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

CHILDREN'S HOSPITAL ASSOCIATION

May 2, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22052

Dear Secretary Becerra and Administrator Milgram:

The American Academy of Child and Adolescent Psychiatry (AACAP), the American Academy of Pediatrics (AAP), and the Children's Hospital Association (CHA) who collectively represent 78,000 child and adolescent psychiatrists, pediatricians, and trainees and 200+ children's hospitals, write today to express our continued concern about ongoing stimulant medication shortages, and request that you **convene all relevant stakeholders for a forum to discuss the impact these shortages are having on patients, families, and their providers and identify actionable solutions that will alleviate these shortages.** Pediatric providers, including child and adolescent psychiatrists, pediatricians, and children's hospitals, along with the patients and families they serve, face an insurmountable struggle with stimulant medication shortages and we are eager to work with you and others on solutions that will have a meaningful impact on these shortages.

The consequences of the shortages have been deeply felt by dedicated pediatric providers, particularly members of AACAP, AAP and CHA, the children and adolescents they treat, and their families. The disruption to the daily lives of affected children and adolescents, and their families, cannot be overstated. Untreated attention deficit hyperactivity disorder (ADHD) can contribute to worsening mental and behavioral health disorders, including mood and substance use disorders, unintended injuries resulting from ADHD-related impulsivity, and long-term impacts on relationship-building, educational achievement, and professional success. Parents and families may also be negatively impacted by the disruption that untreated ADHD can cause in the home, school, and work environments. Parents and caregivers have had to go to extraordinary lengths to find pharmacies that will fill their child's prescription. Even if they can find such a pharmacy, children may not be able to continue on the medication that has worked effectively for them, they may not get the full prescription amount recommended by their

physician, or they may face out-of-pocket costs. Often, the pharmacy's supply is depleted by the time the parent gets to the pharmacy which sets into motion a looping cycle of parent-to prescriber-to pharmacist search for medication supply. Families whose resources are already stretched thin find themselves spending inordinate amounts of time shopping around for their child's next prescription refill, managing their child's deteriorating behavior and mood, and worrying over lost workdays to care for children no longer able to attend school due to behavioral issues.

Furthermore, families that rely on generic stimulant medications have been disproportionately affected by the ongoing stimulant shortages. This situation only exacerbates existing health disparities among economically disadvantaged families who are enrolled in Medicaid and CHIP. Our members report that in some instances, only the brand name medication is available to their patients but insurance company policies like restrictive and ever-changing formularies and prior authorization serve as costly impediments to patient access to what supply is available. We urge you to consider the equity implications of the ongoing stimulant medication shortages. The most recent Youth Behavior Risk Survey Data[i] demonstrate worsening mental health trends for youth between 2011-2021, with indicators for persistent feelings of sadness and suicidality going in the wrong direction. The data also show that Black students more often attempt suicide than their White or Asian counterparts. Lack of access to appropriate medications and treatment worsens these trends.

We understand that there are rules in place dictating quotas of raw materials for stimulant manufacturing and allotments of medications provided to pharmacies, and that prescriptions for all types of stimulant medications have increased over the last few years. However, allocation estimates that rely on the number of prescriptions filled at a pharmacy to predict future demand vastly underestimate true patient need for all the reasons noted previously. We also understand that there is confusion among practitioners and pharmacists in the field about regulations governing manufacturing, prescribing, and dispensing related to controlled substances like stimulant medications. Further, we understand that the supply chain is complex, involving both Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA) regulation as well as private action. However, these circumstances cannot hinder access to appropriately prescribed stimulant medications to those who are stabilized with these medications and cannot function properly without them. We have previously expressed our concerns to both agencies.

In a joint letter to the public dated August 1, 2023,[ii] both the DEA and the FDA outlined steps the agencies were taking to mitigate the impact of the stimulant shortages, including the reallocation of allotted quotas of active ingredients to manufacturers who agree to increase their production. However, we are concerned that the actions outlined in the joint letter have been inadequate to address the impact of the ongoing and unmitigated shortages. We urge

increased transparency and communication with the public on actions being taken by the agencies and when our patients and their families can reasonably expect to see improvements in the availability of stimulant medications at the pharmacy.

As stated above, we respectfully request that you convene all relevant stakeholders, including manufacturers, physicians and other pediatric providers, pharmacies, payers, families, and others involved in the supply chain for a forum where we can discuss meaningful solutions to address these shortages. Please contact Karen Ferguson, Deputy Director of Clinical Practice at AACAP at kferguson@aacap.org, Tamar Magarik Haro, Senior Director of Federal and State Advocacy at AAP at tharo@aap.org, or Natalie Torentinos, Policy Manager at CHA at Nathalie.Torentinos@childrenshospitals.org, to discuss our request further.

Sincerely,

American Academy of Child and Adolescent Psychiatry

American Academy of Pediatrics

Children's Hospital Association

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[i] YRBSS Results | DASH | CDC

[ii] Joint DEA FDA Letter