



August 1, 2023

Dear Americans,

As leaders of the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA), we recognize the important role that prescription stimulants play in the treatment of conditions such as attention-deficit/hyperactivity disorder (ADHD), binge eating disorder, and uncontrollable episodes of deep sleep (narcolepsy). The lack of availability of certain medications in recent months has been understandably frustrating for patients and their families.

Given the interest related to access to these medications, we want to provide an update on the ongoing actions being taken to resolve the shortages of prescription stimulant medications. In addition, we want to acknowledge important issues that will need to be addressed through longer-term coordination by a variety of entities involved in this effort. This is not a problem that the FDA and DEA can solve on our own. We are urging all stakeholders to work together to resolve these shortages as quickly as possible.

The FDA and DEA do not manufacture drugs and cannot require a pharmaceutical company to make a drug, make more of a drug, or change the distribution of a drug. That said, we are working closely with numerous manufacturers, agencies, and others in the supply chain to understand, prevent, and reduce the impact of these shortages.

The current shortage of stimulant medications is the result of many factors. It began last fall due to a manufacturing delay experienced by one drug maker. While this delay has since resolved, we are continuing to experience its effects in combination with record-high prescription rates of stimulant medications. Data show that, from 2012 to 2021, overall dispensing of stimulants (including amphetamine products and other stimulants) increased by 45.5 percent in the United States. According to a U.S. Centers for Disease Control and Prevention report, particularly during 2020–2021, when virtual prescribing was permitted on a widespread basis during the COVID-19 Public Health Emergency, the percentages in certain age groups grew by more than 10 percent. We are calling on key stakeholders, including manufacturers, distributors, pharmacies, and payors, to do all they can to ensure access for patients when a medication is appropriately prescribed. We want to make sure those who need stimulant medications have access. However, it is also an appropriate time to take a closer look at how we can best ensure these drugs are being prescribed thoughtfully and responsibly.

Stimulants are controlled substances with a high potential for abuse, which can lead to addiction and overdose. Therefore, there are limits (also known as quotas) set by DEA for how much of these drugs can be produced. However, for amphetamine medications, in 2022, manufacturers did not produce the full amount that these limits permitted them to make. Based on DEA's internal analysis of inventory, manufacturing, and sales data submitted by manufacturers of amphetamine products, manufacturers only sold approximately 70 percent of their allotted quota

for the year, and there were approximately 1 billion more doses that they could have produced but did not make or ship. Data for 2023 so far show a similar trend.

We (DEA and the FDA) have called on manufacturers to confirm they are working to increase production to meet their allotted quota amount. If any individual manufacturer does not wish to increase production, we have asked that manufacturer to relinquish their remaining 2023 quota allotment. This would allow DEA to redistribute that allotment to manufacturers that will increase production. DEA is also committed to reviewing and improving our quota process.

The FDA is asking professional groups and healthcare providers to accelerate efforts to support appropriate diagnosis and treatment of ADHD, such as further development of additional clinical guidelines for ADHD in adults. In recognition of this need, FDA [awarded a grant](#) to the National Academies of Sciences, Engineering, and Medicine (NASEM) to support a scientific meeting on ADHD in adults and considerations for diagnosis and treatment. FDA also recognizes that further research is needed into the diagnosis and treatment of ADHD and believes that research can help inform the development of alternative treatments and an understanding of the behavioral and societal issues leading to [widespread misuse](#) of these medications in certain groups.

FDA has already taken steps to support the development of alternative treatment options. In 2020, for instance, FDA permitted marketing of a [game-based digital therapeutic](#) to improve attention function in children with ADHD. This device offers a non-drug option for improving symptoms associated with ADHD in children. There are also non-stimulant medications approved to treat ADHD, including one approved in 2021. Additionally, to address continuing concerns of misuse, addiction and overdose of prescription stimulants, the FDA recently issued a [drug safety communication](#) and required updates to the labeling to standardize prescribing information and clearly inform patients, caregivers and healthcare professionals of these risks.

FDA and DEA will continue to do all we can to prevent stimulant drug shortages, limit their impact, and resolve them as quickly as possible. We will consider additional actions to prevent non-medical use and identify efforts to better understand and strengthen the supply chain. We also hope that we can all work together to assure that those who need stimulant medications can get them based on the best clinical knowledge about when they are effective, and avoid them when there is no indication for their use.

We will continue to work together and with all of you to mitigate this drug shortage and provide up to date information.

Sincerely,



Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration



Anne M. Milgram
Administrator
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