Excerpts from Hearing on "Oversight of the Drug Enforcement Administration"
Senate Judiciary Committee
June 22, 2016

DEA Oversight Witnesses: Michael Horowitz, inspector general of the Justice Department; Diana Maurer, director of the Government Accountability Office's Homeland Security and Justice Team; Robin Ashton, head of the Justice Department's Office of Professional Responsibility; and Chuck Rosenberg, acting administrator of the Drug Enforcement Administration, Springfield, Va.

Full Hearing: http://www.judiciary.senate.gov/meetings/06/22/2016/oversight-of-the-drug-enforcement-administration

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WHITEHOUSE: Thank you. I really appreciate that, Senator Blumenthal.

I just wanted to say first that when I came to the Senate, I came here as a former United States Attorney. And my experience with the Drug Enforcement Administration was field experience with their investigative work.

And I found them to be a -- a brave and resourceful and tenacious agency. So, I came in with a great image of DEA from years of experience working with DEA. In fact, the bravest single thing I’ve ever seen a federal law enforcement agent was done by a female DEA agent in a case of ours in Rhode Island.

Then I began to encounter DEA on the administrative side. It began with DEA’s opposition to having electronic health records for prescriptions for controlled pharmaceuticals which was a little hard to justify. But we fought for years finally to a resolution of that.

And that battle was characterized when Ms. Maurer was talking about two year sagas, having to go to the Attorney General to shake things loose, having understandings ignored, having the responses be in the poor to terrible category.

That was our world. We went on to the problem with how DEA was dealing with the pharmaceutical distribution centers, and Senator Hatch and I had to actually do legislation to try to solve that problem.

You have a patient getting a prescription. Behind that you have a doctor who’s actually signed it. Behind that you have a pharmacist who is issuing the prescription. Behind that you have a pharmacy company. And behind that there’s a distribution center that does the -- basically the mechanical provision of getting drugs that have been ordered to the pharmacy from the manufacturers.

The DEA was focusing regulatory attention on those distribution centers in such a way that they didn’t know what would pass the test, and they were not being told that this is what you need to do. But there were constant threats that we’re going to shut you down if you don’t.
And that was causing some of them to say, well, we’re just not gonna be able to -- to use -- prescribe -- I shouldn’t say prescribe -- transit controlled pharmaceuticals. So, we had to get that solved with legislation. But, again, that was an ordeal.

The DEA was doing a parallel approval of drugs after FDA did. And they were taking months and even years to do the parallel approval. Never once did they disagree with FDA. Never once. But it took months and even years to do their box checking so that they finally ended up where they always did.

And we had to, again, legislatively interact to get them to speed up that period. You and I, Chairman, had the issue with the drug shortages in which we couldn’t get letters answered and we had to go to the Attorney General on this.

And now we have the new GAO report that I was one of the requesters that Ms. Maurer referred to about the registrants who are, by virtue of registration, able to prescribe controlled substances, of whom thousands couldn’t be validated. And among them were hundreds who were either dead or incarcerated.

So, it's been a long and painful experience dealing with the administrative side of DEA. And considering where I started with them, with such pride and confidence in their investigative side it's been really, actually, heartbreakingly to me to have to deal with that side of the agency.

I want to add though that exactly consistent with what Mr. Horowitz and Ms. Maurer have said, I think under Acting Director Rosenberg there has been, to use her words, a different tone from the top. And I do think it's starting to sink in, but this business of having to go to the mattresses any time people make a perfectly reasonable request and figure out ways to create delay, obstruction, obfuscation, illumination of words, redaction, it doesn't help the agency.

It doesn't help oversight. And when you get somebody like me who comes in really enormously proud of an agency like this and then over 10 years of dealing with them in Congress has to have this repeated, horrible experience that they just won’t deal honorably with Congress or with oversight.

It's -- it's really important that they get this right. I think it's important that we send a signal that we support Acting Administrator Rosenberg in his efforts because I really do think, and I think -- I -- I -- I think we’ve heard from the witnesses today that they agree that he’s starting to turn around what had become a really toxic culture on the administrative side.

So, Mr. Chairman, thank you very much.

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HATCH: Well, thank you, Mr. Chairman. And Mr. Rosenberg, as you know, earlier this year Congress passed and the President signed this 483, the Ensuring Patient Access and Effective Drug Enforcement Act which I sponsored together with Senator Whitehouse. I’d like to ask some questions about how DEA is implementing this new law and how you expect the law to affect your partnerships with supply chain stakeholders moving forward.

Before doing so, however, I'd just like to say that I hope and expect the DEA is working in good faith to implement this 483 as Congress intended. A recent story in the New York Times contained statements from a former agency employee that suggested some dissatisfaction with the legislation.
Now, I understand another paper may be working on a story as well. I would hope that these stories, which appear to portray an adversarial relationship between DEA, Congress, and -- and stakeholder groups do not influence or accurately reflect the current state affairs.
As you know S483 passed both houses of Congress unanimously, and was the product of a multiyear process in which the agency had numerous opportunities to air its views.

I've worked with DEA on many initiatives through the years and have always enjoyed a good working relationship with the agency. I'd like that relationship to continue.

Now, let me just ask -- one of the important changes S483 makes is to give Controlled Substances Act registrants the opportunity to submit a corrective action plan before DEA administratively revokes or suspends their registration.

This provision, as I've said, is now in effect. What criteria and procedures are DEA -- is DEA using to determine whether a registrant's corrective action plan is adequate? How will you be publishing those criteria and procedures?

Is DEA preparing a proposed rule, for instance, to update the regulations that define the agency's hearing procedures? If you could answer those questions, I'd appreciate it.

ROSENBERG: Yeah. We're -- we're working through that now, Senator. I just started to see the first several corrective action plans submitted. Incidentally they've been submitted in conjunction with cases that are already pending. So, one thing we have to figure out is whether and if -- whether and how they would apply retroactively.

So, I've asked our lawyers and chief counsel, and our folks in diversion to advise me on that. I don't have an answer yet. My job is to make sure we abide by the spirit and letter of the law. And we will work through it diligently. But I don't have an answer yet. It -- we're just beginning to see those first caps sort of, you know, washing up on our shore.

HATCH: I've been told the DEA's relationship with supply chain stakeholders has improved since you've taken the helm at DEA. And I wanna just say I applaud your efforts on this front. How do you see this partnership evolving? Particularly now that S485 has become law. And what are some of the issue areas where you think you can best work together with registrants?

ROSENBERG: Yeah. Thank you for that. So, we have 1.6 million registrants in the United States.

HATCH: Right.

ROSENBERG: And, frankly, if you think about it, you know, logically and holistically the overwhelming majority, 99 plus percent are our allies in this thing. And I think historically we've done a very good job of alienating them. I'm being sarcastic.

What we need is them as partners. Just to give you a simple metric, but in 2015 we had a sort of -- I asked my folks, how many times have we met with industry, with organizations? How many times have we sat down -- sat down with prescribers or doctors, with pharmacists, and we had 300 such interactions, or 339 such interactions in all of 2015.
So far, just in the first six months of this year, we're up to 300. We -- we're gonna probably double the number of interactions. Now, that doesn't mean they're all as good as they should be. But if we're listening to them we're gonna get better.

And we've also been opaque. I think we've been slow. I think we've been opaque. I think we haven't responded to them. We're trying to issue guidelines for them more quickly. We're trying to answer their questions.

So, you know, Senator, take what you say very serious. We -- I have a new head of diversion, and actually he is a star. And I've created a SES positions for the regulatory side and on the enforcement side of diversion.

So, we're trying to give more high-level attention to our diversion folks. More to come on this because I have some more ideas. But I don't want to get ahead of the department on it.

HATCH: Are there any obstacles you currently see to implementation of this 483? Is there anything you think Congress or this committee should be aware of as you implement this new law?

ROSENBERG: I need to work through it. As I mentioned with respect to the new corrective action plans we're seeing, if we have concerns or questions or comments, Senator, I'll be very happy to work with you and your staff. And we'll do it through our Department of Justice.

HATCH: Well, thank you.

ROSENBERG: Thank you, sir.

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DURBIN: Thank you, Mr. Chairman. Mr. Rosenberg, thank you for being with us today. And I think it goes without saying in your testimony and from questions asked, we're all concerned about this opioid crisis. And we are trying to figure out who is responsible when it comes to decisions made that have created this and made it worse.

And I look at your 360 strategy, which you talk about here, and you focus on law enforcement, diversion control, and demand reduction. You go on to say, "Our enforcement activities are directed at the violent cartels and drug trafficking gangs responsible for feeding heroin and prescription drug epidemics in our communities."

There's one key element missing. And it's an element that you have responsibility for. That is the over production of opioids by the pharmaceutical industry. Let's take a look at the numbers. What has happened? In 1993, the DEA allowed drug companies to manufacture 3,520 kilograms of oxycodone.

Twenty-two years later, 2015, the DEA authorized production to increase to 137,500 kilograms of oxycodone. That's a 39 fold increase. To put it in pound terms so Americans are more familiar, in 1993 your agency approved the production of this opioid narcotic to the tune of three and a half tons, three and a half tons, of opioids.

By the year 2015, that number was up to 150 tons of opioids being produced by the pharmaceutical industry.
In that same period of time, the DEA authorized the production of hydrocodone to increase 12 fold. They allowed the production of hydromorphone to increase 23 fold. They allowed the production of Fentanyl to increase 25 fold.

In the year 2014, with DEA approval, DEA approval, the pharmaceutical industry in the United States produced 14 billion opioid pills, enough for every adult in America to have a one month prescription of opioid pills.

In 2014, more than 28,000 people nationwide, 1,652 in my state, died from prescription opioid and heroin overdoses.

You've said all the right things after the fact. You said all the right things about what to do to stop this opioid epidemic. What you have failed to say, what your agency has failed to concede is that they have been the gatekeepers who have opened the gate wide and said to the pharmaceutical companies produce as much as you want.

And then we'll try to figure out how to slow it down once it hits the economy. So, do you accept responsibility as an agency for being part of the problem?

ROSENBERRY: I think we're part of problem.

DURBIN: So, what are you gonna do about it? If these pharmaceutical companies come to you and say next year, we wanna produce even more opioids, what will the DEA say? ROSENBERRY: We're, I think, fairly criticized for -- I can't see the chart very well. But we're fairly criticized for the production amounts. We're also criticized for being responsible for drug shortages. We've seen, Senator, and this is, I guess...

DURBIN: Of opioids? Drug shortages?

ROSENBERRY: No, no, no, no. Not -- not -- not opioids. Oh, thank you. That helps a lot. I think we have to do a better job. And I'm not just -- I know it's gonna just sound like words right now. I'm figuring out what really needs to be done, and working with industry, in collaboration with industry to get this monster under control.

DURBIN: Collaboration hasn't worked out very well. (Inaudible)

ROSENBERRY: No, it hasn't so far. But I think -- and I -- when you asked me if I think some of that is on us, that's why I'm saying yes.

DURBIN: It strikes me that the pharmaceutical companies, and I know this industry is responsible for many lifesaving drugs.

ROSENBERRY: They are.

DURBIN: And I thank them for all their research, and all their investment, and I do not want to deny them a profit. They are exploiting an addiction in America. And you, sadly, your agency, not your personally, but your agency is complicit.

You cannot flood America with opioid pills and then sit back and say, isn't it sad that so many people are using opioids? That so many doctors are overprescribing. And that's an additional part of the responsibility.
ROSENBERG: But that's a part of it. I think...

DURBIN: But you are on the front end decision. You have decided to flood America. The Drug Enforcement Agency has decided to flood America with opioid pills far beyond any medical purpose. Why?

ROSENBERG: I'm gonna push back a little bit on that characterization.

DURBIN: Please.

ROSENBERG: Yeah. Because I‐‐ I don't think we've decided to flood America with pills. We're meeting or trying to meet legitimate industry needed, and legitimate industry request. In turn, right, they are trying to fulfill what their doctors and prescribers and pharmacists are asking for.

I think there's a big problem here. And I think we're a part of it. But I think the characterization that we are flooding...

DURBIN: All right. Let me just ask you that. Fourteen billion opioid pills in the year 2014, enough for every adult in America to have a one month prescription. You don't think you're flooding the market?

ROSENBERG: It's too much. And like...

DURBIN: it certainly is.

ROSENBERG: And like I said, we're five percent of the world's population. We consume 99 percent of the world's hydrocodone.

DURBIN: With a greenlight from the Drug Enforcement Agency. Why? Is anybody stepping back in your agency and saying, this is out control? This is beyond pain management, legitimate pain management? We are feeding the beast that we're trying to kill at the other end of the process.

ROSENBERG: I -- I take your point. But we're -- we have an obligation, I think, to listen to the manufacturers and the prescribers, and try to meet their legitimate requests. Are we failing in this in some way? Yeah. I think so.

DURBIN: There's a lot of responsibility here. And it starts with your agency. You are the ones who decide whether it's a red light or green light on production. Look at what's happened.

ROSENBERG: Well I -- l...

DURBIN: You've got to accept the responsibility as doctors and dentists and other prescribers do, and all the rest of us do. But it starts with your decision.

ROSENBERG: I take your point, Senator. But I -- I also think there are a lot of pieces to this as you recognized. There's a lot of fault to go around. Does some of it reside with us? Yes, it does. Can we do better? We will.

DURBIN: Thank you.

ROSENBERG: Thank you, sir.