GAO Highlights

Highlights of GAO-16-737T, a testimony before the Committee on the Judiciary, U.S. Senate

June 22, 2016

DRUG ENFORCEMENT ADMINISTRATION

Additional Actions Needed to Address Prior GAO Recommendations

Why GAO Did This Study

DEA administers and enforces the CSA to help ensure the availability of controlled substances, including certain prescription drugs, for legitimate use while limiting their availability for abuse and diversion. The CSA requires DEA to set quotas that limit the amount of certain substances that are available in the United States. The CSA also requires those handling controlled substances to register with DEA. In addition, DEA works to disrupt and dismantle major drug trafficking organizations and uses confidential informants to help facilitate its investigative efforts.

This testimony addresses DEA's efforts to address prior GAO recommendations concerning: (1) administration of the quota process, (2) information provided to registrants on their roles and responsibilities under the CSA, and (3) compliance with guidelines regarding confidential informants. This statement is based on findings from three GAO reports issued during 2015, and selected status updates from DEA through June 2016. In its prior work, GAO analyzed quota data, surveyed DEA registrants, reviewed DEA policy documents and interviewed DEA officials. For selected updates, GAO reviewed DEA documentation and held discussions with agency officials.

What GAO Recommends

GAO previously made eleven recommendations to DEA related to the quota process, guidance to registrants, and confidential informants. DEA generally agreed with and has begun taking actions to address the recommendations, and has so far fully implemented two.

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What GAO Found

In three reports issued during 2015, GAO made eleven recommendations to the Drug Enforcement Administration (DEA) related to administering the quota process for controlled substances, providing information and guidance to registrants, and complying with guidelines for overseeing confidential informants. As of June 2016, DEA had taken some actions to address these recommendations but had fully implemented only two of them.

Administering the quota process. In February 2015, GAO found that DEA had not effectively administered the quota process that limits the amount of certain controlled substances available for use in the United States. For example, manufacturers apply to DEA for quotas needed to make drugs annually. GAO found that DEA did not respond within the time frames required by its regulations for any year from 2001 through 2014, which, according to some manufacturers, caused or exacerbated shortages of drugs. GAO recommended that DEA take seven actions to improve its management of the quota process and to address drug shortages. In March 2015, DEA implemented one recommendation to finalize an information sharing agreement with the Food and Drug Administration regarding drug shortages. In June 2016, DEA implemented a second recommendation strengthening internal controls in the quota system. DEA has not fully implemented the other five recommendations. In October 2015, DEA identified steps it planned to take, including developing performance standards for responsiveness to manufacturers, but has not yet completed these actions.

Providing information to registrants. In June 2015, based on four nationally representative surveys of DEA registrants, GAO reported that many registrants were not aware of various DEA resources, such as manuals for pharmacists and practitioners. In addition, some distributors, individual pharmacies, and chain pharmacy corporate offices wanted improved guidance from, and additional communication with, DEA about their roles and responsibilities under the Controlled Substances Act (CSA). GAO recommended that DEA take three actions to increase registrants' awareness of DEA resources and to improve the information DEA provides to registrants. In April 2016, DEA reported that it had taken some steps towards addressing these recommendations, such as developing web-based training and updating the Pharmacist's Manual to reflect new regulations. However, DEA did not mention plans to develop and distribute additional guidance for distributors or pharmacies and therefore has not yet fully implemented GAO's recommendations.

Compliance with confidential informant guidelines. In September 2015, GAO reported that DEA's confidential informant policies were not fully consistent with provisions in the *Attorney General's Guidelines*. For example, DEA did not fully address the requirements to provide the informant with written instructions about authorized illegal activity and require signed acknowledgment from the informant. GAO recommended that DEA update its policy and corresponding monitoring processes to explicitly address these particular provisions in the Guidelines. According to an April 2016 memo and subsequent follow up, DEA has revised its policy accordingly, and it is undergoing internal processing, which is expected to be completed in summer 2016. Until GAO can review the new policy and verify that it complies with the Guidelines, this recommendation remains open.