

**Statement of Senator Dianne Feinstein
As Delivered**

“Improving Management of the Controlled Substances Quota Process”

May 5, 2015

First of all, let me say that I am a fan of DEA. And this is a difficult arena in which to work, and so over the many years I’ve seen a lot of the good work that DEA has done and a lot of criminals brought to heel and imprisoned who sell drugs all over the world.

But today, we are here today to discuss the management of what’s called the controlled substances quota process, and this is mandated by law. The Drug Enforcement Administration is required to determine the amount of a controlled substance a drug manufacturer receives and the drugs it can produce.

This process was the subject of the GAO report obviously that’s before us today. The report, as I understand it, could not establish a causal link between shortages of drugs containing controlled substances and DEA’s management of the quota process.

DEA sets the aggregate production quota for each basic class of Schedule I and II controlled substances. Then it sets bulk and procurement quotas for individual manufacturers.

DEA does not, and cannot, tell individual manufacturers what prescription drugs and in what formulation to produce with their quota allotment.

Manufacturers, in fact, make those decisions.

Despite the fact that the GAO report did not find that DEA’s management led to shortages of drugs containing controlled substances, and I want to point that out, it did raise important issues.

First, DEA has not met deadlines to establish aggregate production quotas, bulk manufacturing or procurement quotas required by its own regulations for any of the past 13 years. And, DEA does not dispute this.

Manufacturers cannot accurately plan for the upcoming production year without timely notification from DEA of what their quota allotment will be. So this does mean a great deal.

Even though DEA has the regulatory power to change these deadlines – this is important – it has taken no steps to do so. This is troubling.

Second, the GAO report notes that when a manufacturer requests a supplemental quota, DEA takes an average of 58 days to respond. Given that manufacturers typically apply for supplemental quotas to avert a shortage, this response time should be quicker and consistent with

the 30 day time frame that is now required by the Food and Drug Administration Safety and Innovation Act.

I understand that DEA's Quota Section is under-staffed, and that the volume of quota applications it receives has increased, both of which may contribute to its lengthy response time.

However, I'm also told that there are three vacancies out of the 10 staff. And I don't quite understand why these three vacancies haven't been filled. It seems to me that DEA has the authority it needs. If it's a question of fees, to see that those fees are adjusted to permit this unit to operate at its maximum. And that is my belief, Mr. Chairman, that they should quickly hire these three people and get on with it.

Third, DEA has taken a number of steps to improve the accuracy of its quota system, but as of 2012, there still was a 10 percent error rate.

Fourth, there must be clear and open communication between DEA and the Food and Drug Administration. Now these agencies are required by law to jointly address any shortages of drugs containing controlled substances, so I was happy to learn that the memorandum of understanding to increase communication between these agencies was recently updated and signed.

Mr. Rannazzisi, let me commend you for that.

So I hope DEA will take certain additional steps to establish and implement formal procedures to identify the information it will share with FDA regarding potential and existing shortages of drugs containing controlled substances, as well as a timeframe for doing so.

I think we are on the right track. I think improvements are being made, and there has not been a quota-related drug shortage since 2011. So I hope we can build on this report and do the right thing.

Last year, I chaired a Caucus hearing on prescription drugs and heroin abuse, in which we praised DEA's work to shut down pill mills and rogue online pharmacies, and collect unused prescription medications.

So DEA has made strong contributions to reducing prescription drug abuse nationwide. And I want to point that out.

However, drug abuse continues to wreak havoc throughout the country, and we are in the midst of an epidemic that kills essentially 44 people every day.

Given the number of prescription opioids dispensed in our country over the past 14 years, it's quadrupled. That's amazing. It's quadrupled.

We've actually had hearings where we learned [that heroin use goes up because people switch from prescription opioids because] prices are up. There's a cost and effect relationship between the two.

But given the number of prescription opioids dispensed in the United States over the past 14 years and the fact that it's quadrupled – there has been no overall change in the amount of pain that Americans report. I think it's worth taking a closer look at the quota process to see if it can be used as another tool to prevent prescription drug abuse and overdose deaths.

I would like to point out that with respect to a young man, who happens to be a constituent of mine, who was in a cell for five days in San Diego with no attention at all.

I, on [July 14, 2014], wrote a letter to the Administrator of the DEA. That's over a year ago. I have received no response to that letter. Subsequently, I wrote a second letter, dated [August 8, 2014] to the Department of Justice, and I intend to pursue this.

And I would ask, and my first question will be, "Will I receive a response to the letter I wrote on August 8, 2014?" I have not received a response to either, which candidly, I very much regret – and I think, when we don't get responses to our letters, Mr. Chairman, that colors our view of the agency. Particularly when we're writing about a constituent who suffered from a real lapse in process.

So thank you very much.