



May 12, 2023

Administrator Anne Milgram
Drug Enforcement Administration
600 Army Navy Drive
Arlington, VA 22202

RE: Stimulant Shortages

Dear Administrator Milgram:

On behalf of the American Association of Psychiatric Pharmacists (AAPP) (f.k.a. the College of Psychiatric and Neurologic Pharmacists), we write to urge you to address the stimulant shortages that continue to impact patients and their families across the country. We appreciate your leadership in removing barriers in access to care and treatment.

About AAPP

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use and neurologic disorders, receive safe, appropriate, and effective treatment. Members are specialty pharmacists, and most are Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorders (SUDs), and psychopharmacology. With a significant shortage of mental health care professionals, psychiatric pharmacists offer another resource to improve outcomes for patients with psychiatric and SUDs.

Role of Psychiatric Pharmacists

Pharmacists graduate with a Doctor of Pharmacy degree, requiring six to eight years of higher education to complete, and have more training specific to medication use than any other health care professional. Psychiatric pharmacists, a specialty within clinical pharmacy, are primarily board certified and residency trained mental health care practitioners who have specialized training in providing direct patient care and medication management for the complete range of psychiatric disorders and SUDs. Psychiatric pharmacists work as treatment team members but also in decision-making and leadership roles in state and federal organizations, academia, and industry.

Psychiatric pharmacists are an important member of the health care team working in collaboration with the patient, guardians of minors, and other healthcare providers including, but not limited to, psychiatrists, other physicians, therapists, social workers, and nurses (including advanced practice nurses). Psychiatric pharmacists provide expert, evidence-based Comprehensive Medication Management (CMM) services for the most complex patients with mental health disorders and SUDs. Psychiatric pharmacists increase capacity of the health care team to provide care and psychopharmacology expertise, as well as improve patient outcomes and reduce overall health care costs.

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AAPP Urges Action Be Taken to Address Stimulant Shortage

Stimulant medications are the most effective pharmacotherapy for the management of attention-deficit/hyperactivity disorder (ADHD) in children, adolescents, and adults.¹ The American Academy of Child and Adolescent Psychiatry (AACAP) and The American Academy of Pediatrics (AAP) recommend stimulants as first-line treatment for individuals 6 years of age and older.^{1,2} While the prevalence of ADHD in children and adolescents has remained stable, the prevalence of diagnoses in adults has increased resulting in a higher demand for these medications. The number of stimulant prescriptions increased more than 10% from 2020 to 2021 during the COVID-19 pandemic, with the most notable increases in adult males and adolescent/adult females.³ Increased rates of ADHD diagnoses among adults highlights the need for clinical practice guidelines for screening, diagnosing, and treatment of ADHD in this population.

Inability to access stimulants in light of shortages presents clinical challenges and risks.

Untreated ADHD results in poorer outcomes for children, adolescents, and adults. Untreated or ineffectively treated ADHD is associated with increased mortality and higher rates of substance use or substance use disorders, incarceration, increased impulsive and risk-taking behavior resulting in increased traffic accidents or speeding tickets, psychiatric hospitalizations, and emergency department visits.⁴⁻⁹ Among children and adolescents, ADHD is associated with impairments in school performance, academic achievement, lower self-esteem, disruptions in peer/family relationships, and accidental injuries.^{5,6,10} Inability to access a preferred, effective stimulant medication to treat ADHD symptoms precipitates these risks.

While the current stimulant shortage has largely focused on Adderall™ and its generic formulations, other stimulant medications are also in short supply. Patriot Pharmaceuticals, a subsidiary of Janssen, has recently stopped production of its generic equivalent of Concerta™. Concerta™ has a unique dosage formulation, the Osmotic Controlled Release Oral Delivery System (OROS)™. While there are a number of generic methylphenidate OROS formulations, only three manufacturers have been rated bioequivalent to the brand medication.¹¹ The elimination of the Patriot Pharmaceuticals product has generated an increased demand for the other bioequivalent formulations creating a drug shortage impacting the methylphenidate supply. In addition, a recent recall of methylphenidate patches will also impact future supply issues.

The stimulant shortage crisis continues to expand to other stimulant formulations with the continued dearth of Adderall™ and its generic beginning to impact the availability of other stimulant formulations. Unfortunately, there appears to be no anticipated end to this crisis with manufacturers unable to provide anticipated supply dates.

We are eager to ensure access to these effective medications. We ask the following be considered:

Electronic Prescribing of Controlled Substances¹²

- **Request a nationwide emergency waiver** that would allow providers to issue a written prescription for stimulant medications, as CII substances, during times of stimulant shortages.
 - Currently, controlled substances must be transmitted to pharmacies via electronic prescribing methods including a separate authorization by a licensed physician. This dual authorization is a security step to prevent illegitimate prescriptions from being transmitted.
 - This requirement inhibits a patient or their caregiver from carrying a paper prescription to a pharmacy with a current supply of the stimulant medication, but instead requires

the physician to re-send the prescription to multiple pharmacies. This generates a delay in prescription transmission which means the pharmacy may be out of the stimulant medication by the time the prescription is received. It may also create multiple active prescriptions for the same patient and same medication because the generation of a new prescription does not invalidate or cancel the previously generated prescription.

- Use of paper prescriptions on tamper-evident paper allows the patient to deliver a prescription in more timely manner should a pharmacy contacted have inventory of the medication.
- The Electronic Prescribing System requirement to generate, transmit, and receive a prescription would be waived.
- This emergency situation should continue until the FDA declares the shortage of these medications has ended.

Material Allocations/Quota Denials

- Access to reasons for increased quota denials would help providers understand which manufacturers may not be available compared to others. The DEA and the Attorney General review manufacturer requests for increased quotas of controlled substances. Providing access to the reasons for denial will help consumers and providers understand the rationale related to drug shortages of controlled substances.
- As this is not the first time a shortage of Adderall™ or its generic formulations has occurred, we are asking for a clear delineation regarding the allocations of raw materials to each manufacturer along with the clear delineation from the manufacturers of the amount of material allocated to each formulation and strength.

We urge the DEA to take action to address stimulant shortages that are adversely impacting patients across the country. If you have any questions, please do not hesitate to contact me at bschimenti@aapp.org or our Health Policy Consultant, Laura Hanen at lahanen@venable.com.

Sincerely,



Brenda K. Schimenti
Executive Director

References

1. Wolraich ML, Hagan JF, Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics*. 2019;144(4):e20192528. doi:10.1542/peds.2019-2528
2. Chaplin S. Attention deficit hyperactivity disorder: diagnosis and management. *Prog Neurol Psychiatry*. 2018;22(3):27-29. doi:10.1002/pnp.511
3. Danielson ML, Bohm MK, Newsome K, et al. Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults - United States, 2016-2021. *MMWR Morb Mortal Wkly Rep*. 2023;72(13):327-332. doi:10.15585/mmwr.mm7213a1

4. *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision*. Fifth. American Psychiatric Association; 2022.
5. Dalsgaard S, Leckman JF, Mortensen PB, Nielsen HS, Simonsen M. Effect of drugs on the risk of injuries in children with attention deficit hyperactivity disorder: a prospective cohort study. *Lancet Psychiatry*. 2015;2(8):702-709. doi:10.1016/S2215-0366(15)00271-0
6. Chorniy A, Kitashima L. Sex, drugs, and ADHD: The effects of ADHD pharmacological treatment on teens' risky behaviors. *Labour Econ*. 2016;43:87-105. doi:10.1016/j.labeco.2016.06.014
7. Barbaresi WJ, Campbell L, Diekroger EA, et al. The Society for Developmental and Behavioral Pediatrics Clinical Practice Guideline for the Assessment and Treatment of Children and Adolescents with Complex Attention-Deficit/Hyperactivity Disorder: Process of Care Algorithms. *J Dev Behav Pediatr*. 2020;41(2S):S58-S74. doi:10.1097/DBP.0000000000000781
8. Konstenius M, Jayaram-Lindström N, Guterstam J, Beck O, Philips B, Franck J. Methylphenidate for attention deficit hyperactivity disorder and drug relapse in criminal offenders with substance dependence: a 24-week randomized placebo-controlled trial. *Addict Abingdon Engl*. 2014;109(3):440-449. doi:10.1111/add.12369
9. Taubin D, Wilson JC, Wilens TE. ADHD and Substance Use Disorders in Young People: Considerations for Evaluation, Diagnosis, and Pharmacotherapy. *Child Adolesc Psychiatr Clin N Am*. 2022;31(3):515-530. doi:10.1016/j.chc.2022.01.005
10. Shaw M, Hodgkins P, Caci H, et al. A systematic review and analysis of long-term outcomes in attention deficit hyperactivity disorder: effects of treatment and non-treatment. *BMC Med*. 2012;10:99. doi:10.1186/1741-7015-10-99
11. U.S. Food & Drug Administration. Orange Book. Approved Drug Products with Therapeutic Equivalence Evaluations. Published March 2023. Accessed April 4, 2023. <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>
12. Drug Enforcement Administration. Electronic Prescriptions for Controlled Substances. Accessed April 6, 2023. https://www.deadiversion.usdoj.gov/ecommm/e_rx/