

# GAO Highlights

Highlights of [GAO-15-202](#), a report to congressional requesters

## Why GAO Did This Study

In the last decade, shortages of prescription drugs containing controlled substances, such as narcotics and stimulants, have increased nationwide, preventing providers and patients from accessing essential medications for treatment. Controlled substances are regulated by DEA because of the potential for abuse and addiction. To prevent diversion of controlled substances, DEA sets quotas that limit the amount of certain substances that are available in the United States.

GAO was asked to examine shortages of drugs containing controlled substances. This report examines (1) the trends in such shortages, (2) the effect on patients and providers, (3) DEA's administration of the quota process, and (4) coordination between DEA and FDA to prevent and mitigate shortages. GAO analyzed data from 2001 through 2013 from the University of Utah Drug Information Service, which is generally regarded as the most comprehensive source of drug shortage data, and from 2011 and 2012 from YERS/QMS, which is the official record for the quota process. GAO interviewed officials from DEA, FDA, organizations representing patients and providers, and drug manufacturers. GAO reviewed relevant statutes, regulations, and documents.

## What GAO Recommends

DEA should take five actions to improve its management of the quota process; DEA and FDA should quickly update their MOU and agree on steps each will take regarding drug shortages. HHS agreed with the applicable recommendations. DEA neither agreed nor disagreed, but raised multiple objections to this report.

View [GAO-15-202](#). For more information, contact Marcia Crosse at (202) 512-7114 or [crosse@gao.gov](mailto:crosse@gao.gov).

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## DRUG SHORTAGES

### Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved

## What GAO Found

Shortages of prescription drugs containing controlled substances have increased sharply in recent years; of the 168 shortages reported from January 2001 through June 2013, nearly 70 percent began after 2007. Such shortages lasted for nearly a year, on average. Additionally, many shortages involved generic pain relievers and drugs where there was only one manufacturer.

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), and organizations representing patients and providers report that during shortages of drugs containing controlled substances, patients may receive less effective care, experience medication errors, or not receive treatment at all. They said providers are also affected as they spend time and resources mitigating the effects of shortages, rather than providing care.

The Drug Enforcement Administration (DEA), an agency within the Department of Justice (DOJ), has not effectively administered the quota process that limits the amount of controlled substances available for use in the United States. Each year, manufacturers apply to DEA for quota needed to make their drugs. DEA, however, has not responded to them within the time frames required by its regulations for any year from 2001 through 2014. DEA officials attributed this lack of compliance to inadequate staffing. Manufacturers who reported quota-related shortages cited late quota decisions as causing or exacerbating shortages of their drugs. Additionally, DEA's weak internal controls jeopardize the agency's ability to effectively manage the quota process. For instance, agency officials said that DEA does not conduct quality checks to ensure the accuracy of the data in its Year-End Reporting and Quota Management System (YERS/QMS). GAO estimates that 44 percent of YERS/QMS records in 2011 and 10 percent in 2012 had errors. DEA officials said that 2011 was the first year manufacturers applied for quota electronically and they expected data from 2012 and beyond to be more accurate. DEA also lacks critical management information because it does not have performance measures related to setting quotas, nor does it monitor data to assess its performance. Moreover, DEA does not have reasonable assurance that the quotas it sets are in accordance with its requirements and cannot ensure continuity of its operations, as it does not have protocols, policies, training materials, or other documentation to manage the quota process.

Despite statutory provisions requiring DEA and FDA to coordinate certain efforts to address shortages of drugs containing controlled substances, the agencies have not established a sufficiently collaborative relationship. For example, DEA and FDA disagree about what constitutes a shortage. DEA officials also said that they do not believe FDA appropriately validates or investigates the shortage information it posts on its website and that posting this information encourages manufacturers to falsely report shortages to obtain additional quota. However, FDA reports that it takes steps to investigate and confirm the shortages on its website. Given such barriers to coordination, DEA and FDA cannot effectively act to prevent or alleviate shortages. Although DEA and FDA have a memorandum of understanding (MOU) in place, it has not been revised since the 1970s and they have been working for more than two years to update it. Officials from both agencies said an updated MOU could facilitate information sharing and help prevent and mitigate future shortages of drugs containing controlled substances.