I encourage your agencies to collaborate and do everything possible to alleviate this shortage as quickly as possible.

Shortages of essential drugs, especially ones that have been on the market for years, have been a persistent problem in our healthcare system. Drug shortages pose significant challenges to the public health because they delay care for patients, frustrate providers who must prescribe alternatives that may be less effective or pose additional risks to the patients, and expose consumers to price gouging by unscrupulous manufacturers. While the number of new drug shortages has declined dramatically in the past decade, the number of ongoing shortages has increased in recent years, according to the Food and Drug Administration (FDA)'s annual report.[1]

Medications that include controlled substances may be especially vulnerable to prolonged shortages, given the complex regulatory structure governing their production and distribution. The Drug Enforcement Agency (DEA) regulates controlled substances due to their potential for abuse and addiction and sets quotas that limit the amount of controlled substances available in the U.S. Every year, manufacturers apply to DEA for the quota needed to make a basic class of a controlled substance.

At the start of the COVID-19 pandemic, Congress waived in-person restrictions on providers prescribing Schedule II controlled substances – such as Adderall – through telehealth. This change led to a surge in ADHD cases diagnosed over video calls and prescriptions for Adderall. Since 2019, the number of total Adderall prescriptions has increased from 35.5 million to 41.2 million – a 16 percent increase.[2] The surge in demand through online providers has caused concerns that many of these new prescriptions may be for inaccurate diagnoses.

[1] "Report to Congress: Drug Shortages for Calendar Year 2021," Food and Drug Administration, available at: https://www.fda.gov/media/159302/download.
[2] "FDA Confirms Widespread Shortages of Adderall," New York Times, October 13, 2022, available at: https://www.nytimes.com/2022/10/13/health/adderall-shortage-adhd.html.

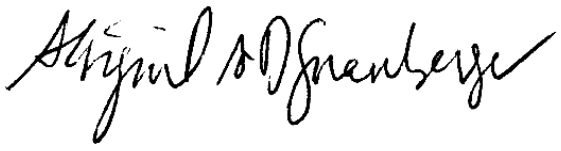
Production has not been able to keep up with the surge in demand and in early October the FDA reported that Adderall, the brand name for the immediate-release formulation of amphetamine mixed salts, went into shortage due to ongoing manufacturing delays at Teva. While other producers continue to manufacture amphetamine mixed salts, there is insufficient supply to meet U.S. demand. The current shortage has been a crisis for patients who rely on Adderall to function, making daily life significantly more difficult.

Patients who rely on Adderall to function daily deserve a comprehensive federal response to ensure access to their medications. Given the complicated regulatory framework around controlled substances and the incentives in the drug industry, addressing the shortage of Adderall will require coordination between FDA, DEA, and industry. As such, please provide answers to the below questions:

1. How do the DEA's final 2023 aggregate production quotas for schedule II-controlled substances respond to patients' concern about the shortage of Adderall and other ADHD medications?[3]
2. How have new flexibilities around telehealth during the COVID-19 public health emergency and resulting increases in prescriptions influenced DEA's production quotas over the past two years?
3. How has the FDA engaged with Adderall manufacturers to address raw material and workforce shortages?
4. How are the DEA and FDA collaborating to identify other manufacturers of ADHD medications and determine their capability to meet legitimate patient needs?
5. What guidance, if any, has the DEA provided to pharmacies seeking to change their supplier or otherwise modify their regular order to have a sufficient supply of Adderall for their patients' needs?
6. How does the DEA monitor and evaluate online providers' prescribing practices to ensure ADHD diagnoses are made accurately and minimize diversion?

Thank you very much for your commitment to protecting patients' access to their medications.

Sincerely,



Abigail D. Spanberger

Member of Congress

[3] "Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2023," December 2, 2022. Federal Register Citation: 87 FR 74168.