

AMERICAN ACADEMY OF
CHILD & ADOLESCENT
PSYCHIATRY

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AMERICAN
PSYCHIATRIC
ASSOCIATION



May 1, 2023

Commissioner Robert M. Califf, MD, MACC
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Ongoing Stimulant Medication Shortages

Dear Commissioner Califf:

As organizations that share a commitment to the nation's mental health and well-being, the American Academy of Child and Adolescent Psychiatry (AACAP) and the American Psychiatric Association (APA) **we write today to gain insight about action the Food and Drug Administration (FDA) is taking to improve the nation's supply of stimulant medications, and to request a time to meet with you or members of your staff to discuss ways to address this situation.** AACAP is the professional home to more than 10,000 child and adolescent psychiatrists, child and adolescent psychiatry fellows, residents, and medical students with a mission to promote the healthy development of children, adolescents, and families. APA is the national medical specialty society representing over 38,000 psychiatric physicians and their patients. In the midst of a national crisis in children's mental health, AACAP and APA are hopeful that the FDA is prioritizing action that improves children's access to evidence-based mental health treatment including ensuring that there is sufficient supply of stimulant medications for the treatment of attention-deficit/hyperactivity disorder (ADHD).

The nation has grappled with a stimulant medication shortage since October of last year, starting with the Adderall shortage, linked to Teva manufacturing delays. Many child and adolescent psychiatrists, general psychiatrists, and other physicians, have been forced to switch their patients' medications, transitioning them to non-Adderall stimulant alternatives, which has its own set of potential pitfalls, including not working as well to curb symptoms of ADHD and commonly occurring comorbid mental disorders. The increased demand for non-Adderall medications has subsequently created shortages of other types of stimulant medications including Ritalin and Concerta, leaving few options for families who are being affected by this crisis. AACAP and APA members have also reported that the time they spend tracking down

appropriate stimulant medications and completing prior authorizations that are linked to the need to switch a patient's medication have taken time away from actual patient care and find this to be an inefficient use of their time amidst the ongoing crisis in children's mental health.

The consequences of the shortage have been deeply felt by AACAP and APA members, 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 ADHD can lead to mental and behavioral 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 (see cases in the attachment). Parents and families are also negatively impacted by the disruption untreated ADHD can cause in the home, school, and work environments. Caregivers are forced to compromise on preferred pharmacy selection, medication preference, out-of-pocket costs, and professional and family obligations in order to fill their child's prescription. 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. The cycle repeats itself when refills are necessary and when health plans impose preauthorization requirements or other coverage limitations. Families whose resources are already stretched thin in many cases find themselves spending inordinate amounts of locating a pharmacy 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 in some cases.

Families who 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. The most recent Youth Behavior Risk Survey Data¹ 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 worsen these trends.

AACAP and APA 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. 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 Adderall. Further, we understand that the supply chain is complex, involving both DEA and FDA regulation as well as private action. However, these circumstances cannot hinder access to appropriately prescribed stimulant medications to those who cannot function

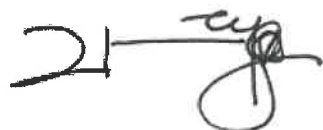
¹ [Youth Risk Behavior Survey Data Summary & Trends Report: 2011-2021 \(cdc.gov\)](https://www.cdc.gov/youthrisk/youth-risk-behavior-survey-data-summary-trends-report-2011-2021)

properly without them. During the current mental health crisis, priority must be given to improving access to effective treatments like these medications. As we understand it, the FDA can take a number of steps to help mitigate a medication shortage that include determining if alternate manufacturers are will and able to increase production, notify affected parties such as hospitals and pharmacies about impending shortages so that plans can be made to obtain alternate sources of inventory, work with manufacturers to ensure adequate investigation into the root cause of the shortage, and review possible risk mitigation measures for remaining inventory.

Attached is a separate document with several recent examples from psychiatrists around the country demonstrating the impact the ongoing stimulant shortage is having on children and families. These cases clearly demonstrate the hardships created by this situation.

We would welcome the opportunity to discuss and collaborate on solutions and messaging to providers and pharmacies, and ways AACAP and APA can support the FDA in addressing the stimulant shortage and ensuring future accessibility to the many safe and effective controlled substance medications for pediatric mental health disorders. Please reach out to Karen Ferguson, Deputy Director of Clinical Practice at AACAP (kferguson@aacap.org) and Brooke Trainum, Director of Practice Policy at APA (btrainum@psych.org), as soon as possible to arrange a time to meet. Thank you for your timely attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Ng', with a stylized flourish at the end.

Warren Y.K. Ng, MD, MPH
President
American Academy of Child and
Adolescent Psychiatry

A handwritten signature in black ink, appearing to read 'R. Brendel', with a long, sweeping flourish extending to the right.

Rebecca Brendel, MD, JD
President
American Psychiatric Association

Attachment

The Impact of Stimulant Shortages on Patients: Cases from Members

Case 1: At an appointment on 1/26/23 parents reported having trouble filling a previous prescription for Concerta 27 mg at the local pharmacy. They paid for it out of pocket on the spot at the pharmacy instead of contacting me out of fear of going without the medication. They could not afford to take more time locating the medication. They also stated they cannot leave work to pick up their 10-year-old son from school if he misbehaves or is suspended during the day. Historically he has high levels of impulsivity which can cause significant safety concerns. For example, within the past 1 year, he impulsively reached for a burning candle on the countertop before anyone could intervene and accidentally set his clothes on fire, resulting in deep second and third degree burns which required hospitalization and skin grafts. In his school program when unmedicated he has eloped from the classroom and has run out to the busy parking area placing himself at risk. He also climbs and jumps from heights without thinking about safety.

The family had purchased the medication from Walmart. I contacted a Walmart pharmacist who told me that Fidelis insurance would only allow specific drug manufacturers to supply the Concerta/MPH ER and they did not have any in their warehouse. They had explained this to the parents and this is why the parents opted to pay for the non-preferred manufacturer out of pocket. This is not a sustainable practice for a family with limited income even with a coupon which was applied. I was advised to try sending this month's prescription to CVS. I therefore sent the next stimulant prescription to the local CVS on 1/26. When CVS tried to fill it, they told the parents it would need prior authorization because they also did not have the correct manufacturer in stock. I tried to complete a prior authorization for the medication that was available at CVS but by the time I had sent it in to the insurance company, etc., the pharmacy had already run out of their supply. On 2/2 the family asked me to send the script to the local Rite Aid. On 2/3 parent contacted me to let me know that Rite Aid did have medication, but they could not fill script because CVS had already billed their insurance for the script even though they did not fill/dispense.

Since the family had contacted me after my practice hours ended Friday and did not use emergency number, I contacted the CVS pharmacy first thing Monday morning. It took two additional phone calls (one to Rite Aid and then again to the family) in order to ensure that everything was settled. The family was finally able to get script filled on 2/6. During this time, the boy went without his medication for two school days and parents elected to keep him out of school on those days (2/3 and 2/6) for fear that he would be too disruptive to the learning environment without his medication (as is historically the case). The boy stayed with his grandfather during the day while out of school but missed out on being educated and socialized and part of his special education program on those days.

Case 2: Parent contacted me concerned that they could not get Concerta 36 mg for their 10 year-old who has recently been moved to a district based special education classroom instead of a self-contained center based classroom. They were worried that without the medication their child would become aggressive, disruptive and possibly get kicked out of the placement and have to return to the self-contained building and experience this as a failure. The parents have limited resources so could not travel far by car to get to another pharmacy.

Fidelis/Medicaid insurance limited the options to pharmacies with the correct manufacturer near either her home or near where her husband was employed. The prescription was canceled and resent three times, each to a different local pharmacy. After the second resend, I instructed the parent to try to contact the pharmacy and ensure that they had medication in stock and then to send me a text message to let me know exactly where to send the script. The message to send this script interrupted another client appointment, however. Given that I had already resent the script twice, I made the choice to interrupt the visit to send the script a third time.

This boy was without his medication for four school days. In this case, I was able to notify the school of the difficulty obtaining medication. The teacher, mother, student, and I made an emergency plan to help minimize problem behaviors in the school community while he was not taking medication. This required that I take additional time to contact all involved parties. The plan minimized transitions in the building, limited mainstream participation, and instead maximized academics being completed in the resource room with a 1:1 teaching assistant. While the plan decreases problem behaviors, it is not sustainable. It limits socialization and feels like a setback for a boy who had just made enough progress to move to a less restricted environment.

Case 3: I am a solo provider, and do not have a large office staff who can spend time calling pharmacies for me or filling in prior authorization forms, so the shortages have taken time away from my ability to care for the rest of my patients and/or the need to send and resend prescriptions is interrupting my day and evening hours. The shortage has caused severe stress for the parents, teachers, classmates and most importantly the children themselves.

Case 4: Parents are having problems locating Adderall for their kids. They are forced to call around to multiple pharmacies. When they locate the medication, they have to get in touch with me ASAP so that I can send in the script. I treat a lot of Medicaid patients in a community health clinic and I'm finding that it's increasingly difficult to get generic Adderall for my patients.

Case 5: I am licensed in California. I recently e-prescribed the patient's usual dose of Adderall IR (10mg twice a day) to their pharmacy, and the pharmacist informed the patient that they are not taking any new stimulant prescriptions for new patients because of the stimulant

medication shortage. My most pressing concern is how to help my patient get their medication? I'm writing as this is hindering patient care, to determine if I have any other options regarding the prescription, and to ask where I can get more information about the stimulant shortage that is impacting patients/providers.