



U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

November 1, 2023

Dear Americans:

On August 1, 2023, I wrote to you with FDA Commissioner Robert Califf to address the lack of availability of certain prescription stimulant medications. As we said then, the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) recognize the important role that prescription stimulants play in the treatment of conditions such as attention-deficit/hyperactivity disorder (ADHD), binge eating disorder, and narcolepsy. I am writing to you now to provide an update on actions DEA has taken, and is taking, to address shortages in prescription stimulant medications and prevent such shortages from occurring in the future.

As a reminder, DEA does 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 regularly engage with manufacturers about their production of drugs, and we set limits (called quotas) for how much of these drugs can be produced.

For amphetamine medications, like Adderall, our data showed that in 2022, manufacturers did not produce the full amount that these limits permitted them to make—resulting in a shortfall of 1 billion doses that could have been produced but were not made or shipped—and the data for 2023 has shown a similar trend. DEA has been in communication with the relevant manufacturers, and 17 out of 18 manufacturers have informed us that they will use their allotted quota amounts and increase production of stimulant medications. Those manufacturers are currently in the process of providing us with information on how long it will take for those stimulant medications to hit pharmacy shelves.

DEA is also actively making changes to our quota allocation process. On August 28, 2023, we changed our quota regulations to reduce the amount of a drug that manufacturers must keep in inventory and to make it easier for manufacturers to voluntarily relinquish their quota allotments in case they are not able to produce a drug. Earlier today, we announced steps we will take to increase manufacturer transparency and receive better real-time data on the status of drug production going forward. These changes include:

- Requiring drug manufacturers to submit their anticipated production timelines for medications to DEA in advance of receiving their quota allotments;
- Requiring drug manufacturers to apply for quota allotments on a quarterly (instead of yearly) basis, so that we are able to provide quota allotments to manufacturers that have demonstrated they are using them to actually make and sell medications for current use;

- Requiring monthly, digital reporting from manufacturers and distributors on the amount of drugs being produced and shipped; and
- Specifying whether a manufacturer's quota allotment is for domestic production or export production, so that we can track how much of a drug is available to Americans.

These changes are designed to help us see shortages coming and adjust more quickly over the long run. We are also taking steps to reduce the burden on patients. On July 27, 2023, we revised DEA regulations to allow patients to transfer electronic prescriptions from one pharmacy to another without going back to their doctor.

As we said in our prior letter, there are still important issues that will need to be addressed through longer-term coordination by DEA, FDA, drug manufacturers, and other stakeholders to resolve these issues in the long term. DEA is committed to ensuring that patients who need stimulant medications have access to them and to ensuring that these drugs are being prescribed thoughtfully and responsibly, and we will continue working with our partners inside and outside of government to do so.

DEA remains committed to ensuring that all Americans can access appropriately prescribed medications. DEA will continue to do all we can to prevent drug shortages, limit their impact, and resolve them as quickly as possible.

Sincerely,

A handwritten signature in black ink, appearing to be 'Anne Milgram', with a long horizontal flourish extending to the right.

Anne Milgram
Administrator