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THE DRUG ENFORCEMENT ADMINISTRATION'S ROLE IN COMBATING THE OPIOID EPIDEMIC

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

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TUESDAY, MARCH 20, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2322 Rayburn House Office Building, Hon. Gregg Harper (chairman of the subcommittee) presiding.

Members present: Representatives Harper, Griffith, Burgess, Brooks, Collins, Barton, Walberg, Walters, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Clarke, Ruiz, Peters, and Pallone (ex officio).

Also present: Representative McKinley.

Staff present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Mike Bloomquist, Staff Director; Ali Fulling, Legislative Clerk, Oversight and Investigations, Digital Commerce and Consumer Protection; Brittany Havens, Professional Staff, Oversight and Investigations; Christopher Santini, Counsel, Oversight and Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Austin Stonebraker, Press Assistant; Hamlin Wade, Special Advisor, External Affairs; Christina Calce, Minority Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; and C.J. Young, Minority Press Secretary.

OPENING STATEMENT OF HON. GREGG HARPER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSISSIPPI

Mr. HARPER. We will call to order the hearing today on the Drug Enforcement Administration's role in combating the opioid epidemic.

Today, the Subcommittee on Oversight and Investigations convenes a hearing on the DEA's role in combating the opioid epidemic. This crisis is a top priority of the nation and certainly of this committee and subcommittee. Opioid-related overdoses killed more than 42,000 people in 2016. That's an average of 115 deaths each day. An estimated 2.1 million people have an opioid use disorder.

Since our earliest hearings in 2012, this subcommittee has been investigating various aspects of this epidemic. In May 2017, the Committee opened a bipartisan investigation into allegations of "opioid-dumping," a term to describe inordinate volumes of opioids shipped by wholesale drug distributors to pharmacies located in rural communities, such as those in West Virginia. From press reports and this investigation, we have learned of opioid shipments in West Virginia that shock the conscience.

Over 10 years, 20.8 million opioids were shipped to pharmacies in the town of Williamson, home to approximately 3,000 people.

Another 9 million opioids were distributed in just 2 years to a single pharmacy in Kermit, West Virginia, with a population of 406.

Between 2007 and 2012, drug distributors shipped more than 780 million hydrocodone and oxycodone pills in West Virginia.

These troubling examples raise serious questions about compliance with the Controlled Substances Act, administered by the DEA.

The CSA was enacted through this committee in 1970. This law established schedules of controlled substances and provided the authority for the DEA to register entities engaged in the manufacture, distribution, or dispensation of controlled substances. The CSA was designed to combat diversion by providing for a closed system of drug distribution in which all legitimate handlers of controlled substances must maintain a DEA registration, and as a condition of maintaining such registration must take reasonable steps to ensure their registration is not being used as a source of diversion. The DEA regulations specifically require all distributors to report suspicious orders of controlled substances in addition to the statutory responsibility to exercise due diligence to avoid filling suspicious orders.

This hearing has two goals. First, the subcommittee seeks to determine how the DEA could have done better to detect and investigate suspicious orders of opioids, such as the massive amounts shipped to West Virginia. The DEA has acknowledged to the committee that it could have done better in spotting and investigating suspicious opioid shipments. What were the deficiencies and has DEA addressed them? DEA has a comprehensive electronic database containing specific information at the pharmacy level. Could DEA use that database more effectively to investigate diversion and to facilitate compliance for the regulated industry?

The second goal is to find out whether the current DEA law enforcement approach is adequately protecting public safety. DEA statistics reveal a sharp decline since 2012 in certain DEA enforcement actions, immediate suspension orders, or ISOs, and orders to show cause. The number of ISOs issued by the DEA plummeted from 65 in 2011 to just six last year. Former DEA officials alleged in the Washington Post and on CBS' "60 Minutes" that the DEA's Office of Chief Counsel imposed evidentiary obstacles and delays for ISO and for orders to show cause submissions from the DEA field. The conflict between the DEA lawyers and the DEA investigators allegedly resulted in experienced DEA personnel leaving the agency and a loss of morale.

The goal of laws regulating controlled substances is to strike the right balance between the public interest in legitimate patients obtaining medications in a timely manner against another weighty public interest in preventing the illegal diversion of prescription drugs, particularly given the rampant and deadly opioid epidemic throughout the Nation. Our investigation is intended to assist the committee's continuing legislative effort to strike the right balance.

It is unfortunate that it's been a battle to get information out of the DEA. We have made recent progress with the DEA, but at this time our investigation still does not have the full picture. DEA has made some commitments that should hopefully help the committee gain the information it needs, and we expect the DEA to honor those commitments.

And I welcome today's witness, DEA Acting Administrator Robert Patterson. We have serious concerns about policy that we need to discuss today. But we are steadfast in our support and certainly want to salute the dedicated workforce at the DEA. We need an effective DEA in this crisis.

I want to thank the minority for their participation and hard work in this investigation, and I now yield to my friend, the ranking member, Ms. DeGette.

[The prepared statement of Mr. Harper follows:]

PREPARED STATEMENT OF HON. GREGG HARPER

Today the Subcommittee on Oversight and Investigations convenes a hearing on the Drug Enforcement Administration's (DEA) role in combating the opioid epidemic. The opioid crisis is a top priority of the nation and of this Committee. Opioid-related overdoses killed more than 42,000 people in 2016—115 deaths each day. An estimated 2.1 million people have an opioid use disorder.

Since our earliest hearings in 2012, this Subcommittee has been investigating various aspects of the opioid epidemic. In May 2017, the Committee opened a bipartisan investigation into allegations of "opioid-dumping," a term to describe inordinate volumes of opioids shipped by wholesale drug distributors to pharmacies located in rural communities, such as those in West Virginia. From press reports and this investigation, we have learned of opioid shipments in West Virginia that shock the conscience:

- Over 10 years, 20.8 million opioids were shipped to pharmacies in the town of Williamson, home to approximately 3,000 people.
- Another 9 million opioids were distributed in just 2 years to a single pharmacy in Kermit, West Virginia, population 406.
- Between 2007 and 2012, drug distributors shipped more than 780 million hydrocodone and oxycodone pills in West Virginia.

These troubling examples raise serious questions about compliance with the Controlled Substances Act, administered by the DEA.

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This hearing has two goals. First, the Subcommittee seeks to determine how the DEA could have done better to detect and investigate suspicious orders of opioids, such as massive amounts of opioids shipped to West Virginia. The DEA has acknowledged to the Committee that it could have done better in spotting and investigating suspicious opioid shipments. What were the deficiencies, and has DEA addressed them? DEA has a comprehensive electronic database containing specific in-

formation at the pharmacy level. Could DEA use that database more effectively to investigate diversion and to facilitate compliance for the regulated industry?

The second goal is to find out whether the current DEA law enforcement approach is adequately protecting public safety. DEA statistics reveal a sharp decline since 2012 in certain DEA enforcement actions, Immediate Suspension Orders (ISOs) and Orders to Show Cause (OTSCs). The number of ISOs issued by the DEA plummeted, from 65 in 2011 to just six last year. Former DEA officials alleged in the Washington Post and on CBS "60 Minutes," that the DEA's Office of Chief Counsel imposed evidentiary obstacles and delays for ISO and OTSC submissions from the DEA field. The conflict between the DEA lawyers and the DEA investigators allegedly resulted in experienced DEA personnel leaving the agency and a loss of morale.

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I welcome today's witness, DEA Acting Administrator Robert Patterson. We have serious concerns about policy to discuss, but we are steadfast in our support and salute the dedicated workforce at the DEA. We need an effective DEA in this crisis.

I also want to thank the Minority for their partnership and hard work in this investigation. I now yield to my friend, the Ranking Member, Ms. DeGette.

Ms. DEGETTE. Thank you so much, Mr. Chairman.

And I am happy to kick off the whole series of hearings with the Energy and Commerce Committee this week with this Oversight and Investigations hearing.

Opioid overdose is now the number-one cause of unintentional death in the United States. Every day we hear reports of Americans dying and leaving loved ones, often children, to pick up the pieces, and these reports are heartbreaking.

The crisis has also had an economic toll. Estimates are that it's cost this country a trillion dollars since 2001, and here's the point at my opening statement where I show that Congress can still be bipartisan because today I want to talk, as the chairman did, about our committee investigation, examining exactly how the opioid epidemic developed.

Our investigation, as the chairman said, focused on West Virginia, which has the highest opioid death toll in the Nation. The numbers that we are seeing coming out are simply shocking. A major 2016 news investigation, for example, reported that distributors shipped 780 million opioids to this state between 2007 and 2012. Again, in 5 years, they shipped 780 million opioids to this small State of West Virginia. Now, we focus on West Virginia but I am hoping that the lessons we learned will apply nationwide, including in my home State of Colorado.

Administrator Patterson, I join the Chairman in welcoming you here. We have a lot of questions and we'd like to know what you think failed us in West Virginia and, more importantly, what we can do to avoid this again. We know something had to have gone wrong. For example, in DEA's own court filings, in 2008 the distributor shipped one pharmacy in West Virginia 22,500 hydrocodone pills per month. But our investigation also found that a number of pharmacies were sent even many times more that amount. For example, the Chairman talked about Kermit, West

Virginia. We looked at one pharmacy in Kermit, which has a few hundred people. Drug distributors supplied this pharmacy with more than 4.3 million doses of opioids, more than 350,000 per month in a single year, and then the next year 4 million doses of opioids.

What on earth were people thinking? Now, when the DEA finally shut down this pharmacy and took its owner to court, the owner admitted at its height the pharmacy filled one prescription per minute. Who could think that this was a legitimate use?

News reports from the time describe pharmacy workers throwing bags of opioids "over a divider and onto a counter to keep pace." One law enforcement agent noticed a cash drawer "so full the clerk could not get it to close properly." And this was not the only pharmacy to receive such massive quantities of opioids. In another example, between 2006 and 2016, distributors shipped over 20 million doses of opioids to two pharmacies in one town of 3,000 people.

I want to know if the DEA thinks that this amount of pills sent to these pharmacies was excessive. In addition, the Controlled Substances Act and applicable regulations required the distributor to tell DEA how many pills that distributor sold and to what pharmacies. DEA compiles this information into a database called the Automation of Reports and Consolidated Orders System. It's called ARCOS.

I want to know how the DEA made use of ARCOS data from 2006 on and whether it relied on that data to monitor the number of pills that distributors sent to West Virginia. Did the DEA perform analytic assessments of the pills the pharmacies received? Did it look at how many pills distributors sent to a town or region as a whole? And if so, I want to know why the DEA didn't act to stop these shipments.

I want to know whether the distributors themselves exercised appropriate due diligence before sending millions of pills to pharmacies. For example, in a letter sent to all drug distributors in 2006 and 2007, the DEA gave them a list of circumstances that might be indicative of diversion, all of which plainly require distributors to know their customers before shipping them any opioids at all. I want to know if the drug distributors met this standard when they shipped those pills to tiny West Virginia and, similarly, did the distributors comply with their obligations. And I want to know also what the DEA is doing right now to stop painkillers from flooding our communities today.

We have had a lot of hearings on this, Mr. Chairman, but this is the first one to look in a hard way at this crisis developed. We spend countless hours of law enforcement time trying to stop illegal drugs from coming into this country and here we are, sending millions of doses of opioids to tiny little towns in West Virginia, all of this supposedly legally.

I think I can speak for the whole committee to say this needs to stop, it needs to stop now, and we need to figure out how we are going to protect our constituents and our citizens.

I yield back.

Mr. HARPER. The gentlewoman yields back.

The chair will now recognize the chairman of the full committee, Chairman Walden, for purposes of an opening statement.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Mr. Chairman, and thank you for your leadership on this very important issue to the people we represent.

For nearly a year, this committee has been investigating how inordinate numbers of pills were shipped to pharmacies in rural West Virginia. The numbers that we have seen thus far, as you've heard, Mr. Patterson, are nothing short of staggering—more than 20 million prescription opioids shipped to a West Virginia town with a population of fewer than 3,000 people. Another West Virginia pharmacy, in a town with a population of fewer than 2,000 people, received an average of 5,600 prescription opioids a day during a single year.

As part of our investigation, we have also looked at the Sav-Rite pharmacies in Kermit, West Virginia, a town with a population of about 400.

During last October's full committee hearing, I asked your colleague at the DEA a very straightforward question: which companies provided the Sav-Rite No. 1 pharmacy with so many opioids that it ranked 22nd in the entire United States of America for the number of hydrocodone pills received in 2006?

After an extended and unnecessary delay, we finally received the DEA data and now know the answer to that question. But this isn't the end of the matter, however.

We have learned that in 2008, a second Sav-Rite location opened just 2 miles away from the original pharmacy. However, the second Sav-Rite was forced to close and surrender its DEA registration after it was raided by federal agents in March 2009. Now, in most instances, this would be a success story. But in this case, the original Sav-Rite pharmacy—the one that had received 9 million pills in just 2 years—stayed open for another two years, and in those 2 years, Sav-Rite No. 1 dispensed about 1.5 million pills into the community. So the question is, how did that happen? How is it possible?

The raid on Sav-Rite 2 was based on observations made during undercover investigations conducted at both Sav-Rite locations as well as a pill mill medical practice. As part of the undercover operation, Federal investigators saw pharmacy customers sharing drugs with one another in the parking lot, and as you've heard, a cash drawer so full the clerk could not close it, and learned that the owner of the Sav-Rite pharmacies apparently developed a "get-rich-quick scheme" with a pill mill medical practice. This scheme may have filled their cash drawers, but it was devastating to the community.

It doesn't make any sense as to why the DEA did not shut down both pharmacies at the same time. They were owned by the same person. They were part of the same criminal scheme. DEA has acknowledged that breakdowns occurred and lessons were learned, in this case and in others.We need to make sure DEA has fixed its own problems so that an effective DEA is part of the many solutions needed to combat the opioid crisis.

As you know, people are dying. Lives are being ruined. We must be united in our efforts to end this horrible epidemic. That is why myself and this entire committee have been so frustrated that it

has taken so long to obtain DEA's full cooperation in this investigation.

And while progress is being made in DEA's efforts—and I appreciated our meeting on Friday—we still have plenty of unanswered questions coming in to today's hearing. So I am hopeful we can learn the answers to those questions today and I am also pleased with the commitments DEA has made to fulfill our remaining requests in this investigation. And I expect those commitments to be honored, period. If they are not, we'll be back talking again soon.

Our most pressing questions are intended to get DEA on a better path. Every one of us on this dais and in this room supports a strong and effective DEA. We know you have an enormous and important job to do with dedicated agents and we are grateful to all those in law enforcement personnel at your agency. Quite simply, we want you to have the tools and the resources you need to help us combat this epidemic, among the other many duties you have at DEA.

So I want to thank you for again being with us today, Acting Administrator Patterson, and we look forward to your candor.

And I would like to yield the balance of my time to the gentleman from Virginia, Mr. Griffith. Before I do that, I would remind the committee we will have two full days of hearings starting tomorrow and Thursday reviewing 25 pieces of legislation on the opioids epidemic, and we hope and expect everyone on the committee to attend those hearings.

With that, I yield to the gentleman from Virginia.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Mr. Chairman, for holding this hearing on DEA's role incombating the opioid epidemic, a top priority of this committee.

For nearly a year, this committee has been investigating how inordinate numbers of pills were shipped to pharmacies in rural West Virginia. The numbers that we have seen thus far are nothing short of staggering—more than 20 million prescription opioids shipped to a West Virginia town with a population of fewer than 3,000 people. Another West Virginia pharmacy, in a town with a population of fewer than 2,000 people, received an average of more than 5,600 prescription opioids a day during a single year.

As part of our investigation, we have also looked at the Sav-Rite pharmacies in Kermit, West Virginia, a town with a population of approximately 400 people.

During last October's full committee hearing, I asked your colleague at the DEA a very straightforward question: Which companies provided the Sav-Rite #1 pharmacy with so many opioids that it ranked 22nd in the entire country for the number of hydrocodone pills received in 2006?

After extended delay, we received the DEA data and now know the answer to that question. This is not the end of the matter, however.

We have learned that in 2008, a second Sav-Rite location opened, just two miles away from the original pharmacy. However, the second Sav Rite was forced to close and surrender its DEA registration after it was raided by federal agents in March 2009. In most instances, this would be a success story. But in this case, the original Sav-Rite pharmacy-the one that received 9 million pills in just 2 years-stayed open for more than two years. In those two years, Sav-Rite #1 dispensed about 1.5 million pills into the community. How is this possible?

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It doesn't make any sense as to why the DEA did not shut down both pharmacies at the same time—they were owned by the same person and were part of the same criminal scheme. DEA has acknowledged that breakdowns occurred, and lessons were learned-in this case and others. We need to make sure DEA has fixed its own problems so that an effective DEA is part of the many solutions needed to combat the opioid crisis.

People are dying. Lives are being ruined. We must be united in our efforts to end this horrible epidemic. That is why myself and this entire committee have been so frustrated that it has taken this long to obtain DEA's full cooperation in this investigation.

And while progress is being made in DEA's efforts, we still have plenty of unanswered questions coming into today's hearing. I am hopeful that we can learn the answers to those questions today. I am also pleased with the commitments DEA has made to fulfill our remaining requests in this investigation. I expect those commitments to be honored. If they are not, we'll be back here again soon.

Our most pressing questions are intended to get DEA on a better path. Every one of us on this dais, and in this room, supports a strong and effective DEA. We know you have an enormous job to do and we are grateful to all of the dedicated law enforcement personnel at the agency. Quite simply, we want you to have the tools and the resources you need to combat this epidemic, among the other many duties of the DEA.

So thank you again for being here with us today, Acting Administrator Patterson. We look forward to your candor, and I would like to yield the balance of my time to the gentleman from Virginia, Mr. Griffith.

Mr. GRIFFITH. Thank you, Mr. Chairman.

We have an implied constitutional responsibility to conduct oversight and ensure that the Controlled Substances Act strikes the correct balance between the public interest in legitimate patients obtaining medications against the weighty public interest in preventing the illegal diversion of prescription drugs.

A key issue is whether the DEA is adequately protecting public safety. DEA statistics reveal a sharp decline and immediate suspension orders—ISOs—since 2012. ISOs are a DEA administrative tool not to punish but to protect the public from rogue doctors or pharmacists who would continue to provide opioids to drug abusers unless their registration was immediately suspended.

Former DEA officials alleged in the Washington Post and on CBS "60 Minutes" that the DEA's office of chief counsel, starting around 2013, changed its evidentiary requirements for ISO submissions from the DEA field. DEA documents provided to the Committee seem to substantiate this allegation.

Now, ISOs remind me of DUI cases in Virginia. When a police officer gets a driver off the road who's been drinking, their license to drive is administratively suspended in order to protect the public.

Trial on the merits is delayed, but not public safety. It's a similar principle here. Immediately suspend the rogue operator and protect the public.

I yield back.

Mr. HARPER. The gentleman yields back.

The chair will now recognize the ranking member of the full committee, Mr. Pallone, for five minutes.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

The opioid epidemic continues to devastate communities and families in every part of America, and every day 115 Americans lose their lives in an opioid overdose.

We must do more to help those struggling with addiction, and I am committed to working with all of my colleagues to advance meaningful legislation and resources to help combat this crisis. Families all across this nation are looking to us for help, and it is my hope that DEA will work cooperatively with us on this effort.

In addition to advancing efforts to respond to this crisis, Congress also has a responsibility to figure out what went wrong and how it went wrong and how to make sure something like this never happens again. And that is why this committee has been engaged in a bipartisan investigation into the role both DEA and drug distributors have in addressing the ongoing opioid crisis and what systems failed to protect the communities that have been so overwhelmed by this epidemic.

So I hope that the lessons we learn will help us address this urgent problem throughout the country, from New Jersey to West Virginia and beyond.

Clearly, something went wrong. The safeguards designed to prevent opioids from being diverted into the wrong hands simply did not work and our committee's investigation has found that drug distributors shipped millions of pills to multiple small-town pharmacies in West Virginia every year. For example, a pharmacy in a town of 2,000 people received 16.5 million doses of opioids over a 10-year period and there were other pharmacies in that area as well.

There is simply no way that there was an actual medical need for this incredible volume of opioids in this rural sparsely-populated area and I would hope that DEA can tell us what broke down in the safeguards that should have protected communities from these abusive practices. These include failures by both the distributors and the DEA.

For example, I have questions about the data that DEA collects and why they did not use it more aggressively to prevent the oversupply of opioids in certain—in certain cases. We know that distributors are required to tell DEA how many pills they ship each month and where those pills go. It is not clear, however, that DEA has used this data in the past, and if DEA is using this data now to help it curtail excessive pill distribution.

Distributors are also required to alert DEA when a pharmacy places an order for what appears to be a suspiciously large quantity of pills. It appears that distributors have not always alerted DEA of those suspicious orders and may not even have had adequate systems in place to identify inappropriately large orders. But at the same time, it is also not clear that DEA has always done enough with the suspicious orders they receive from distributors to alert the agency to possible anomalous shipments, and I hope we can get answers to both of these questions.

And when multiple distributors ship to a single pharmacy, possibly causing an oversupply, it is not clear that DEA has had an adequate system to identify and flag to the distributors that an oversupply problem may be unfolding. Unlike DEA, who has access to comprehensive distribution data, distributors can only see what

they supply to an individual pharmacy. Yet, if DEA is not flagging when multiple distributors are at risk of collectively oversupplying a pharmacy, then the result is another example of a system failure that can lead to diversion.

So it seems likely that failing to report suspicious orders by distributors has hurt DEA's ability to monitor the distribution of controlled substances and I hope that we will hear that this is no longer an issue today, and if it is, I'd like to know what tools DEA needs to help it to enforce this requirement. At the same time, I do hope that DEA is making full use of suspicious orders when they are reported to their field offices.

Finally, Mr. Chairman, while our investigation has focused on what went wrong in West Virginia, I also want to know how DEA is monitoring distributors across the country now. Addictive drugs are still abundant in our communities and now new opioids are also being introduced to the market.

So I hope that DEA is actively or proactively analyzing shipments of these pills and, where appropriate, stepping in and stopping the over-distribution of these drugs.

So I just want to thank Administrator Patterson for appearing before us. This issue is extraordinarily important and no entity can address it alone. DEA and Congress must be allies in combating the opioid crisis and only by understanding what went wrong can we fix this system for the future.

So just, again, I know you're in the hot seat today but this is something that we need to work on together.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Mr. Chairman. The opioid epidemic continues to devastate communities and families in every part of America. Every day, 115 Americans lose their lives to an opioid overdose.

We must do more to help those struggling with addiction, and I am committed to working with my colleagues to advance meaningful legislation and resources to help combat this crisis. Families all across this nation are looking to us for help, and it is my hope that DEA will work cooperatively with us on this effort.

In addition to advancing efforts to respond to this crisis, Congress also has a responsibility to figure out what went wrong, how it went wrong, and how to make sure something like this never happens again. That is why this Committee has been engaged in a bipartisan investigation into the role both DEA and drug distributors have in addressing the ongoing opioid crisis, and what systems failed to protect the communities that have been so overwhelmed by this epidemic.

I hope that the lessons we learn will help us address this urgent problem throughout the country, from New Jersey to West Virginia and beyond.

Clearly, something went wrong. The safeguards designed to prevent opioids from being diverted into the wrong hands simply did not work.

Our Committee's investigation has found that drug distributors shipped millions of pills to multiple small-town pharmacies in West Virginia every year. For example, a pharmacy in a town of 2-thousand people received 16.5 million doses of opioids over a 10-year period. And there were other pharmacies in that area.

There is simply no way that there was an actual medical need for this incredible volume of opioids in this rural, sparsely populated area. I would hope that DEA can tell us what broke down in the safeguards that should have protected communities from these abusive practices. These include failures by both the distributors and DEA.

For example, I have questions about the data that DEA collects, and why they did not use it more aggressively prevent the oversupply of opioids in certain cases. We know that distributors are required to tell DEA how many pills they ship each

month, and where those pills go. It is not clear, however, how DEA has used this data in the past, and if DEA is using this data now to help it curtail excessive pill distribution.

Distributors are also required to alert DEA when a pharmacy places an order for what appears to be a suspiciously large quantity of pills. It appears that distributors have not always alerted DEA of these suspicious orders, and may not even have had adequate systems in place to identify inappropriately large orders. But at the same time, it is also not clear that DEA has always done enough with the suspicious orders they receive from distributors to alert the agency to possibly anomalous shipments. I hope we can get answers to both of these questions.

And when multiple distributors ship to a single pharmacy, possibly causing an oversupply, it is not clear that DEA has had an adequate system to identify and flag to the distributors that an oversupply problem may be unfolding. Unlike DEA who has access to comprehensive distribution data, distributors can only see what they supply to an individual pharmacy. Yet, if DEA is not flagging when multiple distributors are at risk of collectively oversupplying a pharmacy, then the result is another example of a system failure that can lead to diversion.

It seems likely that failing to report suspicious orders by distributors has hurt DEA's ability to monitor the distribution of controlled substances. I hope that we will hear that this is no longer an issue today, and if it is I'd like to know what tools DEA needs to help it enforce this requirement. But at the same time, I do hope that DEA is making full use of suspicious orders when they are reported to their field offices.

Finally, while our investigation has focused on what went wrong in West Virginia, I also want to know how DEA is monitoring distributors across the country now. Addictive drugs are still abundant in our communities, and now new opioids are also being introduced to the market.

I hope that DEA is acting proactively to analyze shipments of these pills and, where appropriate, stepping in and stopping the over- distribution of these drugs.

I want to thank Administrator Patterson for appearing before us today. This issue is extraordinarily important, and no entity can address it alone. DEA and Congress must be allies in combatting the opioid crisis, and only by understanding what went wrong can we fix this system for the future.

Thank you.

Mr. HARPER. The gentleman yields back.

I ask unanimous consent that the members' written opening statements be made part of the record. Without objection, it will be entered into the record.

Additionally, I ask unanimous consent that Energy and Commerce members not on the Subcommittee on Oversight and Investigations be permitted to participate in today's hearing.

Without objection, so ordered.

I would now like to introduce our witness for today's hearing. Today, we have Mr. Robert Patterson, the Acting Administrator for the Drug Enforcement Administration. We appreciate you being here with us today, Mr. Patterson, and you are aware that the committee is holding an investigative hearing and when so doing it has been our practice of taking testimony under oath.

Do you have any objection to testifying under oath?

Mr. PATTERSON. I do not.

Mr. HARPER. Witness response is no.

The chair then advises you that under the rules of the House and the rules of the committee, you're entitled to be accompanied by counsel. Do you desire to be accompanied by counsel during your testimony today?

Mr. PATTERSON. I do not.

Mr. HARPER. Responds that he does not. In that case, I would ask that you rise and please raise your right hand and I will swear you in.

[Witness sworn.]

You are now under oath and subject to the penalties set forth in Title 18 Section 1001 of the United States Code. You may now give a 5-minute summary of your written statement.

You can hit the button on the mic and you have 5 minutes to summarize your testimony.

Thank you again for being here, Mr. Patterson.

TESTIMONY OF ROBERT W. PATTERSON, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION

Mr. PATTERSON. Thank you, and good morning.

Committee Chairman Walden, Subcommittee Chairman Harper, Ranking Members Pallone and DeGette, and distinguished members of the subcommittee, thank you for the opportunity to be here today to discuss the opioid epidemic and DEA's role in combating this crisis.

Over the past 15 years, our nation has been increasingly devastated by opioid abuse, an epidemic fueled for a significant period of time by the overprescribing of potent prescription opioids for acute and chronic pain. This indiscriminate practice created a generation of opioid abusers, presently estimated at more than 3 million Americans.

Over the past few years, we have begun to see a dramatic and disturbing shift. As a result of the increased awareness of the opioid epidemic, prescriptions for opioids have started to decline—obviously, somewhat a success. But organizations, in particular the well-positioned—in particular, the well-positioned Mexican drug cartels have filled this void by producing and distributing cheap powdered heroin, often mixed with illicit fentanyl and other fentanyl-related substances and selling it to users in both traditional powder form and, in some cases, pressed into counterfeit pills made to resemble illicit pharmaceuticals.

There are two central elements DEA is addressing as part of this administration's collective efforts to turn this tide, with a third piece that must also be addressed. First and foremost is enforcement. Based on our investigations, actions are undertaken every day using our criminal, civil, or administrative tools to attack the traffic in illicit drugs and the diversion of the licit supply.

Second is education. I strongly believe there is a real value and a natural fit for the DEA in this space and look whenever possible to partner with leaders in prevention and education.

The third element is treatment. The DEA is committed to doing what we can to improve access to drug treatment and recovery services, working alongside our partners at the Department of Health and Human Services, to utilize evidence-based strategies that minimize the risk of diversion during this public health emergency.

Ultimately, the only way to fundamentally change this epidemic is to decrease demand for these substances and address the global licit and illicit supply concerns through the efforts of DEA and all of its partners. The action of DEA's Diversion Control Division are critical with respect to addressing the licit supply. Diversion of prescription opioids by a few has a disproportionate impact on the availability of prescription opioids. The fact remains that a majority of new heroin users stated that they started their cycle of addic-

tion on prescription opioids. As a result, we are constantly evaluating ways to improve our effectiveness to ensure that our more than 1.7 million registrants comply with the law.

Our use of administrative tools and legislation that changed our authorities in this area has been the subject of numerous media reports. Let me address that issue up front. DEA has continued to revoke approximately 1,000 registrations each year through administrative tools such as orders to show cause, immediate suspension orders, and surrenders for cause. We have and will continue to use all of these tools to protect the public from the very small percentage of registrants who exploit human frailty for profit. Where a licensed revocation is not necessary we have aggressively pursued civil actions and MOUs designed to ensure compliance.

Over the last decade, DEA has levied fines totaling nearly $390 million against opioid distributors nationwide and entered into MOUs with each. DEA has also reprioritized a portion of its criminal investigators and embedded them in with diversion investigators and enforcement groups, referred to as tactical diversion squads. We currently have 77 of these groups nationwide who are solely dedicated to investigating, disrupting, and dismantling individuals and organizations involved in diversion schemes.

DEA's Diversion Control Division has simultaneously worked to improve communication and cooperation with the registrant community. As an example of this outreach, DEA offers year-round training free of charge to pharmacists, distributors, importers, and manufacturers. DEA just completed training more than 13,000 pharmacists and pharmacy technicians on the important role they play in ensuring they only fill valid prescriptions.

In May, DEA will initiate a similar nationwide effort to provide training on the vital role that prescribers play in curbing this epidemic. This effort will start with specific focus on States where we have seen little decrease or, in some increases, an increase in opioid prescribing rates.

Administrative action, civil fines, and criminal cases are all important steps. Where we have fallen short in the past it is by not proactively leveraging the data that has been available to us.

Although I am happy to discuss what happened in the past, I focus my time on moving our agency forward and appreciate the opportunity to update you on where we are today and where we intend to go. For example, in January we utilized ARCOS data overlaid with data from HHS and, when available, state PMP programs. The result was approximately 400 targeted leads that DEA was able to send to its 22 field divisions nationwide for further investigation.

We are working all the Federal agencies in the space while we continue to work well with our colleagues at ONDCP, CCD, NIDA. The mutual issues that we face today have created stronger and critical partnerships with FDA and HHS.

I'll finish up by saying I'd like to recognize the Health Subcommittee's efforts to hold a legislative hearing starting tomorrow on more than 25 pieces of legislation. That effort not only underscores the unprecedented nature and complexity of the opioid crisis but also demonstrates that we must all take action to address this threat together.

Thank you for this opportunity and I look forward to your questions.

[The prepared testimony of Mr. Patterson follows:]

Department of Justice

STATEMENT OF

ROBERT W. PATTERSON
ACTING ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

THE DRUG ENFORCEMENT ADMINISTRATION'S ROLE IN COMBATING THE OPIOID EPIDEMIC

PRESENTED

MARCH 20, 2018

Statement of Robert W. Patterson
Acting Administrator
Drug Enforcement Administration
Before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
March 20, 2018

Chairman Walden, Ranking Member Pallone, and Members of the Committee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss the threat posed by the opioid epidemic. The misuse of controlled prescription drugs (CPDs) is inextricably linked with the threat the United States faces from the trafficking of heroin, illicit fentanyl, and fentanyl analogues.

Drug overdoses, suffered by family, friends, neighbors, and colleagues, are now the leading cause of injury-related death in the United States, eclipsing deaths from motor vehicle crashes or firearms.[1] According to the Centers for Disease Control and Prevention (CDC), there were nearly 64,000 overdose deaths in 2016, or approximately 174 per day. Over 42,249 (66 percent) of these deaths involved opioids. The sharp increase in drug overdose deaths between 2015 to 2016 was fueled by a surge in fentanyl and fentanyl analogue (synthetic opioids) involved overdoses.[2]

The misuse of CPDs and the growing use of heroin, fentanyl, and fentanyl analogues are being reported in the United States in unprecedented numbers. According to the Substance Abuse and Mental Health Services Administration (SAMHSA) 2016 National Survey on Drug Use and Health (NSDUH), 6.2 million people over the age of 12 misused psychotherapeutic drugs (e.g., pain relievers, tranquilizers, stimulants, and sedatives) during the past month.[3] This represents 22 percent of the 28.6 million current illicit drug users and is second only to marijuana (24 million users) in terms of usage.[4] There are more current misusers of psychotherapeutic drugs than current users of cocaine, heroin, and hallucinogens combined.[5]

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[1] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly Report, 2016;64:1378-1382.
[2] CDC WONDER data, retrieved from the National Institute of Health website; http://www.drugabuse.gov as reported on NIDA's website.
[3] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.
[4] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.
[5] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

The increase in the number of people using heroin in recent years – from 373,000 past year users in 2007 to 948,000 in 2016 – is troubling.[6] More alarming is the proliferation of illicit fentanyl and its analogues. DEA investigations reveal that fentanyl and its analogues are increasingly being added to heroin and frequently pressed into counterfeit tablets resembling CPDs. Because of its high potency, the more illicit fentanyl and related analogues are introduced to the 11.5 million people that misused a pain reliever in the previous year, the more likely that drug overdoses will continue to climb.[7]

CONTROLLED PRESCRIPTION DRUGS

In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.[8] This makes prescription opioid misuse more common than use of any category of illicit drug in the United States except for marijuana. Whereas the vast majority of individuals misusing opioid CPDs do not go on to use heroin, this information provides valuable insight into the role that CPDs play in the opioid epidemic and underscores the need for a robust regulatory program that seeks to stop diversion of CPDs.

Black-market sales for opioid CPDs are typically five to ten times their retail value. DEA intelligence reveals the "street" cost of prescription opioids steadily increases with the relative strength of the drug. For example, hydrocodone combination products (a Schedule II prescription drug and also the most prescribed CPD in the country)[9] can generally be purchased for $5 to $7 per tablet on the street. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for $7 to $10 per tablet on the street. Even stronger prescription drugs are sold for as much as $1 per milligram (mg). For example, 30 mg oxycodone (immediate release) and 30 mg oxymorphone (extended release) cost $30 to $40 per tablet on the street. The costs that ensue with greater tolerance make it difficult to purchase these drugs in order to support a developing substance use disorder, particularly when many first obtain these drugs for free from the family medicine cabinet or from friends.[10]

HEROIN

The vast majority of heroin consumed in the United States is produced by powerful Mexico-based transnational criminal organizations (TCOs), such as the Sinaloa Cartel and New

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[6] Center for Behavioral Health Statistics and Quality. (2017). 2016 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD

[7] Center for Behavioral Health Statistics and Quality. (2017). 2016 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD

[8] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[9] On October 6, 2014, DEA published a final rule in the *Federal Register* to move hydrocodone combination products from Schedule III to Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services.

[10] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

Generation Jalisco Cartel, and transported to the United States across the Southwest Border. These TCOs are extremely dangerous, violent, and will continue to leverage established transportation and distribution networks within the United States.

Not surprisingly, some people who misuse prescription opioids turn to heroin. Heroin traffickers produce high purity white powder heroin that costs approximately $10 per bag, and usually contains approximately 0.30 grams per bag. This makes heroin significantly less expensive than CPDs. Heroin produces a "high" similar to CPDs and can keep some individuals who are dependent on opioids from experiencing painful withdrawal symptoms. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by those who began misusing prescription opioids.[11]

According to reporting by treatment providers, many individuals with serious opioid use disorders will use whichever drug is cheaper and/or available to them at the time.[12] Heroin purity and dosage amounts vary, and heroin is often adulterated with other substances (e.g., fentanyl and fentanyl analogues). This means that heroin users are at higher risk of unintentional overdose because they cannot predict the dosage of opioid in the product they purchase on the street as heroin.[13] Additionally, varying concentrations found in diverted or counterfeit prescription opioids purchased on the street have led to increased unintentional drug overdose deaths.

A report published by SAMHSA analyzing data through 2011 found that four out of five recent new heroin users had previously misused prescription pain relievers.[14] The reasons an individual may shift from one opioid to another vary, but today's heroin is high in purity, less expensive and often easier to obtain than illegal CPDs.

Overdose deaths involving heroin are increasing at an alarming rate, having increased more than five-fold since 2010.[15] Today's heroin at the retail level costs less and is more potent than the heroin that DEA encountered two decades ago. It is also not uncommon for heroin users to seek out heroin that dealers claim is "hot," meaning that it is likely cut with fentanyl or its analogues. Users seeking "hot" heroin is an indicator that as higher opioid tolerance levels develop among users, they will continue to seek out more potent forms of opioids.

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[11] U.S. Department of Justice, Drug Enforcement Administration, 2016 National Heroin Threat Assessment Summary, DEA Intelligence Report, April, 2016, *available at*: https://www.dea.gov/divisions/hq/2016/hq062716_attach.pdf.

[12] U.S. Department of Justice, Drug Enforcement Administration, 2014 National Drug Threat Assessment Summary, November, 2014.

[13] Stephen E. Lankenau, Michelle Teti, Karol Silva, Jennifer Jackson Bloom, Alex Harocopos, and Meghan Treese, Initiation into Prescription Opioid Misuse Among Young Injection Drug Users, Int J Drug Policy, Author manuscript; available in PMC 2013 Jan 1, Published in final edited form as: Int J Drug Policy, 2012 Jan; 23(1): 37-44. Published online 2011 Jun 20. doi: 1016/j.drugpo.2011.05.014. and; Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D., "Every 'Never' I Ever Said Came True": Transitions From Opioid Pills to Heroin Injecting, Int J Drug Policy, 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19.

[14] Substance Abuse and Mental Health Services Administration, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Department of Health and Human Services, August 2013, *available at*: https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm

[15] CDC WONDER data accessed on 10/15/17, as reported at NIDA's website: 3,036 heroin overdoses in 2010; 15,446 overdoses in 2016. https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

FENTANYL AND FENTANYL ANALOGUES

Fentanyl is a Schedule II controlled substance produced in the United States and widely used in medicine. It is an extremely potent analgesic used for anesthesia and pain control in people with serious pain problems and in such cases, it is indicated only for use in individuals who have high opioid tolerance.

Illicit fentanyl, fentanyl analogues, and their immediate precursors are often produced in China. From China, these substances are shipped through private couriers or mail carriers directly to the United States or alternatively shipped directly to TCOs in Mexico, Canada, or the Caribbean. Once in the Western Hemisphere, fentanyl or its analogues are prepared to be mixed into the U.S. heroin supply domestically, or pressed into a pill form, and then moved to the illicit U.S. market where demand for prescription opioids and heroin remain at epidemic proportions. In some cases, traffickers have industrial pill presses shipped into the United States directly from China and operate fentanyl pill press mills domestically. Mexican TCOs have seized upon this business opportunity because of the profit potential of synthetic opioids, and have invested in growing their share of this market. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for $3,000 - $5,000 can generate upwards of $1.5 million in revenue on the illicit market.

According to the DEA National Forensic Laboratory Information System (NFLIS), from January 2013 through December 2016, over 58,000 fentanyl exhibits were identified by federal, state, and local forensic laboratories.[16] During 2016, there were 36,061 fentanyl reports compared to 1,042 reports in 2013,[17] an exponential increase over the past four years. The consequences of fentanyl misuse are often fatal and occur amongst a diverse user base. According to a December 2017 CDC Data Brief, from 2015 to 2016, the death rate from synthetic opioids other than methadone, a category that includes fentanyl, doubled from 9,580 (age adjusted rate 3.1) to 19,413 (the age-adjusted rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) doubled between 2015 and 2016, from 3.1 to 66.2 per 100,000).[18]

FLORIDA'S PILL MILLS – START OF THE PROLIFERATION OF CPDs

Between 2005 and 2009, Florida was the epicenter of many illegal operations whereby hundreds of millions of dosage units of controlled substances were diverted into United States illicit markets. During this time, the diversion of millions of dosage units of hydrocodone products was facilitated by rogue internet pharmacies and unscrupulous prescribers who provided prescriptions to drug seekers utilizing internet sites.[19] The *Ryan Haight Online*

[16] U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.
[17] U.S. Department of Justice, DEA, NFLIS, actual data queried on October 13, 2017.
[18] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew GladdenHedegaard, H., Margaret Warner, and Arialdi M. Miniño. Drug Overdose Deaths in the United States, 1999–2016Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly ReportNCHS Data Brief, 2016;64:1378-1382No. 294, Dec 2017. https://www.cdc.gov/nchs/data/databriefs/db294.pdf.
[19] The final rule rescheduling hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act was published in the Federal Register on August 22, 2014, and became effective on October 6, 2014. 79 FR 49661.

Pharmacy Consumer Protection Act (P.L. 110-425) took effect in April of 2009, combined with intensified law enforcement and regulatory actions, virtually eliminated the threat posed by domestic rogue internet pharmacies.

As the number of domestic internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics or "pill mills," particularly in Florida.[20] In 2009, there was a high concentration of pain clinics located in the tri-county area of South Florida (comprised of Broward, Miami-Dade, and Palm Beach Counties). According to data provided by the State of Florida, by 2010, Broward County alone was home to approximately 142 rogue pain clinics. Federal, state, and local law enforcement investigations identified thousands of drug seekers that routinely traveled to Florida-based rogue pain clinics to obtain pharmaceutical controlled and non-controlled substances, such as oxycodone, hydromorphone, methadone, tramadol, alprazolam, clonazepam, and carisoprodol. After obtaining controlled prescription drugs, these individuals would travel back to their home states and illegally distribute the drugs that ultimately flooded the illicit market in states along the entire East Coast and Midwest.

WEST VIRGINIA

During this same timeframe, some DEA-registered practitioners in West Virginia turned their practices into pill mill operations, indiscriminately writing prescriptions for opioids. One pill mill operation in Kermit, West Virginia, was highlighted in a 2016 article published by the *Charleston Gazette-Mail* in which roughly nine million opioid pills were sent over the course of two years to a town with a population of 392 people.[21] DEA, along with its Federal, State, local, and tribal partners, identified the individuals involved in violations of the Controlled Substances Act (CSA) and worked with the U.S. Attorney's Office for the Southern District of West Virginia to arrest several individuals, all of whom were sent to jail for their crimes. Stemming from the same operation, DEA and its State and local counterparts took action taken against the Sav-Rite Pharmacy in Kermit, including the arrest of the owner and forfeiture of more than $400,000.

Unfortunately, West Virginia continues to be the State with the highest rate of death due to drug overdoses with 52 overdose deaths per 100,000 population in 2016.[22] Consequently, DEA has devoted additional resources to West Virginia by increasing its presence in the State. In 2016, DEA established an Assistant Special Agent in Charge position in Charleston, West Virginia. A senior level manager now oversees the entire State from the State's capital, rather than Washington, DC. Additionally, in 2016 DEA added a second Tactical Diversion Squad (TDS) in Clarksburg and in 2017 DEA headquarters deployed one of its two "mobile" TDS groups to West Virginia. These groups pursue criminal investigations against those who traffic CPDs. In 2018, DEA is deploying six new heroin enforcement teams focused on

[20] It addition, the amount of heroin seized at the South West border increased over 300 percent from 2008 to 2013.

[21] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html, retrieved March 7, 2018.

[22] Hedegaard H, Warner M, Minino AM. Drug overdose deaths in the United States, 1999 – 2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017/CDC.

combatting the flow of heroin and illicit fentanyl. The enforcement teams will be based in communities facing significant challenges with opioids, including Charleston, West Virginia, and five additional locations.

DEA has also established a new Field Division in Louisville. This office covers Kentucky, Tennessee, and West Virginia and will enhance DEA enforcement efforts within the Appalachian mountain region and unify drug trafficking investigations under a single Special Agent in Charge. DEA anticipates that this change will produce more effective investigations on heroin, fentanyl, and prescription opioid trafficking, all of which have a significant impact on the region. The division will also better align DEA with the U.S. Attorney's Office districts in those areas, similar to current Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Federal Bureau of Investigation (FBI) offices, and also with the Appalachia High Intensity Drug Trafficking Areas Program. Funded by the White House Office of National Drug Control Policy (ONDCP).

DEA LESSONS LEARNED AND RESPONSE TO THE PROLIFERATION OF CPDs

Effective Registrant Outreach

Due to the complexity of DEA's regulatory program, the Diversion Control Division has worked aggressively to improve its communication and cooperation with its more than 1.7 million registrants, who represent medical professionals, pharmaceutical drug manufacturers, and those in the drug supply chain. DEA works with its registrant population by: (1) hosting Pharmacy Diversion Awareness Conferences (PDACs) throughout the country; (2) administering the Distributor Initiative Program with a goal of educating distributors on how to detect and guard against diversion activities; and (3) maintaining an open dialogue with various national associations such as the National Association of Boards of Pharmacy (NABP), American Medical Association (AMA), Federation of State Medical Boards A, and other groups to address diversion problems and educate the medical community on improving prescribing practices.[23] By the end of 2017, DEA had hosted 100 PDACs in 50 states (as well as the District of Columbia and Puerto Rico) training more than 13,100 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled. In May 2018, DEA will initiate a nationwide program to offer similar training to individual practitioners.

In addition to the training opportunities offered to registrants, DEA has also begun a program to proactively send targeted email messages to various segments of its registrant population on matters of mutual interest. For example, in February 2018, DEA sent correspondence to 1.3 million doctors nationwide alerting them of the CDC's recommendations for opioid prescribing for acute pain and alerted practitioners of a free training webinar available from CDC. DEA is working on similar correspondence alerting these same practitioners about resources available from SAMHSA on locating a substance abuse treatment provider in their state. We have also sent targeted messages to DEA's Schedule I researcher population on

[23] In FY2017 alone, Diversion has participated in 1,407 outreach efforts.

enhancements made to streamline the registration process for them, as well as to the manufacturer and distributor populations on new enhancements aimed at assisting them with fulfilling their regulatory responsibilities to identify and report suspicious orders. In the coming months, DEA will send targeted messages on certain practitioners on how they may utilize telemedicine to treat opioid use disorder.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement, but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly champions robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. Missouri will become the 50th, pursuant to the Governor's Executive Order in July 2017. As of January 2018, 40 of these states require controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance, in certain circumstances, as mandated by each state's legislation.[24]

While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to pain clinics and physicians that are operating unscrupulously and outside of the law, making interconnectivity between PDMPs vital. As a result, ONDCP and the Bureau of Justice Assistance (BJA) currently offer assistance for interstate and state-tribal PDMP linkages. CDC supports states to advance interventions for preventing prescription drug overdoses, through its *Prevention for States* program, which could include activities focused on improving interoperability between PDMPs and Electronic Health Record (EHR) technology and provide real-time provider access. The Indian Health Service (IHS) developed a policy that requires federal IHS facilities to report all controlled substance prescriptions to their respective State PDMPs and requires federal prescribers to check State PDMPs prior to prescribing opioids for a period longer than seven days. Forty-four states[25] are currently able to exchange prescription data between certain states. In some instances, data sharing may be limited to a single neighboring state. In other instances, data sharing may span states within a specific region. There are currently two interstate data sharing hubs in operation: RxCheck, BJA's open standards solution developed and operated in partnership by the IJIS Institute (IJIS) with funding from BJA; and PMP Interconnect (PMPi), a proprietary solution operated by NABP. As of August 2017, nine states are live or are implementing interstate data sharing using both hubs, 36

[24] PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20180102.pdf retrieved March 6, 2018.

[25] States with the capacity to participate in interstate data sharing include Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Idaho, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Hampshire, New Mexico, New York, North Dakota, New Jersey, Nevada, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Wisconsin, West Virginia.

states are live or are implementing interstate data sharing using the PMPi hub only, and 4 states are live or are implementing interstate data sharing using the RxCheck hub only.

Federal partners are working to address the interoperability. Brandeis University's PDMP Training and Technical Center, funded by BJA, has assisted the IHS to improve interoperability between IHS, its pharmacies and PDMPs. The BJA currently provides funding to 30 states through the *Harold Rogers PDMP program* for PDMP implementation or enhancements or enhanced data sharing, including interstate data sharing. CDC supports work in states to enhance and maximize PDMPs as a public health and clinical tool.

Law enforcement access to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects personally identifiable information is vital. Access to information in support of active State and Federal investigations varies widely from state to state, with some states requiring a court order in order for law enforcement to obtain data.

Medication Disposal

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 (P.L. 111-273) and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the issue of the misuse of prescription drugs and related substance use disorders, and promotes awareness that one source of these drugs is often the household medicine cabinet, as 53% of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free.[26] These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of March 2018, 3,812 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on October 25, 2017. As a result of all fourteen National Take Back Days, DEA, in conjunction with its State, local, and tribal law enforcement partners, has removed a total of 9.02 million pounds (4,508 tons) of medications from circulation. The DEA's next National Take Back Day is scheduled for April 28, 2018.

[26] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

Automated Reporting and Consolidated Orders System (ARCOS) Data

ARCOS reporting is required by 21 U.S.C. §827(d)(1) and applicable DEA regulations. Manufacturers and distributors of schedule I, II, or III narcotic controlled substances (and GHB) must report the manufacture, sale, purchase, loss, or other disposition of these controlled substances (e.g., a manufacturer's sales to distributors; a distributor's sales to pharmacies, hospitals/clinics, and doctors). DEA's Diversion Control Division has taken numerous steps to examine sales and monitoring processes in ARCOS. For example, Diversion Control utilizes various reports and records to monitor trends or determine anomalous transactions, which can then be developed into investigative leads. A unit within the Diversion Control's Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution. This unit prepares regular threat assessment reports for each of DEA's 22 Field Divisions to prioritize DEA resources in furtherance of criminal, civil, and regulatory investigations. Additionally, DEA is working on enhancements to the ARCOS system, which will require those entities submitting data to ARCOS to fix any transaction errors in order for the report to be accepted. This will help the ARCOS system to capture more accurate data and provide a more "real time" snapshot of the flow of controlled substances within the drug supply chain. Finally, DEA is working collaboratively with a coalition of 41 States Attorneys General and a second coalition of 7 States Attorneys General to provide non-public, law enforcement sensitive ARCOS data to support their active investigations against certain manufacturers and distributors.

Suspicious Order Reports (SORs)

Since the enactment of the CSA in 1970, all DEA registrants who distribute controlled substances have a statutory duty to "maintain effective controls against diversion" of controlled substances into other than legitimate medical, scientific, and industrial channels. The first regulations implementing the CSA in 1971 contained a provision regarding "suspicious orders of controlled substances." This provision, which has remained essentially unchanged since 1971, currently appears in 21 CFR § 1301.74(b) and reads as follows: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

These reports are currently fielded and verified by DEA personnel and can be used as a tool to identify and pinpoint vulnerabilities throughout the closed system of drug distribution. Since 2010, DEA has found that certain distributors were not adequately following their internal controls or not reporting suspicious orders. Through negotiated settlements involving civil penalties and compliance agreements and other means, DEA has worked with DEA-registered manufacturers and distributors to strengthen suspicious order monitoring and reporting. DEA is also exploring ways to ensure that suspicious orders would be submitted to a central database. Centralized reporting would provide for a more efficient review, dissemination, and investigation of suspicious activity.

In addition, we have launched a new tool within the ARCOS system to assist drug manufacturers and distributors with their regulatory obligations under the CSA. The tool will allow a distributor (or manufacturer) to enter the DEA registration number of a prospective purchaser (pharmacy, hospital, doctor, etc.) as well as a drug code for the controlled substance the buyer wishes to purchase and the ARCOS application will return a count of the number of registrants who have sold that particular controlled substance to that prospective purchaser in the last 6 months. This new query application will help distributors identify red flags indicative of suspicious orders.

Finally, DEA Diversion Control urges DEA registrants and the public at large to "submit a tip" regarding possible CSA violations, including: illicit drug distribution or trafficking; suspicious online pharmacies selling controlled substances over the internet; and the illegal sale and distribution of a prescription drug by individuals, including doctors and pharmacists. These tips are submitted to a DEA Field Divisions for prompt action by either a DEA Special Agent or a professional staff member. These tips are submitted through DEA's Diversion Control website (https://www.deadiversion.usdoj.gov/tips_online.htm). DEA also maintains a telephone hotline (877-RxABUSE) for the community to submit tips which may establish leads relating to the potential diversion of controlled substances.

Tactical Diversion Squads

DEA Tactical Diversion Squads investigate suspected violations of the CSA and other federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and DEA registrants who knowingly divert controlled substance pharmaceuticals). Between March 2011 and present, DEA increased the number of operational TDSs from 37 to 77. In addition, DEA established two mobile TDS that can deploy quickly to "hot spots" around the country in furtherance of the Diversion Control Division's mission.

Production Quotas for Schedule II Opioids

The Diversion Control Division is responsible for setting Aggregate Production Quotas (APQs) every year. These APQs are the "total quantity of each basic class of controlled substance listed in Schedule I or II necessary to be manufactured during the following calendar 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."[27] Since 2014, DEA has observed a decline in prescriptions written for certain Schedule II opioids. These declines have led to overall reductions in licit demand which in turn, have

[27] 21 CFR 1303.11(a)

directly impacted the factors DEA considers when establishing the APQs for Schedule II opioids. In October 2016, DEA announced a 25 percent reduction (or more) in the 2017 APQs for many prescription opioids, including oxycodone, hydrocodone, fentanyl, hydromorphone, and morphine. Hydrocodone was reduced to 66 percent of the previous years' (2016) level. In late 2017, DEA announced a nearly 20 percent reduction in the 2018 APQs (from the 2017 levels) for controlled substances, and these reductions included the aforementioned opioids as well as oxymorphone, codeine, and meperidine. These decreases can be attributed to combined local, state, and federal activities and interventions, including creating new partnerships, enforcing current regulations, and dissemination of provider education and guidance documents, including the CDC *Guideline for Prescribing Opioids for Chronic Pain* released in March 2016. In addition, we are encouraged that more states have enacted and enforced laws mandating the use of PDMPs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

DEA's 360 Strategy

To counter the opioid crisis, DEA initiated and continues to expand upon its 360 Strategy. The strategy leverages existing Federal, State, local, and tribal partnerships to address the problem on three different fronts: law enforcement, diversion control, and demand reduction. Our enforcement activities are directed at the violent cartels and drug trafficking gangs responsible for feeding the heroin and prescription drug epidemic in our communities. We are also enhancing our diversion control efforts and working with community partners for them to implement evidence-based programs and efforts designed to reduce demand and to prevent the same problems from resurfacing.

As part of the 360 Strategy, DEA recently partnered with Discovery Education, a division of Discovery Communications, to develop and distribute a prescription opioid and heroin education curriculum to middle and high school students, their teachers, and parents. We are calling it *Operation Prevention* and have started nationwide deployment of this program. Our goal is to educate children about the science of addiction and the true danger of prescription opioids and heroin, and to "kick start" life-saving conversations in the home and classroom. This award-winning program is available at no cost to schools nationwide and includes resources such as standards-aligned lesson plans, interactive student activities, parent resources and more – all available through an online portal. Operation Prevention launched in October 2016 with a virtual field trip, viewed live by more than 200,000 students, in all 50 States and in seven foreign countries. This program will run for at least three consecutive school years (through spring 2019) and is free for all law enforcement, prevention, treatment, and community groups to use and distribute. As of February 2018, the program has reached more than 2.1 million students.

Since its implementation in 2016, the 360 Strategy has been implemented in eight cities– Louisville, Kentucky; St. Louis, Missouri; Pittsburgh, Pennsylvania; Milwaukee, Wisconsin; Dayton, Ohio; Albuquerque, New Mexico; Charleston, West Virginia; and Manchester, New Hampshire. DEA is expanding this program to additional locations including Salt Lake City, Utah and New Jersey in 2018. Our enforcement efforts will continue across the United States with our law enforcement and community partners.

CONCLUSION

The United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of misuse of prescription opioids. DEA can and must do better and will continue to use all criminal, civil, and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. DEA expects that demand for opioids will continue to be met in part by Mexican-based TCOs that produce high purity heroin, which is being laced with fentanyl, fentanyl analogues, and other synthetic opioids, and then pressed into counterfeit pills. DEA will continue to address this threat by pursuing these TCOs, which have brought tremendous harm to our communities. Working with DOJ and our interagency partners, DEA will continue to engage our international counterparts, especially China. We look forward to continuing to work with Congress to find solutions necessary to address the threats posed by controlled prescription drugs, heroin, fentanyl, and other synthetic opioids.

Mr. HARPER. Thank you, Mr. Patterson. It'll now be the opportunity for members to ask you questions regarding your statement and look for solutions to the problems that we have and I will begin by recognizing myself for 5 minutes for questioning.

Over the past year, this committee has been investigating opioid dumping and as part of this probe the Committee found some disturbing examples, and I will share a couple of these, some that we have touched on. A single pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779, received over 16.5 million hydrocodone and oxycodone pills between 2006 and 2016. Distributors sent 20.8 million opioid pills to Williamson, West Virginia, population 2,900, during the same period, and in 2006 a pharmacy located in Kermit, West Virginia, population 406, ranked 22nd in the entire country in the overall number of hydrocodone pills it received with a single distributor supplying 76 percent of hydrocodone pills that year.

Would you agree that, on its face, these distribution figures represent inordinate amounts of opioids shipped to such rural markets?

Mr. PATTERSON. I would.

Mr. HARPER. Distributors are required to file reports of shipment amounts on certain controlled substances to the DEA database called the Automated Reports and Consolidated Ordering System, or ARCOS. These reports are filed monthly. Is that correct?

Mr. PATTERSON. Sir, either monthly or quarterly.

Mr. HARPER. What's the distinction between when one is done quarterly or monthly? Who makes that determination?

Mr. PATTERSON. It is done by a distributor or a manufacturer.

Mr. HARPER. OK. Ten years ago, would the ARCOS database have been able to flag DEA diversion investigators about unusual patterns such as the stunning monthly increases of shipment amounts or disproportionate volume of controlled substance sales at a pharmacy?

Mr. PATTERSON. Ten years ago, I think that would be doubtful.

Mr. HARPER. OK. Did the DEA attempt to leverage the data in ARCOS to help support DEA investigations of opioid diversion in West Virginia?

Mr. PATTERSON. Back at that time frame?

Mr. HARPER. Just tell me when. When did they start utilizing that?

Mr. PATTERSON. Sir, so ARCOS data I think pre probably 2010 was an extremely manual process. As that system has gotten more robust and, certainly, through the last handful of years we've used that in a much more proactive manner.

Mr. HARPER. Would the DEA ARCOS database be able to flag such signals of opioid diversion today? Your answer is, obviously, a yes.

In 2006 and 2007, DEA sent at least three letters to wholesale drug distributors regarding their compliance obligations under the Controlled Substances Act. The letters reminded the companies of their duties to monitor and report suspicious orders of opioids. Yet, during this time, according to DEA enforcement actions, drug distributors failed to maintain effective controls against diversion.

Why did the DEA communications with industry fail to prevent the kinds of major breakdowns apparent in West Virginia?

Mr. PATTERSON. I think when you go back to that timeframe on the suspicious orders reports, there were two major failures. One was either a lack of information contained therein or not filing them in this instance that they had. I think that started the problem, quite frankly and a lot of the frustration came from chasing down the registrants and ultimately reminding them of their responsibility in this regulated area.

Mr. HARPER. Over the last 10 years, the DEA reached settlements with drug distributors for failing to maintain effective controls against diversion of opioids or failing to report suspicious orders. Yet, after these settlements, drug distributors continued to fail to comply with the regulatory requirements. Why were these initial settlements not effective in achieving compliance from these distributors?

Mr. PATTERSON. And again, this goes back to the frustration of the day, and I know that the folks that were in diversion back in 2010 and 2012 struggled with the fact that these MOUs or MOAs have been put in place with these companies and they blatantly violated them again.

Mr. HARPER. So how is DEA utilizing ARCOS today? Is it effective today?

Mr. PATTERSON. So, sir, ARCOS as a stand-alone database is a good pointer. I think, as I said in my opening statement, ARCOS data and what we have learned, combined with state PMP HHS data, gives you a much better outlier problem.

In some of the cases that we have looked at, depending on the situation, ARCOS data would not have found those particular issues, right. If it's a smaller level or a single place. So the reality is is what we need is all of these data sets essentially working in conjunction with each other.

Mr. HARPER. Are there movements to improve ARCOS? Is that constantly monitored and updated and refined?

Mr. PATTERSON. So we are constantly working with this data now in a very proactive way. We've joined with two state coalitions of states' attorneys-general to work with data sharing in this space, especially with the PMP data as well as our counterparts at HHS.

Mr. HARPER. Thank you, Mr. Patterson.

The Chair now recognizes the ranking member, Ms. DeGette from Colorado, for 5 minutes.

Ms. DEGETTE. Thank you so much, Mr. Chairman, and I agree, Mr. Patterson, that we do need to look forward how we can improve things. But I don't think we can do it without examining the past, and this ARCOS system is the perfect example.

I want to spend a few minutes following up on what the chairman was asking you, my understanding is ARCOS was in place during this whole time period, 2006 to 2016, correct?

Mr. PATTERSON. That's correct, ma'am.

Ms. DEGETTE. And so what was happening the data was just being reported in but nothing was really being done with it. Isn't that correct?

Mr. PATTERSON. I would say it was used in a very reactive way.

Ms. DEGETTE. Right. So you said that a lot of times you wouldn't have been able to tell this from ARCOS.

I am going to assume, though, if we had been analyzing this data we would have found the 184,000 pills per month that McKesson was sending to Kermit if someone had looked at it. Wouldn't you think so?

Mr. PATTERSON. I do agree with that.

Ms. DEGETTE. Yes. And wouldn't you agree that in Kermit—I think you said yes when the chairman said this—it was 2.2 million pills in a year in Kermit.

All you'd have to do is look at that raw data and see that, wouldn't you?

Mr. PATTERSON. That's correct.

Ms. DEGETTE. And so really the fact—well, let me—let me ask you another question. The Controlled Substances Act and the applicable regulations require the distributors to know their customer.

So distributors are supposed to report orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency to the DEA.

Isn't that correct?

Mr. PATTERSON. It is, ma'am.

Ms. DEGETTE. So it's not just the DEA that has a burden to analyze the ARCOS data and to identify problems. But even before that, the distributors have a burden, right?

Mr. PATTERSON. The key burden is actually on the distributor.

Ms. DEGETTE. Right. Exactly. So do you think that if you were McKesson Corporation and you were looking at all these prescriptions in Kermit, would you think they knew those customers?

Mr. PATTERSON. Well, one, the obligation was there to know their customers.

Ms. DEGETTE. Right. Do you think that you possibly could know the customers when you're sending that many prescriptions in there?

Mr. PATTERSON. I think McKesson's answer would be that they did their part on this.

Ms. DEGETTE. Well, what's your answer?

Mr. PATTERSON. Obviously, I think they should have done more.

Ms. DEGETTE. Well, I would think so. Do you think that orders of this magnitude—2.2 million doses of hydrocodone to one Sav-Rite pharmacy—do you think that that's an order of an unusual size?

Mr. PATTERSON. I do, ma'am.

Ms. DEGETTE. And do you think that it deviates from a normal pattern?

Mr. PATTERSON. I do.

Ms. DEGETTE. OK. Let me ask you another question.

Now, looking back on this case, do you think that the distributors in all of these situations that the Chairman and I have been talking about—do you think that they failed to adequately exercise good due diligence over what they were doing?

Mr. PATTERSON. Certainly, on the appearance of it. I can't tell you what their due diligence was. But——

Ms. DEGETTE. Oh, we are going to ask them that. Don't worry. You're not here to represent them.

Now, in December, the Washington Post and "60 Minutes" reported that McKesson distributed large volumes of opioids from its

Aurora, Colorado distribution facility in 2012. One pharmacy that received these shipments reportedly sold as many as 2,000 opioids per day. Have you retroactively applied ARCOS data to the Colorado situation to see if there were distribution patterns similar to what we saw in Kermit, West Virginia?

Mr. PATTERSON. I believe that's the case, ma'am, that ultimately the DEA litigated and received a settlement. I don't know if we went back currently and have looked at that same number.

Ms. DEGETTE. And what was the settlement?

Mr. PATTERSON. It was $150 million.

Ms. DEGETTE. From McKesson to——

Mr. PATTERSON. The U.S. government.

Ms. DEGETTE. The U.S. government. As a result of McKesson's failure to adequately follow the law on distributing those opioids. Is that right?

Mr. PATTERSON. That's correct.

Ms. DEGETTE. And so what do you think Congress can do so that we don't have a total slip-up like we did in all of these cases in West Virginia and around the country, really?

Mr. PATTERSON. Well, look, the fundamental change that we have already made is our recognition of how we can use the various data sets and paying attention to what we are doing.

The outreach to industry—and I think this is a topic that I assume will come up at some point—we have to work with the industry and the industry, obviously, has their responsibility.

But we have 1,500 people to monitor 1.73 million registrants.

Ms. DEGETTE. So, really, you think the initial burden to assess this is on the industry. But then the DEA has an important enforcement?

Mr. PATTERSON. Oversight.

Ms. DEGETTE. Yes, thank you.

Thank you, Mr. Chairman.

Mr. HARPER. Gentlewoman yields back.

The chair will now recognize the chairman of the full committee, Mr. Walden, for 5 minutes for questions.

Mr. WALDEN. Thank you, Mr. Chairman.

Mr. Patterson, we need to find out whether DEA is really addressing the lessons you say DEA has learned.

Case in point is the one I raised, the questionable enforcement approach regarding the two Sav-Rite pharmacies in Kermit, West Virginia that I mentioned in my opening statement.

Sav-Rite No. 2 was shut down in April of 2009, correct?

Mr. PATTERSON. I don't know the specific dates. I know there were two pharmacies. One was shut down and one wanted criminal——

Mr. WALDEN. Yes, our data show April of 2009 Sav-Rite 2 was shut down. Sav-Rite 1 was not shut down until over 2 years later when the owner of the pharmacy entered a guilty plea to charges that he illegally issued prescriptions, correct?

Mr. PATTERSON. That's correct.

Mr. WALDEN. And in April 1st of 2009, an article in the local Herald Dispatch reported that the two Sav-Rite pharmacies and a local pain clinic were under federal investigation for operating a drug operation. The article reported an affidavit from Federal in-

vestigators who stated there were two overdose deaths linked to this network.

So my question is why did DEA shut down Sav-Rite No. 2 but not Sav-Rite No. 1 in April of 2009 if both pharmacies were part of a network linked to deaths?

Mr. PATTERSON. Sir, I would have to get back to you on that one particular issue and I will you the reason why. It's my understanding it was part of the criminal process in that case and I don't know the answer for why that was. But I would be happy to get that back to you.

Mr. WALDEN. Thank you.

So why would the DEA even consider such an arrangement when it knew the owner operated the pharmacies 2 miles apart, one of which the DEA claimed to be the prime reception location for the flood of pills—that's a direct quote—being sent to the area and linked to overdose deaths? Same owner, same operator, 2 miles apart?

Mr. PATTERSON. I agree with you, and it's something I will get back to you on.

Mr. WALDEN. During the time the DEA allowed Sav-Rite No. 1 to remain in operation, this pharmacy received somewhere between 1 and 2 million hydrocodone and oxycodone pills. Allowing Sav-Rite 1 to continue to dispense such a volume of opioids posed a continuing risk to public health and safety. Isn't that right?

Mr. PATTERSON. I would agree.

Mr. WALDEN. So, Mr. Patterson, what's the biggest priority? Protecting public safety or deferring to an ongoing criminal investigation?

Mr. PATTERSON. It should have been to protect public safety.

Mr. WALDEN. So in this case, the government originally entered a plea agreement with the pharmacy owner that didn't even call for any prison time. The lack of any prison time troubled the judge and eventually the defendant was sentenced to 6 months in prison.

What kinds of evidentiary challenges would have been involved in such a case and would putting an immediate suspension order on hold really help solve these challenges?

Mr. PATTERSON. So putting an immediate suspension order on hold, again, I don't know the particular facts of that criminal case and I would be happy to get back to you.

I will tell you that I have a very strong opinion and this has been relayed throughout our agency that whether it's an immediate suspension or whether a surrender for cause, that if we are having harm issues that that suspension needs to occur even in lieu of a criminal prosecution.

Mr. WALDEN. And have you gone back and looked? Are there any records in your possession that would speak to this issue of why that decision was made?

Mr. PATTERSON. I would be happy to go back and look, sir.

Mr. WALDEN. And will you provide those to us unredacted?

Mr. PATTERSON. I would be happy to take that back and take a look at it for you.

Mr. WALDEN. That wasn't the answer I was looking for.

Mr. PATTERSON. I don't want to commit to the department's files. But I would be happy to take that back and I will take your concern back about getting them unredacted.

Mr. WALDEN. Yes. We've had this discussion in private. We'll have it in public. We'll have it in private.

The long and short of it is we just want to find out what was going on, what was the thinking, why the change in operation. People died and things were not—we don't want to see your agency repeat that.

We are beholden to the constituents we represent and I think the public has a right to know, don't you?

Mr. PATTERSON. I fully understand your concern and I agree with you.

Mr. WALDEN. Would this happen again today?

Mr. PATTERSON. Certainly, I think with our mentality, the answer would be no. Like I said, what we wish to do, sir, is stop public harm. I've had this conversation with U.S. attorneys' population, states' attorneys' population.

I see in too many instances on ISOs, current ones that I sign off on, where there has been a delay that I don't find appropriate.

Mr. WALDEN. So how do you weigh when to proceed with an ISO versus a criminal case?

Mr. PATTERSON. I would take it, quite frankly, no different than what we would do in a criminal case in the field, and in this case, I find that we have the ability.

So we have certain protocols where we evaluate risk of ongoing criminal activity in traditional criminal cases. In this case, because the person has a registration, we can immediately stop that harm.

Mr. WALDEN. And what's immediate? Is that 90 days? Twenty-five days? Tomorrow?

Mr. PATTERSON. I think the frustration in this is it takes time to build even that ISO charge, which is the reason why, in a lot of cases, we've gone to surrenders for cause or a voluntary surrender in which we go in and try and remove that registration.

Mr. WALDEN. So how long are we talking about to build that case?

Mr. PATTERSON. I think probably, in an efficient manner, 45 to 90 days.

Mr. WALDEN. So during that period, they can continue to dispense these drugs?

Mr. PATTERSON. The same way an illicit person would be out on the street as we gather the evidence we needed to present the charge.

That's why, sir, I go back to my point on surrender for cause, or a voluntary surrender. If I can walk in and lay out to that person why they need to surrender that and I can do it in a day and that's the method that we have actually been using much more aggressively than the ISO process, then we are going to do that.

Mr. WALDEN. What's the average time to go to a voluntary surrender?

Mr. PATTERSON. It depends. With very aggressive people it happens relatively quickly. There's always a quick balance with a criminal case and then evidence that they need to look at for that.

And, like I said, again, our conversations with prosecutors in the field have been that decision has to get made quickly.

Mr. WALDEN. All right. I know my time has expired.

I would imagine Mr. Griffith is going to have a comment or two on this as well.

With that, Mr. Chairman, I yield back, and thank you again.

Mr. HARPER. Thank you, Mr. Chairman.

The chair now recognizes the ranking member of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. Patterson, I want to ask you about another pharmacy in West Virginia so I can better understand why DEA was not able to stop the distributors from oversupplying certain pharmacies. This one is the Family Discount Pharmacy in Mount Gay-Shamrock, West Virginia. Mount Gay-Shamrock has a population of just under 2,000. DEA's data shows that distributors shipped 16.5 million opioid pills to this pharmacy between 2006 and 2016, including 2 million pills in three consecutive years. By contrast, the Rite-Aid Pharmacy down the street received a total of about 2 million pills during this entire 11-year period.

So do you agree that over 16 million pills is an excessive amount of opioids for Family Discount Pharmacy to have received relative to the size of the town it served?

Mr. PATTERSON. Especially when you compare it to the other pharmacy. Correct.

Mr. PALLONE. I thank you.

One distributor has provided evidence suggesting that between May 2008 and May 2009 they sent DEA 105 suspicious order reports stating that this pharmacy regularly ordered high volumes of pills.

For example, this distributor apparently told DEA that Family Discount ordered 25 500-count hydrocodone bottles on June 16th, 2008, and that's 12,500 pills just in the one day. On October 10th, Family Discount ordered 32 500-count hydrocodone bottles, or 16,000 pills in a single day, again, for a town of only 2,000 people.

Now, merely reporting these suspicious orders does not absolve the distributor of its additional responsibilities. Is that correct?

Mr. PATTERSON. That's correct.

Mr. PALLONE. So distributors still have to actually refuse shipments to suspicious pharmacies?

Mr. PATTERSON. They can, yes.

Mr. PALLONE. Additionally, it appears that distributors continue to ship this pharmacy over a million opioid pills each year in the 5 years after these reports were made and even the distributor who told us they reported the pharmacy to DEA continued to supply them after submitting those reports.

So, Mr. Patterson, it would appear that, again, something broke down to allow so many opioids to be shipped to this pharmacy. Just tell us what happened here. Why are so many opioids sent to this pharmacy at the same time that DEA has received a number of suspicious order reports? What do you think happened?

Mr. PATTERSON. Sir, so, again, on any of these individualized cases I am going to have to go back and take a look at the specific instances of what happened.

I will give you, I think, the concern I have with the ARCOS—not just ARCOS data but the suspicious orders, which is that was a decentralized function. It would go out to our division—those reports.

We are now bringing those in as well to our headquarters for proper deconfliction and visibility of what we see. I will take on face value the facts that you just proffered to me and I would be happy to go back and take a look at the Family Discount scenario. As I sit here, I don't have the particulars on the case from that time.

Mr. PALLONE. Well, we appreciate your following up. That's obviously why we are asking the questions. I don't expect you to know everything right off the bat.

But let me just say this. Between 2006 and 2010, did the DEA have any data analysts assigned to scrutinize information from distributors about the amount of pills shipped to particular pharmacies? Did you have any kind of data analysts, in that respect?

Mr. PATTERSON. So my understanding of the people that were handling the ARCOS data it was a completely manual process, meaning everything was coming in on paper or tapes, which would have to be verified.

So you have this 1-month to 3-month delay to begin with. They would have to have errors in their report that would go back and forth. So what you found yourself with is a set of data that sometimes would take a year-plus to get correct, and then in that timeframe, sir, we are using it very much as a reactive tool. In other words, someone would come in and provide some piece of information on a pharmacy or a doctor or some other issue and then they would go and look at the ARCOS data. It was not done in a——

Mr. PALLONE. So does that mean then, if I understand you, that it would be too long a period of time before would they realize how excessive this was?

Mr. PATTERSON. Well, if it was still ongoing, obviously, it would be an ability to look at that current situation. In a lot of these cases you see where these problems occurred for either a year or two and then disappeared or they were ongoing. But——

Mr. PALLONE. And is that problem being corrected or what do you suggest we do?

Mr. PATTERSON. It has been corrected, sir. So, again, I think that for the Committee to understand is ARCOS is an extremely different tool in 2018 than it was even in 2010 or 2011.

Mr. PALLONE. So you feel that you already have the tools to correct it—you don't need anything else?

Mr. PATTERSON. I feel that tool, with other data, is an important way for us to look proactively at the very specific issues that we are talking about today.

Mr. PALLONE. All right. Thank you.

Mr. HARPER. The gentleman yields back.

The chair will now recognize the gentleman from Texas, Mr. Barton, for 5 minutes.

Mr. BARTON. Thank you, Mr. Chairman.

This is a difficult hearing because I think everybody has the same bottom line. But your agency doesn't appear to be willing to

aggressively try to help us solve this or at least deal with this crisis.

According to the latest numbers that this committee staff has, 115 people a day are dying of opioid overdoses and two-thirds of those are legally prescribed drugs. So about 80 people a day are dying from taking legally-prescribed prescription drugs. Now, they may be getting that prescription in an illegal way—in other words, they don't really need it. You're the head of the agency that's supposed to do something about it.

Now, I don't know much about you but, apparently, your background has been on the illegal side of DEA. Is that correct?

Mr. PATTERSON. That is correct.

Mr. BARTON. OK. How long have you been in your current position?

Mr. PATTERSON. Since October of 2017.

Mr. BARTON. OK. And I doubt that you volunteered for the job. We still don't have a Trump administration appointee who's been recommended to the Senate. So for the foreseeable future in terms of drug enforcement the buck stops with you, even though you're, as I understand it, a career civil servant. Is that correct?

Mr. PATTERSON. That's correct.

Mr. BARTON. OK. Are you familiar with the Washington Post articles that have been running the last 3 to 4 months? One of them talks about the tension between the field enforcement offices and the Washington administrative officials.

Mr. PATTERSON. I have.

Mr. BARTON. OK. Do you agree or disagree with the basic thrust of those articles—that the enforcement people were very enthusiastic and willing to really go after the distribution centers and the drug manufacturers and the pharmacies and the Washington staff, for lack of a better term, stonewalled them or toned them down?

Mr. PATTERSON. So I believe that's an overstatement. I think you have a number of issues that, quite frankly, play out in this space, some of which have to do with personalities. But I don't find that the folks in the field, for the most part, had this belief that they were shut down. I do think there were people that felt that way at headquarters but not necessarily in the field.

Mr. BARTON. Are you familiar with a gentleman named Clifford Lee Reeves, II?

Mr. PATTERSON. I am.

Mr. BARTON. You don't think he stonewalled them or toned them down?

Mr. PATTERSON. Sir, as I've talked about with everybody I've met on this situation, I will simply explain this. I could put three people in a room and talk about probable cause and they could all have different opinions on——

Mr. BARTON. Well, let me put it this way. You and your associates in Washington have stonewalled this committee for the last 6 or 7 months.

It took a threat of Chairman Walden to subpoena the attorney general of the United States to finally break loose some documents. We didn't get those documents, I understand, until yesterday. Now, that's not the Washington Post, sir. That's your people in Wash-

ington interacting with Energy and Commerce Committee staff on a bipartisan basis. That's not hypothetical. That's real.

Now, we are as much a part of the problem as anybody because the Congress has not aggressively addressed it. But we are beginning to, and as long as you're the head of the DEA, I personally, as Vice Chairman of this committee, expect you to work with us and to tell your people to work with the committee staff. Can you do that?

Mr. PATTERSON. Sir, I took over this job in October. I met with——

Mr. BARTON. OK. I want to know will you do what I just asked you to do? Yes or no. Will you tell your people to work with committee staff to help address this problem?

Mr. PATTERSON. Of course, and I have since November and we've been turning documents over since that time.

Mr. BARTON. Well, you didn't turn them over until yesterday, sir, and some of the documents you turned over were so redacted that it just looked like black marks on the pages.

Mr. PATTERSON. Sir, we've been turning documents over since November to the tune of more than 10,000 pages of documents that have come over here in the last month.

Mr. BARTON. Yes, and how many of those pages do you think are useable?

Mr. PATTERSON. Well, we sat down yesterday with staff to go——

Mr. BARTON. Because this hearing was today.

Mr. PATTERSON [continuing]. The concerns. Sir, I would respectfully disagree with that.

Mr. BARTON. Well, at least you're respectfully disagreeing and I appreciate that.

Mr. PATTERSON. I am fully committed, sir, to working with this committee and being as transparent as I can be.

Mr. BARTON. Well, you just remember, 80 people a day are dying because of legal prescription drugs that are probably being illegally prescribed. Remember that.

I yield back.

Mr. HARPER. Gentleman yields back.

The chair will now recognize the gentlewoman from Florida, Ms. Castor, for 5 minutes.

Ms. CASTOR. Thank you, Chairman Harper.

Administrator Patterson, I am sure you know about the multidistrict opioid litigation in the Northern District of Ohio, which consolidates over 400 lawsuits brought by cities and counties and other states' communities against the drug distributors, manufacturers, and pharmacy chains. The most important source of information in that major lawsuit is going to be most likely the ARCOS data, and I understand DEA initially resisted providing ARCOS data to the federal judge.

A DEA official testified in response to my question in the Health Subcommittee hearing last month that the resistance was based upon a need to protect proprietary information. But now the court in this case has recently entered a protective order describing how the parties should treat the confidential ARCOS data when DEA disclosed it.

It's apparent to me that the ARCOS data will be pivotal in appropriately resolving the case and assigning accountability. Do I understand now that DEA has agreed to provide 9 years of data on opioid sales including the identifies of manufacturers and distributors that sold 95 percent of opioids in every State from 2006 to 2014?

Mr. PATTERSON. That is correct, under the protective order.

Ms. CASTOR. Under the protective order. So this will not be the last major challenge to manufacturers and distributors and others that are responsible. Will DEA likely cooperate in those cases too? Have you set up a standard—is this a decision, going forward, that other judges and litigants can count on?

Mr. PATTERSON. I would believe it's under the same circumstances and conditions that we would comply the same way with anyone else that came in under those same terms.

Ms. CASTOR. So when will that data be provided to the Federal court in the northern Ohio case?

Mr. PATTERSON. I can get back to you on the date. I think it's very short term.

Ms. CASTOR. OK. The Committee's analysis of ARCOS data has been very concerning. The trends in West Virginia—we've just really skimmed the surface, I think.

My colleagues have outlined some of these. I am concerned that there are other regions all across the country where distributors may have supplied pharmacies with excessive quantities of opioid pills and that that information may be overlooked.

How is DEA currently using the older ARCOS data, say, from 2006 to the present to go back and look at past crimes, and if you could explain what you're doing now.

Mr. PATTERSON. No, I appreciate the question and I think it's an important issue.

So the 400 packages that we just put out are current-day packages that we want to investigate—in other words, where harm is continuing. I shouldn't say where harm is definitely continuing but where those outliers are that we want to go back and take a look at, why is that occurring, right?

Some of these actually end up being reasonable issues. There's an oncology department there. There's some reason why there's a higher level of that medication going to that area.

I think the key is is that once we get a handle on current issues that we are dealing with we want to roll backwards and look at 2012, 2013, 2014, and 2015 where we still have the ability to take a look at that data and make it make sense.

I can tell you that there's a number of cases ongoing in DEA without going into detail on them, looking at just that issue right now with manufacturers and——

Ms. CASTOR. And what is the statute of limitations? If you go back and the Committee has seen some of this in graphical forms where 2006 it ramped up and then because now the spotlight is being shined on it that the excessive distribution has scaled down.

Do you have the ability to go back and hold them accountable for that peak dangerous distribution of opioids?

Mr. PATTERSON. So on the criminal side, I believe it would be 5 years. On civil, I would have to find out. I am not sure how far back you can go civilly.

Ms. CASTOR. So you are——

Mr. PATTERSON. As long as it is an ongoing issue, then you fall into that timeframe.

Ms. CASTOR. And there was a lot of criticism by the Pulitzer Prize-winning Charleston Gazette Mail that the state didn't take advantage of data at their fingertips. How are you cooperating with states in providing that data so they can hold folks accountable?

Mr. PATTERSON. So this gets back to the issue, I think, with PMP which—and this is why these two data sets are so critical with each other.

We see the distribution to the pharmacy. PMP data in the states will then show you the distribution out of the pharmacy, right. So that whole connection, that's where those other outliers become very critical for us to take a look at.

Some states, and this is the issue that we have addressed throughout the members that we've met through and the states that we've talked to, some states share this data. Some states require a subpoena, which is also fine. Some states don't share. This is a problem that we have and, frankly, I think an issue that I would hope that someone looks at on a legislative fix, at a minimum to make the states cooperate with each other because you have bordering states, in some cases, that are still not participating and cooperating with each other, which is exactly how a lot of this diversion happens.

Ms. CASTOR. Thank you very much. I yield back.

Mr. HARPER. Gentlewoman yields back.

Before we proceed, I want to clarify for the record that the DEA has been producing documents and the vast majority of the roughly 9,700 pages we have received have come in during the last month.

Those documents had substantial redactions. Staff identified key documents for you and yesterday the DEA brought up some of those for us to view in camera. And I will note that those documents still contain some redactions.

So there's still much work to be done. I wanted to clarify that for the record, that the bulk of these came in after Chairman Walden's press conference and we'll continue to work with you in this effort.

Mr. PATTERSON. Thank you, sir.

Mr. HARPER. Now the chair will recognize the Vice Chairman of the Subcommittee, the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. GRIFFITH. Thank you, Mr. Chairman.

Mr. Patterson, I am going to need your assistance on some of this because what I am going to do is ask a series of questions which require a yes or no answer.

First, if you would take a look at the email before you dated 5/6/2011. I show it to you here, and I would ask unanimous consent to put that into the record.

Mr. HARPER. Without objection.

[The information appears at the conclusion of the hearing.]

Mr. GRIFFITH. And apparently, secret DEA official wrote, because his name is blacked out, our first and most prominent social responsibility as government officials in the DEA is to protect the public. I think that trumps all other activities. I think that's what Congress/citizens would expect us to do. You agree with that statement, don't you? Yes or no.

Mr. PATTERSON. Yes.

Mr. GRIFFITH. One of the key tools for DEA to fulfill this mission is through an immediate suspension order—I will henceforth refer to those as ISOs. This is an administrative tool used as an emergency intervention to stop a rogue doctor or pharmacist from continuing to prescribe or dispense opioids that would possibly kill drug seekers and/or put the public at risk.

You agree with that as well, don't you?

Mr. PATTERSON. I do.

Mr. GRIFFITH. An essential element for requesting the ISO is concern about imminent danger to public health or safety. A pharmacy in Oviedo, Florida received an increase of oxycodone of almost 2,500 percent compared to 1 year earlier. Local police arrested customers in the parking lot of this pharmacy for selling/trading pills. Police officers were concerned customers were getting high in the parking lot and getting on the roads, endangering the public. The continued dispensing of opioids by this pharmacy with its parking lot of drug pushers and drug users who get high and then drive on the public roads would pose an imminent danger to the public, wouldn't you agree? Yes or no.

Mr. PATTERSON. Yes.

Mr. GRIFFITH. You would also agree, I assume, that speed is crucial in issuing imminent suspension orders to protect the public? Yes or no.

Mr. PATTERSON. I would.

Mr. GRIFFITH. I will just tell you, 45 to 90 days that you told the Chairman of the Full Committee is not acceptable. Please refer to another email before you and I ask unanimous consent to put that in the record and this one is dated August 22nd—or 20th—there's two different dates on it.

Mr. HARPER. Without objection.

Mr. GRIFFITH. 2013.

All right. The email chain in August 2013 shows that DEA lawyers were requiring the DEA field to submit an expert witness report to describe the expert's assessment of data and documents prior to submitting either or both request for an immediate suspension order and orders to show cause.

Are you aware of this new requirement that was imposed in 2013? Yes or no.

Mr. PATTERSON. No.

Mr. GRIFFITH. And I expected that.

Regarding medical experts being required, DEA counsel Lee Reeves wrote, "To be clear, this is not a chief counsel office requirement policy. This is the requirement of the administrator and the courts."

Are you aware that the medical experts are required by the DEA administrator? Yes or no.

Mr. PATTERSON. No.

Mr. GRIFFITH. Mr. Reeves also wrote that as a general matter, these cases without expert testimony are the exception rather than the rule.

So, generally, DEA is requiring medical expert testimony before the field can submit an ISO to the chief counsel's office for review. Is this still the policy of the DEA? Yes or no.

Mr. PATTERSON. It is not a policy, no.

Mr. GRIFFITH. I appreciate that. Thank you.

Mr. Reeves cites the DEA administrator's decision in the Ruben case for requiring medical experts. However, the Ruben case is a show cause case, not an ISO.

This decision basically says that if a state doesn't provide guidance on certain medical standards, the DEA must use an expert to explain why the doctor's activities fell below the standard of care. However, you would not need a medical expert if the state had a statute of regulations on prescribing standards. Yes or no, or I don't know?

Mr. PATTERSON. I don't know that.

Mr. GRIFFITH. All right. Fair enough.

Let's discuss this policy of requiring experts, and I know that you're trying to shift from some of that but let's discuss it.

It would take some time for the DEA field to find a medical expert, wouldn't you agree?

Mr. PATTERSON. I would.

Mr. GRIFFITH. And to obtain the services of a medical expert the DEA would have to issue a sole source contract and the agency and the expert would have to figure out and reach an agreement on fee and deliverables. Isn't that true?

Mr. PATTERSON. I don't necessarily know about the contract but it would require some type of compensation.

Mr. GRIFFITH. And after all of that, the medical expert would need to review prescription monitoring program, data patient files, and other information. It's going to take some time for the medical expert to review and render an opinion, isn't it?

Mr. PATTERSON. It would.

Mr. GRIFFITH. Yes. After the medical expert completes the review then the chief counsel's office would need additional time to review the field submission of the request for an immediate suspension order. Isn't that true?

Mr. PATTERSON. Yes.

Mr. GRIFFITH. This scenario assumes no delays along the way, and realistically this process, in many ISO cases, will take weeks, won't it?

Mr. PATTERSON. I would believe so.

Mr. GRIFFITH. And that's where you get your 45 to 90 days. If the DEA registrant sought a restraining order against the ISO, the delay in timing getting the medical expert and going through all the steps we just went through would in fact weaken the DEA's case in court for immediacy, wouldn't it?

Mr. PATTERSON. I would believe so.

Mr. GRIFFITH. Yes, it would.

And so in fact, insisting on an expert medical testimony for the ISO—I get the trial in cheap, the merits. But to protect the public, insistent on a medical expert in advance is endangering the public

and endangering your case on the ISO because it takes away the immediacy factor. Wouldn't you agree?

Mr. PATTERSON. Yes, and I——

Mr. GRIFFITH. OK. I got to keep moving because I am already out of time.

All right. Maybe I can get some more opportunity later. Thank you, Mr. Chairman. I yield back.

Mr. HARPER. Gentleman yields back. The chair will now recognize the gentleman from California, Mr. Ruiz, for 5 minutes.

Mr. RUIZ. Mr. Patterson, thank you for coming. I am a board-certified emergency physician and I can't tell you how personally I take it whenever a patient comes in overdosed, not breathing, and blue.

It's not uncommon to see a blue-colored patient being strolled in in an emergency situation, having been dumped from a car from friends who found this person overdosed, not breathing. And as emergency physicians we cut to the chase and we start resuscitating the patient. We know exactly what to do no matter if it's from overdose of opiates or any other reason why a patient is comatose. Whether we start the ABCs—airway breathing circulations—and we bring them back, as much as possible.

So I am going to cut to the chase here and ask you to be very frank and direct.

You screwed up. The DEA knew that there was a lot of opioids being shipped, an extraordinary amount and not outliers, and when you said earlier that there's two things that you were going to do from now on it's very concerning that those two things were to recognize how to use the data, and two, pay more attention to what you're doing. That leads me to believe that you were collecting data that you did not know how to use, and two, you weren't paying attention to your job within the DEA.

So I am going to be very straightforward. What are you doing different now that you're going to recognize how to use the data?

Mr. PATTERSON. Sir, I appreciate the concern and I think what I've tried to explain is the data—when we are talking about a lot of these cases that you have brought up we are talking about a time period in which this data was——

Mr. RUIZ. OK. Be specific on what are the changes you're going to do now. Not giving me the reasons why or an excuse. Tell me what are you going to do now that's different.

Mr. PATTERSON. So let me give you a handful of the differences.

Mr. RUIZ. Yes.

Mr. PATTERSON. On the suspicious orders, we have regulations that are in the final stretch to deal with that. We have a website that's now been built for the distributors to understand their customers better where they can go in and see partial information on other people that distributed to that particular pharmacy for the past 6 months.

We are working with all of our other partners both in the Health and Human Services side and the states to try and combine all this data, to look at it in a very proactive manner.

Mr. RUIZ. What are your flags? What numerical equations have you used to flag something for the pharmacies and for the distributors?

Mr. PATTERSON. I would have to get you what the specific flags are for them. I mean, they——

Mr. RUIZ. Are they new flags or are they old flags, like——

Mr. PATTERSON. No, they're our baselines for any given area as to traditional, what the prescribing rates have been in those particular areas and anything that's an anomaly to that is a flag.

All right. So when we've talked about these issues before we have a——

Mr. RUIZ. And who's looking at those flags? Who's the one in your department who's actually putting their eyes on this computer and reporting these?

Mr. PATTERSON. A unit within the diversion.

Mr. RUIZ. OK. And how many people are in that unit?

Mr. PATTERSON. I would have to get that number for you.

Mr. RUIZ. OK, because you have——

Mr. PATTERSON. Again, most of it's generated by computer.

Mr. RUIZ. OK.

Mr. PATTERSON. So it's not necessarily a manpower-intensive endeavor to do.

Mr. RUIZ. OK. And so when you said that now you're going to start paying attention to what you're doing, tell me about that. What are the organizational changes that you have made to start paying attention to doing your job?

Mr. PATTERSON. I don't think I said now that we are doing it. I think we've been doing it for a period of time.

Mr. RUIZ. Well, you said moving forward that now, what you have to do is to pay attention to what you're doing. That means to imply that there was some kind of slip-up before.

So what exactly are you doing? What are the changes? I want to practice my ABCs for a patient who's coming in. I want to know what you're doing exactly that you're going to make sure that this doesn't happen again.

Mr. PATTERSON. Again, that's some of the issues I just talked to you about and how we use data, or not community outreach. Well, community outreach with the prescribing——

Mr. RUIZ. Have you changed any organizational structure? Is there any accountability metrics that you have included in your department? Have you increased the staffing in certain areas?

What are you doing to pay better attention to your job?

Mr. PATTERSON. Over the past few years, we've increased staffing and diversion. We have a new head of diversion control coming in. He and I have sat down and spent time on this particular issue as to other proactive ways we can look at it. I met with the U.S. attorney and states' attorneys to talk about these issues of working criminal cases or civil cases and how they impact our administrative issues for the criminal prosecutions.

They want to continue to gather evidence. If we have some harm that's being done and we can stop it, then we have to start to balance this out in a better and more proactive way. So there are dozens of things we are doing differently. This is not just a one issue fix.

Mr. RUIZ. Well, those are the things that I am particularly concerned and want to know more about because that's what's going to create the change is by making changes in your department in

order to use your data more efficiently and also to start paying attention whether it's through computers or personnel, because a computer can flag all it wants to flag but if a human is not taking those warnings and having action based on what your computer is flagging then it's just going to be a flashing flagging computer.

Mr. PATTERSON. Understood.

Mr. HARPER. Gentleman yields back.

The chair will now recognize the gentleman from Texas, Dr. Burgess, for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

And Mr. Patterson, I want to acknowledge that I asked for you to come to my office and you complied with that, and for that I am deeply appreciative with the information that you shared with me.

Obviously, this is something about which many of us feel very, very strongly. Clearly, we want to get some answers.

The subcommittee has interest in knowing about differences between voluntary suspension orders and immediate suspension orders. I will stipulate that both exist and that we could argue which is a more propitious path to follow. Are there other tools you have in your tool box in addition to immediate suspension order and the voluntary suspension order?

Mr. PATTERSON. Sure. There's a whole range. There's letters of admonition, orders to show cause. There's a host of administrative tools that we have that we can use in this space, and depending on—and to go back to an issue that Mr. Griffith had brought up, depending on, quite frankly, whether it's a doctor or a pharmacy may be a very different reaction than what we would do or evidence we would gather against maybe a distributor.

Mr. BURGESS. Let me ask you a question, because I can't take credit for it—my staff did this—but went to your Diversion Control Division and pulled down a document that's called "Cases Against Doctors" and this is produced by the U.S. Department of Justice and Drug Enforcement Administration.

I presume it's your product. It's about a hundred pages long. It goes back, basically, to 2002 through October 12th of 2017. It's a hundred pages or about three cases per page, so that's 300 cases against doctors in the last 15 years. Does that sound about right?

Mr. PATTERSON. Sir, I don't know. That's a complete list of all doctors that cases have been worked or is it a guide to help people and where people have gotten into trouble?

Mr. BURGESS. Well, I will tell you what concerns me as I look through this is that most of the dates are pre-2009. So I guess my question would be where is the data from 2010 onward and perhaps that's something we can follow up with together because I do share the provider's perspective on this. We want to be able to provide pain relief when it's required of us and it's appropriate.

At the same time, we obviously do not want to be jeopardizing public safety and the integrity of society the way the opiate crisis is endangering us currently. But I think this could be very important information. You referenced, at the start of your testimony, that over-prescribing is perhaps one of the number-one problems. Well, if that's the case, then it's this sort of information that is, I think, going to be very helpful to us as policy makers how do we develop the correct policy.

Let me just ask you, did I understand this figure correctly? You referenced $309 million in fines at the DEA level. Is that correct?

Mr. PATTERSON. In civil fines, $390 million or $309 million.

Mr. BURGESS. So OK, that ballpark—$300 to $400 million.

We'd appropriated a billion dollars in cures for treatment of this problem. We are looking at another $6 billion in the appropriations bills that are coming through right now. So you see the disparity there.

Someone, whether it be suppliers, prescribers is causing a problem to exist. You're finding them but it's only minuscule compared with the amount that it's actually costing society in trying to save people, salvage people, get people back to productivity.

That doesn't even address the fact that, again, people are taken out of being productive citizens when they enter into this type of behavior. Is that correct?

Mr. PATTERSON. I agree, sir. And may I just add? So these fines come as, again, and some of the members have already mentioned this balance, right, of ensuring pain medicines for people.

So I think the fines generally come with, quite frankly, the heavier piece of that is the memoranda of understanding or memoranda of agreement of how they'll behave, moving forward.

Mr. BURGESS. Correct. I get that.

Let me just ask you this, because I think it was Mr. Barton referenced 80 people a day who were dying—115 was the total number but 80 per day are dying because of what you described as over-prescribing. And then we've got these lists that in my observation are not up to date. Do we know how many people were dying a day from over-prescribing in 2007, 2008, 2009 in that timeframe? Do you have a figure?

Mr. PATTERSON. I don't have it here. I would be happy to get that stat for you. It still was an alarming number, even back in that time period, sir.

Mr. BURGESS. And then that begs the question. And again, I appreciate the effort that you're putting into it now. But it's been right there in front of us for well over a decade, decade and a half and, clearly, it requires all hands on deck in our approach. And, again, I appreciate your being very forthcoming with my office and I appreciate that.

Mr. Chairman, I will yield back.

Mr. HARPER. Gentleman yields back.

The chair will now recognize the gentlewoman from New York, Ms. Clarke, for 5 minutes.

Ms. CLARKE. I thank you, Mr. Chairman, and I thank our ranking member.

Mr. Patterson, it's clear in many cases certain drug distributors supply very large volumes of opioids to some pharmacies in West Virginia. But we've also seen from DEA's data that many of these pharmacies were buying from multiple distributors. For example, in 2009, the West Virginia pharmacy, Hurley Drug, received over 2 million opioid pills from six different distributors, including over 300,000 from one distributor, over 600,000 from a second distributor, and over 900,000 from a third.

So it's bad enough if one distributor over-supplies a pharmacy. But when you look at the total shipments that Hurley Drug re-

ceived from all distributors, it was about 2 million pills, which is over seven times what a similar pharmacy will be expected to receive, according to DEA's own data.

So DEA is the only entity that can see the volumes that multiple distributors are simultaneously sending to a single pharmacy. Is that correct?

Mr. PATTERSON. From the distributor level, yes, ma'am.

Ms. CLARKE. So, Mr. Patterson, was DEA performing analytics a decade ago to identify these kinds of patterns at individual pharmacies?

Mr. PATTERSON. Again, ma'am, in a reactive manner at that time.

Ms. CLARKE. OK. So I would like to look at DEA's data on another pharmacy in West Virginia—Sav-Rite Pharmacy in the small town of Kermit received hydrocodone from five different distributors in 2008. A few distributors provided relatively normal amounts that don't seem to raise alarms. However, one distributor shipped 1.2 million pills and another shipped nearly 2 million. All told this pharmacy got nearly 4 million pills that year, which is nearly 15 times what a similar pharmacy would be expected to receive, according to DEA's data.

Mr. Patterson, if you rely on distributors to report suspicious orders from pharmacies, how do you flag pharmacies trying to stay under the radar by buying from multiple distributors?

Mr. PATTERSON. So, ma'am, this is where, again, the data that we use today—not the data, I shouldn't say the data—but how we use the data is very different today, and this is also where the critical nature comes into us working with the states.

Those same pharmacies, that PMP data which show that amount of distribution from those pharmacies, so we have that distributor in and then the pharmacy out, depending on the PMP program.

So the key is for us to work together on that and, again, I can say repeatedly in 2008, 2009, and 2010 we did not use this data in the way that we are now using it and I think that's the key.

I get that we have this issue from a decade ago, that we have to resolve in terms of how we used it. And, again, where we fell short in that we'll take responsibility for it. I think the system is much more robust and used in a much different way in——

Ms. CLARKE. So can you give us a little bit more insight into how you're proactively analyzing the data to ensure that pharmacies are not being over supplied by multiple distributors? That has not come across clearly to us this morning. How are you actually doing that disruption?

Mr. PATTERSON. Again, so as we talked about in the opening, we are proactively looking at data not just across DEA and that ARCOS database that we've talked about but HHS, PMP programs where we are sharing that information and looking to proactively target outliers.

Ms. CLARKE. So what happens once you're flagged in this regard?

Mr. PATTERSON. So we——

Ms. CLARKE. What exactly happens?

Mr. PATTERSON. We send that information out to the field for investigators—those TDS groups or diversion groups, depending on how they're being used to go out and work those cases to find out

is it a legitimate amount of prescriptions that are going there or is there illegitimate diversion occurring in those areas.

Ms. CLARKE. And has that worked thus far? Because, you said this was over a decade ago. I am assuming that you have already begun sort of this new protocol. What are your findings?

Mr. PATTERSON. Yes, ma'am. So the interesting thing is of those 400 packages that went out, a good majority of what we saw in that data and the outliers and what they identified were ongoing cases that we already had, which shows that that data set works to develop and target those areas where we have problems.

To the extent that we didn't have cases on those other ones and they were warranted, we've opened cases on those facilities or doctors or distributors to take a look at that behavior.

Ms. CLARKE. Mr. Patterson, I just want to share with you that this is an ongoing crisis. Once we are able to disrupt this supply chain, we know that these supply chains become supplanted by more nefarious actors.

And so, I really want to impress upon you and your agency to be as forward leaning in this regard as possible because once those pills are cut off, we know that that's when the illicit trade picks up in velocity.

Mr. PATTERSON. Yes, ma'am. And as we've talked about, again, in the opening, I think that shift has already occurred.

Ms. CLARKE. Thank you. I yield back, Mr. Chairman.

Mr. HARPER. Gentlewoman yields back. The chair will now recognize the gentleman from New York, Mr. Collins, for 5 minutes.

Mr. COLLINS. Thank you, Mr. Chairman, and thank you, Mr. Patterson for being here.

I think you can tell and your get out of jail free card today, you have been in this particular job 5 months. I would hope 5 months from now you would not be giving many of the same answers.

Following up on what Mr. Ruiz said, I think we are just all frustrated. There seems to be the bureaucracy mindset in the DEA today, much like we've seen in the VA. And we are finally seeing heads rolling in the VA. Not as fast as we want. I am just curious, because there's no doubt there was an abject failure of the DEA, going back the last 10 years.

Have a lot of heads been chopped off? Have you got a new team in place?

Mr. PATTERSON. Sir, so as I said, we have a new head of Diversion Control. I think the last two people that have done that job have done and both successful in turning around that program.

Mr. COLLINS. Well, not to interrupt but to interrupt, I think the right people can turn this around in 48 hours. I am a turn around guy. That's what I've spent my whole life doing.

You bring a new team in and people get called in the office every day and they walk out saying, somebody just hit me up the side of the head with a baseball bat. I am either going to get my act together or I am going to get out of Dodge.

This isn't a time to be polite or nice or let's do better tomorrow. No, this is an abject failure, and if I am sitting in that seat and McKesson processed 1.6 million orders and only 16 were deemed suspicious, that's absurd. I don't know what kind of computers you have but that's absurd. It means no one was watching.

And you can say well, that was being done in the district level. But it's indefensible. When we look in West Virginia and two suspicious orders so, let's maybe jump ahead, and in 2008, Cardinal Health was fined $34 million for not reporting suspicious orders.

All right. So let's go forward 8 years later. They're still not doing it. Two guesses. First—second one doesn't count. How much do you think you fined them 8 years later for the same problem? Thirty-four million dollars, the same amount. In most places the second offense—all right, first offense $34 million, eight years later the same problem, the same fine? Should have been tenfold. Should have been $340 million dollars.

What did your agency do? And this was a year and a half ago. You guys don't get it and if you're not—this committee agrees on a lot. I don't think we've ever agreed across the board on an issue as much as we are agreeing your agency needs to be turned upside down, not just a little shakeup here and there but turned upside down. It starts with you. If you can't do it, you ought to get out.

So when I look at some of the things—so we have distributors. We have pharmacies. We have doctors. Well, I happen to live next door—literally, next door to one of the doctors, Dr. Gosy, in Clarence, New York, and I saw his six sports cars parked out there with all new—his name in the community was Dr. Pain. And this wasn't something new.

When I look back, it took the DEA a good 7 years to come after my next door neighbor. By the way, he doesn't live there anymore. But he had set up a script line in 2012 where people could call in and fill scripts with PAs under basically no supervision.

So at what point—how could you allow a single physician—my next door neighbor, literally, in Clarence, New York—to write more prescriptions for opioids, millions of them, than any other doctor or in fact any other hospital in the State of New York?

There's 20 million people in New York. My particular town of Clarence has about 50,000 people, and one doctor in the town of Clarence was writing more prescriptions than any doctor in the State of 20 million people or any hospital including New York City.

Took you guys 5 years to figure out there might be something suspicious? Would you agree that's unacceptable?

Mr. PATTERSON. Sir, so I wouldn't have any data on a particular prescriber. DEA doesn't hold that set of data.

Mr. COLLINS. Well, he's now been indicted. They've seized his cars. They've seized his bank accounts.

Mr. PATTERSON. So at some point, whether that was a DEA case or a state local case, I don't know what it was that investigated him and——

Mr. COLLINS. It was a federal case.

Mr. PATTERSON. OK. So at some point we learned of that and then there was——

Mr. COLLINS. Yes, but what's going on with your computer systems and other things? It takes you 4 or 5 years. I know how computers work, pretty much. I don't know how old yours are. Maybe they're XT tabletops. I am not sure.

But this kind of data should be instantaneously available.

Mr. PATTERSON. And, sir, I go back to the states control prescription monitoring program, not DEA. We control into a pharmacy. The doctor——

Mr. COLLINS. Well, maybe you should be kicking some butt going down the chain. I mean, if I was sitting in your job and you're on the hot seat right now, and you're telling me now, I mean, placing the blame on the states, that doesn't cut it in our world here. We are not looking to place blame. We are looking for solutions.

My time has expired. We look forward to you coming back in another 4 or 5 months and having a different set of answers.

Thank you, sir.

Mr. HARPER. Gentleman yields back.

The chair will now recognize the gentleman from New York, Mr. Tonko, for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair.

I want to find out if DEA uses data gathered through its ARCOS system to game disability into how many opioid pill distributors send to a town or region as a whole, even if the distributions are spread out over multiple pharmacies.

Administrator Patterson, one town examined by the committee was Williamson, West Virginia, population 3,000. Our committee's investigation focused on two pharmacies in Williamson. The first is Tug Valley Pharmacy.

Mr. Chair, could I ask that we please show minority exhibit three on the screen?

OK. We have here the Tug Valley Pharmacy. According to DEA's ARCOS data, between 2006 and 2016, Tug Valley Pharmacy received over 10 million doses of opioids from 13 different distributors. This includes over 3 million pills just in 2009. So Administrator Patterson, this is an unbelievable quantity of opioids for a pharmacy this size in a town of 3,000. Does DEA believe the amount of opioids this pharmacy received was excessive?

Mr. PATTERSON. In 2009 I would say so, sir.

Mr. TONKO. And, again, Mr. Chair, if we could please put minority exhibit four up on the screen. This is the second pharmacy in Williamson—Hurley Drug—that we see on the screen here.

ARCOS data show that Hurley received over 10.5 million doses of opioids from 11 different distributors between 2006 and 2016. This includes over 2 million doses in both 2008 and in 2009. Mr. Patterson, again, this strikes me as an excessive amount of opioids for a pharmacy in a town of 3,000 to receive.

Do you agree that this is unreasonable?

Mr. PATTERSON. I would agree.

Mr. TONKO. I've mentioned that both of these pharmacies are located in Williamson and, incidentally, both of them are still in operation today.

I want to show you where they are located. So if we could please post minority exhibit five on the screen, and combined distributor shipped over 20.8 million doses of opioids to these two pharmacies, which you can see on our screen, are located only blocks apart and they did that 20.8 million doses of opioids between 2006 and 2016.

Mr. Patterson, between 2006 and 2016, what kind of ARCOS data analyses did DEA do to alert it when distributors shipped an

unwarranted amount of opioids into a town or region so that it could stop these excessive distributions?

Mr. PATTERSON. Again, sir, I would have to go back and look at that specific example and look at the data set in terms of where those periods of time were.

As I already testified previously, we use the data in a very different way today than we did then. But I would want to go back and specifically look at the time frame and what was going on and I can get back to you on that.

Mr. TONKO. If the data were used today, as you use it today would it have avoided something like this?

Mr. PATTERSON. I would hope so.

Mr. TONKO. Well, can we have a little more of an answer? I am hoping is good, but——

Mr. PATTERSON. I would like to—part of the important issue that we are talking about today is to go back and look at these specific examples.

Like I said, I have seen examples where on ARCOS data we actually can't see some of these anomalies. So I think, in taking these examples back and looking at them and we are using a time frame of 2006 to 2016, I can't tell you for the last couple of years what that ARCOS data has been, as I sit here.

Traditionally, what we've seen is very high levels of distribution into those places between 2008 to 2010 or 2011 when we started to look at this data in different ways.

Still not nearly as proactively as we do today. But that's why I would like to take this example back and look and get back to you on essentially what's happened with that.

Mr. TONKO. Thank you.

I have been dealing with this issue a great deal in my district and when I hear of opioids being the gateway to the illness of addiction, it's very disturbing, and the heartache and the pain and, unfortunately, the death associated with that illness is a crisis and we need to do something very valuable here and I would implore that the folks at DEA be smarter in their approach.

And with that, I yield back, Mr. Chair.

Mr. HARPER. Gentleman yields back.

The chair now recognizes the gentleman from Pennsylvania, Mr. Costello, for 5 minutes.

Mr. COSTELLO. Thank you, Mr. Chairman.

Are you aware that the DEA's chief ALJ authored quarterly reports describing DEA's declining use of ISOs and noted in June 2014, "an alarming low rate of agency diversion enforcement activity" on a national level?

Mr. PATTERSON. I have read those, yes.

Mr. COSTELLO. For the last several years, the chief ALJ has reported declining number of ISOs to the DEA administrator on a quarterly basis. This issue had also been raised in the committee's investigation.

Why has the number of DEA ISOs declined significantly over the past few years?

Mr. PATTERSON. I think there's two things when you look at those statistics.

I think that, although warranted, the statistics were very high in 2010 and 2011 because of the issue that we were dealing with in Florida and how those ISOs were being used. I think during this latter part we have gotten to a point of in trying to expedite the surrender of registrations we have much more gone into a posture of trying to get voluntary or surrender for cause orders.

Mr. COSTELLO. Is there still a need today, as there was in 2011, for the DEA enforcement tool of ISOs?

Mr. PATTERSON. Yes.

Mr. COSTELLO. A 2013 report by the chief ALJ stated the DEA's chief counsel had "instituted a new vetting QA initiative" that could be slowing the progress of diversion cases.

What was this initiative?

Mr. PATTERSON. I don't know if it was initiative or if it was guidance. I think the——

Mr. COSTELLO. What was the guidance? Yes.

Mr. PATTERSON. I think the issue at play here was directed towards distributors, not necessarily directed at doctors and pharmacies.

Mr. COSTELLO. Have you provided that guidance in full to this committee?

Mr. PATTERSON. We have not.

Mr. COSTELLO. Will you?

Mr. PATTERSON. That's a conversation that we've had with Mr. Walden and we'll continue to work forward on that——

Mr. COSTELLO. When a state revokes the medical license of a doctor, that doctor is no longer eligible to have a DEA registration associated with that medical license, correct?

Mr. PATTERSON. That's correct.

Mr. COSTELLO. When the doctor no longer has state authority to prescribe does the DEA have to conduct any further investigation or can DEA execute revocation of DEA registration by just obtaining the certificate of the medical license revocation?

Mr. PATTERSON. We can do an order to show cause.

Mr. COSTELLO. No investigation is needed?

Mr. PATTERSON. That's correct, because they've lost state authority.

Mr. COSTELLO. After a state revocation of the doctor's medical license, how quickly is DEA notified about the revocation and how long does it take for DEA to revoke the doctor's DEA registration?

Mr. PATTERSON. That's where we need to be working with the state medical boards to learn of that information. Our field division offices are responsible for that.

Mr. COSTELLO. Are the vast majority of DEA enforcement actions in diversion litigation cases comprised of these no state authority cases that do not involve DEA investigation?

Mr. PATTERSON. In terms of the orders to show cause?

Mr. COSTELLO. That's correct.

Mr. PATTERSON. That's correct.

Mr. COSTELLO. Yes?

Mr. PATTERSON. Yes.

Mr. COSTELLO. Is it estimated to be about 80 percent of their actions?

Mr. PATTERSON. I would believe that's probably a fair number.

Mr. COSTELLO. Mr. Chair, I would like to yield the balance of my time to you, Mr. Griffith.

Mr. GRIFFITH. Thank you very much.

When I was asking you questions earlier, we talked about the ISOs and the apparent requirement—I know you didn't do it but the apparent requirement for a medical expert in advance of issuing an ISO and the fact that that would take a number of weeks and you said 45 to 90 days. I went through all the different steps that might actually lead to that.

So you agree that it's the DEA's mission to protect the public safety and we agree that there's a tremendous amount of delay and part of that delay in no small measure is the requirement that before you get that administrative tool of the ISO you have to get a medical expert.

So can you, as acting administrator, agree with me today that you would be willing to reexamine the medical expert requirement?

Mr. PATTERSON. Absolutely.

Mr. GRIFFITH. And I appreciate that.

Mr. PATTERSON. And again, we are using the word requirement. I think these documents are in reference to distributors and not doctors and pharmacies. But I would be happy to go back and look into that further.

Mr. GRIFFITH. Yes, it was actually reference to doctors and pharmacies. But that's OK. As long as we are working it out, that's where we want to go. We want to make things better.

And one of the reasons that I get so passionate about this is you saw Mr. Tonko's minority slide of Hurley Drug earlier. Well, Hurley, Virginia, is 33 miles from Williamson, West Virginia, where that drug store is located. And anybody with any sense knows that a big bunch of those pills were coming into my district.

Likewise, I had some additional questions that dealt with the fact that we have problems with red flags being raised that apparently takes a while to be picked up on.

So we had a doctor in Giles County who was sending his patients over to West Virginia to get drugs. We have a situation in Martinsville where they have, according to the CDC, they prescribe more opioid pain killers than anywhere else in the U.S. per capita and where another doctor was prescribing opioids for patients in North Carolina.

So I look forward to working with you to solve these problems. But these are real world problems, real world people, and real word deaths.

Mr. PATTERSON. I agree with you.

Mr. GRIFFITH. I yield back. I now recognize Congresswoman Walters for five minutes.

Mrs. WALTERS. Thank you, Mr. Chairman.

Mr. Patterson, it's my understanding that the DEA often uses tips and information it receives from state and local law enforcement to develop cases against entities or individuals suspected of engaging in or facilitating illicit drug diversion. Is that correct?

Mr. PATTERSON. Correct.

Mrs. WALTERS. According to the DEA, the Automated Reports and Consolidated Ordering System, or ARCOS, provides the agency with retail level data regarding controlled substance transactions.

Does this mean, for example, ARCOS can show many doses of hydrocodone or oxycodone an individual pharmacy received in a given year?

Mr. PATTERSON. Yes.

Mrs. WALTERS. In fact, as part of its investigation, the Committee has obtained and analyzed ARCOS data for parts of West Virginia to great effect. So we recognize how important a tool it can be.

In February of this year, DEA announced that it was adding a feature to ARCOS that will allow manufacturers and distributors to view the number of companies that have sold a particular controlled substance to a prospective customer in the preceding 6 months.

Mr. Paterson, does this policy enable companies to see the amount of controlled substances its current customers are receiving from other suppliers?

Mr. PATTERSON. Yes. Part of the suspicious orders is them knowing their customers to know when to file these concerns.

Mrs. WALTERS. Does the newly added features in ARCOS provide state and local law enforcement with greater access to the system's retail level data?

Mr. PATTERSON. I would have to find out if it provides at the state level. When we work investigations with the state level—the state and local level, obviously, we can share that data as part of an investigation.

This is also part of the issue that we are dealing with the states' attorneys general on as to how to share these data sets to be more proactive.

Mrs. WALTERS. OK. According to a letter the DEA sent to the committee in November of last year, DEA will share ARCOS data with law enforcement on a need to know basis and when they are operating in coordination with the DEA for investigative purposes.

So is it fair to say that the state and local law enforcement entities do not have access to DEA ARCOS data on a real-time basis?

Mr. PATTERSON. If we are working an investigation we'll share that data in real time with them.

Mrs. WALTERS. OK. Is DEA developing any proposals that will enhance state and local law enforcement's ability to access and utilize ARCOS data?

Mr. PATTERSON. Again, we are working jointly with them and this also goes back to the effort with our states attorneys general.

Mrs. WALTERS. OK. In order to effectively combat the opioid epidemic we need an all hands on deck approach. The DEA has data that could assist state and local law enforcement to identify potential sources of illicit drugs in their communities and I think the agency should be exploring every avenue to provide this data to law enforcement as quickly as possible.

It seems to me that providing state and local police with access to ARCOS data would be beneficial to the DEA as well, effectively providing the agency with additional eyes and ears on the ground, likely resulting in additional leads being produced to the agency.

Mr. Patterson, will you commit to examine ways to improve state and local law enforcement's access to ARCOS data so that bad ac-

tors might be able to be identified with greater frequency and effectiveness?

Mr. PATTERSON. Yes, ma'am.

Mrs. WALTERS. Thank you, and I yield back the balance of my time.

Mr. HARPER. I now recognize the gentlelady from Indiana, Mrs. Brooks.

Mrs. BROOKS. Thank you, Mr. Chairman.

Hello, Mr. Patterson. Since 2011, the number of immediate suspension orders issued by the DEA, as you have even noted, declined significantly from a high of 65 in 2011 down to a low of 6 in 2017. So I want to talk about that a little bit.

Are there instances in which the DEA pursues an immediate suspension order, the ISO, in parallel with related potential criminal investigation?

Mr. PATTERSON. So, ma'am, since October, so the administrator's position signs the ISOs when they're issued. What I have traditionally seen is because of the process of where a criminal case is being investigated there's been a delay in the ISO process as they're gathering evidence.

One of the concerns I have, and it goes back to, again, what Mr. Griffith said, is that cuts against the very argument that we have an imminent problem that we are trying to deal with.

So, again, my conversations that I've had with both U.S. and states attorneys are is that we have to act much faster in these cases in terms of if we have ongoing harm and we have the ability to stop that harm, even at the peril of a criminal case, then that's what we should be doing.

Mrs. BROOKS. And let's be clear. The U.S. doesn't do the immediate suspension orders. Those are done by the DEA.

Mr. PATTERSON. The DEA. It's an administrative action.

Mrs. BROOKS. And are you saying that the U.S. attorneys were asking—as a former U.S. attorney are you saying the U.S. attorneys were asking or telling DEA not to issue ISOs?

Mr. PATTERSON. In trying to gather evidence in their criminal case.

Mrs. BROOKS. I understand, but that can take months if not years sometimes in criminal cases. Do you believe that's what happened prior to you coming in October of 2017—that delays happened?

Mr. PATTERSON. I think that's been an ongoing theme of what some of these delays are caused by.

Mrs. BROOKS. And why would the DEA delay that type of administrative action in pursuit of a criminal investigation? Why?

Mr. PATTERSON. Because people believe that the criminal investigation is an important endeavor towards whether it's that doctor or that pharmacy.

Mrs. BROOKS. Well, it is very important, no doubt, because that person is, obviously, distributing—or the belief is distributing illicitly. But why would an immediate suspension—is that so that undercover operations can happen with the physician?

Mr. PATTERSON. Yes, ma'am.

Mrs. BROOKS. And the prescriber?

Mr. PATTERSON. The gathering of evidence.

Mrs. BROOKS. And what is the new guidance, and I appreciate the importance of gathering of evidence, but what is the new guidance relative to ISOs and criminal investigations that you are contemplating or that are in place now, and is that guidance in writing?

Mr. PATTERSON. So it is not formalized. This is conversations that I've been having with the AGAC, the, you know, advisory——

Mrs. BROOKS. I served on the attorney general's advisory counsel.

Mr. PATTERSON. And to the extent that I've been meeting with states' attorneys to try and talk to them about the same issues.

So I think we have to, again, a lot of this is striking a balance. I, frankly, feel that a lot of these cases can be worked backward on the criminal aspect.

I understand that their desire in a lot of these cases is to be able to get contemporaneous evidence, use undercover, right, as opposed to having to use witnesses that have come in that maybe not have the best of backgrounds.

So I understand that balance. The concern I have, like I said, if we are using an ISO, it feels awful weird to be signing that ISO a year after we learned of that problem.

Mrs. BROOKS. And I noticed in the document that Dr. Burgess had there was some of that, that the ISO was a year after the arrest even.

Mr. PATTERSON. Correct.

Mrs. BROOKS. Although at the time of the arrest, typically that individual would be under their medical licensing procedures as well. Is that correct?

Mr. PATTERSON. Correct.

Mrs. BROOKS. But wouldn't it make more sense to in many ways implement an ISO in the middle of the criminal investigation because those can take months if not years, and in the meantime we've got all of these people dying.

Mr. PATTERSON. I couldn't agree with you more and, quite frankly, even in the absence of the ISO, my concern is is that why aren't we trying to get a voluntary surrender as quickly as we have. And we have a lot of offices that do that in a very expeditious manner.

Mrs. BROOKS. And will your proposed guidelines impose a cap on the length of time it can be delayed? Is that the kind of discussion you're having. You're looking at, like, 30 days? Forty-five days?

Mr. PATTERSON. I think, striking that balance, we have to figure out where the days are. There will probably always be that exception that comes up and I think as long as people are willing to—whether it's a U.S. attorney or a states' attorney that is willing to put in writing why we need to delay and we can evaluate that, I think that's something.

The process itself I think we have to work through. Like I said, we have new head of diversion control. This is an issue that has been bothering me greatly. Since October I've seen these and I've signed them and I have generally the same question every time, which is why are they taking so long.

Mrs. BROOKS. And for the record, I would just like to acknowledge when I became a U.S. attorney in 2001 one of the very first huge cases we did was against a doctor, Dr. Randolph Lievertz, for over-prescription of oxycodone, and DEA in 2001, 2002 and beyond

said prescription drugs were going to be the next crisis in this country. Didn't start in 2010, didn't start in 2011. It was back in 2001, 2002, and we had a huge focus on it during that period of time and it's just really been very devastating, seeing that we fell off of that commitment it feels like in the last several years. I yield back.

Mr. HARPER. Gentlewoman yields back.

The chair will now recognize the chairman of the Full Committee for some follow-up questions. Mr. Walden.

Mr. WALDEN. Thank you. I appreciate the indulgence of the committee.

You raise an interesting issue about the U.S. attorneys weighing in here and saying to the DEA, stop—don't do your ISO—we want to proceed with the criminal investigation.

One question—do they have the authority to override your ISO authority? That would be one. And then I want to know the who, what, when, where, why.

Who are the U.S. attorneys that interceded on which cases in what areas and told the DEA suspend, and do they have that authority? Because, to Mrs. Brooks' point, people continue to die during this period, and I want to know this—this is part of our public policy debate here is does a U.S. attorney's office somewhere have the authority to tell you don't do the ISO, don't stop the death because we got to investigate and go criminal, which will have a bigger penalty, which I respect.

But is it one agent somewhere? One U.S. attorney in one state, is that why West Virginia went off the rails? And so I would like you to get back to the committee with answers to those questions.

Mr. PATTERSON. I would be happy to do so, sir. And look, what I can assure this committee is I think this is a topic that we have had some robust discussion on lately as we've gone through these and I will also assure you that the direction of this administration is to stop the harm as quickly as possible.

Mr. WALDEN. But I think you should be able to answer the one question. Do the U.S. attorneys have the authority to overrule your agency's decision making? I know you weren't there running it at the time.

Mr. PATTERSON. I would believe that we could issue the ISO even against the wishes of a U.S. attorney or a state's attorney. It probably doesn't help relationships to take those kinds of unilateral actions.

But, that said, I think part of this is the education of us holding up these things, why they look at either criminal or civil actions.

Mr. WALDEN. I would go back to Mr. Griffith's analogy. If you have got a drunk driver driving down the road, you don't wait until they have the fatal accident to pull them over and stop them.

Mr. PATTERSON. I couldn't agree with you more.

Mr. WALDEN. You can prosecute them along the way and I would think you could make the case, going backwards, because the prescriptions have been written. The pills have been sent out.

These two pharmacies we raised with you months ago are, my understanding, still operating in West Virginia. Are they not?

Mr. PATTERSON. I don't know. Those are the ones I have to go——

Mr. WALDEN. They're not operating. All right.

Well, if you can get back to us on the who, what, when, where, why on these U.S. attorneys that would be good.

Thank you.

Mr. HARPER. Gentleman yields back.

The chair will now recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Mr. Patterson.

Mr. Patterson, I suspect you know that currently I am the only pharmacist serving in Congress, and Mrs. Brooks makes a good point. This is not something that started in 2010 or 2011. It was going on in 2001 and 2002. I was practicing back then. Now, granted, I haven't practiced in quite a while. It's probably been 4 or 5 years since I practiced. But I still know what's going on out there.

We've been kind of nibbling or you have been nibbling around the edges here. There have been great questions asked here but I want to follow up on the questions that Representative Collins asked about the beginning of where this problem starts and that's the doctors who are writing these prescriptions.

Now, I am not naive enough to believe that there aren't pharmacies out there that are in collusion with doctors or filling fraudulent prescriptions. But I want to talk about the doctors who are writing these prescriptions who are obviously out of control and why it's taken DEA so long to get them in control or under control.

I will just give you an example. I served in the Georgia State legislature for 10 years. I sponsored the legislation that created the prescription drug monitoring program back in 2009. I was jumping up and down then, saying this is a problem, we've got to get it under control, and it was falling on deaf ears. There are doctors right now in our community that our pharmacists won't fill prescriptions for. They just say no, that doctor's out of control, I don't fill for that doctor.

I was working one President's Day. We were out during our session. On President's Day we are always out. I had someone come into my pharmacy, a young lady who had the holy trinity of drug abuse—180, oxycodone, Xanax, and Soma, three prescriptions there. I looked at them. She gave me her driver's license from Florida. I said, I am not filling these prescriptions. She drove off in a car with Kentucky driver's license plates.

Now, I am not going to fill those prescriptions unless I have a legitimate prescription, OK, and I didn't want to fill that. But you're putting me in the position where I've got to judge whether that patient is legitimate or not. I am not trained in law enforcement, but as a pharmacist. But I want to know why, when there are doctors out there who are writing these prescriptions why can't you get them quicker?

Mr. Collins is right. You ought to be able to turn that around in 48 hours. The first time I get three prescriptions for 180 of the oxycodone, Xanax, and Soma I know that doctor is out of control. Something's wrong there.

I had a doctor who we didn't fill for, Dr. B. I went home about a year ago and some of the pharmacists were telling me, oh, they finally busted Dr. B. I thought, wow, why did it take them 5 years to bust him? We never filled his prescriptions for 5 years but he

kept on practicing. Well, they didn't exactly bust him. They got him for Medicare fraud. Didn't even get him for writing those prescriptions—never did.

Another example here, Dr. D.N. He got literally thousands of people addicted to these medications, and then he goes before the Composite Medical Board and gets slapped on the wrist, and they come back and they make him practice under the supervision of another doctor. That's his penalty. Now he lives on the waterfront, a beautiful home, beautiful cars, and yet thousands of people have been addicted because of these prescriptions that he has written.

We wouldn't fill his prescriptions. He's a rogue doctor. We are not filling those. Tell me why it takes you so long to get to the alpha, to the beginning, to the doctors who are writing these prescriptions who are out of control. Explain that to me, because I don't understand it.

All you have to do is go into a community and say, what doctors do you not fill for, and the pharmacists will tell you, we don't fill for this doctor and we don't fill for that doctor.

Mr. PATTERSON. Well, and that's, quite frankly, what we have to rely on. Look, the one thing I am not going to do in this space is shift blame anyplace. This is a collective——

Mr. CARTER. Well, it appears to me that that's what you're doing because Mr. Collins is right. You can turn this around in 48 hours. Just get those doctors out of there.

Mr. PATTERSON. But in the cases of these doctors, look, when we do our reviews we ask information, try and solicit people to essentially, in the registrant community to come in and talk about the registrants they have problems with.

If that doesn't happen, then our next course is someone that's been arrested that says, this is what's happening in a criminal case.

Mr. CARTER. But you can understand our frustration. When we don't fill prescriptions for that doctor but for years—literally, 4 or 5 years, they continue to practice.

Mr. PATTERSON. I understand, and this is where PMP data becomes absolutely critical and it's because that isn't——

Mr. CARTER. But what can we do to help you to be able to get these doctors under control? What can we do? Tell me what we can do in Congress.

Mr. PATTERSON. The PMP data is really what it boils down to.

Mr. CARTER. We've had the PDMP since 2009 in Georgia.

Mr. PATTERSON. But, sir, DEA doesn't have access to that data. It depends on the state.

Mr. CARTER. Can you shut the doctor down? Can DEA shut the doctor down or is that up to the Composite Medical Boards of the states?

Mr. PATTERSON. No, if we had someone that was showing us that a doctor was over-prescribing then——

Mr. CARTER. But when you get this information of pill dumping you know that that pharmacy is getting those prescriptions from somewhere. Then that ought to be an indication to you. We need to go to that community and we need to find out what's going on here. They're coming from somewhere.

Mr. PATTERSON. Understood.

Mr. CARTER. Thank you, Mr. Chairman.

Mr. HARPER. Gentleman yields back.

The chair will now recognize the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. MCKINLEY. Thank you, Mr. Chairman. As not a member of this committee, I appreciate you giving me the opportunity to raise some issues with that.

Again, Mr. Patterson, thank you for being here. Are you familiar with this book written by John Temple called "American Pain?"

Mr. PATTERSON. No, sir.

Mr. MCKINLEY. This is about the clinic down in south Florida that was the epicenter of the opioids. I really would suggest that you and everyone else that's paying attention to this read that book.

But anyway, because with all due respect for the way some of your testimony has gone on this about ARCOS, he was able to assemble all of this book about drug abuse without access to ARCOS. So for someone to say that we couldn't access it, we couldn't use it because it was manual, it was too much information, this man was able to put it together and be able to demonstrate tthis "American Pain" clinic down in south Florida prescribed two times the amount of medicine of all the doctors combined in the State of Ohio. He was able to put that together long hand, and he's not an agency with all the resources you have to be able to do that. He also was able to put together all of the pill mills in Florida combined. So nine times the amount of pain medicine that was issued by every state in the country. He did that long hand.

So with all due respect, I don't think you can hide behind the fact that you didn't have the resources to be able to do this because it was coming in manually.

If I could, I am curious about the production quotas with it because in the book he talks about how speed pills back in the 1970s were becoming a problem, and DEA stepped up and they cut the production by 90 percent and the problem went away.

And then in the 1980s we had a problem with Quaaludes—same thing. They cut the production and it went away. Now, fast forward to today or what we've been dealing with over the last 10 years or so, the opioids.

We continue to increase the production of opioids, continue to distribute those. Didn't we learn anything from the past experience, that we should be cutting back? And it wasn't until 2017 that we actually had our first reduction. But it's still nearly 50 percent more than we were 10 years ago in production of opioids.

How would you respond to that? Didn't we learn anything?

Mr. PATTERSON. No, I understand that, sir.

And look, the quota numbers are set, unfortunately, to ensure access to the patients and you can see the disturbing trend that happened with quotas. The industry said more and more people needed these prescriptions.

We worked aggressively in the last year and a half to try and work on the quota issue and pull this back. I give a lot of the credit to the states.

Mr. MCKINLEY. If I could recover my time, because I think that perhaps I know you're meaningful to do this, to correct it, but it

failed, because I am coming from that state that has 52 drug overdoses per 100,000 people. We are leading the Nation with this. Someone has to get to this.

So I am just curious, I know you have the ability to transfer resources and funds within DEA. So my question goes back to you—have you made any transfer back into West Virginia? Are you going to put more resources there in West Virginia as a result of your ability to do transfer?

Mr. PATTERSON. We have, and we are continuing to do so.

Mr. MCKINLEY. We just put in a year or so ago down, a tactical diversion squad in Clarksburg. I think that's the second one we have in West Virginia. Is that correct?

Mr. PATTERSON. That's correct.

Mr. MCKINLEY. Leading the Nation—is that sufficient? Do you think that you have diverted enough attention into West Virginia that you don't need to divert any more funds and resources into West Virginia?

Mr. PATTERSON. Sir, the creation of the Louisville division, which polled three states all struggling with this same problem: Tennessee, West Virginia, and——

Mr. MCKINLEY. I am sorry. I am just dealing with West Virginia. It's the epicenter. You know that and I know that——

Mr. PATTERSON. Sir, so we——

Mr. MCKINLEY [continuing]. It has been there for nearly 10 years. It's been the highest level and we've not seen the resources come in to West Virginia.

And now I appreciate very much that you put a tactical diversion squad, or your predecessor did, into Clarksburg. But I've got to think there is a lot more attention needs to go with it because if this man can do this by long hand, can put this information together, I think you all could do it. With your resources, you could do a far better job and save a lot of lives and turn some families around.

So I am asking you, please, to look at more diversion into West Virginia—some of the funds and resources that you can to help out in this situation.

Mr. PATTERSON. Again, sir, we've been working on that and we are continuing to put more resources into that particular division.

Mr. MCKINLEY. So what are the optics on this, in the 10 seconds I've got left? How am I going to be able to measure whether you're successful with what you're doing?

Because just last year in county we've already had a 50 percent increase in overdose drug—overdose deaths in West Virginia in my county. How are we going to measure this? Are we going to see a drop next year?

Mr. PATTERSON. Look, the concern we have had is that we've seen the shift into fentanyl and other illicit substances. The goal is to continue to drive down the prescription rates and the diversion of prescription pills, and we are going to have to work this licit market and, frankly, the place——

Mr. MCKINLEY. Again, what are the optics? Am I going to see a decline next year?

Mr. PATTERSON. I would hope we see declines across the board. I think some states are going to take longer than others, sir.

Mr. MCKINLEY. Thank you. Yield back.

Mr. HARPER. The gentleman yields back.

The chair will now recognize the vice chairman, Mr. Griffith, for follow-up questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. Appreciate it, and this question was from Mrs. Brooks, who, unfortunately, had to step out for a minute.

Do the Medicaid fraud control units run by the state AG's offices still exist in many states?

Mr. PATTERSON. I would have to find out, sir.

Mr. GRIFFITH. All right, because what she was indicating was was that these particular MFCUs who are going after Medicaid fraud often can also pick up over prescribing data and that that's a collaborative unit that you all ought to be looking at in the various states to figure out who the rogue doctors are and that would help you in that regard as well.

Mr. Patterson, moving on, can you explain to me how can you all maintain that voluntary registration surrender can be as effective a tool in protecting the public safety as an ISO if it takes years to get the voluntary surrender as in the case of the owner of the Sav-Rite No. 1 in Kermit, West Virginia?

Mr. PATTERSON. I would assume in that case and, again, I need to get the particular facts on it—the voluntary surrender probably came as part of the criminal case.

Mr. GRIFFITH. And so what you would do is you would reverse that order and have the voluntary surrender or an ISO happening early on?

Mr. PATTERSON. Absolutely, sir.

Again, I can't go back and necessarily understand why certain people did certain things——

Mr. GRIFFITH. But you can make sure, going forward, that we shorten the time?

Mr. PATTERSON. Absolutely, sir.

Mr. GRIFFITH. All right. In your written testimony, you mentioned prescription drug monitoring programs as a tool that can be used to combat prescription drug diversion.

How does the DEA currently utilize the PDMP data in its investigations?

Mr. PATTERSON. So this varies state to state because the concern is, again, is our access to this data and how we can access this data and that is a state by state decision. And so every state varies. This is one of the big conversations that we've had with the 48 states that are parts of these two coalitions.

Mr. GRIFFITH. All right. Let us know how we can help.

Your written testimony also mentioned that law enforcement access to PDMP data varies widely from state to state, as you have just told us. Can you tell me what the DEA is doing to address those concerns and to address any access barriers the agency currently faces with respect to the PDMPs?

Mr. PATTERSON. Again, working with all the states individually on these issues and to the extent that we can leverage the coalitions to help us in that.

Look, in a perfect world we have a federal PDMP process that we can take all this data and put together. I think in a less than

perfect world at a minimum the states all need to be able to share this data with each other.

Mr. GRIFFITH. And in your experience, are there areas—and you just have gone over some of it—but is there some other areas that we might be able to improve the PDMP process?

Mr. PATTERSON. I think that's the key piece.

Mr. GRIFFITH. All right.

I appreciate it, Mr. Chairman. I yield——

Mr. HARPER. The gentleman yields back.

Mr. Patterson, just to give you a little update, I am going to recognize Mr. Carter in just a minute for a follow-up question. Then Ms. DeGette and myself will have concluding questions and we'll be done shortly. So thank you for being here with us today.

The chair will now recognize Mr. Carter, the gentleman from Georgia.

Mr. CARTER. Thank you, Mr. Chairman. I will be very brief.

I just want to follow up, Mr. Patterson. You're correct, you can't do anything about what happened years ago. But you can do a lot about what's happening now. I want to give you a sincere caution here.

What's happening with the wholesalers when they are limiting the pharmacies from getting a certain amount of drugs whereas that has all the best of intentions—what it causes sometimes is for some of our patients not to be able to get the medications that they need and I just warn you to please be careful with that. There are patients out there, i.e., hospice patients, who truly need these medications.

We found ourselves running out and we couldn't order it from the wholesalers because we'd already used up our limit for that month. So that put these people in a very precarious position and it's not a good position.

It's a very bad feeling for a pharmacist to have to profile and have to go out and say, oh, this patient doesn't need pain medication. Who am I to say that the long-haired tattooed body-pierced person is not in pain? That's not fair.

We've got to make sure that we get this under control and I still maintain that starting with the physicians and tell me what I can do to help you, to give you the tools that you need so that you can react quicker and get them under control when they get out of control.

That's all I am asking you to do is tell me what you need because I promise you I will do my best to get you those resources so that you can get these rogue physicians—and they're not all of them but some of them—a good amount of them are out of control and they get out of control quickly and it gets out of control very, very quickly.

Thank you, Mr. Patterson.

Mr. PATTERSON. Understood.

Mr. HARPER. The gentleman yields back.

The chair will now recognize the ranking member, Ms. DeGette, for concluding questions.

Ms. DEGETTE. Thanks, Mr. Chairman, and I want to echo, this is a rough topic, Mr. Patterson, and we know you haven't been

there that long. But we also know that it's urgent that we get this right. It's just urgent for the safety of our constituents.

There's just a couple of areas I wanted to clarify. Mr. Collins was asking you some questions about these—the settlement that the DOJ has had with some of the distributors because of issues—reporting suspicious orders and it's really important that they report these suspicious orders to you because you can't do your job unless you get this reporting. Isn't that right?

Mr. PATTERSON. Absolutely.

Ms. DEGETTE. Now, for example, the DOJ has reached two settlements with Cardinal Health. In 2008, Cardinal agreed to pay $34 million to resolve allegations that it shipped large quantities of opiates to pharmacies without reporting those orders to the DEA.

And then in 2012 again, Cardinal agreed to pay $44 million to resolve similar claims. Now, do you know, broadly speaking, why the Department of Justice decided to pursue these cases against Cardinal?

Mr. PATTERSON. I don't, ma'am. I know that, from the documents I have seen on the 2012 case, the frustration was is that the MOUs or MOAs in that scenario essentially they had gone back and violated again.

Ms. DEGETTE. Right.

Mr. PATTERSON. So that is probably the basis for——

Ms. DEGETTE. That's your understanding?

Mr. PATTERSON. Yes, ma'am.

Ms. DEGETTE. Now, McKesson similarly reached two agreements with DOJ agreeing to pay $13.25 million in 2008 and again $150 million in 2017 to resolve allegations that it failed to report suspicious orders. Would you suspect it's the same kind of a situation that you talked about a minute ago?

Mr. PATTERSON. Yes, ma'am.

Ms. DEGETTE. Now, do you agree that suspicious order reports are a key part of preventing diversion?

Mr. PATTERSON. Absolutely, because, again, I go back to the fact that the manufacturers and distributors are the key registrants that we need to hear from.

Ms. DEGETTE. Right. Right.

Now, if distributors fail to report suspicious orders, they really do undermine your ability to oversee the supply chain. Is that right?

Mr. PATTERSON. Yes.

Ms. DEGETTE. One more topic, and this is following up on something Ms. Walters was asking you about, and I don't think maybe you understood her question.

On this website that you have been talking about that you have for distributors to look at, it lets other distributors see if other distributors are providing to these pharmacies. But it does not tell volume. Isn't that correct?

Mr. PATTERSON. I would have to check it. I believe it does. It goes back a 6-month window. But I would get back to you on that particular issue.

Ms. DEGETTE. I think so, because it's my understanding that the distributors object to disclosing volume. Here, your associate's handing you something.

Mr. PATTERSON. No volume.

Ms. DEGETTE. No volume. OK. And, from my perspective I can understand what they're saying about that impacting trade secrets and so on.

But the problem, from my perspective, is if you're just saying, OK, we are going to have a website where you can see if other distributors are providing in that area, if you don't know the volume then it's really hard for somebody to see whether there's an abuse going on or not. Wouldn't you agree with that?

Mr. PATTERSON. Yes, ma'am.

Ms. DEGETTE. I think this website is something we should probably talk about more and maybe you can supplement your answers to see how we can use that effectively, because just knowing if other people are going in there I don't think that's going to solve our problem.

Thanks, Mr. Chairman. I yield back.

Mr. HARPER. The gentlewoman yields back.

Just for clarification, it appears in 2008 that Cardinal Health paid $34 million in civil penalties and then again in 2016 an additional $10 million was paid out through one of its subsidiaries, Kinray—if that clarifies that.

Through our investigation, Mr. Patterson, the committee has learned certainly that as early as 2008 the DEA received almost daily suspicious order reports, which received millions of opioids that had been tied to known pill mill physicians like Mr. Collins' neighbor that he referenced. Yet, most continue to remain in operation and it's unclear to what extent, if any, DEA followed up on the suspicious order reports it received.

So tell us what is the process that the DEA takes when evaluating suspicious order reports it receives and the actions that the agency takes in response?

Mr. PATTERSON. So, sir, when those come in they're currently reviewed by and looked at for investigation by the divisions. This is one of the changes that we are making by bringing this into headquarters process.

Some of these companies, obviously, have districts all throughout the country. One of the reasons why we want to look at them is because we want to look at them as a corporation, not just as individual entities or other problem areas.

So that is a change that we are doing. I would be happy to go back and look at specific issues on——

Mr. HARPER. Sure.

Mr. PATTERSON [continuing]. Any of SORS database and what was or wasn't done. I think the decentralization—we have had structural problems, I would say, in terms of how we used not just some of this information but how we looked at it.

Those structural changes we are rapidly trying to get a handle on to make these—especially in the suspicious orders reports more beneficial because, one, we need them for the registrants, but two, we have to do something with them when we get them. And you

have discussed implementing the process to improve and to process those suspicious orders at DEA headquarters.

Has DEA identified breakdowns in the way its field division processes suspicious order reports in the past and what corrections or adjustments have been made or do you anticipate being made?

Mr. PATTERSON. So, again, I think the uniformness of how we look at these things and the accountability that we hold the people to when we get these reports is critical.

So that's one of the big changes for us to make sure that as we are looking at these—I have had conversations with all of the staff in this space, whether, it goes back to the ALJ or the folks in chief counsel that do it with our expectations, to go back to what Mr. Collins was talking about.

It has not been comfortable conversations. But we have to essentially do the things that we are supposed to be doing each and every day and personalities can't play a role in this.

Mr. HARPER. And when you were making decisions at DEA headquarters, the personnel at the headquarters probably have field experience in some level in DEA. Would that be a fair assessment?

Mr. PATTERSON. That's correct.

Mr. HARPER. And as you're looking at these, are you also taking into consideration those that are in the field now maybe that have never been to headquarters to try to get their input on the actual boots on the ground?

Mr. PATTERSON. I think it's important and, look, I haven't spent years in this diversion world. In fact, I've really only done it for about the last 18 months as the deputy and now as acting.

What I will tell you is that fresh sets of eyes on problem sets are always critically important.

Mr. HARPER. OK.

You talked about well, what do we do—prevention, education, treatment. Your role is really in enforcement and prosecution, at least laying the groundwork for that.

The problem that we see as we look at this in great detail is local law enforcement does not have the capability to take care of this issue. That's why you see many of these cases coming out of rural areas. So we would certainly want to make sure that you're doing things to pivot, to take care of the rural areas in this country as you're looking at that.

Now, there were a number of times that you referenced, I will get back to you or we'll get you that information. So just know that we'll have follow-up on that.

Mr. PATTERSON. Absolutely.

Mr. HARPER. And we'll look for that.

We should be able to work together on this, and just know that we are not happy that the chairman of the full committee, Chairman Walden, had to even call for a press conference.

So we want to make sure, going forward, there are things that we need to know or things that we need to inquire on or things that you have for us. We would prefer more openness between the committee and the DEA, going forward.

And with that we thank you for your time today, for what turned into a fairly long time for you. It's been helpful to us and we look forward to the follow-up questions that we have.

I want to thank the members who have attended today and participated in today's hearing and I will remind members that they have 10 business days to submit questions for the record and I would ask, Mr. Patterson, if you would see that those are responded to promptly as you receive those.

With that, the subcommittee is adjourned.

[Whereupon, at 12:23 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
EST. 1795

March 16, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "The Drug Enforcement Administration's Role in Combating the Opioid Epidemic."

The Subcommittee on Oversight and Investigations will hold a hearing on March 20, 2018, at 10:00 a.m. in 2322 Rayburn House Office Building, entitled "The Drug Enforcement Administration's Role in Combating the Opioid Epidemic." The purpose of this hearing is to discuss the response of the Drug Enforcement Administration (DEA) to the opioid crisis, including the detection and investigation of suspicious orders of opioids, and DEA's enforcement approach to the opioid epidemic.

I. WITNESS

- Robert W. Patterson, Acting Administrator, U.S. Drug Enforcement Administration.

II. BACKGROUND

The U.S. continues to experience an opioid epidemic, with opioid-involved overdose deaths currently being the leading cause of injury death in the U.S., taking the lives of 115 Americans per day.[1] According to a recent report issued by the Centers for Disease Control and Prevention (CDC), prescription or illicit opioids were involved in nearly two-thirds of all drug overdose deaths in the U.S. during 2016, a 27.7 percent increase from 2015.[2] In total, more than 351,000 lives have been lost since 1999 due to an opioid-involved overdose.[3]

Beginning in April 2014, through numerous hearings, the Subcommittee has undertaken a comprehensive examination into the root causes of the opioid epidemic and explored possible solutions to enable greater access to effective, evidence-based treatment for substance use disorders. On May 8, 2017, the Committee launched an investigation into the distribution of prescription opioids, initially sending letters to the three largest wholesale drug distributors in the

[1] Centers for Disease Control and Prevention, Understanding the Epidemic, Opioid Overdose, Aug. 30, 2017, https://www.cdc.gov/drugoverdose/epidemic/index.html.
[2] Centers for Disease Control and Prevention, Vital Signs: Trends in Emergency Department Visits for Suspected Overdoses – United States, July 2016-September 2017, Mar. 9, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm.
[3] Centers for Disease Control and Prevention, Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016, https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4.

U.S. as well as the DEA.[4] The Committee expanded this investigation to include two additional wholesale drug distributors, and sent a second letter to the DEA on October 13, 2017.

Role of the DEA in Combatting the Opioid Epidemic

The DEA was established within the Department of Justice by Executive Order on July 1, 1973, when the Office of National Narcotics Intelligence and the Office for Drug Abuse Law Enforcement were merged, and the Attorney General was granted additional authority to coordinate federal efforts to combat illicit drug abuse.[5] Today, the DEA is the federal agency principally responsible for enforcement of the Controlled Substances Act (CSA), enacted under Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[6] The CSA established the schedules for controlled substances[7] and provided authority for the DEA to register entities engaged in the manufacture, distribution, or dispensation of these substances as well.[8] The CSA also established registration requirements[9] and provided the authority for the DEA to deny, revoke, or suspend such registration(s) if it determined the registrant to be out of compliance with the mandates of the CSA.[10] The CSA was designed to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure their registration is not being used as a source of diversion. The DEA regulations require all distributors to report suspicious orders of controlled substances.[11] In addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted to non-medical, scientific, or industrial channels. Failure to exercise such due diligence could provide a statutory basis for revocation or suspension of a DEA registration.[12]

The CSA also authorized the DEA to establish annual production quotas for controlled substances.[13] According to the CDC, the number of prescription opioids sold to pharmacies, doctors' offices, and hospitals in the U.S. nearly quadrupled from 1999 to 2010, yet there was no increase in the the number of patients treated for pain during this time period.[14] In August 2017, the DEA announced its intention to reduce the amount of controlled substances, including opioids, manufactured in the U.S. by 20 percent in 2018.[15] The reduced 2018 production figures

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[4] *See* H. Comm. Energy & Commerce, *Letters to Distributors and the DEA Regarding Alleged Pill Dumping in West Virginia,* May 9, 2017, https://energycommerce.house.gov/news/letter/letters-distributors-and-dea-regarding-alleged-pill-dumping-west-virginia/.
[5] Reorganization Plan No. 2 of 1973, 3 C.F.R. 785 (1971 – 1975 Comp.) *reprinted at* 21 U.S.C. § 801.
[6] Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91 – 513, 84 Stat. 1236, 1296 (1970).
[7] 21 U.S.C. § 812.
[8] 21 U.S.C. § 822.
[9] 21 U.S.C. § 823.
[10] 21 U.S.C. § 824.
[11] 21 C.F.R. 1301.74(b).
[12] 21 U.S.C. § 823(e) and 21 U.S.C. § 824(a).
[13] 21 U.S.C. § 826.
[14] Centers for Disease Control and Prevention, *supra* note 1.
[15] Press Release, U.S. Drug Enforcement Admin, DEA proposes reduction to amount of controlled substances to be manufactured in 2018 (Aug. 4, 2017) *available at* https://www.dea.gov/divisions/hq/2017/hq080417.shtml.

were finalized by DEA in November 2017.[16] Recently, the Attorney General issued a memorandum to DEA, directing the agency to examine its regulations governing aggregate production quotas and noting "[s]tudies have indicated that the United States is an outlier in the number of opioid prescriptions issued each year."[17]

According to its Fiscal Year (FY) 2019 budget request, the DEA regulates more than 1.73 million registrants that are licensed to manufacture, distribute, and prescribe controlled substances.[18] Among the tools available to DEA to ensure compliance with the CSA, and to protect the public health and welfare, are Immediate Suspension Orders (ISOs) and Orders to Show Cause (OTSCs), the latter of which require a registrant to prove to the DEA Administrator why the registrant's DEA registration should not be revoked or suspended.[19] If, however, the DEA Administrator determines that a DEA registrant's activities constitute an imminent danger to the public health or safety, the Administrator may issue an ISO, which requires the immediate surrender of the registrant's DEA registration, pending the final resolution of an accompanying OTSC.[20]

Decline in Enforcement Actions Initiated by DEA

Throughout the last two decades, the opioid epidemic has worsened. In 2016, opioids were involved in 42,249 overdose deaths – an amount five times higher than the number of opioid-involved deaths reported in 1999.[21] The impact of the opioid epidemic has become so pronounced that it has caused the overall life expectancy in the U.S. to decline during the past two consecutive years.[22] The opioid epidemic has also received widespread media coverage and elicited responses at every level of government. Yet, since 2011, the number of ISOs issued by the DEA has significantly declined.

According to data provided by the DEA, the number of ISOs issued by the agency declined from 65 in 2011, to six in 2017.[23] The DEA has publicly stated that the high number of ISOs issued during the 2011 and 2012 time frame were due to actions the DEA took to shut

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[16] Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2018, 82 Fed. Reg. 51873 (Nov. 8, 2017).
[17] Memorandum from Hon. Jefferson Sessions, Attorney Gen., United States of America, to Robert Patterson, Acting Adm'r, U.S. Drug Enforcement Admin., Mar. 1, 2018, https://www.justice.gov/file/1040226/download.
[18] U.S. Dep't of Justice, FY 2019 Budget and Performance Summary – Drug Enforcement Administration (DEA), https://www.justice.gov/jmd/page/file/1033151/download (last visited Mar. 11, 2018).
[19] *See* 21 U.S.C. § 824(c) and 21 C.F.R. § 1301.37(b).
[20] *See* 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36.
[21] Centers for Disease Control and Prevention, Drug Overdose Death Data, Dec. 19, 2017, https://www.cdc.gov/drugoverdose/data/statedeaths.html.
[22] Lenny Bernstein and Christopher Ingraham, *Fueled by drug crisis, U.S. life expectancy declines for a second straight year*, WASH. POST, Dec. 21, 2017, https://www.washingtonpost.com/national/health-science/fueled-by-drug-crisis-us-life-expectancy-declines-for-a-second-straight-year/2017/12/20/2e3f8dea-e596-11e7-ab50-621fe0588340_story.html?utm_term=.9b960a164076.
[23] *See* Office of Sen. Orrin Hatch, DEA Immediate Suspension Orders 2008-2017, https://www.hatch.senate.gov/public/_cache/files/80f96e98-6c08-4bd8-bdec-ee8c99cf7596/ISO%20&%20Show%20Cause%20Order%20Charts%20for%20the%20Record.pdf.

down numerous rogue "pill mill" pharmacies in Florida.[24] However, statements and allegations made by current and former DEA officials suggest the number of ISOs issued by the agency also declined because of internal policy changes.[25] To date, the DEA has not addressed these allegations directly.

Prescription Opioid Distribution Investigation

In May 2017, the Committee opened an investigation into the distribution of prescription opioids by wholesale drug distributors, with a specific focus on unusually large opioid shipments to small pharmacies in West Virginia. Between 2007 and 2012, distributors sent more than 780 million hydrocodone and oxycodone pills to the state.[26] In that timeframe, 1,728 West Virginians fatally overdosed on those two drugs.[27]

While the investigation is ongoing, the Committee uncovered additional statistics that raise questions about the adequacy of due diligence performed by wholesale drug distributors, and the companies' adherence to the CSA's requirement that they implement a suspicious order monitoring program and report any suspicious orders to DEA.[28] The statistics also raise questions about the DEA's oversight of its registrants in West Virginia as the opioid crisis continued to worsen.

Among the Committee's findings: a single pharmacy in Mount Gay-Shamrock, West Virginia—population 1,779—received more than 16.5 million hydrocodone and oxycodone pills between 2006 and 2016; distributors sent 20.8 million opioid pills to Williamson, West Virginia—population 2,900—during the same period; a pharmacy in Kermit, West Virginia—population 406—ranked 22nd in the entire country in 2006 in the overall number of hydrocodone pills it received, with a single distributor supplying 76 percent of its hydrocodone pills that year.

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[24] *See Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act Before S. Comm. on the Judiciary*, 115th Cong. (2017) (statement of Demetra Ashley, Acting Assistant Adm'r, U.S. Drug Enforcement Admin). In her written testimony, Acting Assistant Administrator Ashley stated, "DEA issued 104 ISOs between FY2011 and FY 2012, with all but four being issued against practitioners . . . and pharmacies. Those actions were largely attributed to significant efforts to combat pill mills in Florida . . . The number of ISOs issued in FY 2011 and FY2012 were seen as atypical by historical DEA data."

[25] *See e.g.* Lenny Bernstein and Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control,* WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.f19aef7fe849; Bernstein and Higham, *'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a whimper,* WASH. POST, Dec. 17, 2017, https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?hpid=hp_rhp-banner-low_mckesson-603am-hed%3Ahomepage%2Fstory&utm_term=.f620afa9efdc; and Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News 60 Minutes, Dec. 17, 2017, https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.

[26] Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail, Dec. 17, 2016, https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html.

[27] *Id.*

[28] *See* 21 C.F.R. § 1301.74

III. ISSUES

The following issues may be examined at the hearing:

- What is DEA's role in responding to the opioid epidemic?
- Why did the number of enforcement actions initiated by DEA decline while the opioid epidemic continued to worsen?
- What changes, if any, did DEA make to the evidentiary standards or policies related to Immediate Suspension Orders or Orders to Show Cause?
- How has DEA learned from past practices in order to improve its response to the opioid epidemic?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Brittany Havens, Christopher Santini, or Andrea Noble of the Committee staff at (202) 225-2927.

From: [redacted]
To: Rannazzisi, Joseph T.
Sent: 5/6/2011 4:59:39 PM
Subject: RE: Bates

Joe,
Well said! That's been my contention from the start. The activities by Bates are egregious and the company took no efforts to protect the public or to change their operating methodologies (especially after they had some official notice from the DEA). Our first and most prominent social responsibility as government officials in the DEA is to "protect the public." I think that trumps all other activities. I think that's what Congress/citizens would expect us to do. As such, your position is right on target!

[redacted]

From: Rannazzisi, Joseph T.
Sent: Friday, May 06, 2011 1:33 PM
To: [redacted]
Cc: Masumoto, Scott S.; Harrigan, Thomas M.
Subject: FW: Bates

FYI

From: Rannazzisi, Joseph T.
Sent: Friday, May 06, 2011 4:31 PM
To: Gleason, Robert (Chris)
Cc: Goggin, Wendy H.; [redacted]
Subject: RE: Bates

Chris,

I've discussed the case with division management and I've been informed that the criminal section agrees with pushing forward toward the PI hearing. [redacted] The A made a finding of that threat based on her knowledge and experience and the facts before her, and there is no evidence that her finding was unfounded. [redacted] I would much rather have a record showing the agency attempted to defend its authority but lost. [redacted]

Joe

From: Gleason, Robert (Chris)
Sent: Friday, May 06, 2011 2:32 PM
To: Rannazzisi, Joseph T.
Cc: Goggin, Wendy H.; [redacted]
Subject: Bates

Joe,

[redacted]

Thanks,

Lee

C. Lee Reeves
Associate Chief Counsel
U.S. Department of Justice
Drug Enforcement Administration
Diversion & Regulatory Litigation Section

Phone: [redacted]
Fax: [redacted]
Email: [redacted]

Mailing Address:
8701 Morissette Drive
Springfield, VA 22152

From: [redacted]
Sent: Monday, August 19, 2013 5:24 PM
To: Reeves, Lee
Cc: [redacted]
Subject: CCD Interpretation of Policy

Good Afternoon!

I was in DEA HQ last week and met with a number of OD Section Chiefs. Several of them advised me that on a number of recent occasions, CCD has required them to submit an "expert witness" report and review of documents (e.g., prescription monitoring programs data, patient files, etc.), prior to submitting either (or both) requests for Immediate Suspension Orders and Orders to Show Cause.

I informed my colleagues that we (in the Houston Division) had not encountered this issue in the past, but given that we have a case we plan on sending up to you shortly, where we will be seeking one or both of those, I thought I should write to ask you whether that is a requirement and/or CCD policy?

As you might guess, if the "expert witness" review process is now a mandatory requirement and practice, given the current fiscal climate we all face, as the Diversion Program Manager, it will be difficult if not impossible for me to justify and authorize expenditures for expert witness review on a case(s) which has not been at least tentatively accepted by your office, so...I thought it prudent to touch base with you on this ahead of time (prior to our sending up the case I referred to above) and seek any guidance or other suggestions you might have.

If it would be more productive/efficient, perhaps we can discuss this by telephone, at your convenience.

Thank you.

[redacted]
Diversion Program Manager

From: Reeves, Lee
To: [redacted]
Sent: 8/22/2013 4:07:00 PM
Subject: FW: CCD Interpretation of Policy

As an FYI, I've sent this to OD/Russ Holske.

From: Reeves, Lee
Sent: Tuesday, August 20, 2013 11:48 AM
To: [redacted]
Cc: [redacted]
Subject: RE: CCD Interpretation of Policy

[redacted]

Thank you for your email regarding the use of and need for medical experts. I appreciate the opportunity to clear up what I believe may be some misconceptions on the nature and origin of the need for medical experts in diversion cases involving allegations of improper prescribing.

Here's some background:

A prescription for a controlled substance is not "effective" unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Under the Controlled Substances Act, it is fundamental that a practitioner must establish a bona fide doctor-patient relationship in order to act "in the usual course of . . . professional practice" and to issue a prescription for a "legitimate medical purpose." *See United States v. Moore*, 423 U.S. 122, 142-43 (1975); *United States v. Lovern*, 590 F.3d 1095, 1100-01 (10th Cir. 2009); *United States v. Smith*, 573 F.3d 839, 857 (8th Cir. 2009); *see also* 21 C.F.R. § 1306.04(a) ("an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances").

As the Supreme Court has explained, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing Moore, 423 U.S. 122, 135, 143 (1975)). Both DEA and federal courts have held that "establishing a violation of the prescription requirement 'requires proof that the practitioner's conduct went "beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence."' *Laurence T. McKinney*, 73 Fed. Reg. 43,260, 43,266 (2008) (quoting *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006)). Establishing that a practitioner's conduct exceeded "the bounds of any legitimate medical practice" necessarily requires an understanding of what conduct would, or arguably would, constitute legitimate medical practice. Because such determinations require specialized knowledge, training, and/or judgment, expert testimony is generally necessary to sustain allegations of improper prescribing.

** ** **

To be clear, this is not a Chief Counsel's Office requirement/policy. This is the requirement of the Administrator and the courts, as evidenced by decisions they have issued on this subject, including the Administrator's very recent decision in *Ruben* (in which the Administrator rejected evidence related to undercover buys which were not supported by expert testimony). I cannot tell you in advance, without knowing the facts of a case, whether expert testimony will be needed to support a particular allegation (whether in an ISO or an OTSC). However, we are and remain willing to assist you in determining whether an expert is required in a given case, and urge you to please contact us so that we can discuss the merits of proceeding without or with an expert. To reiterate, there is no Chief Counsel/CCD requirement or policy that there needs to be a medical expert in every case. It depends on the nature of the allegations as well as the facts underlying that case.

It is important to note that Chief Counsel has brought cases and prevailed without expert testimony where the evidence that the practitioner knew that he was engaged in a blatant drug deal. *See, e.g., Robert F. Hunt*, 75 Fed. Reg. 49,995, 50,003 (2010) (holding, without expert testimony, that physician lacked a legitimate medical purpose in issuing prescriptions to undercover officers in view of physician's admission that he falsified medical records "just to cover [his] ass" and that practitioner's notation in patient's medical file of a history of osteoporosis that "has nothing to do with [the undercover], it just has to do if the State ever comes in to monitor my charts that I have a reason for prescribing [controlled substances]"). As a general matter, however, these cases are the exception rather than the rule.

I understand and appreciate the cost concern that you have raised, and I have raised this issue with OD here. Given that diversion-related activities (including the retention of experts) are fee-funded, the fact of sequestration is not relevant. It is my understanding from OD that obtaining funds for an expert should be not be a significant hardship. I encourage your office to submit a request to OD for expert witness funding when appropriate.

Please don't hesitate to let me know if I can answer any other questions.

Thanks,

Lee

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

May 10, 2018

Mr. Robert W. Patterson
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Patterson:

Thank you for appearing before the Subcommittee on Oversight and Investigations on March 20, 2018, to testify at the hearing entitled "The Drug Enforcement Administration's Role in Combating the Opioid Epidemic."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, May 24, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Gregg Harper

Gregg Harper
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

OCT 23 2018

The Honorable Gregg Harper
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Robert W. Patterson, former Acting Administrator of the Drug Enforcement Administration, before the Subcommittee on Oversight and Investigations on March 20, 2018, at a hearing entitled "The Drug Enforcement Administration's Role in Combating the Opioid Epidemic." We apologize for our delay and hope that this information is of assistance to the Committee.

The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program. Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter.

Sincerely,

Prim Escalona

Prim F. Escalona
Principal Deputy Assistant Attorney General

Enclosure

cc: The Honorable Diana DeGette
Ranking Member

Questions for the Record
Drug Enforcement Administration
For a Hearing Entitled
"The Drug Enforcement Administration's Role in Combating the Opioid Epidemic"
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
March 20, 2018

Questions from Chairman Gregg Harper

1. **How do you define "success" in improving DEA's efforts to combat the opioid epidemic? What performance metrics is DEA using to track such progress?**

Response:

Due to the complexity of the Drug Enforcement Administration's (DEA) regulatory program, the Diversion Control Division has worked aggressively to improve its communication and cooperation with its nearly 1.8 million registrants, who represent medical professionals, pharmaceutical drug manufacturers, and those in the drug supply chain. DEA works with its registrant population by: (1) hosting Pharmacy Diversion Awareness Conferences and Practitioner Diversion Awareness Conferences (PDACs) throughout the country; (2) administering the Distributor Initiative Program with a goal of educating distributors on how to detect and guard against diversion activities; and (3) maintaining an open dialogue with various national associations such as the National Association of Boards of Pharmacy (NABP), American Medical Association (AMA), Federation of State Medical Boards, and other groups to address diversion problems and educate the medical community on improving prescribing practices. By the end of 2017, DEA had hosted 100 PDACs in 50 states (as well as the District of Columbia and Puerto Rico) training more than 13,100 pharmacists, pharmacy technicians, and others on the important role they play in ensuring that valid prescriptions for controlled substances are filled. In early May 2018, DEA initiated a nationwide program to offer similar training to individual practitioners.

In addition to the training opportunities offered to registrants, DEA has also begun a program to proactively send targeted email messages to various segments of its registrant population on matters of mutual interest. For example, in February 2018, DEA sent correspondence to 1.3 million prescribers nationwide alerting them of the Centers for Disease Control and Prevention's (CDC) recommendation (part of CDC's Prescribing Guideline for Chronic Pain) for opioid prescribing for acute pain and alerted practitioners to a free training webinar available from CDC. DEA will be sending similar correspondence alerting these same practitioners about resources available from the Substance Abuse and Mental Health Services Administration (SAMHSA) on locating a substance abuse treatment provider in their state. We have also sent targeted messages to DEA's Schedule I research population on enhancements made to streamline the registration process, as well as to the manufacturer and distributor populations on new enhancements to assist them in fulfilling their regulatory responsibilities to identify and report

suspicious orders. In the coming months, DEA will send targeted messages to certain practitioners on how they may utilize telemedicine to treat opioid use disorders.

Over the last several years, DEA has also noticed a downward trend in the amount of prescriptions for controlled substances being written by prescribers. At the same time, DEA has increased the number of administrative actions (e.g., Immediate Suspension Orders (ISOs), Memorandums of Agreement (MOAs), Letters of Admonition). DEA has also seen an increase in reports through Rx Abuse Hotline, and higher participation and amounts collected at National Prescription Drug Take Back Initiatives (NTBIs)). Specifically, combined ISO and Order to Show Cause (OTSC) actions in Fiscal Year (FY) 2017 and FY 2018 have more than doubled since 2014.

Year	Orders to Show Cause Filed	Immediate Suspension Orders Filed
2014	32	8
2015	62	5
2016	57	9
2017	79	6
2018	71	20

2. What is the process that the DEA takes when evaluating the suspicious order reports it receives and the actions the agency takes in response? How long has this evaluative process been in place and how does it differ from DEA's previous suspicious order evaluation process?

Response:

Since the enactment of the Controlled Substances Act (CSA) in 1970, all DEA registrants who distribute controlled substances have a statutory duty to "maintain effective controls against diversion" of controlled substances into other than legitimate medical, scientific, and industrial channels. The first regulations implementing the CSA in 1971 contained a provision regarding "suspicious orders of controlled substances." This provision, which has remained essentially unchanged since 1971, currently appears in 21 CFR § 1301.74(b) and reads as follows: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

These Suspicious Order Reports (SORs) are currently fielded and verified by DEA personnel and can be used as a tool to identify and pinpoint vulnerabilities throughout the closed system of drug distribution. Since 2010, DEA has found that certain distributors were not adequately following their internal controls or not reporting suspicious orders. Through negotiated settlements

involving civil penalties, compliance agreements, and other remedies, DEA has worked with DEA-registered manufacturers and distributors to strengthen suspicious order monitoring and reporting. DEA is also exploring ways to require that suspicious orders are submitted to a central database. Centralized reporting would provide for a more efficient review, dissemination, and investigation of suspicious activity.

In addition, we have launched a new tool within the Automation of Reports and Consolidated Orders System (ARCOS) to assist drug manufacturers and distributors with their regulatory obligations under the CSA. The tool will allow a distributor or manufacturer to enter the DEA registration number of a prospective purchaser (e.g., pharmacy, hospital, or doctor), as well as a drug code for the controlled substance it wishes to purchase. The ARCOS application will return a count of the number of registrants who have sold that particular controlled substance to that prospective purchaser in the last six months. This new query application will help distributors identify red flags indicative of suspicious orders.

Finally, DEA's Diversion Control Division urges DEA registrants and the public at large to "submit a tip" regarding possible CSA violations, including illicit drug distribution or trafficking; suspicious online pharmacies selling controlled substances over the internet; and the illegal sale and distribution of a prescription drug by individuals, including doctors and pharmacists. These tips are submitted through the Diversion Control Division website at https://www.deadiversion.usdoj.gov/tips_online.htm. DEA also maintains a telephone hotline (877-RxABUSE) for the community to submit tips that may establish leads relating to the potential diversion of controlled substances. These tips are submitted to a DEA Field Division for prompt action by either a DEA Special Agent or a professional staff member.

3. What is the current guidance on the amount of time it should take the DEA Chief Counsel's Office to review and respond to an Immediate Suspension Order request?

Response:

The Office of Chief Counsel does act and always has acted with expediency when reviewing and processing requests for ISOs. The Office of Chief Counsel, Diversion and Regulatory Litigation Section routinely collaborates with investigative personnel to guide and assist them before the ISO request is submitted to the Diversion Control Division, Pharmaceutical Investigations Section. As part of the case intake process, the Diversion and Regulatory Litigation Section, Pharmaceutical Investigations Section, and investigative personnel from the field work collaboratively to ensure that the requisite evidence has been collected and to confirm the strategy moving forward. Whether and how quickly an ISO can be charged varies from case to case, and necessarily depends on several factors, including whether the requisite evidence has been gathered, the restrictions (if any) on the administrative case placed by the prosecutor's offices handling parallel criminal or civil matters, as well as other investigative needs (e.g., timing the service of the ISO with search and arrest warrants).

4. Does DEA compare the number of opioids a pharmacy receives during a given period of time to the regional average that are received by nearby pharmacies?

If so, how long has that been part of DEA's monitoring practice and how does the agency determine the applicable region? If not, why not?

Response:

When DEA initiates a case against a registrant, the investigators use all of the tools available and gather as much information as possible in order to build a strong case. The comparison of opioids received between a targeted pharmacy and regional average received by nearby pharmacies is taken into account; however, there may be legitimate mitigating circumstances that can explain a sudden surge (e.g., the establishment of a long-term care facility nearby). As such, this calculation is only one method used by law enforcement officers and diversion investigators in determining if a registrant is in violation of the CSA.

5. **What does the DEA believe it means for a drug distributor to "know your customer?" What kind of due diligence are the distributors expected to exercise over their customers and how often should they be conducting this due diligence?**

Response:

It is fundamental for sound operations that distributors and manufacturers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature.

Some states have restrictions on distribution practices that are more stringent than the federal rules. The extent of compliance with state law is taken into consideration when civil, administrative, or criminal actions against a distributor are under consideration. It is required that any regulated person or entity verify that a customer for controlled substances possesses a valid DEA registration or is exempt from that requirement.

The granting of a DEA registration signals only a proper application, the establishment of the required records system, and the required security system at the time of the on-site inspection by DEA. The registration is not a confirmation of proper ongoing business practices and does not relieve the registrant of the responsibility to evaluate such transaction.

Certain regulations also speak to the duty of a registrant. For example 21 C.F.R. § 1301.74(a) states, "[b]efore distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance."

Further, 21 C.F.R. § 1301.74(b) states, "[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered

by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders or unusual frequency."

6. If a distributor is supposed to know their customer, how is it possible that pharmacies, located in rural West Virginia communities, had orders for egregious volumes of opioids filled by these distributors for years?

Response:

DEA defers to the distributors to provide the response to this question. The distributors are best suited to address this matter as it involves their business practices.

7. How many DEA diversion investigators were assigned to West Virginia in 2006, and how did DEA make this staffing determination? How many DEA diversion investigators are assigned to West Virginia currently?

Response:

In 2006, there were two diversion investigators assigned to West Virginia, and currently, there are six diversion investigators assigned to West Virginia. DEA considers many factors when compiling its submission for the President's Budget. Our analysis included the development of proposals that identify priorities focused on anticipated program needs and that will allow DEA to continue to target the most significant drug trafficking threats including Consolidated Priority Organization Targets (CPOTs), Priority Target Organizations (PTOs), and other significant drug trafficking organizations (DTOs).

As you may know, between 2006 to 2010, a handful of DEA-registered practitioners in West Virginia turned their practices into pill mill operations by writing prescriptions indiscriminately to individuals for an opioid (in this case hydrocodone combination products), often in combination with a benzodiazepine. These illegitimate prescriptions were submitted to and filled by a pharmacy.

DEA, along with its federal, state, and local partners, identified the individuals involved in violations of the CSA and worked with the U.S. Attorney's Office for the Southern District of West Virginia to arrest the following individuals, all of whom were sent to jail for their crimes.

Date of Arrest	Individual	Registration Number
December 19, 2011	William F. Ryckman, MD Owner, Mountain Medical Center	BR5346033 (surrendered 5/13/10)
February 2, 2012	James Wooley, Pharmacist Owner, Strosnider, DBA: Sav-Rite Pharmacy	FS1092787 (surrendered 4/7/2009 BS7437064 (surrendered 2/2/2012)
May 24, 2012	Diane E. Shafer, MD	BS6435780 (surrendered 12/16/09)
March 19, 2013	Myra Sue Miller, employee of William Ryckman	Not applicable

In addition to the above mentioned arrests and license revocations, the following individuals' registrations were revoked:

Individual	Registration Number
Augusto Abad, MD	FA1136806 (surrendered 2/26/10)
John Tiano, MD	BT7431884 (surrendered 12/15/09)
Katherine Hoover, MD	BH0267890 (retired 7/10/10)

The six DEA registrations noted above were revoked following a voluntary surrender (in some instances pursuant to the terms of a plea agreement). That means that DEA did not need to use its OTSC or ISO authority in these cases, and therefore they do not contribute to the OTSC and ISO statistics that we have previously shared with the Committee. In this way, voluntary surrenders can be just as effective at stemming the diversion of controlled substances as OTSCs and ISOs.

Following these investigations, in December 2013, a total of $1.5 million in assets were seized from these pill mill operators. Myra Miller forfeited her interest in the Mountain Medical Center's two commercial buildings valued at approximately $610,000 along with over $475,000 in cash seized from her residence. Another $413,000 from a bank account in William Ryckman's name was also forfeited. Diane Shafer forfeited $134,000, and Katherine Hoover forfeited $88,000. Funds seized by the Federal Government were then awarded to the West Virginia State Police as part of the Department's Asset Forfeiture Equitable Sharing Program which disperses seized funds to various state and local law enforcement agencies involved in federal investigations.

In addition to the above, the Diversion Control Division has also taken numerous steps to examine sales and monitoring processes. For example, the Diversion Control Division utilizes various reports and records to monitor trends or determine anomalous transactions which can then be developed into investigative leads. A unit within the Diversion Control Division's Pharmaceutical Investigations Section uses aggregated ARCOS data to identify patterns and trends in the flow of narcotic controlled substances through the closed system of drug distribution. This unit is now proactively preparing quarterly threat assessment reports for each of DEA's 23 Field Divisions to prioritize DEA's limited resources in furtherance of criminal, civil, and regulatory investigations against DEA registrants.

DEA has devoted additional resources to West Virginia by increasing its presence in the state. In 2016, DEA established an Assistant Special Agent in Charge in Charleston, WV. This senior level manager now oversees the entire state from the State Capitol, rather than from Washington, D.C. Also in 2016, DEA added a second Tactical Diversion Squad (TDS) in Clarksburg. In 2017, DEA headquarters deployed one of its two "mobile" TDS groups to West Virginia, which pursues criminal investigations against those who traffic controlled prescription drugs. On January 1, 2018, DEA established the new Louisville Field Division, its 22nd Division Office in the United States. This office covers Kentucky, Tennessee, and West Virginia and will enhance DEA enforcement efforts within the Appalachian mountain region and unify drug trafficking investigations under a single Special Agent in Charge. DEA anticipates that this change will produce more effective investigations on heroin, fentanyl, and prescription opioid trafficking, all

of which have a significant impact on the region. The division will also better align DEA with the U.S. Attorney's Offices in those areas, similar to current Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Federal Bureau of Investigation (FBI) offices, and also to the Appalachia High Intensity Drug Trafficking Areas (HIDTA) Program.

Finally, after the explosion and subsequent demise of illegal pill mills in Florida, DEA analyzed and reallocated several hundred positions from its Miami Field Division to other offices across the country, including West Virginia, to better utilize its limited resources.

8. The press reports and the Committee's investigation show internal conflicts between DEA lawyers and DEA investigators that apparently went on for years. Where was the DEA Administrator, and later the Acting Administrator who followed her, during this conflict? Why didn't the former head of the Agency resolve this dispute and unite the agency?

Response:

Then DEA Chief Counsel, Wendy Goggin, addressed this issue with the subcommittee staff during her interview on March 23, 2018. We believe the information shared in meeting addressed this concern.

9. What actions are you taking to improve morale at the DEA?

Response:

Many of the issues highlighted regarding morale are not reflective of the current state of DEA. Within the last two years, DEA has undergone senior leadership changes within the office of the Administrator, Chief Counsel, and Diversion Control Division. DEA does not believe that there are any overarching morale concerns within the organization.

10. How does the DEA currently utilize PDMP data in its investigations?

Response:

As you are aware, prescription drug monitoring programs (PDMPs) are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement, but access varies according to state law. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly champions robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Law enforcement access to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects personally identifiable information is vital. However, access to information in support of active state and federal investigations varies widely from state to state, with some states requiring a court order in order for law enforcement to obtain data.

DEA utilizes PDMP data in support of its ongoing investigations, particularly to bolster its cases against prescribers or other entities that are acting outside of the law. This data is only one piece of the totality of circumstances that are considered when DEA is pursuing a case against a DEA registrant.

11. What is the DEA doing to address any access barriers the agency currently faces with respect to PDMPs?

Response:

DEA and law enforcement face many challenges when trying to access and utilize PDMP data. As mentioned in the response to Question 10 above, law enforcement access to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects personally identifiable information is vital. However, access to information in support of active state and federal investigations varies widely from state to state, with some states requiring a court order in order for law enforcement to obtain data.

While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to pain clinics and physicians that are operating unscrupulously and outside of the law, making interconnectivity between PDMPs vital. As a result, the Office of National Drug Control Policy (ONDCP) and the Department's Bureau of Justice Assistance (BJA) currently offer assistance for interstate and state-tribal PDMP linkages. CDC's Prevention for States program supports states' advancements to identify and prevent prescription drug overdoses, which includes activities focused on improving interoperability between PDMPs and Electronic Health Record (EHR) technology and providing real-time provider access. Forty-four states are currently able to exchange prescription data between certain states. In some instances, data sharing may be limited to a single neighboring state. In other instances, data sharing may span states within a specific region. There are currently two interstate data sharing hubs in operation: RxCheck, BJA's open standards solution developed and operated in partnership by the IJIS Institute (IJIS) with funding from BJA; and PMP Interconnect (PMPi), a proprietary solution operated by the National Association of Boards of Pharmacy (NABP). As of August 2017, nine states are live or are implementing interstate data sharing using both hubs, 36 states are live or are implementing interstate data sharing using the PMPi hub only, and 4 states are live or are implementing interstate data sharing using the RxCheck hub only.

Federal partners are working to address interoperability. Brandeis University's PDMP Training and Technical Center, funded by BJA, has assisted the IHS to improve interoperability between IHS, its pharmacies, and PDMPs. BJA currently provides funding to 30 states through the Harold Rogers PDMP Program for implementation, enhancements, or enhanced data sharing, including interstate data sharing. CDC supports work in states to enhance and maximize PDMPs as a public health and clinical tool.

In addition, DEA has entered into information sharing agreements with multiple coalitions of state Attorneys General and an individual state Attorney General. Pursuant to those agreements, each of which have confidentiality provisions, state Attorneys General have committed to assisting the DEA obtain PDMP information from their states. Law enforcement access to this data is crucial to help build the strongest cases possible against those actors who are acting outside of the law.

Question from the Honorable Michael C. Burgess

12. I recently reviewed a document published by the Drug Enforcement Administration's Diversion Control Division listing all of the DEA investigations of physician registrants that resulted in the arrest and prosecution of the registrant. I was surprised to see that this list, despite going back to the early 2000s, is only 103 pages long. This list also shows that recent activity has been diminishing, despite that the number of opioid deaths has substantially increased in recent years. What is the reason for the decline in data regarding arrests and prosecution of physician registrants since 2010?

Response:

DEA has seen an increase of doctors in voluntarily surrendering registrations, which results in the diminishing numbers of prosecutorial actions being taken against prescribers.

Questions from the Honorable Tim Walberg

13. How long from start to finish should it take to issue an Immediate Suspension Order (ISO)?

Response:

How quickly an ISO can be charged varies from case to case, and necessarily depends on several factors, including whether the requisite evidence has been gathered, the restrictions (if any) on the administrative case placed by the prosecutor's offices handling parallel criminal or civil matters, as well as other investigative needs (e.g., timing the service of the ISO with search and arrest warrants).

14. Do you expect the field division to act with expediency when they identify a situation that could warrant the use ofan ISO?

Response:

Yes, the Office of Chief Counsel, Diversion and Regulatory Litigation Section routinely collaborates with investigative personnel before the ISO request is submitted to the Diversion Control Division, Pharmaceutical Investigations Section. As part of the case intake process, the Diversion and Regulatory Litigation Section, Pharmaceutical Investigations Section, and investigative personnel from the field work collaboratively to ensure that the requisite evidence has been gathered and to confirm the strategy for moving forward.

15. If too much time passes between a field division's request for an ISO and a DEA lawyer's approval of the ISO, could that undermine the original evidence and justification the field relied upon in their request foran ISO?

Response:

DEA personnel routinely collaborate to make sure that all administrative actions (including OTSCs and ISOs) are supported by the requisite evidence and are processed as quickly as possible. Specifically, the Office of Chief Counsel, Diversion and Regulatory Litigation Section routinely collaborates with investigative personnel before the ISO request is submitted to the Diversion Control Division, Pharmaceutical Investigations Section. As noted above, whether and how quickly an ISO can be charged can and does vary from case to case, and necessarily depends on several factors.

16. Would you expect the Chief Counsel's office to act with expediency when they receive an ISO request from the field?

Response:

The Office of Chief Counsel does act and always has acted appropriately when reviewing and processing requests for ISOs.

17. I'd like to draw your attention to a case that originated in my home state of Michigan. This case shows the practical consequences of some of the questions my colleague from Virginia, Mr. Griffith, asked you.

In December 2013, Dentist Mark Kamp agreed to pay $125,000 to settle claims that he wrote hundreds of illegitimate prescriptions for hydrocodone and other drugs - this includes drugs given to at least two Birmingham Public School bus drivers. According to emails obtained by the Committee, DEA agents wanted to issue an ISO against Mr. Kamp at least eight months earlier, presumably because of the immediate danger to the community. But an email sent April 23, 2013 from a senior attorney evaluating the case appears to indicate that the Office of Chief Counsel believed a medical expert would be needed to review prescriptions and patient charts and render an expert opinion before the issuance of an ISO.

On the same day the attorney made that assessment, someone involved with the case- we don't know who because the name is redacted- wrote back to ask whether DEA attorneys would require the field to obtain a medical expert before submission of any ISO. The person flagged both the associated cost and delay and stated this was not required in past cases brought against physicians and pharmacies. That email seemingly went unanswered for more than a month, until DEA attorneys finally provided the requested guidance. According to Dr. Kamp's settlement, he continued issuing illegitimate prescriptions for controlled substances through September 2013, though he eventually surrendered his DEA registration.

a. But in a case in which an ISO is being sought, do you expect the Chief Counsel's Office to respond to questions about the case in a timely manner? Does this seem like an undue delay to you - both on the part of the Chief Counsel's office for not responding to the question, but also on the part of the field for waiting a month to follow up?

Response:

As previously mentioned, the Office of Chief Counsel does act and always has acted appropriately when reviewing and processing requests for ISOs. The Office of Chief Counsel, Diversion and Regulatory Litigation Section routinely collaborates with investigative personnel before the ISO request is submitted to the Diversion Control Division, Pharmaceutical Investigations Section. Whether and how quickly an ISO can be charged can and does vary from case to case, and necessarily depends on several factors noted above.

18. Another email obtained from DEA seems to indicate that the Chief Counsel' s Office provided some internal guidance on deadlines for responding to an ISO request from the field. One email from May 2013 references a 3-day window in which DEA attorneys should review and act on ISO requests if the evidence submitted was stale. The unknown author of the email also poses a question to Lee Reeves about whether DEA attorneys are required to act on all ISO requests within 7 days. What is the current guidance on the amount of time it should take the DEA Chief Counsel's Office to review and respond to an ISO request?

Response:

As previously mentioned, whether and how quickly an ISO can be charged can and does vary from case to case, and necessarily depends on several factors, including whether the requisite evidence has been gathered, the restrictions (if any) on the administrative case placed by the prosecutor's offices handling parallel criminal or civil matters, as well as other investigative needs (e.g., timing the service of the ISO with search and arrest warrants). However, the Office of Chief Counsel does act and always has acted appropriately when reviewing and processing requests for ISOs.

Questions from the Honorable Frank Pallone, Jr.

19. How many instances has DEA identified- using proactive analysis of ARCOS data- of distributors shipping potentially excessive amounts of opioids in the last two years? How many instances has DEA identified- using proactive analysis of ARCOS data-of pharmacies receiving potentially excessive amounts of opioids in the last two years?

Response:

DEA identified 160 distributors that shipped potentially excessive amounts of opioids from January 2016 to June 2018 using proactive analyses of ARCOS data.

DEA identified 7,680 pharmacies that purchased potentially excessive amounts of opioids in the last two years: 2,073 in 2016, 4,228 in 2017, and 1,379 from Jan – June, 2018 using proactive analyses of ARCOS data. These pharmacies were identified in top purchaser or above average listings, in the United States, a state, county, or zip code. DEA also utilized a Department of Health and Human Services (HHS) dataset (Medicare Part D) to identify 181 pharmacy outliers.

20. What types of proactive ARCOS analytics does DEA now perform that would identify a pharmacy that received amounts of controlled substances from each of its distributors that would not raise red flags, but when aggregated among all of its suppliers would total a sufficiently large amount that could be considered suspicious? In how many instances has DEA performed such analyses and identified such pharmacies in the last two years? What actions, if any, did DEA take after identifying such information in those instances?

Response:

In the ARCOS online system, pharmacy totals are automatically aggregated among all of its suppliers unless distributor totals are needed separately. The ARCOS system aggregates continuously, and supplier totals are automatically generated. Additionally, all Diversion Investigators (DIs) have access to the ARCOS system and can run their own reports and analysis. All ARCOS leads and analytical results are sent to DEA Field Offices and/or our federal, state, and/or local law enforcement partners for further investigation.

21. What types of proactive ARCOS analytics does DEA now perform that would identify a geographic region (e.g., by three-digit ZIP code prefix) that received suspiciously high amounts of opioids? In how many instances has DEA performed such analyses and identified such geographic areas in the last two years? What actions, if any, did DEA take after identifying such information in those instances?

Response:

DEA currently sends out proactive Targeting Analysis packages to the various field offices when a red flag has been raised through a review of ARCOS data and has not been resolved by the

registrant. Those leads are continuously generated and used by the field, in addition to and with other sources of information, to determine if the registrant is acting outside of the closed system of distribution. DEA also sends out an annual threat assessment to the various field offices that can be used to help identify areas where potential diversion may be occurring within those geographic locations. ARCOS data is not the sole determining factor in deciphering if diversion is occurring but can be a useful tool when combined with other investigative tools to determine if a registrant is a bad actor. The actions taken by DEA as a result of these investigations has varied depending upon the discovery of diversion and if the registrant was continuing to be non-compliant.

22. How many full time equivalent (FTE) employees does DEA have dedicated to proactively analyzing ARCOS data for the purposes of identifying troubling trends (such as potential diversion, fraud, or abuse) and potential investigations into distributors and pharmacies?

Response:

DEA currently has two units that are dedicated to analyzing ARCOS data – the Targeting and Analysis Unit and the ARCOS Unit. The Targeting and Analysis Unit is responsible for reviewing ARCOS reports, running various analytics, and sending targeting packages out to the field offices for further investigation or to support any current on-going investigations that were initiated in another manner (e.g., a tip from a Confidential Source or a report into our RX Abuse Hotline). The ARCOS Unit is responsible for verifying the information that is input by the manufacturers and distributors who are required to report to ARCOS on a quarterly basis.

23. To what extent does DEA share ARCOS data with state law enforcement agencies, attorneys general, public health agencies, and other state agencies? How often does DEA share this data, and what amount of granularity does DEA provide (e.g., does the data identify distributors and pharmacies)?

Response:

It has long been DEA policy to share ARCOS data (and other DEA information) with state law enforcement agencies, state Attorneys General, state public health agencies, and other state agencies involved in active civil or criminal cases involving controlled substances. The frequency and nature of the information shared varies and is dependent upon the number of active investigations.

In April 2018, the Department filed a motion to participate as a "friend of the court" in the ongoing Multi-District Litigation (MDL) against opioid manufacturers and distributors. That litigation, which has been consolidated in the Northern District of Ohio, involves more than 900 lawsuits brought predominately by state and local governments against opioid manufacturers and distributors. DEA has provided the MDL parties ARCOS data concerning the most commonly abused prescription opioids. . The shared ARCOS data encompasses transactions between January 1, 2006 and December 31, 2014 and is not redacted. Therefore, it identifies distributors, manufacturers, and pharmacies The DEA also

provided the parties with select SORs. All of the information the DEA provided in the MDL is covered by a protective order.

DEA also recently entered into information sharing agreements with two separate coalitions of state Attorneys General and an individual state Attorney General. Each agreement has a confidentiality provisions. DEA intends to provide the state Attorneys General who enter into those agreements the same information it provides the parties in the MDL.

24. During your testimony, you stated that DEA intends to change the way it uses suspicious order reports that it receives from distributors. What does DEA now do with the suspicious order reports it receives from distributors? What changes does DEA intend to make with the suspicious order reports?

Response:

Since the enactment of the CSA in 1970, all DEA registrants who distribute controlled substances have a statutory duty to "maintain effective controls against diversion" of controlled substances into other than legitimate medical, scientific, and industrial channels. The first regulations implementing the CSA in 1971 contained a provision regarding "suspicious orders of controlled substances." This provision, which has remained essentially unchanged since 1971, currently appears in 21 C.F.R. § 1301.74(b) and reads as follows:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

This information is currently fielded and verified by DEA personnel across its 22 Field Divisions and can be used as a tool to identify and pinpoint vulnerabilities throughout the closed system of drug distribution. Since 2010, DEA has found that certain distributors were not adequately following their internal controls or not submitting suspicious orders. Through fines and other remedies, DEA has developed agreements with DEA-registered manufacturers and distributors to strengthen suspicious order monitoring and reporting.

25. How many suspicious order reports does DEA now receive from distributors annually?

Response:

DEA currently has one active MOA with a distributor pursuant to settlement agreement that requires them to submit SORs electronically to DEA headquarters. Over the years there have been a number of registrant distributors and manufacturers who have also been under MOA's as a result of administrative actions taken against them. DEA headquarters has received 1,204,400 electronic SORs from 135 distinct registrants from 2007 to 2018.

DEA is also in the process of creating a centralized reporting system in which all manufacturers and distributors would be required to report suspicious orders, therefore creating a quicker turnaround time for investigation into verified suspicious orders.

26. How many cases has DEA initiated against registrants as a result of suspicious order reports it received in the last two years?

Response:

SORs are regularly used as one element to build a case against a registrant that appears to be acting outside of the regulations set forth in the CSA. These reports are used in conjunction with various other elements to support taking criminal, civil, or administrative action against a registrant and are not enough in and of themselves to make a case against registrant.

27. What is the status of DEA's draft regulations that would require suspicious orders to be reported electronically and to DEA's central office?

Response:

DEA regulations requiring a suspicious order to be reported electronically to DEA headquarters are in the process of being drafted and will undergo the required inter- and intra-agency review.

28. Has DEA provided any additional guidance or outreach to registrants regarding what constitutes a suspicious order? If so, please provide details of such guidance or outreach, including copies and the date such guidance was provided or outreach was conducted.

Response:

DEA continues to provide guidance on what constitutes a suspicious order through formal training and informal interactions with registrants. Since the enactment of the CSA, all DEA registrants who distribute controlled substances have a statutory duty to "maintain effective controls against diversion" of controlled substances into other than legitimate medical, scientific, and industrial channels. The first regulations implementing the CSA in 1971 contained a provision regarding "suspicious orders of controlled substances." This provision, which has remained essentially unchanged since 1971, currently appears in 21 C.F.R. § 1301.74(b) and reads as follows: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

29. Which DEA division is responsible for determining what recommendation to provide the Administrator to take a particular administrative action against a registrant (e.g., Order to Show Cause or Immediate Suspension Order)?

Response:

Each DEA Field Division is responsible for determining which recommendation to provide to the Administrator with regards to a particular administrative action (e.g. OTSC or ISO) that will be taken against a registrant within their own division. That recommendation is then reviewed by the Office of Chief Counsel prior to obtaining concurrence or nonconcurrence from the Assistant Administrator of the Diversion Control Division. Under regulation, OTSCs may only require concurrence at the Diversion Control Division level. ISOs require concurrence or nonconcurrence from the Administrator.

30. During your testimony, you stated that DEA has begun to use ARCOS data in a more proactive manner to identify potential diversion cases. In an April 2, 2018 press release, DEA announced that in February and March, "DEA surged the efforts of special agents, Diversion investigators, and intelligence research specialists to analyze 80 million transaction reports from DEA-registered manufacturers and distributors" that resulted in 366 leads and 188 active investigations, culminating in 28 arrests, 54 other enforcement actions, and 283 administrative actions. However, during your testimony, you referred to "approximately 400 targeted leads" that DEA developed based on ARCOS and other data, and that "of those 400 packages that went out, a good majority of what we saw in that data and the outliers and what they identified were ongoing cases that we already had..."

a. To clarify, how many of those 188 investigations were initiated as a result of DEA identifying leads through proactive analysis of its ARCOS data (as opposed to analyzing ARCOS data to support already ongoing investigations)? What actions were taken in those cases?

Response:

The cited investigative data is derived from DEA's case management system, which does not track the initiating factor (e.g., a tip from the public, information that is discovered in a different investigation, ARCOS information provided to an office, etc.), so we are unable to provide that information. The reference to ARCOS data helped to underscore the fact that investigations are supplemented by ARCOS data and that ARCOS data is not used as the sole determining factor in the initiation of investigations.

Questions from the Honorable Yvette Clarke

31. How can the DEA take a more nuanced approach to managing the supply of legal schedule II opioid medications? As we are seeing, simply cutting legal production is going to cause irreparable harm to hospice and palliative care patients and families in the New York 9th and nationwide?

Response:

The quota system is a nimble regulatory tool in which DEA establishes individual quotas for manufacturers based on a variety of information. The quota is then 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. It is outside DEA's regulatory authority to compel a manufacturer to use its quota to manufacture a specific drug product that may be in shortage. In situations where DEA is made aware of the need for an increased quota and an increase can be adequately justified, DEA works quickly to make the necessary adjustments. However, 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.

32. How does the DEA plan to deal with the shortage of both injectable opioids and benzodiazepines?

Response:

Since January 31, 2018, the Diversion Control Division has received comments from hospital groups and stakeholders. These groups have expressed serious concerns regarding the shortages of injectable products that contain Schedule II controlled substances, namely fentanyl, meperidine, hydromorphone, and oxymorphone. In response to the concerns raised by these groups, the Diversion Control Division established a "working group" to assess the alleged shortages, began holding conference calls with various vested entities from industry to cancer centers, and continues to keep stakeholders apprised of its efforts.

Early in 2018, the working group discovered that two companies, who had requested additional procurement quota, alleged that the drug shortages were being created by DEA. We take such claims seriously and have researched this issue. Based upon that research, DEA has determined that these two manufacturers had significant discrepancies in reports they submitted to DEA. DEA relies upon the information in those reports when establishing each manufacturer's quota, specifically their Year-End Report (YERS) and quarterly reports submitted to ARCOS. In order to address the deficiencies in those reports, DEA is currently performing administrative inspections at both companies to resolve these inaccuracies.

Since mid-February, three DEA-registered manufacturers of injectable products have received increases to their respective procurement quotas in accordance with DEA regulations (21 C.F.R. § 1303.12). DEA is communicating directly with these manufacturers and will continue to adjust individual procurement quotas as necessary. DEA is working tirelessly, in coordination with the

Food and Drug Administration (FDA)'s Drug Shortage team, and will continue to review all potential solutions to help address the issue.

Questions from the Honorable David B. McKinley

33. On March 1, 2018, Attorney General Sessions issued a directive for you to reform DEA's drug quota regulations, including a potential interim final rule with immediate effectiveness that would govern quotas for next year. When can we expect this and can you provide my office with an update?

Response:

DEA final rule titled "Controlled Substances Quotas" was published on July 16, 2018 and became effective on August 15, 2018. *See* 83 F.R. 32784.

34. Does federal law require that drug quotas must be based on legitimate patient needs, not what drug makers want in terms of production?

Response:

Data and considerations utilized by DEA to establish quotas includes: total net disposals (i.e., sales) for the current and preceding two years; estimates of medical need (provided by the FDA); actual and estimated inventory; U.S. export requirements; product development requirements; manufacturing losses and other factors that affect "yield"; and documented theft and loss data (i.e., diversion). 21 U.S.C. § 826(a) requires the Attorney General to determine the total quantity and establish production quotas to be manufactured each calendar year for each basic class of controlled substance in Schedules I and II, and ephedrine, pseudoephedrine, and phenylpropanolamine. These aggregate production quotas (APQs) 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. DEA is charged with the management of controlled substances and chemicals for scientific, medical, research, and industrial applications, while also preventing diversion of these same substances and chemicals. To manage this complex system, DEA requires that manufacturers of Schedule I and II controlled substances and the importers and manufacturers of ephedrine, pseudoephedrine, and phenylpropanolamine (Combat Methamphetamine Epidemic Act (CMEA) List I chemicals) apply for quotas to control the quantity of material produced or procured per calendar year.

35. Does the Controlled Substances Act require quotas to be set at the amount America "needs" or quotas be set at the amount that drug makers "want"? *[see* 21 U.S.C. § 826(a) ("total quantity ... to provide for the estimated medical ... needs of the United States")]

Response:

As set out in the response to Question 34 above, DEA considers a variety of factors when proposing the APQs for the following year. Please note that the APQs are established through notice and comment rulemaking procedures after an assessment of the factors described in 21 C.F.R.§ 1303.1 l(b), including:

(1) Total net disposal of the class by all manufacturers during the current and two preceding years;
(2) Trends in the national rate of net disposal of the class;
(3) Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;
(4) Projected demand for such class as indicated by procurement quotas requested pursuant to 21 C.F.R. § 1303.12; and
(5) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

In this way, the APQs represent more than retail sales resulting from prescriptions issued by practitioners nationwide. The APQs include quantities required for product development, manufacturing losses, research, exports, various categories of non-saleable materials, and inventory levels of 50 percent for bulk manufacturers. The APQ values can vary based on the number and status of new products being researched (material set aside and not saleable), international contracts (for exports), manufacturers establishing contracts with backup active pharmaceutical ingredients (API) suppliers, and new manufacturers entering the market.

36. Is the current quota system flawed because it relies too heavily on drug maker's estimate of how many pills they can sell?

Response:

No, as highlighted in the responses to Questions 34 and 35 above, DEA takes into account multiple data points and considerations when establishing quotas.

37. As I referenced in my testimony, the DEA cut the supply to methamphetamines and other drugs that were being abused in the 1970's and 1980's and had success in reducing abuse problems. Yet the quota for prescription opioids was consistently raised by the DEA from the 1990's to present day. Would it not be accurate to say that these unchecked increases in opioid quotas were one of the root causes of this crisis?

Response:

The APQ for each year is established on the best actual and forecasted data provided to the DEA in the Spring of the previous year, from various sources as required by 21 C.F.R. § 1303.11. Throughout the course of the following calendar year, each individual manufacturer's quota request is analyzed using actual year-to-date data at the time of submission and annualized for the remainder of the calendar year. This quota review process allows DEA to administer quota

allotments based on current trends and recent changes in an individual manufacturer's national rates of disposal, FDA notifications, changes in production cycles, current inventory position, as well as yield, stability, and recall issues (*see* 21 C.F.R. §§ 1303.23-1303.26 and 1303.12). This individualized analysis typically results in lower individual quota allotments than originally predicted by the DEA, which were based on actual and forecasted data received from the various sources during the initial APQ analysis completed prior to the start of the calendar year.

Since 2014, DEA has observed a decline in prescriptions written for certain Schedule II opioids. These declines have led to overall reductions in licit demand that in turn, have directly impacted the factors DEA considers when establishing the APQs for Schedule II opioids. In October 2016, DEA announced a 25 percent reduction (or more) in the 2017 APQs for many prescription opioids, including oxycodone, hydrocodone, fentanyl, hydromorphone, and morphine. Hydrocodone was reduced to 66 percent of the previous year's (2016) level. In late 2017, DEA announced a nearly 20 percent reduction in the 2018 APQs (from the 2017 levels) for controlled substances, and these reductions included the aforementioned opioids as well as oxymorphone, codeine, and meperidine. These decreases can be attributed to combined local, state, and federal activities and interventions, including creating new partnerships, enforcing current regulations, and dissemination of provider education and guidance documents, including the CDC Guideline for Prescribing Opioids for Chronic Pain released in March 2016. In addition, we are encouraged that more states have enacted and enforced laws mandating the use of PDMPs by medical providers and pharmacists which provides prescribers with valuable information to guide their medical decisions.

38. When the quotas were being set, wasn't in DEA's responsibility to ensure that they were being used for legitimate patient needs? Did patients in Williamson, West Virginia, population 2,900 need 21 million opioids over a 10 year period (2006-2016)? Was there not negligence on the part of the DEA in increasing these quotas and if so, who is being held responsible?

Response:

DEA is responsible for determining the total quantity and establish production quotas for each basic class of controlled substance in Schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States. However, the quota provisions of the CSA were not designed to work in isolation in combatting the diversion problem. Under the full scheme of the CSA, the nearly 1.8 million registrants must work in concert with DEA for an effective diversion control program. A prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. Therefore, when noncompliant registrants willfully write fraudulent prescriptions for controlled substances, reductions in quota would simply reduce the total amounts of controlled substances being supplied to both the licit and illicit markets.

39. If the quotas are based on legitimate patient need, then why can't we be more transparent in terms of the manufacturer's justification for how many pills they want to make?

Response:

DEA supports transparency and continues to make strides to increase transparency in many different facets across the agency. In instances pertaining to quota justification, DEA is required to protect the commercial information of innocent parties. It is the policy of the United States Government—enforced by the threat of criminal sanction—to protect as confidential the business records commercial enterprises are compelled to give the government. *See* 18 U.S.C. § 1905 ("Whoever, being an officer or employee of the United States or of any department or agency thereof . . . publishes, divulges, discloses, or makes known in any manner . . . any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.") For this reason, generally DEA does not disclose information to the public that it believes is either confidential or proprietary. An important exception to this rule is when DEA cooperates with and shares information with local, state, tribal and federal Agencies. *See* 21 U.S.C. § 873.

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