



Supply Crisis: The Effects of Persistent ADHD Medication Shortages

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Abstract ADHD is a neurodevelopmental disease characterized by attention deficiency and hyperactivity. This condition is frequently identified in children and is among the most prevalent of its kind. ADHD often continues until adulthood. For a long time, stimulant medicine has been the preferred pharmacological treatment for individuals, including children and adults, diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD). Multiple studies have demonstrated the effectiveness of Adderall® in improving attention, reducing hyperactivity-impulsivity, managing aggression, controlling disruptive behavior, and enhancing academic production [1]. This article primarily examines the statistical usage of Adderall before and after the COVID-19 pandemic. It also explores the factors contributing to the scarcity of Adderall and analyzes the repercussions of this shortage.

Keywords Attention deficit hyperactivity disorder, Adderall, amphetamine salts, shortage, covid -19

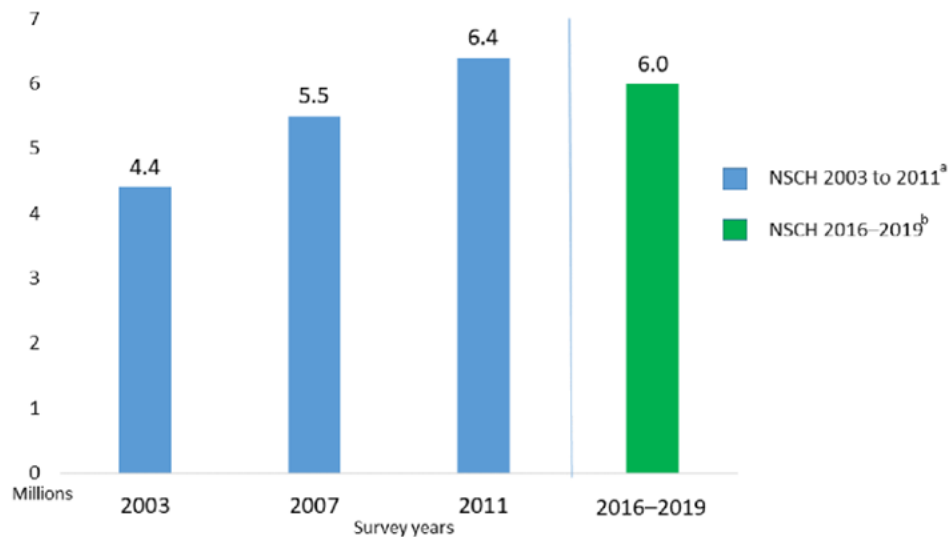
1. Introduction

Attention deficit hyperactivity disorder (ADHD) is a controllable neurobehavioral condition characterized by enduring and dysfunctional symptoms of hyperactivity/impulsivity and inattention [2]. Adderall is a medication consisting of amphetamine and dextroamphetamine, which is authorized by healthcare providers for the treatment of attention-deficit/hyperactivity disorder (ADHD) and narcolepsy. Initially developed in 1920, the medication was predominantly employed to alleviate weariness and enhance alertness during the Second World War. The substance is composed of a combination of four salts, precisely two amphetamine salts and two dextroamphetamine salts, in equal amounts. The amphetamine salts consist of aspartate monohydrate and amphetamine sulfate, while the dextroamphetamine salts consist of dextroamphetamine sulfate and dextroamphetamine saccharate [3]. The FDA announced a shortage of Adderall and Adderall IR, two brand names for the same immediate-release version of amphetamine mixed salts, on their medicine shortage webpage on October 12, 2022 [4].

2. Statistics

Over the past few decades, there has been a consistent rise in the number of diagnoses with attention deficit hyperactivity disorder (ADHD). National population surveys indicate a surge in the prevalence rate from 6.1% to 10.2% between 1997 and 2016 [5].





Utilizing data gathered between the years 2016 and 2019, a national survey of parents predicted that 6.8 million children, ranging in age from 3 to 17, have ever been diagnosed with ADHD. For this range, we have 3-5 years: 265,000, representing 2% of the total. Ages 6 to 11, 2.4 million are 10% of the total. Adolescents aged 12 to 17 years: 3.3 million, representing 13%. The prevalence of ADHD diagnosis is higher in boys (13%) compared to girls (6%) [6].

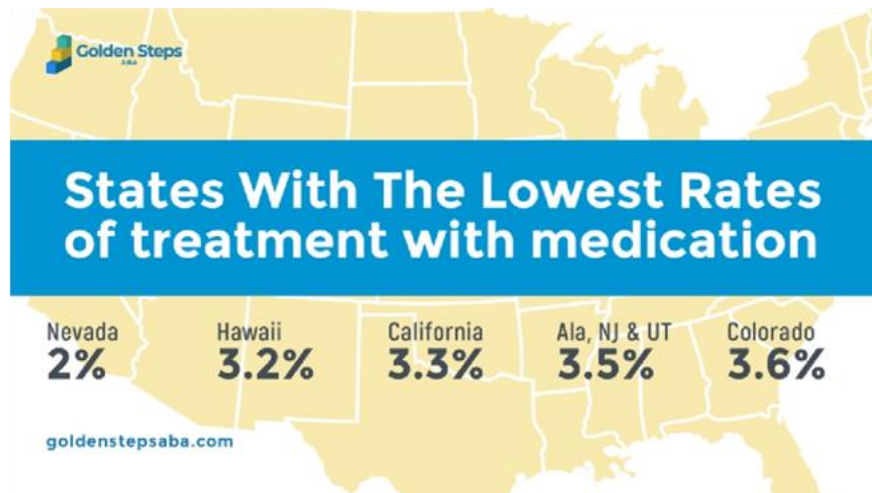
The number of prescriptions for stimulants has been rapidly increasing. Between 2012 and 2022, there was a 57.9% increase in the number of stimulant prescriptions provided, rising from 50.4 million in 2012 to 79.6 million in 2022. The number of prescriptions dispensed has consistently climbed yearly, except for 2017. The most significant yearly percentage increase in both prescription and patient counts occurred between 2021 and 2022, with a growth rate of 8.5%. Prescriptions filled annually per patient rose from an average of 4.5 in 2012 to 5.7 in 2022 [7].

3. Shortage

The United States Food and Drug Administration (FDA) declared a scarcity of several Adderall formulations in October 2022. Several factors contribute to the shortage.

- Change from DSM-4 TR to DSM-5: The introduction of the DSM-V in 2013 substantially expanded the diagnostic criteria for ADHD. One notable modification permitted the simultaneous presence of autism spectrum disorder (ASD) and ADHD, a possibility that was absent in earlier versions. Due to the significant coexistence of ADHD and ASD, it is evident that this change, among others, played a role in the increase of ADHD prevalence by including a substantial number of children who were previously not considered [8]. Consequently, this leads to a rise in patients and prescriptions. Consequently, this led to a surge in patients and medications.
- Increased awareness: One potential explanation is that there has been an increase in awareness and comprehension of ADHD among healthcare professionals and the general population, resulting in more diagnoses [9].





- **Telemedicine:** Telemedicine can be described as a coin with two distinct sides. The increase in ADHD diagnoses can be related to the suspension of the 2008 Ryan Haight Act by the USA Department of Health and Human Services in January 2020. This act imposed rigorous regulations on the prescribing of restricted drugs using telepsychiatry. Under this emergency policy, telehealth clinicians could issue online prescriptions for restricted medications without requiring an in-person evaluation [10]. On the other side of the same coin, in some areas of the nation, there is a lack of access to specialists who can provide accurate diagnoses of Attention Deficit/Hyperactivity Disorder (ADHD) and subsequent treatment. One effective solution to address this issue is by implementing telemedicine. Telemedicine enables remote access to expertise via a secure two-way video conference. This eliminates geographical obstacles and the limitations of local experience, allowing for diagnosing and treating patients of any age [11].
- **Manufacturer issues:** The most prominent supplier of both brand-name and generic versions of Adderall IS Teva Pharmaceutical (TEVA). Some others include Novartis (NVS), Lannett (LCI), Mallinckrodt Pharmaceuticals (MNK), and Takeda Pharmaceutical (TAK) are some additional well-known companies [12]. Teva Pharmaceuticals has established production and research and development (R&D) facilities in India, which saw a series of strict lockdowns in 2020. In addition to its three operational pharmaceutical ingredients (API) production facilities, the business possesses two completed pharmaceutical formulation plants and two additional research and development (R&D) facilities located in India [13].
- **Controlled substance:** The active ingredient in Adderall is a restricted amphetamine salt, and its manufacturing process involves coordination between the FDA, pharmaceutical companies, and the DEA, which establishes an annual limit on the quantity of tightly regulated amphetamines that manufacturers are allowed to utilize. The Sandoz representative indicated that just a portion of their requests for increased output were granted. [14]. In a collaborative statement addressed to the public and made public on August 1, the commissioner of the FDA and the administrator of the DEA expressed their intention to reassess the allotments. They highlighted that manufacturers were able to market just 70% of the authorized quantity of prescription stimulants in the year 2022 [15]. It appears to be a situation of assigning blame, with the patients being the most affected.

4. Repercussion

The scarcity of stimulants has caused significant distress to children, families, and their healthcare providers. From a public health perspective, policymakers must comprehend the complex nature of these shortages and collaborate to mitigate their severe and far-reaching consequences in the future [16].

- **Children and students:** Neuropsychological research on individuals with ADHD, both children and adults, reveals deficiencies in various cognitive domains, including selective attention, memory, reaction time, information processing speed, and executive control functions such as set-shifting and



working memory. The efficacy of prescription stimulants in improving classroom management, attentiveness, and academic production in children is widely recognized. Prescription stimulants can enhance note-taking abilities, improve performance on tests and worksheets, increase writing productivity, and facilitate the completion of homework assignments [17].

- Caregivers: Most caregivers are parents of young children. Numerous testimonials describe the inconvenience of having to visit multiple pharmacies to get a prescription filled or phone multiple pharmacies to confirm the availability of a specific medication. This situation can be pretty stressful for parents or caregivers.
- Doctors: Determining the appropriate dosage for a patient with ADHD involves trial and error. The doctor prescribes different potencies to ensure the patient's correct dosage. However, if the medication is unavailable, the doctor must repeatedly initiate the process of determining the appropriate dosage, which can be exasperating for both the doctor and, more importantly, the patient. Thus, this can result in a lack of confidence in the doctor's ability to manage the symptoms effectively.

5. Prospective Solution

The DEA sets limits on how much drug can be produced by each manufacturer. They are actively working to meet the demands of the patient and have taken various steps like:

- Drug manufacturers must provide the DEA with their projected manufacturing timetable for medications before getting their quota allotment.
- Drug manufacturers apply for quota allotment on a quarterly basis instead of early.
- Monthly reports from manufacturers and distributors are required on the amount of drugs being manufactured and shipped.
- On July 27, 2023, the DEA revised the regulation to allow patients to transfer electronic prescriptions from one pharmacy to another without returning to their doctor.
- DEA can also make sure that the manufacturer meets their set limit.
- On the other hand, the pharmacist and doctor's office can work together to help the patient get the medication; an example of this is if the patient needs Adderall 25 mg and the pharmacy doesn't have it in stock but has, say, the 15 and 10 mg Adderall, they can dispense that after verifying and getting a new prescription for the available strength.
- The other option is trying for a different stimulant like methylphenidate or Vyvanse, which are still available in the market.

6. Conclusion

The scarcity of Adderall raises apprehensions regarding its effects on persons dependent on the medicine for attention deficit hyperactivity disorder (ADHD). To summarize, resolving this scarcity necessitates cooperative endeavors among pharmaceutical producers, regulatory entities, and healthcare practitioners to guarantee the uninterrupted availability of essential pharmaceuticals for individuals reliant on them. In addition, investigating alternate therapies and increasing knowledge of ADHD and narcolepsy can enhance the overall strategy for assisting persons impacted by scarcity.

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