Department of Justice

TESTIMONY OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

CAUCUS ON INTERNATIONAL NARCOTICS CONTROL
UNITED STATES SENATE

FOR A HEARING ENTITLED

IMPROVING MANAGEMENT OF THE CONTROLLED SUBSTANCES QUOTA PROCESS

PRESENTED ON

MAY 5, 2015

Testimony of Deputy Assistant Administrator Joseph T. Rannazzisi
Office of Diversion Control
Drug Enforcement Administration
before the
Caucus on International Narcotics Control
United States Senate
May 5, 2015

INTRODUCTION

Chairman Grassley, Co-Chairman Feinstein, and distinguished Members of the Caucus on International Narcotics Control, on behalf of the men and women of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss the recent report by the U.S. Government Accountability Office (GAO) entitled, "Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination Between DEA and FDA Should be Improved."

DEA shares the concerns of this Caucus and the public at large over the issue of drug shortages. It is vital that an adequate and uninterrupted supply of pharmaceutical controlled substances be available for effective patient care. This is and will remain a top priority for DEA. DEA is also charged with protecting the public health and safety by preventing, detecting, and eliminating the diversion of controlled substances from the closed system of distribution. We accomplish this through our enforcement of the Controlled Substances Act (CSA) and its implementing regulations. The CSA and its implementing regulations ensure that effective controls are in place to prevent, detect, and eliminate controlled substances from being lost, stolen, or otherwise diverted to illicit use.

DEA recognizes that it is a public health concern when pharmacies cannot dispense legitimate pharmaceutical controlled substances to patients, but the reasons for shortages are complex. For instance, a number of shortages during GAO's audit period were the result of one manufacturer's production problems. These production problems threatened the quality and therefore the safety of those medicines, which led to recalls, plant shutdowns, and subsequent production delays. DEA has and will continue to work collaboratively with the Food and Drug Administration (FDA) to address such circumstances. Our agencies recognize the value of collaboration and sharing information as well as the importance of protecting the proprietary information that drug manufacturers share with both DEA and FDA. To this end, DEA and FDA recently updated our Memorandum of Understanding so that we can share data that may be necessary to address drug shortages.

This is but one way that DEA is working to implement the recommendations offered by the GAO. DEA will continue to carefully consider all the recommendations made by the GAO intended to enhance DEA's quota program.

BACKGROUND

Prescription drug abuse is a nationwide epidemic and more must be done to prevent, detect, and deter the diversion of pharmaceutical controlled substances that supply drug addiction and abuse. DEA's role in this effort is as the primary agency responsible for coordinating the drug law enforcement activities of the United States. DEA's Diversion Control Program (DCP) is a strategic component of DEA's law enforcement mission. DEA Office of Diversion Control administers the DCP and implements and enforces the CSA.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market. It also charges DEA with establishing the total quantity of each basic class of Schedule I and II controlled substances, ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each year. These quantities provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.

QUOTA

When Congress passed the CSA, the quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling "the quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs . . ." 1970 U.S.C.C.A.N. 4566 at 4590. The quota system generally requires DEA to determine the amount of each basic class of Schedule I and II controlled substances, ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each year "to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks." 21 U.S.C. § 826(a). This essentially allows DEA to monitor the total amount of Schedule I and II controlled substances, ephedrine, pseudoephedrine, and phenylpropanolamine that enters the closed system of distribution.

DEA's quota system for the basic classes of controlled substances consists of three types of quota summarized below: Aggregate Production Quota (APQ), Individual Manufacturing Quota, and Procurement Quota.

- *Aggregate Production Quota*: The Administrator determines the total amount of each basic class of Schedule I and II controlled substance necessary to be manufactured in a calendar year to provide for the estimated medical, scientific, research, and industrial need of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.

- *Individual Manufacturing Quota*: Amount of a basic class allocated to registered bulk manufacturers in order to manufacture the substance by producing, preparing, propagating, compounding, or processing it from another substance.

- *Procurement Quota*: Issued to registered manufacturers who desire to obtain any Schedule I and/or II basic class of controlled substances in order to further manufacture that substance by packaging, repackaging, labeling, relabeling, or producing dosage forms or other substances.

DEA establishes the APQ for approximately 200 Schedule I and II controlled substances annually. Additionally, it establishes and revises over 4,000 individual initial and revised quotas for more than 400 bulk and dosage-form manufacturers registered to handle Schedule I and II controlled substances. The factors considered in determining quotas include the following:

- Information provided by the Department of Health and Human Services;[1]
- Total net disposal of the basic class by all manufacturers;
- Trends in the national rate of net disposal of the basic class;
- An applicant's production cycle and current inventory position;
- Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and stability issues; potential disruptions to production; and unforeseen emergencies.

Once issued, a quota may be increased or decreased, as appropriate. Any registrant who holds an individual manufacturing quota for a basic class of a Schedule I or II controlled substance may, at any time, request an increase in that quota in order to meet estimated net disposal, inventory, and other requirements during the remainder of the year. In addition, the Administrator may, at any time, reduce an individual manufacturing quota for a basic class of controlled substance in order to prevent the aggregate of the individual manufacturing quotas from exceeding the APQ for that basic class.

DEA only authorizes quota at the manufacturer level for entities that manufacture active pharmaceutical ingredients (API), entities that manufacture substances into dosage forms, and entities that repackage or re-label drug products that contain Schedule I or II controlled substances. Once the aggregate quota is established, individual manufacturers can receive authorization to manufacture a specific amount of a basic class of controlled substance. DEA, however, cannot require the manufacturer to actually manufacture API, specific drug products, or manufacture amounts or specific dosage forms in accordance with their quota application or

[1] The Department of Health and Human Services, pursuant to 42 U.S.C. § 242, provides information that may include, but is not limited to, forecasts on the usage of particular controlled substances for the following calendar year.

supporting documents therein. DEA also cannot require manufacturers or distributors to distribute substances down through the supply chain.

A bulk manufacturer may extract or synthesize API in an authorized calendar year, and hold it in inventory until any subsequent calendar year. Of equal importance, the CSA prohibits DEA from establishing quotas in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance. 21 U.S.C. § 826(a). These limitations on DEA's authority are critical to understanding the effect that quota can have on the availability of a specific drug product at the retail level or at the emergency medical service (EMS) provider level.

QUOTA PROCESS

It is unlawful for a registrant to manufacture a controlled substance in Schedule I or II that is: (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by DEA. 21 U.S.C. § 842(b). Accordingly, the pertinent regulations require manufacturers to submit quota applications to DEA by May 1 of the year preceding the year to which the APQ applies. 21 C.F.R. § 1303.22. DEA is also required to publish in the Federal Register a notice of the proposed APQ by the same date, May 1 of the year preceding the year to which the APQ applies. 21 C.F.R. § 1303.11(c).

Since manufacturers do not submit their applications until May 1, and often submit revised applications after May 1, it is not possible for DEA to publish a notice of the APQ by the same date if DEA is to thoroughly consider each application in determining the overall need necessary to establish the APQ. In order to fully consider all applications and supporting justifications, DEA has not historically published the notice of the APQ until a few months after May. Most recently, for quota year 2015, the proposed notice was published on July 2, 2014; for quota year 2014, the proposed notice was published on July 3, 2014; and for quota year 2013, the proposed notice was published on August 3, 2012. Though these notices do not meet the regulatory deadline, they represent significant improvements that we have been able to achieve since the GAO initiated their review.

When the CSA was enacted in 1970, it required DEA to establish individual manufacturing quotas by July 1 of the year preceding the year in which the quota is to be utilized. The corresponding regulation, promulgated in April, 1971, mirrored this requirement. 21 C.F.R. § 1303.21. Subsequently, in 1976, Congress changed this requirement to October 1. 21 U.S.C. § 826(c). The corresponding regulation, however, has not been changed to reflect the additional three months' time to establish individual manufacturing quotas, and still requires DEA to establish individual manufacturing quotas by July 1 of the preceding year in which the quota is to be utilized. DEA met this statutory requirement most recently for quota years 2014 and 2015, and DEA expects to continue to meet this requirement.

DEA acknowledges that changes are necessary to allow manufacturers and DEA sufficient time to request and establish quota respectively. Manufacturers need sufficient time to estimate and provide adequate justification for annual quota requests and DEA needs sufficient time to consider all applications, propose and finalize the APQ, and issue individual

manufacturing and procurement quotas before the relevant quota year. DEA recognizes the importance of having regulatory certainty and we are carefully considering how best to amend the relevant regulations.

For the period January 2010 to June 2013, GAO reported that there were 40 FDA-reported shortages of drug products containing Schedule II controlled substances, and of those, seven were alleged to have been caused or exacerbated by quotas. The remaining 33 reported shortages of drugs containing Schedule II controlled substances were caused by other factors that cause shortages of drugs generally such as manufacturing delays, capacity issues, and product quality issues.

As noted above, DEA establishes individual quotas for manufacturers which are used to produce all drug products that contain that controlled substance. The manufacturer determines the allocation of that quota to the various products (and strengths) it produces and it is beyond DEA's control to compel a manufacturer to use its quota to manufacture a specific drug product that may be in shortage. In situations where DEA was made aware of the need for an increased quota, and an increase could be adequately justified, DEA worked quickly to make the necessary adjustments. We note, however, that since the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) was enacted in July, 2012, no special requests for expedited quota review have been forwarded to DEA.[2]

GAO recommended that DEA establish performance measures related to quotas, such as tracking the number of incomplete or revised quota applications or the amount of time to process or respond to a quota application. We are carefully considering this recommendation.

CONCLUSION

There can be no doubt that drug shortages adversely affect the public health. Drug shortages occur across the continuum of pharmaceutical characteristics—e.g., brand, generic, controlled, non-controlled, over-the-counter, dosage forms and dosage strengths, analgesics, sedatives, stimulants. Shortages can be caused by a variety of factors, most of which, as has been noted, are beyond the control of DEA and FDA. Nonetheless, we remain committed to working with FDA and with manufacturers and distributors to prevent shortages of products containing Schedule II controlled substances wherever possible.

[2] FDASIA amended the CSA to provide that no later than 30 days after receipt of a quota request submitted by the manufacturer of a controlled substance on the FDA list of drug shortages, DEA shall complete review of the request and take action to address the shortage by increasing the APQ and/or the individual manufacturing quota to the level requested. 21 U.S.C. § 826(h). If such action is not necessary to address the shortage, DEA shall provide a written response detailing the basis for the determination. It should be noted that even if FDA requested DEA to increase the APQ pursuant to 21 U.S.C. § 356c, the CSA permits DEA to increase an individual manufacturing quota only upon application by a registered manufacturer. 21 U.S.C. § 826(c) and (e).