United States Senate

WASHINGTON, DC 20510

June 2, 2023

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

Dear Administrator Milgram:

My staff and I met with you and the head of the Food and Drug Administration (FDA) on April 18 to discuss urgent supply chain concerns, as well as federal regulation, related to the widespread shortage in Oregon and nationwide of amphetamine mixed salts, the generic medication for Adderall that treats attention deficit hyperactivity disorder (ADHD). Following our meeting, I anticipated robust and timely follow-up. That has not happened, and I am deeply disappointed on behalf of the Oregonians I represent.

Specifically, I expected that the DEA and FDA would issue a joint statement on ADHD medication to clarify the role and management of drug manufacturing quotas, as well as the conflicting reports from agencies, manufacturers and pharmacies, to help the public better understand the causes of these generic drug shortages. The DEA itself stated in 2018 that it would follow legal requirements to increase quotas when a shortage arises and provide a written response if the agency determines a request for an increase is unnecessary. No such written response appears to be available even as manufacturers have said the DEA has denied their quota increase requests.

ADHD can severely interfere with daily activities, including work and school, but stimulant medications like amphetamine mixed salts are commonly used treatments that are very effective and safe. As I pointed out in the April 18 meeting, in rural areas of Oregon largely served by independent pharmacies, these generic medication shortages may require unsustainable expenses for both the pharmacies and the consumers. In addition, these shortages can create challenging travel times of 60-90 minutes each way – especially in the winter months – to have access to this much-needed medicine. Shortages of these generics have also had a domino effect causing shortages of alternative medications to treat ADHD that may themselves be less effective. Pharmacies across Oregon are closing, in part due to unsustainable costs. Rural healthcare and access to medication should be a significant consideration for the agency.

I am concerned that despite the heightened national attention to these medication shortages, the quotas and agency actions appear to focus solely on manufacturer production at the national level without appropriate attention to prescriptions that cannot be filled at the pharmacy counter. Reportedly, that inability is due to lack of supply of affordable medications, limits that distributors have placed on pharmacy orders, and high out-of-pocket consumer costs. Further, the

agency's actions to date fail to reflect regional impacts or how manufacturers may use quotas to manufacture branded drugs instead of more accessible generic ones.
You agreed that greater transparency in the process would help the ongoing work of the DEA to reform the system, so I hope you will take these considerations into account in the promulgation of new regulations.

I understand the DEA has an important role to play to protect the health and well-being of our communities and to reduce the risk for abuse and diversion of controlled substances, including prescription drugs. However, I am very concerned that many folks suffering with ADHD will not get the health care they need, which impacts their daily life, and in the worst case may lead them to use potentially lethal non-prescribed drugs.

I am requesting answers to the following questions and requests:

1. Please provide a timeline on DEA rulemaking to provide transparency into allocation of aggregate production quota of controlled substances/chemicals used in controlled prescription drugs and individual domestic manufacturer quotas.

2. How does the DEA consider the limited availability of alternative medications in the evaluation of quota increase applications, such as an application for methylphenidate (branded as *Ritalin* or *Concerta*) given the shortage of amphetamine mixed salts?

3. What information does DEA have on the distribution/retail level on the transaction of controlled substances, if any, including canceled orders and sharp changes in price?

4. Congress required the DEA in the SUPPORT ACT to promulgate final regulations for a special registration for telemedicine under U.S. Code Title 21, Section 831(h), which the agency did not propose to do in its March 1st proposed rule or May 10th final rule. Will the DEA commit to the inclusion of final regulations for the special registration for telemedicine in the final rules on telemedicine flexibilities the agency plans to promulgate?

5. I would also like a recommendation from your office on how to improve the quota process so that regional and rural shortages for controlled prescription drugs gain the same attention as those in larger cities, and access to generic medications is prioritized when it comes to adjustments to the quotas.

I am expecting a timely response to these questions and concerns, as well as a joint statement from your agency and the FDA that comprehensively explains the reasons for the continued shortage of ADHD medications and how the agencies are tackling this crisis. Thank you for your attention to this matter and your work to reduce the illicit use of controlled substances in the country.

Sincerely,

Ron Wyden
United States Senator

CC:
The Honorable Robert Califf
Commissioner
Food and Drug Administration