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INSIGHT

The Federal Role in Addressing the Adderall Drug Shortage

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Adderall is a combination medication (amphetamine/dextroamphetamine) used to treat attention deficit hyperactivity disorder (ADHD). The immediate release formulation of Adderall and its generic versions have been in a shortage for several months in the United States. The shortage was reportedly caused by a number of factors including an increase in Adderall prescriptions over the past several years. Additional causes of this and other drug shortages may include manufacturing and quality issues (e.g., contaminants); lack of transparency (e.g., lack of information about drug quality and supply reliability); and business decisions made by individual firms (e.g., low profit margins leading to market exit and mergers resulting in a limited number of manufacturers). Some have also pointed to U.S. reliance on foreign sources for raw materials used to make medications.

The Food and Drug Administration (FDA) is responsible for addressing U.S. drug shortages. However, because Adderall is a Schedule II controlled substance under the Controlled Substances Act (CSA), the Drug Enforcement Administration (DEA) also regulates the available supply of Adderall.

This Insight describes the federal role in managing drug shortages in the United States in the context of the current Adderall shortage and provides some policy options for Congress.

FDA Role in Addressing Drug Shortages

FDA's authority to mitigate drug shortages has been expanded in response to previous shortages. For example, the Food and Drug Administration Safety and Innovation Act of 2012 (P.L. 112-144) amended the Federal Food, Drug, and Cosmetic Act to require manufacturers of selected critical prescription drugs to notify FDA of supply disruptions in certain instances and to require FDA to publish a list of drug products that are in shortage. Other requirements, and authorities granted under this and other laws, are discussed in CRS In Focus 11058, *Drug Shortages: Causes, FDA Authority, and Policy Options*. Amendments made by the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136, CARES Act) were intended to increase FDA's ability to mitigate drug shortages and included, among other authorities, an expansion of manufacturer reporting requirements and an enhancement of FDA's ability to expedite the review of selected products or procedures. Provisions in the Consolidated Appropriations Act, 2023 (P.L. 117-164), further enhanced FDA's ability to mitigate product shortages in part by

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enhancing FDA's visibility into foreign medical product supply chains and directing FDA to provide guidance to members of industry relating to product expiration date extensions.

FDA responds to drug shortages in a variety of ways. For example, FDA may collaborate with industry stakeholders to determine reasons for drug shortages. FDA may also choose to support the extension of expiration dates for products, expedite the approval of new production lines or raw source materials to support the increased manufacturing of a product, or work with manufacturing firms to identify additional avenues for increased drug manufacturing.

FDA also works with DEA to address drug shortages, and both FDA and DEA are required to report to Congress regarding the conditions of and agency decisions concerning drug shortages, including the agencies' actions to mitigate them.

DEA Role in Regulating Drug Supply

As part of its mission to prevent diversion of controlled substances while ensuring an adequate supply for U.S. need (and as required under the CSA), DEA sets annual aggregate production quotas as well as individual manufacturing quotas for controlled substances in Schedules I and II of the CSA. DEA tracks the production of controlled substances, enforces various reporting requirements, and receives year-end reports from manufacturers. Manufacturers may request adjustments to their given quotas at any time.

DEA sets individual manufacturing quotas for the active ingredient in Adderall (amphetamine/dextroamphetamine). At least one drug manufacturing company pointed to issues in adjusting its manufacturing quota with DEA during the Adderall shortage but provided no details or further information on issues with DEA processing of its quota application. Drug manufacturers will generally not share this detailed information, and DEA does not provide details regarding individual quota applications, because the details are considered confidential and proprietary to the manufacturer.

Telehealth and the Increase in Adderall Prescriptions

During the public health emergency related to the COVID-19 pandemic, DEA made special allowances for the practice of telemedicine (where a practitioner is at a location remote from a patient and communicates with or treats the patient using a telecommunications system) and prescribing to accommodate patient access to controlled substances. Factors related to this ease of access appears to have contributed to the increase in Adderall prescriptions during the pandemic. (This is not to say the prescriptions were medically inappropriate.) However, at least one DEA registrant is alleged to have unlawfully dispensed Adderall during this time. The public health emergency and related special telemedicine accommodations are set to expire on May 11, 2023 (although DEA indicated telemedicine flexibilities may temporarily be extended). This may contribute to a decline in prescriptions issued for Adderall.

Potential Policy Options for Congress

Drug manufacturers have reported that they do not expect the Adderall shortage to continue much longer, but drug shortages in the United States remain a serious and persistent public health concern. Congress may consider a range of policy options to address future shortages such as enhancing reporting requirements for drug manufacturers (e.g., strengthening penalties for a manufacturer's failure to report a permanent discontinuance in or interruption of the manufacture of a drug); incentivizing production of certain drugs in shortage; and incentivizing manufacturers to invest in new technologies and develop and maintain high-quality manufacturing practices.

Congress may also consider amending the CSA to change manufacturing quota processes and requirements. As DEA has noted, quotas are determined based on prescription and other data, thus aiming

to ensure an adequate supply for patients and research while preventing overproduction that may lead to diversion for misuse. In the past, DEA has been pressured to both increase and decrease supplies of Schedules I and II controlled substances. However, the agency relies on its statutory and regulatory requirements while it contends with a dual and sometimes conflicting mission in ensuring an adequate supply while preventing diversion and misuse.

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