Prepared Statement of Chairman Chuck Grassley of Iowa
Senate Caucus on International Narcotics Control
Hearing on "Improving Management of the Controlled Substance Quota Process"
Tuesday, May 5, 2015

Today's hearing addresses a timely and important topic. Shortages of prescription drugs that contain controlled substances have increased sharply over the past decade. According to the Government Accountability Office (GAO), from January 2001 to June 2013, 168 shortages of these drugs were reported. Of those, almost 70 percent began in 2007 or later. The shortages lasted an average of one year, and some lasted for multiple years. Many of the affected drugs were pain relievers, anti-anxiety medications, and stimulants.

According to the Food and Drug Administration (FDA), these shortages can pose a significant threat to public health. Shortages can delay or deny needed care for patients, cause the use of less effective or more risky medications, and burden both patients and providers in other ways. According to one study, hospitals spend $216 million annually in labor costs alone to manage the effects of drug shortages.

Many of the drugs affected by shortages are pain medications that present a serious risk of addiction to patients. So of course doctors need to be cautious when they prescribe them. But when they are truly needed, these medicines should at least be available for doctors as a treatment option.

Against this backdrop, in May 2012, Senator Whitehouse and I asked GAO to investigate these shortages. The Controlled Substance Act requires the Drug Enforcement Administration (DEA) to manage the amounts of controlled substances permitted to be manufactured or imported for medical use each year in the United States. It does this through a quota process, which also involves setting individual quotas for various manufacturers and producers. As a result, Senator Whitehouse and I asked GAO to focus on the DEA's administration of the quota process and the coordination between DEA and FDA to prevent and mitigate shortages. In February of this year, GAO issued its report, which has led to our hearing today.

While I'm glad to finally see the results of GAO's review, this report could have been finished much sooner if DEA had cooperated with GAO from the start. DEA refused to comply with GAO's requests for information from a particular DEA database for over a year. In fact, I had to get personally involved in the process to make sure GAO had the information it needed. I understand that certain information must be kept closely held. But Congress, through GAO, simply must have access to the information required to conduct oversight. And this report is an excellent example of why that's so.

In short, GAO found that DEA hasn't effectively administered the quota process, and that DEA and FDA haven't established a sufficiently collaborative relationship relating to their management of shortages. According to the report, DEA hasn't met its annual deadline to propose aggregate production quotas or to establish bulk procurement and manufacturing quotas for

individual manufacturers in any year from 2001 through 2014. Manufacturers report that these delays have prevented them from adequately planning ahead to meet demand.

GAO also concluded that DEA's weak internal controls, including controls to ensure data reliability, may hinder its ability to manage the quota process. For example, according to GAO, the database DEA uses to manage the process is often inaccurate, and DEA doesn't adequately review the quality of the information housed in it. GAO estimated that in 2011, 44 percent of records in the database contained errors, and in 2012, 10 percent of the records in the database contained errors. While that trend is moving in the right direction, it still reflects an unacceptably high error rate.

GAO also found that DEA was missing critical information about the quota process because it doesn't employ performance measures or monitor data to determine whether its process is effective. In addition, DEA doesn't have written policies, procedures or guidance in place to guide its staff managing the quotas. According to GAO, this deficiency threatens DEA's ability to oversee this highly complex process, especially as institutional memory is lost due to staff turnover.

Finally, and perhaps most concerning, GAO found that DEA and FDA simply don't have a sufficiently collaborative relationship to work together to manage the drug quota process and to prevent shortages. The two agencies don't even agree on the definition of a drug shortage. This lack of coordination and collaboration severely hinders their ability to work together for the benefit of patients that need these medicines.

At the conclusion of its report, GAO offered a series of recommendations to both DEA and FDA, to try to improve management of the quota process. I'm sure we'll have the opportunity to talk about a number of them today. It was heartening that the Department of Health and Human Services agreed with the two recommendations directed to the FDA. But it was disappointing that DEA didn't explicitly agree or disagree with the recommendations applicable to it, but instead chose to object to certain aspects of the report. For if there is one thing that the report makes clear, it's that the quota system for these drugs isn't functioning as it should – and it seems apparent that both DEA and FDA need to make changes in order for that to happen.