AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY
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American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

December 4, 2023

Administrator Anne Milgram
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Re: Proposed Aggregate Production Quota 2024 (Docket No. DEA-1228P)

Dear Administrator Milgram:

The American Academy of Child and Adolescent Psychiatry (AACAP) and the American Academy of Pediatrics (AAP) appreciate the opportunity to provide comments on the Drug Enforcement Administration's notice on the Proposed Aggregate Production Quota 2024 for schedules I and II of the Controlled Substances Act. AACAP is the professional home to more than 10,000 child and adolescent psychiatrists, fellows, residents, and medical students with a mission to promote the healthy development of children, adolescents and families through advocacy, education, and research. AAP is a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

As AACAP shared in a detailed letter earlier this year, shortages of stimulant medication have had an outsized impact on the patients and families our members serve by placing further strain on families that are already living with challenges, with those most likely affected by the shortages already experiencing economic disadvantages. On behalf of the physicians our two organizations represent, and the children and youth they serve, we appreciate the DEA's transparency around quota-setting for 2024, and for sharing plans for future policy revisions that would enable the development of methods to ensure more precise quotas of these medications in the future. We are also pleased to see that recent measures have been taken to reallocate unused active ingredients for stimulant medications, directing them toward manufacturers that are willing to increase their production, in addition to the actions DEA has committed to in this notice to better understand the supply chain dynamics for controlled substances, commit to ensuring that all Americans can access appropriately prescribed medications, and to quickly identify and address drug shortages.

Stimulant medications are safe and evidence-based treatment for attention deficit hyperactivity disorder (ADHD) in children. Demand for stimulant medications rose during the COVID-19 Public Health Emergency, as more children and adults were diagnosed with ADHD and clinicians began treating long-COVID related "brain fog" with stimulant medications. As the long-term effects of COVID continue to unfold and more Americans have access to medical care via telehealth, flexibility in setting quotas for stimulant medications will be necessary to anticipate and quickly address ongoing changes in stimulant medication demand. AACAP and AAP are pleased to see the DEA's commitment to establish and maintain reserve stocks of stimulant medication for this reason.

AACAP and AAP also ask that the DEA and the Food and Drug Administration (FDA) work together to simplify and clearly delineate the responsibilities and processes of manufacturers, distributors, and pharmacies in managing supply and demand of these medications as each sector plays a role in what quantities of stimulant medications make it to the pharmacy shelf and are available to consumers. As you undertake this work, we encourage you to engage parents of children who have experienced shortages when trying to fill them at the pharmacy as well as physicians and their staff who often spent countless, unpaid, hours trying to find a pharmacy able to fill a parent's prescription for their child.

In addition to the adverse impacts on physician practices, these shortages negatively impact our patients. Physician practices spend a lot of time finding the medication and dose that works best for a child, and this is often after they have not responded to other brands. Shortages of stimulants may require that physicians switch children to medications that may be less effective for them which have significant consequences for their mental health, family dynamics, and school performance. Additionally, because the alternative medications may not be covered by their insurance plans' formulary, families often experience significant costs and other coverage barriers such as prior authorizations.

Improved transparency and communication about the production and distribution processes and the patient experience will facilitate a more timely response to potential shortages in the future and help restore the public's trust in this process.

AACAP and AAP appreciate the opportunity to provide comments on this notice. We would also be happy to talk further about these issues and bring the expertise of our members to the discussion.

Please contact Karen Ferguson, Deputy Director of Clinical Practice, AACAP, at kferguson@aacap.org or Tamar Magarik Haro, Senior Director, Federal and State Advocacy, AAP, at tharo@aap.org with any questions you may have.

Sincerely,

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President

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President