Department of Justice
Drug Enforcement Administration

Office of Congressional Affairs

Springfield, VA 22152

August 1, 2023

The Honorable Ron Wyden
United States Senate
Washington, DC 20510

Dear Senator Wyden:

Thank you for your outreach regarding the availability of amphetamine products, including Adderall, used in the management of attention-deficit/hyperactivity disorder (ADHD). DEA takes these issues very seriously and has been working diligently to both understand their cause and solve them.

As background, at the manufacturing level, the pharmaceutical supply chain consists of two sets of manufacturers:

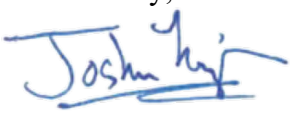
- Bulk manufacturers, who produce the active ingredient in a medication.
- Dosage form manufacturers, who purchase the active ingredient from the bulk manufacturers and use it to create individual doses of a medication for patient use.

DEA's 2022 dosage form quotas permitted dosage form manufacturers to produce over 38,418 kilograms of amphetamine products—and while DEA believes that bulk manufacturers have produced enough amphetamine to enable manufacture of those 38,418 kilograms—only 26,953 kilograms of amphetamine doses were actually shipped from dosage form manufacturers to distributors. That shortfall of 30% equals approximately 1 billion doses of amphetamine products.

To help solve this issue, on May 18, 2023, DEA's Acting Assistant Administrator sent the attached letter to all bulk and dosage form manufacturers of amphetamine and amphetamine products. The letter notes that DEA is prepared to quickly evaluate applications from amphetamine dosage form manufacturers seeking permission to produce increased amounts of amphetamine doses. DEA hopes that this letter encourages any dosage form manufacturers who have excess production capacity to increase their rate of production of individual doses of amphetamine products.

We appreciate your ongoing interest in DEA's work and we welcome the opportunity to work together on these important issues.

Sincerely,



Joshua R. Lipman
Chief
Office of Congressional Affairs

Attachment

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Dear DEA Registered Manufacturer:

DEA is aware of concerns related to the availability of various mixed salt amphetamine products, such as Adderall, used in the management of attention-deficit/hyperactivity disorder (ADHD) and subsequent reports from patients who have been unable to fill prescriptions for these drugs.

DEA takes this issue very seriously and is committed to ensuring that all Americans can access appropriately-prescribed medications. We are working with our federal partners at the Food and Drug Administration as well as manufacturers and distributors throughout the supply chain to understand the causes of these shortages and work to solve them.

As part of these efforts, DEA has conducted an internal analysis of inventory, manufacturing, and sales data submitted by manufacturers through ARCOS and through reports submitted to DEA's Quota Management System. That analysis shows that dosage manufacturers have not utilized the full extent of their authorized quotas. In 2022, DEA authorized dosage manufacturers to generate 38,418 kg of amphetamine medications—which equates to approximately 3.3 billion amphetamine dosage units. But dosage manufacturers only shipped approximately 26,953 kg of amphetamine medications—which equates to approximately.2.3 billion amphetamine dosage units. In other words, approximately 1 billion dosage units were authorized but not shipped—that is approximately 30%.

Similarly, data submitted for 2023 suggest that current quotas are adequate to meet patients' needs, but dosage manufacturers have not utilized the full extent of those quotas. DEA's Diversion Control Division stands ready to expeditiously review and adjudicate individual applications under the current authorized quota levels for amphetamine, in accordance with DEA regulations.

Sincerely,

THOMAS PREVOZNIK
Digitally signed by THOMAS PREVOZNIK
Date: 2023.05.17 07:57:12 -04'00'

Thomas W. Prevoznik
Acting Assistant Administrator
DEA Diversion Control Division