



Testimony
Before the Senate Caucus on
International Narcotics Control, U.S.
Senate

For Release on Delivery
Expected at 10:00 a.m. ET
Tuesday, May 5, 2015

CONTROLLED SUBSTANCES

DEA Needs to Better Manage Its Quota Process and Improve Coordination with FDA

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Chairman Grassley, Co-Chairman Feinstein, and Members of the Caucus:

I am pleased to be here today to discuss our recent report on the Drug Enforcement Administration's (DEA) quota setting process for controlled substances and the agency's coordination with the Food and Drug Administration (FDA) during shortages of drugs containing these substances.¹ Drugs that contain controlled substances, such as narcotics, sedatives, and stimulants, play an important role in health care.² These drugs are used to treat patients experiencing seizures, traumatic injuries, and other medical crises. They may also be taken by patients with a prescription to manage pain and other ailments. Controlled substances are required to be regulated by DEA in accordance with the Controlled Substances Act (CSA) because individuals may abuse them and become psychologically and physically dependent on them. As part of its work to prevent diversion of controlled substances, DEA sets limits, known as quotas, on the amount of certain classes of controlled substances available for use in the United States.

In the last decade, shortages of drugs containing controlled substances have increased nationwide, preventing providers and patients from accessing medications that are essential for treatment. Both DEA, an agency within the Department of Justice (DOJ), and FDA, an agency within the Department of Health and Human Services (HHS), have important responsibilities in preventing and responding to shortages of drugs containing controlled substances. In addition to preventing diversion, DEA works to ensure that an adequate and uninterrupted supply of controlled substances is available for legitimate medical and other needs. As part of its mission, FDA works to prevent, alleviate, and resolve drug shortages. The Food and Drug Administration Safety and Innovation Act (FDASIA), enacted in 2012, also contains provisions that require DEA and FDA to coordinate their respective efforts during shortages of drugs containing controlled substances subject to quotas.

¹GAO, *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved*, [GAO-15-202](#) (Washington, D.C.: Feb. 2, 2015).

²A controlled substance is one that is included in one of five schedules under the Controlled Substances Act. A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in the United States and its potential for abuse and physical or psychological dependence. 21 U.S.C. §§ 802(6), 812.

Within DEA, the Quota Unit in the Office of Diversion Control is responsible for establishing quotas for each basic class of schedule I and II controlled substances, such as amphetamine or morphine.³ The Quota Unit calculates and proposes three types of quotas related to schedule I and II controlled substances that are then established by the agency; the CSA and DEA's implementing regulations specify dates by which DEA must propose and establish its quotas. Aggregate production quotas (APQ) limit the total amount of bulk materials that may be manufactured or synthesized in the United States and are subsequently made available for use in the manufacture of drugs containing schedule I and II controlled substances. Bulk manufacturing quotas limit the amount of a basic class of schedule I or II controlled substances that an individual bulk manufacturer can manufacture through the extraction or synthesis of plant material or other controlled substances. Procurement quotas limit the amount of a basic class of schedule I or II controlled substances that an individual manufacturer can procure from a manufacturer of bulk raw materials in order to manufacture into dosage forms of a drug or into other substances. In setting APQs and bulk manufacturing and procurement quotas, DEA considers information that includes data from DEA's internal system for tracking controlled substances transactions, known as the Automation of Reports and Consolidated Orders System (ARCOS). It also considers past histories of quota granted for each substance from DEA's system for tracking and recording quota applications and decisions, known as the Year-End Reporting and Quota Management System (YERS/QMS), among other things.

When FDA is notified of a supply disruption of certain drugs that contain controlled substances subject to quotas, FDASIA requires that FDA request that DEA increase quotas applicable to that controlled substance, if FDA determines that it is necessary.⁴ Similarly, when FDA has determined that a schedule II drug is in shortage in the United States, manufacturers may submit quota applications requesting that DEA

³Quotas are not established for schedule III, IV, and V controlled substances, which have a currently accepted medical use, a lower potential for abuse, and a lower physical and psychological dependence relative to schedule I and II controlled substances. In this statement, we refer to the Office of Diversion Control's UN Reporting and Quota Section as the Quota Unit.

⁴Such drugs are those that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition. Pub. L. No. 112-144, § 1001, 126 Stat. 993, 1099-1100 (2012) (codified at 21 U.S.C. § 356c).

authorize additional quota for that substance. FDASIA requires that DEA respond to these requests from manufacturers within 30 days.⁵

My remarks today focus on two of our report's findings related to (1) DEA's administration of the quota process for controlled substances, and (2) DEA and FDA coordination activities to prevent and mitigate shortages of drugs containing controlled substances. In addition to information from our report, my remarks include selected updates regarding actions DEA and FDA have taken subsequent to the issuance of that report. For our February 2015 report, we reviewed the CSA, DEA's regulations, and other documentation and interviewed DEA officials about the agency's administration of the quota process. We reviewed Federal Register notices for APQs for years 2001 through 2014. We also analyzed the source documents for a sample of 440 YERS/QMS records from 2011 and 2012 (15 percent of the total records during these years for certain controlled substances with medical use). We compared DEA's approach for setting quotas to the requirements in the CSA and DEA's regulations, as well as to relevant federal standards for internal controls and our prior work related to the establishment of agency performance measures.⁶ In addition, we interviewed manufacturers about their experiences with DEA's quota process. Lastly, we reviewed FDASIA and other documentation and interviewed DEA and FDA officials about their coordination activities and compared it to our past work related to interagency collaboration and the necessary elements for a collaborative working relationship.⁷ Our February 2015 report includes a detailed explanation of the methods we used to conduct our work. To update selected information in March and April 2015, we reviewed DEA and FDA documentation and contacted FDA officials. We conducted the work for the report on which this statement is based in accordance with generally accepted government auditing standards. Those statements require that

⁵This requirement applies where the manufacturer's request pertains to a schedule II controlled substance that is on the list of drugs in shortage maintained by FDA under section 506E of the Federal Food, Drug, and Cosmetic Act (established by section 1004 of FDASIA). Pub. L. No. 112-144, § 1005, 126 Stat. at 1105 (codified at 21 U.S.C. § 826(h)).

⁶See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999) and GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, [GAO/GGD-96-118](#) (Washington, D.C.: June 1996).

⁷See GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

It is important to note that completion of our work was significantly delayed by DEA. In particular, DEA refused to comply with our requests for information from and about YERS/QMS and ARCOS until intervention by senior DOJ officials. We first requested access to YERS/QMS materials and data in January 2013, but did not obtain needed information until March 2014. We recognize that DEA has legitimate interests in protecting certain types of sensitive information from public disclosure. We share that interest as well and follow strict security guidelines in handling such information, which we provided in writing to DEA. DEA's prolonged resistance to sharing sensitive information with GAO—an agency that has a broad statutory right of access to agency records—impeded our ability to conduct audit work efficiently and to provide timely information to congressional clients.

DEA Has Not Effectively Administered the Quota Process

We found significant weaknesses involving DEA's management of the quota process for controlled substances. We found that DEA had not responded to manufacturers' annual quota applications for bulk manufacturing and procurement quotas by its regulatory deadline of July 1 for any year from 2001 through 2014.⁸ From our analysis of a random probability sample of YERS/QMS source documents, we estimate that DEA took an average of 182 days in 2011 and 178 in 2012 beyond July 1 to establish annual bulk manufacturing and procurement quotas. Similarly, DEA has not proposed APQs on or before May 1, as required by its regulations, for any year from 2001 through 2014.⁹

⁸21 C.F.R. §§ 1303.12(c), 1303.21(a). We also found that DEA did not meet the CSA requirement for establishing bulk manufacturing quotas for 2001 through 2013 by October 1. 21 U.S.C. § 826(c). However, it did meet this deadline recently. DEA established manufacturers' 2014 annual bulk manufacturing quotas in September 2013. When manufacturers apply for quota for use in the next year, we term this an annual quota application.

⁹21 C.F.R. § 1303.11. The CSA does not designate when DEA is to propose or establish APQs.

We estimate that on average DEA took nearly 60 days to respond to supplemental quota applications in 2011 and 2012.¹⁰ While there are no required time frames for DEA to respond to supplemental applications in the CSA or DEA's regulations, as of July 2012, FDASIA requires DEA to respond to manufacturers' quota requests that relate to shortages caused by quotas within 30 days.¹¹ Although this 30-day time frame was not yet a requirement in 2011 and for much of 2012, it is worth noting that DEA responded to 21 percent of supplemental applications within 30 days during those years, suggesting this requirement could pose a challenge during a future shortage.

DEA officials attributed the agency's lack of compliance with its required time frames to inadequate staffing of the Quota Unit. DEA officials said the agency has not been able to find candidates with the right skills who are also able to pass the background checks required for employment, and offers to qualified candidates have been declined. In addition, they added that the quality and timeliness of manufacturers' quota applications affects DEA's ability to meet its required time frames for proposing APQs and establishing manufacturers' quotas. For example, DEA officials said that manufacturers continue to revise their annual applications as manufacturing conditions change throughout the year, such as when manufacturers' gain or lose business.¹² However, DEA officials also recognized the importance of manufacturers submitting revisions as conditions change, to ensure they receive appropriate amounts of quota. Despite these challenges, DEA officials said that they expect the agency will be compliant with its CSA time frames in the future because of changes made to the quota process in 2011, specifically the reorganization of the Quota Unit and moving to an electronic system for the quota process (YERS/QMS).¹³

Manufacturers have expressed concerns about DEA's timeliness in establishing quotas and have asserted that the amount of time it takes

¹⁰When manufacturers apply for a revision to their quota during the current year, we term this a supplemental quota application.

¹¹Pub. L. No. 112-144, § 1005, 126 Stat. at 1105 (codified at 21 U.S.C. § 826(h)).

¹²Manufacturers may request a revision to their bulk manufacturing or procurement quota at any point. 21 C.F.R. §§ 1303.12(d), 1303.25(a).

¹³As of April 2015, DEA's website shows that the reorganization of the Quota Unit continues to be provisional.

DEA to respond to their annual and supplemental quota applications has caused or exacerbated shortages of some drugs containing schedule II substances. Ten manufacturers reported to FDA that quota related issues caused 7 of the 40 shortages of drugs containing schedule II substances from January 2010 through June 2013.¹⁴ DEA officials do not agree that quotas can cause such shortages because the agency authorizes quotas at the basic class level of a substance, such as amphetamine or morphine. DEA cannot authorize quota for specific drug products containing those substances, as this is precluded by the CSA. Because of concerns with the reliability of DEA's data, among other things, we could not confirm whether DEA's lack of timeliness in establishing quotas has caused or exacerbated shortages.¹⁵ However, we disagree that the actions DEA takes in setting quotas at the class level would have no bearing on the drug products that are made with those substances. While manufacturers are ultimately responsible for what they manufacture with the quota authorized by DEA, their decisions are made within the confines of the amount and timing of quota granted by DEA.

Additionally, we found that DEA's weak internal controls jeopardize the agency's ability to effectively manage the quota process. DEA does not have adequate controls to ensure the reliability of YERS/QMS, which it uses to track manufacturers' quota applications and record its quota decisions. DEA officials described some data checks, such as managers verifying that information entered into YERS/QMS by the Quota Unit is accurate. However, the agency does not have systematic quality checks,

¹⁴These 7 shortages were of drugs that included the substance classes of amphetamine, methylphenidate, or oxycodone, and began in either 2010 or 2011. According to FDA's data, there were several instances of shortages of drugs containing each of these substances between January 2010 and June 2013 and some, but not all, were reportedly caused by quotas. The other 33 shortages were caused by factors such as manufacturing delays, capacity issues, and product quality issues. We previously reported that these are the same factors that cause shortages of drugs generally. For more information on the reasons for shortages of all drugs, see GAO, *Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability*, [GAO-14-194](#) (Washington, D.C.: Feb. 10, 2014).

¹⁵In conducting our work, we requested data from ARCOS in order to track the drugs that manufacturers reported to be in shortage because of quota to examine their movement through the supply chain before, during, and after the reported shortage. However, we identified significant data reliability issues with ARCOS and ultimately concluded that data from this system were unreliable for our purposes. This, among other things, prevented us from assessing whether any shortages of drugs containing controlled substances were directly caused by insufficient quotas.

such as periodic comparisons of YERS/QMS records to source documents, to ensure that the data are accurate or the checks it has in place are sufficient. A lack of systematic data checks is inconsistent with federal standards for internal control.¹⁶ The lack of systematic data checks is also concerning because we estimate 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. We did find a substantial decrease in errors in the data for 2012 when compared to 2011; however, YERS/QMS is the official record of how much quota is requested by manufacturers and authorized by DEA. Maintaining accurate records is important for managing the quota process, and that maintenance has implications for future quota applications submitted by manufacturers because YERS/QMS automatically populates a new application with information on quotas previously authorized by DEA from the prior 2 years.

We also found that DEA lacks critical management information because it does not have performance measures related to setting quotas or ensuring an adequate and uninterrupted supply of controlled substances, nor does it monitor YERS/QMS data to assess its performance. DEA officials said that such performance measures would be inappropriate because of the complexity of individual quota applications and the difficulty of projecting the number of quota applications for future years. DEA officials also said that the agency has no plans to monitor or analyze YERS/QMS data or to produce aggregate information on its timeliness in establishing quotas or other such performance measures. Federal standards for internal control state that establishing performance measures and monitoring data to assess a program's performance are important management tools.¹⁷ Absent such measures and corresponding monitoring, DEA is missing important information for program managers to use when making decisions about program resources and the agency cannot effectively demonstrate program results.

Finally, we found that DEA lacks protocols, policies, training materials, or other documentation to manage the quota process. Instead, DEA officials said the agency relies on its regulations and the CSA to serve as

¹⁶GAO/AIMD-00-21.3.1.

¹⁷GAO/AIMD-00-21.3.1.

guidance on how to conduct these activities. According to federal internal control standards, agencies should have written documentation, such as detailed policies, procedures, and practices, to fit their operations and ensure that they are an integral part of operations.¹⁸ The need for detailed policies, procedures, and practices is particularly important because the activities conducted by Quota Unit staff are very complex, requiring staff to weigh data from at least five different sources that may have contradictory information. DEA officials told us that they ensure consistency in their decision-making by having the Deputy Assistant Administrator of the Office of Diversion Control review and authorize every quota decision that is made. However, given the volume of quota applications that DEA processes each year—over 3,000 in 2012—it is unreasonable to assume that one senior manager can devote sufficient time to review these decisions and ensure that quotas are set in accordance with DEA’s regulations and the CSA. Further, the lack of written guidance poses a risk to the continuity of the agency’s operations should personnel leave or be reassigned.

Our report contained four recommendations to DEA to ensure it is best positioned to administer the quota process. Specifically, we recommended that DEA (1) strengthen its internal controls of YERS/QMS, (2) establish performance measures related to quotas, (3) monitor and analyze YERS/QMS data, and (4) develop internal policies for processing quota applications and setting aggregate, annual, and supplemental quotas. In commenting on a draft of our report DEA did not explicitly agree or disagree with these four recommendations. In some instances, DEA indicated that it had already taken steps consistent with them or said that it is supportive of strengthening its management of the quota process.

¹⁸[GAO/AIMD-00-21.3.1.](#)

Lack of Effective Coordination May Hinder the Ability of DEA and FDA to Address Future Drug Shortages

Our report also identified several barriers that may hinder DEA and FDA from effectively coordinating with each other during a quota-related drug shortage. One barrier is that DEA and FDA sometimes disagree about whether a shortage exists because the two agencies define shortages differently. FDA defines a drug shortage as a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.¹⁹ In determining whether a shortage exists, FDA assesses if there is enough supply to meet demand by evaluating potential substitutes for the drug in shortage to determine whether drugs are clinically interchangeable. In contrast, DEA officials told us that there is no shortage, from DEA's perspective, as long as there is quota available to manufacture a given controlled substance, regardless of which particular manufacturers are producing the product and which strengths or formulations are available. Although there has not been a reported shortage of a drug containing a controlled substance caused by quotas since FDASIA's enactment in 2012, the law requires the agencies to coordinate certain efforts to address such a shortage if one occurs. By not reaching agreement about what constitutes a drug shortage, it is unclear whether they will be able to successfully coordinate.

Another barrier to effective collaboration is DEA's lack of compatible policies, procedures, and other means to operate across agency boundaries, should FDA notify DEA of a request for additional quota. FDA established such policies and procedures in September 2014, but DEA officials said that the agency does not plan to establish formal policies or procedures to coordinate the agency's response with FDA.²⁰ A lack of such policies or procedures is not consistent with key practices for effective collaboration. Additionally, while FDASIA directs DEA to respond within 30 days to manufacturers that request additional quota pertaining to a schedule II drug on FDA's drug shortage list, the law does not specify how quickly DEA must respond to a request from FDA to address a shortage of a life-sustaining drug and the agencies do not have an

¹⁹Pub. L. No. 112-144, § 1001, 126 Stat. at 1100 (codified at 21 U.S.C. 356c(h)(2)). In September 2014, FDA changed its definition of a drug shortage to be consistent with FDASIA. According to FDA, this is not a substantive change in definition and does not alter how FDA works on matters regarding drug shortages. In general, FDA focuses on shortages of medically necessary drugs that have a significant effect on public health.

²⁰See FDA, *Manual of Policies and Procedures, Drug Shortage Management*, MAPP 4190.1 Rev. 2 (Sept. 3, 2014).

agreement in place regarding this matter. A time frame for DEA to respond is particularly important, given that a request from FDA means it has determined that there is a shortage of a life-sustaining drug that an increase in quota is necessary to address. If DEA does not agree with FDA's determination of a shortage, it is not clear whether or how quickly DEA would respond.

Finally, both agencies stated that they were subject to restrictions on exchanging the proprietary information they receive from drug manufacturers, which may be helpful to prevent or address shortages of drugs containing controlled substances. The agencies had been working for more than 2 years on developing a new memorandum of understanding (MOU) to facilitate the sharing of such information. On March 24, 2015, the MOU was finalized. It establishes procedures regarding the exchange of proprietary and other sensitive information between FDA and DEA in both written and verbal communications. It also specifies that information must be shared in accordance with applicable laws, regulations, and policies, and safeguarded against improper use. However, the agreement does not specify precisely what information is to be shared, or who it is to be shared with. Instead it calls for this to be designated in separate plans that are to be expeditiously established. According to the MOU, the two agencies can begin to share information while the plans are in development if both parties agree that it is necessary and appropriate to their respective missions, or if it is considered an "emergency circumstance"—a term the MOU does not define.

Our report included a recommendation that DEA expeditiously establish formal policies and procedures to facilitate coordination with FDA as directed by FDASIA, including a specific time frame in which it will be expected to respond to FDA's requests to expedite shortage-related quota applications. We also made two additional recommendations to both DEA and FDA to strengthen their abilities to respond to shortages of drugs containing controlled substances. We recommended that the two agencies promptly update the MOU, and that has now been accomplished. We also recommended that in the MOU or in a separate agreement, the agencies specifically outline what information they will share and the time frames for sharing such information in response to a potential or existing drug shortage. The MOU did not include these details.

In commenting on a draft of our report DEA did not explicitly agree or disagree with these three recommendations but indicated that it has already taken steps consistent with some of them. HHS agreed with the two recommendations we made to FDA.

Chairman Grassley, Co-Chairman Feinstein, and Members of the Caucus, this concludes my prepared statement. I would be pleased to respond to any questions you may have.

GAO Contacts and Staff Acknowledgments

For future contacts regarding this statement, please contact Marcia Crosse (202-512-7114 or crossem@gao.gov). Individuals making key contributions to this statement include Geri Redican-Bigott, Assistant Director; Cathleen Hamann; Rebecca Hendrickson; and Janet Temko-Blinder.

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