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OVERSIGHT OF THE DRUG ENFORCEMENT ADMINISTRATION

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COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE
ONE HUNDRED THIRTEENTH CONGRESS

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OVERSIGHT OF THE DRUG ENFORCEMENT ADMINISTRATION

WEDNESDAY, APRIL 30, 2014

**UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
*Washington, DC.***

The Committee met, pursuant to notice, at 10:10 a.m., in Room SD-226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Whitehouse, Klobuchar, Grassley, Hatch, Sessions, and Flake.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Good morning. I apologize for the delay. I thank the Senators who are here: Senator Grassley, Senator Sessions, Senator Flake, and of course, Senator Whitehouse, who will take over this hearing at some point.

I had a chance to chat with Administrator Leonhart in the back, and I appreciate very much having you here.

This hearing comes at an important time. Our Nation continues to struggle with an old and unfortunately persistent problem: the seemingly unrelenting addiction to powerful controlled substances. But I think a lot about that problem is evolving and changing. The drugs of choice are evolving, along with the path to addiction for many Americans.

As I said to Administrator Leonhart, it is a lot different from the days decades ago when I was a prosecutor or when Senator Sessions or Senator Whitehouse were prosecutors. Prescription drug abuse has reached epidemic levels. Overdoses from prescription opioids now account for more than half of all drug-related deaths. That is something we did not see not very long ago.

Around the country, law enforcement is now demonstrating a strong commitment to creative approaches to combating drug abuse. We have seen that enforcement alone is not enough. No amount of arrests or seized drugs can truly break America's drug habit. We need a comprehensive approach—one that includes prevention, treatment, and re-entry services.

A month ago I brought the Senate Judiciary Committee to Rutland, Vermont. Rutland is a very small city, and like rural towns across the country, it has seen a surge in addiction to heroin and other opioids. But the community has come together to respond in remarkable ways. At that hearing it was not a case of people point-

ing fingers at each other. They were saying, "We are all in this together."

The police department almost functions as a community organizer. They partner with early intervention coordinators, social workers, and even building inspectors to address addiction from every angle.

I am encouraged to see that the Justice Department is similarly committed to a comprehensive approach. Through its Smart on Crime Initiative, the Department is supporting prevention and re-entry efforts and promoting fairer sentences.

The DEA is committed to addressing drug abuse through prevention. The DEA has long supported educational programs that aim to reduce demand for drugs. I view in the same light the Office of Diversion Control, which controls the distribution of prescription drugs.

Now, I was pleased to see that, in conjunction with DEA, authorities in Vermont just last weekend recovered over 3,300 pounds of unused prescription drugs through a takeback event. Now, 3,300 pounds—remember, we are a State of only 620,000 people. This was enormous. That means hundreds of thousands of unwanted pills are no longer sitting on shelves and susceptible to abuse. Effective diversion control means effective addiction prevention.

While the DEA is doing critically important work in many areas, I do have some concerns that I have raised. I have concerns about some of the DEA Special Operation Division's investigative techniques. We have discuss this privately, and given the sensitivity of it, we will not discuss it openly in this hearing. But it is an area in which additional oversight is needed, and I want the DEA to cooperate with those of us who have the responsibility of oversight.

I have repeatedly sought answers regarding the DEA's involvement in a 2012 counternarcotics operation in Honduras, in which four Honduran civilians were killed including a 14-year-old boy. And the DEA must make changes to ensure this type of tragedy does not happen again. I realize that is before your time, but I want you to take a look at that because if they have not taken steps to ensure this would not happen again, I would have difficulty supporting DEA's participation in such operations in the future, either wearing my hat in this Committee or in the Appropriations Committee.

Administrator, thank you very much, and thank you for the time you spend on this. I am eager to hear your ideas, and right after we hear from Senator Grassley, we will go to you.

[The prepared statement of Chairman Leahy appears as a submission for the record.]

**OPENING STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM THE STATE OF IOWA**

Senator GRASSLEY. Welcome, Administrator Leonhart. Thank you for coming. Your agency faces many challenges as it tries and works to keep us safe from dangerous drugs.

I am going to point out in my questioning and in my statement that some of those problems coming from the executive branch make your job even harder from my point of view.

The United States is experiencing this epidemic that the Chairman spoke about of opioid abuse, particularly heroin and prescription painkillers. We recently had a survey where 700,000 Americans reported using heroin in the past year. That seems to be increasing.

We read about the death of Philip Seymour Hoffman, pointing out as just one example of a heroin overdose.

Law enforcement, including your agency, has a critical role to play in responding to the epidemic. And, of course, we cannot arrest our way out of this, but we can maintain the current law enforcement tools that help the DEA go after those who are trafficking heroin.

Unfortunately, as I said about the executive branch making your job more difficult, there is disagreement on this Committee on this issue, but I think the sentencing bill that the administration supports does just the opposite. The proposed Smarter Sentencing Act that recently passed out of this Committee cuts the mandatory minimum sentences for those who manufacture, import, or distribute even heroin—and it cuts that sentence in half. These are penalties for dealers, not users. In the midst of the heroin epidemic, as I said to you, I think that this makes no sense.

I do not want you to take my word for it. In opposing the bill, the Federal prosecutors themselves wrote that the current system of penalties is the “cornerstone” of their ability “to infiltrate and dismantle large-scale drug-trafficking organizations and to take violent armed career criminals off the streets.” That is a quote from Federal prosecutors. And I do not want to remove that cornerstone.

Another challenge for your agency that I hope to discuss is the mixed message from the administration that young people get about the dangers of marijuana use. The Department of Justice declined to challenge State laws that have legalized marijuana, despite the obvious conflict with Federal law. In an interview, the President said this, that it was “important” that these States “go forward” with legalization. This has caused confusion and uncertainty about whether using marijuana is really something to be discouraged.

We had a recent scientific study that served as a reminder of how dangerous marijuana use can be. A paper published earlier this month in the Journal of Neuroscience concluded that even casual marijuana use was associated with potentially harmful changes to the brains particularly of young people.

The Department of Justice apparently concluded that so long as the States that legalize marijuana create effective regulatory schemes, then Federal enforcement did not consider that a priority. Those priorities include the prevention of violence, increased use among minors, and diversion of marijuana to other States. But we are seeing particularly in recent news stories minors getting very much involved in that use, and even sale and diversion of marijuana to other States. They are telling me even in Iowa there is a lot of marijuana coming from Colorado.

So I hope the administration is taking a look at the announcement they made of what they considered a priority for prosecution.

As a result, it is hardly surprising that a senior DEA official recently told the Senate Caucus on International Narcotics Control

that what was happening in these States—meaning Washington or States where there has been recreational marijuana or even medicinal marijuana—is “reckless and irresponsible.”

At this point, those words apply equally to the Department of Justice’s policy that has permitted States to legalize a drug for recreational purposes that Congress has chosen to make illegal.

As the above examples attest, marijuana is being combined with cookies and candy in Colorado in a way that is attractive to young people, including children. I hope to discuss the legislation that Senator Feinstein and I introduced last year called “Saving Kids From Dangerous Drugs Act,” that we can get something done to deter this kind of marketing.

I am going to put the rest of my statement in the record, Mr. Chairman.

[The prepared statement of Senator Grassley appears as a submission for the record.]

Chairman LEAHY. Thank you very much. We will look at any legislation you or anybody else may come up with. I am always worried about whether legislation steps on States’ rights and what they might be doing.

Please go ahead, Ms. Leonhart.

STATEMENT OF HON. MICHELE M. LEONHART, ADMINISTRATOR, U.S. DRUG ENFORCEMENT ADMINISTRATION, WASHINGTON, DC

Administrator LEONHART. Chairman Leahy, Ranking Member Grassley, and Members of this Committee, it is my honor to appear before you to discuss the Drug Enforcement Administration and our role in reducing crime and protecting the American people from drugs. I welcome the opportunity to continue the successful and positive relationship that DEA and the Department of Justice have with this Committee.

Throughout our more than 40-year history, DEA has successfully pursued the world’s most violent and prolific drug-trafficking organizations, and this includes the Sinaloa cartel, whose leader, Joaquin “El Chapo” Guzman, was arrested earlier this year by Mexican authorities. And as the head of the Sinaloa cartel, Guzman contributed to the death and destruction of millions of lives all around the world, and the arrest of the world’s most wanted international drug trafficker is a major step forward in our shared fight against drug trafficking and violence.

In the past year, ten more of the most wanted drug traffickers, known as “CPOTs” by the Department of Justice and otherwise known as “kingpins,” have been arrested. Six were extradited to the United States, and among them was Daniel “El Loco” Barrera, who for more than 20 years led an organization that distributed hundreds of tons of cocaine around the world, leaving a trail of violence in his wake. Barrera was considered one of the last true drug kingpins in the Andean region.

Since we started tracking CPOTs in 2003, a total of 179 have been identified around the world, and of those, through our enforcement efforts, 75 percent have been indicted, 55 percent have been arrested, and 31 percent have actually been extradited to the United States, and this is a record that we are very proud of.

By keeping the pressure on drug traffickers and stripping them of almost \$27 billion in revenue since 2005, we have prevented the use of these funds to fuel the next round of drug production and other nefarious activities. This is one of DEA's contributions to the comprehensive national drug control strategy, which has guided a decrease in the overall rate of illicit drug use in America by 35 percent in the past 35 years. And just like the efforts to eliminate cancer or poverty, the fight against drug abuse is a generations-long struggle, and it will not be won overnight.

Since 2006, the number of current users of any form of illicit drug other than marijuana dropped 8 percent, and regular cocaine use dropped 32 percent between 2006 and 2012, and at the same time, methamphetamine use is down by 40 percent. But we still have areas of concern.

An estimated 6.8 million Americans regularly use prescription drugs for non-medical reasons. As troubling, 80 percent of first-time heroin users started by using prescription pain pills.

The availability of both heroin and marijuana is growing. In 2012, 438,000 Americans were addicted to heroin, and 10 times that number were dependent on marijuana. From 2007 to 2012, the number of regular heroin users in this country more than doubled, and not surprisingly, overdose deaths have increased as well.

One trend we have seen over and over again is that drug use rises as the perception of risk decreases. We are seeing that now with marijuana. From 2008 to 2013, past month use of the drug increased among all 8th, 10th, and 12th graders surveyed. These increases parallel softening attitudes about the perceived risk of harm and disapproval associated with marijuana use.

Marijuana use is a very serious problem in this country, and here are some of the facts:

Marijuana-related emergency room visits increased by 48 percent between 2007 and 2011. One out of every 15 high school seniors is a near-daily marijuana user. In fact, since 2009, more high school seniors have been smoking marijuana than smoking cigarettes. And researchers have found that adolescents who use marijuana at least 4 days per week lost an average of 8 IQ points.

These facts paint a picture of the choices we have to make and of the future we will be facing. Drug abuse is devastating on a personal level, and drug trafficking poses a serious threat to society because of the violence and the hazards that accompany it and the terrorist organizations that are often funded by it.

So now is not the time to sound the retreat but, rather, we should be redoubling our efforts. DEA will continue attacking these threats using tools and techniques that have worked so well for us in the past: close relationships with Federal, State, local, and international partners, information sharing and case coordination, and going after what drug traffickers value most—that is, their money.

I have great confidence that DEA, with your support, will continue to build on our gains and overcome the challenges that lie ahead, and those challenges are not insignificant. Today's drug traffickers exploit new and evolving technologies to communicate, to launder ill-gotten gains, to facilitate the smuggling of drugs and weapons, and develop new substances that can be abused.

So thank you for your partnership, and I look forward to continuing to work with this Committee and Congress on these important issues, and I ask that my written statement be added to the record.

Chairman LEAHY. It will be placed in the record.

[The prepared statement of Ms. Leonhart appears as a submission for the record.]

Chairman LEAHY. We do appreciate you being here. After all, you are somebody with 30 years of law enforcement experience, starting as a Baltimore City police officer, then as a DEA special agent, so you can speak with firsthand knowledge of many of these issues.

I am concerned with how prescription opioids have become the drug of choice in America. I think we have seen it all over the country. Demand for treatment has skyrocketed. Deaths from overdose have far eclipsed all other drugs. Opioid addiction all too often leads to heroin, as you know. We see this in every State, including my own of Vermont. And that is why it is concerning to see powerful new opioids without any abuse deterrent technologies enter our communities.

The most recent example I have been told about is Zohydro. What is DEA doing to monitor the use of this? And what will you do if you find widespread abuse?

Administrator LEONHART. Thank you, Senator, for mentioning the opioid problem. It is the Nation's fastest growing drug problem, and it is not confined to large cities or the west coast versus the east coast. It is across our country. So DEA shares your concerns.

We also share the concern with any new opioids that come on the market and are prepared and have to be prepared for additional use to become additional abuse and—

Chairman LEAHY. Does that include Zohydro?

Administrator LEONHART. We anticipate, because it is really the first hydrocodone, pure hydrocodone product coming out, that we will have addicts that will seek it out just because it is pure hydrocodone. We are concerned because anytime you put a new opiate on the street—we all remember the days of Oxycontin, when that was released. This is a drug that is coming out without any tamper-resistant ability to prevent it being crushed, smoked, and snorted by addicts.

So we are very concerned, but we also believe that the enforcement efforts that we have put forth and what we have done to really move our agencies toward prioritizing prescription drugs will help alleviate, will help confront any additional use or abuse we see.

Chairman LEAHY. I would hope also the manufacturer would start cooperating with you; otherwise, they face the potential for backlash from Congress, which is something they probably would not want to face. So I hope they do cooperate with you.

We also consistently hear from Vermont law enforcement that a stronger DEA presence is needed in southern Vermont. You have agents stationed in Burlington. Where are we toward the possible permanent assignment in southern Vermont of DEA agents?

Administrator LEONHART. Well, to help in Rutland—and I have met with the police chief and met recently with members of the Vermont Highway Patrol, we have been very active working in

Vermont. We have actually—even though Burlington is a small office, we have actually sent agents temporarily, TDY on a continuous basis, to help in Rutland and make sure that we have an enforcement presence there.

I am hoping by the end of the week or even earlier next week that I will be having a conversation with the U.S. Attorney in Vermont who has been talking to our special agent in charge. And as we make decisions about moving forward with resources or reallocating resources, I will take into account what his needs are and what he feels DEA could do to assist him in his district.

Chairman LEAHY. And by highway patrol, I assume you mean the Vermont State Police, which do a lot—

Administrator LEONHART. That is correct.

Chairman LEAHY [continuing]. More than patrolling the highway. They handle many other things. I am very proud of what they do.

I sent a letter earlier this year expressing my concerns about certain DEA investigative techniques. Some of that information remains classified. Some has been deemed law enforcement sensitive. We do need more of a public dialogue. Senator Whitehouse and I have both raised this. So will you cooperate with our Committee's oversight? Will you advocate within the executive branch for additional transparency with respect to DEA's investigative efforts?

Administrator LEONHART. Senator, I am limited in what I can talk about regarding those programs.

Chairman LEAHY. I understand.

Administrator LEONHART. But just be assured we have had oversight of those programs since 1992, and we will work with you. I know that we have come up to brief some Members of this Committee, and we will continue to look at ways to improve. And if it is found that additional oversight is needed, we welcome a look at what we have been doing.

Chairman LEAHY. Well, Senator Whitehouse and I and others will continue to ask questions about that. I always worry when things are suddenly classified, and I realize that a lot of things should be, but sometimes things are classified because they do not stand the light of day. And we want to make sure that is not the case. And I know that some of these practices have been suspended by the Department of Justice pending review, and that is what I mean about facing the light of day. Sometimes they do not stand up for that. And without going into classified matters, we will discuss this further.

I also sent last year a letter regarding the counternarcotics operation in Honduras in 2012 that killed four civilians, including a 14-year-old boy. In response to my letter of last year, I received a response this week.

Have you changed at DEA these types of counternarcotics operations as a result of the Honduras experience? Are you doing things to minimize casualties, especially civilians?

Administrator LEONHART. Senator, I assure you that we have looked at that operation from many sides to figure out, number one, how to learn from that; number two, you know, working with our Honduran counterparts, making sure that we are providing them the best training that we can. I want to assure you that we

feel very, very bad about any tragedy, and this with the loss of four civilians is included.

We going forward, however, have looked at ways that we could improve operational planning, how we can improve the training that we are giving.

Chairman LEAHY. Considering the corruption and other problems in Honduras, I would hope that you and your department would put very strict controls because otherwise, we could have real problems.

And, last—and I realize I have gone over my time—the farm bill has provisions for hemp research by universities and State departments. A lot of hemp is used in clothing and other material. People want to conduct serious research, not only in my State but a lot of other States. When are you going to provide guidance to the public on how to conduct this research? And will you work with the U.S. Department of Agriculture, which is looking at the research here, on the commercial nature of hemp in clothing and everything else?

Administrator LEONHART. Yes, Senator. With the passage of the farm bill as well as directed from the Deputy Attorney General from last August on priorities, use of resources for the Department on marijuana cases, the Department is currently reviewing both of those to better understand how we need to go forward with hemp issues. And working with the U.S. Department of Agriculture and other stakeholders, we will make sure that once decisions are made by the Department, that we put out guidance and that we work with those stakeholders.

Chairman LEAHY. Thank you, and I apologize to Senator Grassley for going over time, and I yield to him.

Senator GRASSLEY. I do not complain because you go over time because you always give me equal time.

Chairman LEAHY. That is right.

Senator GRASSLEY. I am going to repeat a sentence that I gave in my opening statement. It is hardly surprising that a senior DEA official recently told the Senate Caucus on International Narcotics Control that what was happening in these States—meaning Washington and Colorado and maybe also, I think, by implication where there was medicinal marijuana—is “reckless and irresponsible.”

So I want to go then to the Cole memo of last August where the Department of Justice established a number of Federal priorities to guide its marijuana enforcement activities in States that legalized it. However, the memo also warned that, “If State enforcement efforts are not sufficiently robust to protect against the harms set forth above, the Federal Government may seek to challenge the regulatory structure itself.”

Now, I do not agree that the administration should be talking about what they are going to prosecute or not prosecute, but if they follow closely whether or not the State is doing what the Justice Department said you had to do if they were not going to have prosecution, then that makes it a little more responsible.

So then leading up to my question, the first three priorities listed in the Cole memo are: one, preventing the distribution of marijuana to minors; two, preventing revenue from the sale of marijuana going to criminal enterprises involving drug-trafficking gangs

and cartels; and, three, preventing the diversion of marijuana to other States.

So a simple question: Could you tell us what the trends are in Colorado in these areas?

Administrator LEONHART. Senator, on those enforcement priorities you discussed, obviously DEA and our State and local law enforcement partners are concerned about marijuana going from Colorado or Washington to surrounding States. And we are very concerned about what we see happening in Colorado.

Take, for instance, Kansas, and we have talked to our partners in Kansas, and they have already been seeing a 61-percent increase in marijuana seizures coming from Colorado, and these seizures were destined for 18 other States. They have also seen an increase, a 49-percent increase in money seizures of money going back to Colorado that they assume were a part of the proceeds coming back from marijuana loads. So that is of great concern to us, as is the first priority, which is preventing the distribution of marijuana to minors.

Senator GRASSLEY. Now, on that latter point, you have seen some of that very much advertised on recent news reports about 4th graders selling marijuana for \$11 as an example. When you said you are concerned about sales to minors, have you observed sales to minors like I think I have heard in the news reports?

Administrator LEONHART. Well, not only in Colorado, but other States that have marijuana dispensaries, where we have seen that, those instances give us reason to take action, and we have. We have closed down dispensaries. We have done investigations, and especially, you know, I am thinking of one in particular in California where we got a call from a school principal who warned us that a local dispensary had put notices on the cars in the high school parking lot advertising, you know, "Stop by."

We also have complaints from citizens about their kids being stopped on the way to school and being given—or asked to come into the store and being given samples. So those are what causes most of our investigations.

Senator GRASSLEY. Maybe as a matter of a summary, would you say that the trends are moving in the right direction or the wrong direction?

Administrator LEONHART. The trends are what us in law enforcement had expected would happen.

Senator GRASSLEY. Okay. So it does not end up being a surprise to you.

As a follow-up to that, and my understanding is that you are not involved in the prosecution—I mean, in carrying out the Department of Justice's recommendations on prosecution, but have you talked to anyone at the Department of Justice who is monitoring what is happening in Colorado for the purposes of re-evaluating its decision not to challenge the State law? And, second, do you know whether anyone there is actually doing so?

Administrator LEONHART. Well, I can tell you we have been talking with the Department of Justice and the U.S. Attorney in Colorado. In fact, on Friday, we were able to—based on an indictment, we made arrests for exactly what we have been concerned about. These were Colombian nationals who had invested in a marijuana

business in Colorado. We took action. Part of the investigation went down last fall, and we were able to obtain indictments and make arrests, and there is more to come.

So we have been working with the Department and working with the U.S. Attorney's Office to bring cases that we at DEA feel are significant and violate those eight factors.

Senator GRASSLEY. Do you think that some of the things you just told me have led to any discussion about revisiting the decision not to challenge the State law? Has it gone that far?

Administrator LEONHART. I am not aware of any discussion. I know the stakeholders within Government—ONDCP, HHS, and others—you know, we are finding a way to look at the data that is coming out from those States so that we are in a better position to assess what is going on.

Senator GRASSLEY. But then is that information being accumulated to advise people in prosecution whether or not these States ought to be left alone or not? That is what I was getting at. Do you think it is being revisited by the people that originally made the decision as a result of some of the things you can tell them if they listen to you?

Administrator LEONHART. I believe that they are assessing it. To what extent they are assessing it, I do not know.

Senator GRASSLEY. Okay. Let me go to the heroin epidemic. I am sure you would agree that enforcement of our drug-trafficking laws is an important component of the Federal response to our country's heroin epidemic, so I ask a question about heroin trafficking.

First, I want to be clear about whether mandatory minimums are applicable to heroin users or dealers. The law currently applies a 5-year mandatory minimum sentence for possessing with the intent to distribute 100 grams of heroin. So my first question is: How many hits does 100 grams of heroin contain? And is that number of hits consistent with someone who is just a plain dealer?

Administrator LEONHART. Well, Senator, to answer your question, this packet is a 1-gram packet, so 100 of these. Depending on the experience of the user—because it will change. If you are a novice user, you will not need as much. If you are an experienced user, you will need more. And this is not taking into account what type of heroin it is or what part of the country this is coming from. But, on average, with one hit being about 30 milligrams, this one packet—100 of these would produce about 3,300 to 3,500 uses.

Senator GRASSLEY. Okay. Well, then, is that number of hits consistent with someone who is just a plain user?

Administrator LEONHART. That in our world would be dealer quantities.

Senator GRASSLEY. Okay.

Administrator LEONHART. Traffickers.

Senator GRASSLEY. I will have to end with this because my equal time is just about up. As I mentioned earlier, our Federal prosecutors making these cases on the line every day have told us that the system of penalties in place now is a critical tool for them to be able to dismantle drug-trafficking networks to keep our communities safe. Do you and your DEA line agents find the mandatory minimum sentence to be a valuable tool? And if so, explain why you consider it a valuable tool?

Administrator LEONHART. Having been in law enforcement as an agent for 33 years, a Baltimore City police officer before that, I can tell you that for me and for the agents that work for DEA, mandatory minimums have been very important to our investigations. We depend on those as a way to ensure that the right sentences are going to equate to the level of violator that we are going after.

Senator GRASSLEY. Tell Senator Leahy he can have 23 more seconds. I went over that.

[Laughter.]

Senator GRASSLEY. Thank you very much, Mr. Chairman.

Senator WHITEHOUSE [presiding]. Thank you very much, Senator Grassley.

I have two questions that I will address now with the Administrator. The first has to do with the development of your policies as prescription drugs, and the abuse of prescription drugs, and particularly opioid prescription drugs, increasingly dominates America's drug abuse problem. My worry is that as you direct more law enforcement attention to that problem and more regulatory attention to that problem, you may intrude on the legitimate and proper use of those prescription drugs. And I am wondering what the structure is within DEA for evaluating those concerns, because while it is definitely a concern that we address the abuse of these prescription drugs, it is also a concern if an 80-year-old woman who is alone in the world and living in a nursing home is in terrible pain at 2 o'clock in the morning and there is no way for her to get relief from her pain because we have made it such a fortress of regulation around her bedside that you have to get a doctor up at 2 in the morning to go do that, and that is not likely to happen.

How does the sensitivity to the concerns of the elderly and other needy users of these drugs, legitimate users of these drugs, play into your calculation?

Administrator LEONHART. Senator, at DEA, you know, we have the Office of Diversion Control, and working with them, it is very important to strike that balance. It is very hard, but it is very important to us because—

Senator WHITEHOUSE. Who is the advocate for that balance within DEA?

Administrator LEONHART. Well, I am the advocate for the balance, but so are the men and women that are working not only in the Office of Diversion Control but even with our special agents in charge, and I can give you an example. We have—

Senator WHITEHOUSE. I mean more specifically, in terms of the development of this regulation, there are people who are going to be involved in it. Is there somebody in that who actually has the task of trying to look at this from the legitimate user's point of view and make sure that that point of view is brought into the discussion?

Administrator LEONHART. Several different levels, and it depends on what regulation, but regulations that require rulemaking always have a comment period, and so the regulations that we have put out as interim or as proposed rulemaking, all of those comments have come back, and we have had some that have come back with 200-plus comments. All of those comments are taken into consideration and addressed. And so those comments and concerns are

looked at by the Office of Diversion Control in coming up with a final rule, but they are also looked at—

Senator WHITEHOUSE. So the comment process is really key to that, because it is outside voices coming through the comment process that are really the advocacy voice on this side of that balance.

Administrator LEONHART. It is outside voices, but as the rule moves within the agency at the chief of diversion control level, he is looking at it, and he has done a very good job making sure that there is that balance. And then before it gets to the Deputy Administrator or myself, there is discussion about impact on any rule that we sign with the Office of Diversion Control.

Senator WHITEHOUSE. Okay. As this goes forward, just do not forget the elderly lady alone and in pain as you are trying to crack down, very legitimately, on these abused but regulated and lawful prescriptions.

The other question is on electronic prescribing. The agency and I have had a long back-and-forth on this subject, and after a considerable effort and considerable time, ultimately you changed the regulations to allow electronic prescribing of controlled substances, which I think was a huge step forward.

One of the values of that is allowing for law enforcement access to data that the system produces so that you know if a podiatrist is prescribing lots of hydrocodone, maybe that is worth looking into. If the same individual is going to five different doctors and five different pharmacies and getting prescriptions filled for oxycodone, maybe that is worth looking into. And if somebody goes from 50 prescriptions a month to 500, maybe that is worth looking into.

But I do not see that developing very effectively between DEA and the States, and I am told that the Office of the National Coordinator for Health Information Technology is right now working to develop consensus standards for exchanging this kind of information with the prescription drug monitoring programs. I am not aware that DEA is actually involved in that conversation. Similarly, there is a White House initiative called the “National Strategy for Trusted Identities in Cyberspace,” which helps deal with authentication and other issues when you are dealing with electronic information. And I am not aware that DEA is involved in that process either.

Are you involved in those processes, and should you be?

Administrator LEONHART. Senator, I will go back and check on the first one you mentioned. I am not aware of, and we very well could be. On the second one, I know we have been involved in the certification process, if that is what you are talking about. We have certified the companies that then go in and bless whatever technology is going to be used. So we are often involved in the conversation. But having been involved with the trusted IDs, as you—the conversation as you have just described, I will need to get back to you on that.

Senator WHITEHOUSE. Okay. Well, I look forward to working with you. I think that the value of moving toward electronic prescribing for controlled substances from an enforcement point of view is to be able to identify peculiarities and outliers for further law enforcement investigation. And if you are not engaged in getting that done, you are not helping the program go forward.

I will stop right here and end the tradition of going well over time and yield to Senator Sessions.

Senator SESSIONS. Thank you, Mr. Chairman, and I agree with you that prescription drugs, as we described in Mobile a number of years ago, the illegal use of prescription drugs is a winnable war. I mean, it is something that can be controlled, and I believe a united effort can make real progress in that. I hope you will continue to work at it.

Isn't it true that a number of illegal prescription drugs that are found on the streets may actually have been paid for by Medicaid, Medicare, or private insurance and, indeed, represent a fraud on those companies and the taxpayers?

Administrator LEONHART. You are absolutely correct, Senator. In fact, a number of our cases we work with other agencies who are investigating Medicaid and Medicare fraud. That is quite common in our diversion investigations.

Senator SESSIONS. Our little plan was simply with the police department that everybody arrested with an illegal prescription drug, the case would not be plea bargained until they told where they got the drug, and we ended up forfeiting two drug stores who were distributing drugs out the back door illegally.

My experience in this area came when President Reagan appointed me United States Attorney in the early 1980s, and we commenced a community-wide effort to create a climate of hostility to drug abuse. At that time, according to the authoritative University of Michigan study, over 50 percent of high school seniors acknowledged that they had used an illegal drug within the last year. That was a dramatic statistic. It threatened the future of our young people in every community in America. Groups came together to educate, to try to reverse that trend. As a part of that, those experts told us law enforcement, effective prosecution, arrest of drug dealers, as well as an effort to create a climate of hostility to drugs were all part of the goal. And within 10 years, the percentage of high school students using illegal drugs had dropped below 25 percent. That was a tremendous achievement.

The murder rate in 1980 per 100,000 was over 10; whereas, it dropped to under 5 today. And we have seen a continual drop. I think that even violence, would you not agree, is often connected to drug use and drug abuse?

Administrator LEONHART. You are absolutely correct. I think that there is a correlation between the fact that we did approach the drug issue not only from enforcement but also from a demand reduction and messaging point. I think there is a correlation there. A 35-percent reduction in overall drug use since 1979, the same with high school seniors, and we see that same drop in violent crime. So I do see a connection.

Senator SESSIONS. And you are seeing it edge upward now in recent years in drug use among young people?

Administrator LEONHART. We were doing very good, we were doing very good until the messaging changed, and we started to see—we had an exploding prescription drug problem, and that has now become a heroin problem as well. But all the other numbers were dropping. Like I mentioned in my opening statement, we have seen cocaine use drop to all-time lows in this country. We have

seen meth use drop by almost a third. So I believe that it is the holistic approach, you know, prevention on the front end, treatment, and enforcement, because a lot of people are not going to treatment without that nudge from law enforcement. It is important.

Senator SESSIONS. Without that nudge from law enforcement. That is what the treatment people and the experts I dealt with said, some of the best. You have to be able to arrest people, and then you are intervening in their destructive habit, and you have a chance then to change their lives many times. And I have seen that with drug courts and other type ideas.

But I have got to tell you, you said the messaging changed, and I think some people are irresponsible in what we are hearing about particularly marijuana. I thank you and some of your officials in DEA for speaking out and telling the truth about the dangers of marijuana. This is not a non-dangerous drug. And I got to tell you, in terms of messaging, the President's statement to me, I spent 12 years working with grassroots citizen groups to change the approach to drugs and the climate of drugs and to make it a hostile climate for drugs and explain the dangers of drug use.

For 1 year, we met every single week—the mayor, the chief of police, the head of mental health—and we discussed these issues.

This is why it is so painful to me and to every person who has dedicated themselves and given time, effort, and money to reversing drugs, for the President of the United States to say, "As has been well documented, I smoked pot as a kid. And I view it as a bad habit and a vice, not very different from cigarettes that I smoked as a young person up through a big chunk of my adult life. I do not think it is more dangerous than alcohol."

That is the President of the United States gratuitously making a statement of extraordinary importance. It has the potential to eviscerate the work of thousands of Americans, hundreds of thousands really, to try to explain the dangers of drugs.

So let me ask you, did the President consult with you before he made that statement?

Administrator LEONHART. I have not talked to the President about that interview.

Senator SESSIONS. Do you know if he talked to the drug czar, the Office of National Narcotics and Drug—

Administrator LEONHART. I do not know who he talked to.

Senator SESSIONS. I do not think he talked with medical experts either, who tell us repeatedly of the dangers particularly to young people from marijuana use, much less others.

Isn't it true that you do go through trends where we have seen a move from prescription drugs to heroin?

My time is up. I will stop there, but maybe I will submit a written question. We need to find out more about the abuse and growth of heroin. In Alabama, we have seen a 400-percent increase in deaths in Birmingham from heroin use, from 14 in 1910 to the upper 70s last year. That is a dramatic increase in deaths from heroin in Birmingham, Alabama.

Thank you, Mr. Chairman.

Senator WHITEHOUSE. Thank you, Senator Sessions. And we all appreciate the experience that Senator Sessions brings to this equation as the former U.S. Attorney for his State.

Senator SESSIONS. As the Chairman has been himself.

Senator WHITEHOUSE. I now recognize Senator Klobuchar, and before we start her clock, let me express my appreciation to her for the work that she has done, I think really leading this Committee, on synthetic drugs, bath salts, and so forth, and trying to improve the scheduling response to that. Senator Klobuchar.

Senator KLOBUCHAR. Well, thank you very much, Mr. Chairman, and thank you for holding that all-day meeting yesterday with Senator Portman about addiction and the work that needs to be done. I was pleased to take part in that.

And we welcome you, Administrator Leonhart. You spent many years in Minnesota—how many years?

Administrator LEONHART. Most of my childhood.

Senator KLOBUCHAR. Yes, well, we are proud to have you in this job. As you and I talked about last week, I recently led a delegation to Mexico a few weeks ago on the topic of sex trafficking as well as heroin, and I think we asked every single official there, including the Attorney General of Mexico and the head of the Federal police, about what was going on with heroin. I was there with Senator Heitkamp and Cindy McCain, wife of Senator John McCain. And as you know, about 50 percent of the heroin is grown in Mexico and 60 percent of the heroin that we have come into the U.S. is either grown or distributed through Mexico.

Just as Senator Sessions was talking about, we have seen a lot of overdoses in Minnesota. In the first half of 2013 alone—this is the first half—91 people died of opiate-related overdoses in Hennepin and Ramsey County alone. It was a significant increase. Hospital visits for heroin nearly tripled from 2004 to 2011. And in the 7,000-person community of St. Francis, Minnesota, three young people have died of opiate overdoses since May, just to give you a sense of why this was important to me, why it was one of the reasons I went down to Mexico. And the things we learned there was, as you know—and you and I talked about the prosecutors there and the police working with our law enforcement and DEA are really ramping it up on the cartels. They were able to capture—Mexican police captured El Chapo in Mexico, long-time boss of the powerful Sinaloa drug cartel, which dealt in heroin. And talking to them, it appears there are still many issues with some of this now, with taking on some of the leadership of the cartels, we now have smaller gangs dealing in some of these drugs. We have lower-level kidnappings, express kidnappings for a day, and talking to the Mexican authorities, three things: one, that they are trying to beef up their southern border as they are seeing that pure heroin coming up from other countries down there, something we do not always think about; second, we pushed on the eradication issue, which has been successful in parts of Colombia, as we are starting to see not just the black tar heroin coming out of Mexico but some of their own white powder heroin; and then, of course, the third is the continuing coordination with our own DEA and law enforcement in going after these cartels.

This comes at a time where Mexico is so eager to partner with not just the United States but Canada as part of the New Day in North America, and there is so much potential for our economies to work together. And I actually see some potential in a major way for us for exporting things down there if they can grow a middle class and take care of some of this violence which has really prohibited them from getting—reaching their full potential.

So if you could talk a little bit about your efforts with Mexico.

Administrator LEONHART. Thank you, Senator, for sharing what you discussed on your trip, and thank you for the interest, especially bringing up the heroin issue on your trip.

The relationship between officials in Mexico and the DEA and the greater U.S. Government law enforcement community is still at an all-time high, very, very good collaboration, and that is why we have the success of being able to, you know, take into custody Chapo Guzman and how that impacts drug trafficking around the world, because he was such a big figure.

We have a number of operations and a number of initiatives that we are working jointly with our Mexican counterparts and the other Government agencies, and this is starting to pay off in dividends, not just with El Chapo's arrest but also the arrest of other leaders and mid-level leaders of Los Zetas, of the Gulf cartel, of the Beltran-Leyva organization, and all of these organizations that really are responsible for most of the cocaine, most of the heroin, most of the drugs—meth—that are landing in our communities.

So when Senators take an interest in pushing for good relationships with our Mexican partners, we need to thank you for that.

Senator KLOBUCHAR. Another issue which you and I have discussed at length is the bill—and this does relate to heroin, since four out of five heroin users now got their start with prescription drugs and got addicted to prescription drugs and then turned to heroin when they cannot find the prescription drugs, and often-times end up dead or addicted for life. One of the things that we passed 4 years ago, Senator Cornyn and I, passed out of this Committee and was signed into law, was the Secure and Responsible Drug Disposal Act. The idea here is to change some of the rules to make it easier for drug takebacks, not just have them once every 3 months in communities where we know they are collecting tons, but try to find more permanent arrangements in long-term care facilities as well as potentially pharmacies if the pharmacy is giving them the opportunity, not required but to take back these drugs, how easy that would be as we no longer want to tell people to flush these drugs down the toilet because of the water supply or my favorite, grind them up with coffee grinds and put them in the garbage, because I do not have a lot of coffee grinds in my house.

So I think that is not realistic for busy families, and I am hopeful that we can get these done. You know, we have been frustrated by how long it took, and I heard a little rumor that maybe you got some comments back from the Office of Management and Budget this week, and that that means it is then back in your court, if that were to happen, how long do you think it will take to get these rules out?

Administrator LEONHART. Well, I can tell you that we did get them back, and we have already taken care of a couple of the con-

cerns. There is still a concern that we need to address, but we are hoping that we can do that very quickly. We remain optimistic, because I know we have all been waiting a very long time to have these regulations in place so that people can have kind of a 24/7 way to dispose of the medications that have for year languished in their medicine cabinet.

Senator KLOBUCHAR. Well, I appreciate that, because every time I see one of the public service ads, which I think are very good, showing someone open the medical cabinet and then seeing their kid's face because their kid is taking the drugs that should not be in there anymore, I always think, "Okay, this is great. We are doing this. It is going to stop people from getting addicted and then moving on to heroin." But if they do not know what to do with the drugs and they have no real place to put them, we have a problem. So I appreciate that and urge you to get these rules done as soon as possible.

Thank you very much, Administrator.

Senator WHITEHOUSE. Thank you, Senator Klobuchar.

Now we turn to Senator Hatch who, among other things, is the lead on the Designer Anabolic Steroid Control Act with me.

Senator HATCH. Well, thank you. It is certainly a pleasure always to work with you and other Members of this Committee. I appreciate the effort you put forward.

Welcome, Ms. Leonhart. We are so grateful to have you here. I first want to raise the problem of marijuana cultivation on land in my home State of Utah that the Federal Government currently owns. The Federal Government owns a majority of land in only five of the 50 States, and that figure is actually around 70 percent of my home State of Utah.

Now, people in most of the country do not know what that means, but Utahans certainly do. It means that the Federal Government has the responsibility to address issues and problems related to the Federal land itself. And this is not the first time I have addressed the Federal Government's failure to live up to that responsibility.

Last year, for example, I offered an amendment to the immigration bill that would enhance penalties for marijuana cultivation on Federal land. Now, this Committee adopted my amendment by unanimous consent. These activities pose a direct threat to public safety in and around our communities.

Do you agree that this is a serious problem and that it is the Federal Government's responsibility to solve it?

Administrator LEONHART. I do, Senator, and, you know, we have worked with our State and local counterparts in Utah and have done a number of cases, just as you have mentioned, that have been on public lands.

Senator HATCH. I appreciate that.

Administrator LEONHART. It seems that we each year are seizing more and more plants until recently. We have almost seen a shift off of public lands, though, to indoor grows, but the importance of continuing to go after the growing on public lands is, number one, it is an enforcement priority for the Government because that is Government property; growing on public lands, there is a lot of concern because we see Mexican trafficking groups take hold on a

number of those grows. We also are concerned because of the dangers, you know, someone hiking through the woods coming across a grow. There have been instances, not just in Utah but instances in other States, where there have been booby traps, and it is dangerous.

So we have continued our efforts. We continue to run an eradication-suppression program. We continue to fund State and local authorities who pledge to go and take enforcement on public lands. And we will continue to do so, and I know you have been very supportive in our efforts, and I want to thank you for that.

Senator HATCH. Well, thank you. The problem I just described is getting worse for two related reasons:

First, with the second-highest percentage of Federal land ownership in my home State, Utah sits next to Colorado, which now has legalized marijuana. The international drug cartels that already had been invading Federal land to cultivate illegal drugs will inevitably work to increase supply to meet the increased demand.

And, second, even though your prepared statement says that the administration “continues to steadfastly oppose marijuana legalization,” the Justice Department announced that it will not challenge the legalization of marijuana in either Colorado or Washington. In addition, the administration says it wants to lower sentences for drug offenders and even invites those now in prison to apply for clemency.

Now, to me, those are not welcome developments in a State like Utah where the Federal Government should be doing more to prevent its land from being used to fuel the problem.

Now, do you agree that legalization of marijuana will increase the demand for marijuana and possibly other drugs as well?

Administrator LEONHART. Senator, the administration opposes legalization of marijuana, and I believe one of the reasons it does oppose it is we know that where we see marijuana legalized, you should expect more use.

Senator HATCH. Okay. Your prepared statement details some of the evidence that marijuana is, in fact, harmful to a person's physical and intellectual development and may very well impair their quality of life. Now, research also shows, however, that whether a person will use drugs depends very much on whether that person believes that the drug is harmful.

According to the Monitoring the Future Study, the perception of harm for regular marijuana use among 12th graders has steadily declined. Young people increasingly see marijuana as legal and medicinal rather than harmful. And now we see innocent-looking edibles such as what appear to be cookies or even candy that ABC News has reported can be exponentially more potent than when marijuana itself is smoked.

I have here in my hand an Alert Bulletin from the Colorado Information Analysis Center dated March 19, 2014. It says that there has been an increased amount of marijuana-infused products sold to the public and that these products include fruit chews, cupcakes, and even butter and banana bread—in fact, more than that.

Mr. Chairman, I ask consent to place this bulletin in the record at this point.

Senator WHITEHOUSE. Without objection, it shall be included in the record.

[The bulletin appears as a submission for the record.]

Senator HATCH. Thank you, Mr. Chairman.

Now, Ms. Leonhart, I think the inevitable result of this trend will be increased use, abuse, and addiction. Do you share my concerns on this?

Administrator LEONHART. You have a right to be concerned, and as law enforcement officers, we are very concerned about that, especially when we see some of these edibles—the people who are making them and selling them are calling them “adult gummy bears,” but you cannot even tell the difference between, you know, kids’ gummy bears and those laced with marijuana.

So we are very concerned, and it is one of the reasons why the Department of Justice in the August 29th memo with the eight factors—and they have, you know, factors in there related to kids, selling to kids. It is another reason why they put that memo out in anticipation that the States that pass legalization will put in place aggressive—not just on paper but real aggressive oversight, regulatory systems to take care of that. And we are very concerned about those edibles and about the high concentration. You know, a person you heard about, the young student who jumped out a window after eating the cookie, which was, you know, seven or eight servings, not just one. We are concerned about all of that. The marketing, when these packages look like they are marketed for kids, they look like candy bar wrappers. We share your concern.

Senator HATCH. Well, I appreciate it.

Mr. Chairman, can I ask one other question?

Senator WHITEHOUSE. Of course. It is just the two of us. Please proceed. Take the time you need.

Senator HATCH. See what a great Chairman he is?

I mentioned earlier what I consider to be the administration’s misguided invitation for Federal prisoners to seek clemency in these cases. Now, the President has the authority to grant clemency in individual cases, and I would be the first to stand up for that right, and I think it should be exercised from time to time, and I decried some of the former Presidents not exercising clemency a little more than they do.

But I cannot remember a President using that authority to change sentences for an entire category of Federal prisoners simply because he does not think that they should be in prison.

Now, Congress alone has authority to determine sentencing policy, but I do not think the President appears to understand that. He is, in effect, trying to set sentencing policy on his own.

Now, I do not expect you to comment on the President’s decision, but I did want to state for the record that I think he is going too far, that he is misusing his authority. And I will help him on clemency because I think sometimes we do not use that power enough as President. But I think he should work with us in Congress rather than against Congress, and I think that I would just recommend that to the President as part of this hearing.

But States choosing to legalize marijuana will in some way regulate that to commercial activity. But as you know, the same criminal organizations that profit from selling marijuana deal also in

drugs such as heroin, cocaine, methamphetamine, as well as engaging in human trafficking and other drug-related crimes.

Now, law-abiding citizens and legislators may distinguish between such things, but traffickers and other criminals do not distinguish between them. They simply follow the money.

What is the DEA doing to ensure that stores and dispensaries that legally sell marijuana do not act as fronts for illegal activities? And, further, how are you monitoring that marijuana being sold in these dispensaries is not obtained from criminals?

Administrator LEONHART. Senator, we are concerned about that. On the first part, we have continued—where we see in Colorado or Washington, where we see these dispensaries that are impacting the eight factors in the August 29th memo, we are taking action. Just the action—and I am not sure if you were here, but I mentioned earlier about an action that we took in Colorado on Friday. Concerns for us were that the money that went into this business came from Colombia and Colombian nationals. So we took action and we will continue to take action where we see violations of those eight Federal priorities.

Senator HATCH. Thank you. Mr. Chairman, I appreciate you giving me this extra time.

Senator WHITEHOUSE. I am delighted to do it.

Senator HATCH. Thank you, Madam.

Senator WHITEHOUSE. The topic of the mandatory minimums has come up on several occasions, and I just wanted to close with a comment on that. I have been the U.S. Attorney for Rhode Island, and I have been the Attorney General of Rhode Island, and clearly from a law enforcement perspective, there is enormous value to mandatory minimums. But as I think both courts and prosecutors agree, they also represent a shift of power from the court to make sentencing decisions to the prosecutors and to law enforcement to have sentencing decisions implicitly made through charging decisions. And the power that gives prosecutors can be very helpful. I have used it myself, because the threat of how you charge a case can turn a defendant in to a cooperator, and a cooperator can turn into a valuable witness against an even more dangerous defendant.

So as we approach this issue, I think we have to recognize that this was an important tool in the hands of law enforcement. But at the same time, I think we also have to recognize that, from a cost-benefit equation, some people who ended up in prison for very lengthy terms for relatively minor offenses were not—the effort was not serving the public, was not serving the public safety, and it was not serving the taxpayer.

And so we are clearly in a conversation on that right now, particularly in the Judiciary Committee, as it relates to the Durbin-Lee Smart Sentencing Act. I think that is a conversation that is well worth having, and I think there is room for progress there.

There are clearly two sides to the equation, but I wanted to make sure that the record of this hearing recognized the other side of the equation, which is that, from a public safety and effectiveness point of view, these mandatory minimums have their downsides as well as their upsides.

I also wanted to express concern with something, Madam Administrator, that you said to Chairman Leahy with regard to a pro-

gram that has been of interest to Members of this Committee. You indicated, if I wrote it down correctly, that you all have briefed Members of the Committee. I do not believe that has actually taken place. I think what has taken place is that Members of the Committee asked to be briefed, and we were told that that was not possible because of an ongoing agency review. And then when we pressed, we were allowed a law enforcement-sensitive staff briefing, which consisted of the staff being told that they could not be briefed on this because there were not Members present.

So I think that was a not entirely satisfactory turn of events given that Members had been excluded from the meeting. The only thing that was offered was a staff briefing at that point.

So we are working our way through that, and I think we are going to get our briefing, but I do want to do two things: one is a question for the record to the Drug Enforcement Administration for whatever constitutional basis you think there is for a claim that congressional oversight is limited by ongoing agency review. To me that is a constitutional proposition that has no support and no substance. It appears to have been the basis for delaying the member briefing, and so perhaps you are aware or your general counsel is aware of constitutional principles I am not aware of, and I would like to have them put on record as a response to a question for the record in this hearing how they would answer that question.

Pushing for that briefing has been kind of a challenging experience. Pushing to try to get the e-prescribing rules changed, which took 3 years, was a challenging experience. Senator Grassley and I helped referee the battle between DEA and GAO over GAO's inquiries into drug shortages. That was kind of a challenging experience. And as I look at the e-prescribing connection to prescription drug monitoring programs, once again it seems that we see challenges. I do not know if that is representative of a larger, ongoing bureaucratic culture of non-cooperation at DEA, but as these individual events begin to stack up, episodes begin to look like a pattern. And perhaps in response to a question for the record, you could explain DEA's position with regard to those different instances, because I do not think that the agency wants to develop a reputation as an agency that does not cooperate and does not work well with others.

Administrator LEONHART. You are absolutely right.

[The information referred to appears as a submission for the record.]

Senator WHITEHOUSE. I assume that you have no concern with first responders getting access to naloxone for overdoses when—

Administrator LEONHART. We are very supportive of that, in fact, helped raise that with the International Association of Chiefs of Police who passed a resolution so that their members were aware that that is a very good way for police departments and first responders to attack the heroin and opiate overdose problem.

Senator WHITEHOUSE. Good. And I think we all applaud Attorney General Holder for having made the statement that he did and pushed this issue forward from local first responders, whether law enforcement or EMT or Fire, to be prepared for the circumstances as we are presented with them more and more. I had a hearing—I should not say a hearing—a conference yesterday, Senator

Portman and I did, on addiction and recovery, and one of the statistics that emerged from that is that 105 Americans die every day from overdoses. And to the extent we can stem that toll of death and tragedy by having our first responders properly prepared, that seems like a good thing to do.

So I thank you for appearing before the Committee. I thank the DEA for their courage and their vigilance in executing their law enforcement responsibilities. You and I have a friend in common who is a DEA agent whose career includes a particular instance of very great bravery, done for a very important purpose, and I think of DEA in those terms very often. So we wish you well in the work that you do, and we look forward to continuing a healthy and robust relationship between this Committee and your agency.

The record of this hearing will remain open for one additional week if anybody wishes to add anything, and subject to that, the hearing is closed.

Administrator LEONHART. Thank you.

[Whereupon, at 11:32 a.m., the Committee was adjourned.]

[Additional material submitted for the record follows.]

A P P E N D I X

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Witness List

Hearing before the
Senate Committee on the Judiciary

On

“Oversight of the Drug Enforcement Administration”

Wednesday, April 30, 2014
Dirksen Senate Office Building, Room 226
10:00 a.m.

The Honorable Michele M. Leonhart
Administrator
United States Drug Enforcement Administration
Washington, DC



Department of Justice

TESTIMONY OF

MICHELE M. LEONHART
ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

FOR A HEARING ON

OVERSIGHT OF THE DRUG ENFORCEMENT ADMINISTRATION

PRESENTED ON

APRIL 30, 2014

**Written Testimony of Administrator Leonhart
Before the Senate Judiciary Committee
Wednesday, April 30, 2014
Washington, D.C.**

Chairman Leahy, Ranking Member Grassley, and Members of the Committee: Good morning, and thank you for inviting me to testify regarding oversight of the Drug Enforcement Administration (DEA). As the leader of DEA, an organization of almost 10,000 employees dedicated to a vital mission, I would like to express our collective appreciation for the support that this Committee has shown us over the years. Furthermore, I welcome the opportunity to continue our partnership and to share DEA's recent accomplishments with you and the American people.

DEA, in its unique capacity as the world's preeminent drug law enforcement agency, identifies, investigates, disrupts, and dismantles drug trafficking organizations (DTOs) responsible for the production and distribution of illegal drugs. DEA is responsible for enforcing the provisions of domestic controlled substance and chemical diversion trafficking laws and consequently works closely with our local, state, federal, and international counterparts. Enforcement is, and will always be, our top priority.

Throughout DEA's 40-year history, we have safeguarded Americans from the dangers associated with the drug trade. In recent years, DEA investigations, partnered with other Federal, State, local, and international law enforcement counterparts, have resulted in the successful arrest of major international criminals, including arms trafficker Viktor Bout, 'The Prince of Marbella' Monzer Al Kassar, Afghan drug lord Haji Baghco, Colombian drug trafficker Daniel Barrera-Barrera (aka Loco Barrera), former President of Guatemala Alfonso Portillo. Most recently, DEA supported the Mexican government's successful efforts to apprehend the head of the world's largest and most prolific drug trafficking organization, Joaquin "El Chapo" Guzman Loera.

We have also had many notable successes in the effort to reduce drug abuse in this country since DEA's inception in 1973 by combating illicit drug availability. According to the most recent National Survey on Drug Use and Health, the overall rate of illicit drug use in America has dropped by roughly 35 percent since 1979.¹ Since 2006, we have seen sharp decreases in the number of current users of cocaine (32 percent) and methamphetamine (40 percent).² Statistics like these demonstrate that through a balanced drug control strategy, one that includes strong enforcement, education, prevention, and treatment components, we can make significant progress in protecting our nation from the dangers of drug use.

¹ National Household Survey on Drug Abuse, 1979 percentage shown on ONDCP graph <http://www.whitehouse.gov/blog/2013/02/12/are-drugs-today-really-cheaper-purer-and-more-available-ever>. National Survey on Drug Use and Health, 2012 percentage shown on graph <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf>

² Past month illicit drug use among persons aged 12 or older, National Survey on Drug Use and Health, 2006 to 2012.

While these overall trends are positive, we still face significant challenges. Recently, the Centers for Disease Control and Prevention (CDC) reported that 38,329 people died from a drug overdose in the United States in 2010, the most recent year for which information is available.³ Nearly 60 percent of those drug overdose deaths (22,134) involved prescription drugs. And of those deaths, 75 percent (16,651) involved an opioid analgesic, also known as prescription painkillers. These deaths represent not just a statistic, but our family members, friends, neighbors, and colleagues. Years of over prescribing prescription painkillers and decreased perception of risk associated with drug use, particularly opiate abuse, has created too many new addicts. The rates are alarming: in 2011, 2.1 million Americans abused or were dependent to opioid pain relievers and 438,000 were addicted to heroin.⁴

DEA intelligence indicates that South American and Mexican drug trafficking organizations have exploited this increased demand by producing heroin with increased purity that is not only more readily available, but also cheaper. That product enters the United States primarily across our southwest border and, not surprisingly, the amount of heroin seized there has increased nearly 300 percent from 2008 to 2013. During roughly the same time period (2008 to 2010), heroin-related overdose deaths have increased by 45 percent.⁵ This disturbing increase may be attributable to increased purity and a younger, less experienced user population. As the Administration takes a multifaceted approach to curb the availability of prescription-based painkillers on the illicit market, those addicted to opioids who are not seeking medication-assisted therapy may increasingly turn to cheaper or more easily-obtained alternatives, such as heroin.

In addition, approximately 4.3 million people abuse or are dependent upon marijuana, more than any other illicit drug.⁶ Currently, marijuana is the most widely available and commonly abused illicit drug in the United States. In 2012 alone, nearly 32 million people ages 12 and older reported using the drug within the past year,⁷ and in 2013 one out of every 15 high school seniors is a near daily marijuana user.⁸ A major study published in the Proceedings of the National Academy of Sciences in August 2012, found that long-term marijuana use started in the teen years has a negative effect on intellectual function in adulthood; the more persistent the person's dependence on marijuana, the more significant the impairment.⁹ Heavy marijuana users¹⁰ also reported that the

³ Drug Overdose in the United States: Fact Sheet. www.cdc.gov/homeandrecreationsafety/overdose/facts.html (accessed March. 18, 2014).

⁴ Muhuri, et al. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the US. Center for behavioral Health Statistics and QualityData Review. SAMHSA (2013). 2013.

⁵ Centers for Disease Control and Prevention, National Center for Health Statistics (accessed February 11, 2013) <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5729a1.htm>

⁶ Substance Abuse and Mental Health Services Administration. Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings. Department of Health and Human Services. [September 2013]. Available:

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHResults2012.htm#fig7.2>

⁷ Substance Abuse and Mental Health Services Administration. Results from the 2012 National Survey on Drug Use and Health: Detailed Tables. Department of Health and Human Services. [September 2013]. Available:

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect6peTabs1to54-2012.htm#Tab6.1A>

⁸ "American teens are more cautious about synthetic drugs." University of Michigan Press Release, December 18, 2013. P. 3 www.umich.edu/news.

⁹ -Meier et al., "Adolescent-onset cannabis and neuropsychological health." Proceedings of the National Academy of Sciences. [August 27, 2011]. Available: <http://www.pnas.org/content/early/2012/08/22/1206820109>

drug impaired several important measures of health and quality of life, including physical and mental health, cognitive abilities, social life, and career status.¹¹ These statistics help describe the effects of marijuana and the health and safety implications on the users themselves, their families, and our communities.

DEA's enforcement responsibility as it pertains to marijuana and other drugs are clearly delineated in federal law. The Administration continues to steadfastly oppose marijuana legalization, and DEA will continue to build cases against individuals and organizations that are using state marijuana laws as a pretext to engage in large-scale trafficking of marijuana and other illicit drugs to other states; target marijuana businesses near schools, parks, and playgrounds; and take action against those who cause environmental damage by growing marijuana on our public lands. But our responsibility and dedication to the American people goes further – to educate about the misperceptions and dangers associated with drug abuse. The Food and Drug Administration has noted that “there is currently sound evidence that smoked marijuana is harmful,” and “that no sound scientific studies support medical use of marijuana for treatment in the United States, and no animal or human data support the safety or efficacy of marijuana for general medical use.”¹²

Twenty-one states and the District of Columbia have now legalized marijuana’s use for certain medical conditions. These laws authorize the smoking of marijuana plants or the consumption of crude extracts that have not undergone scientific testing demonstrating that they are both safe and effective. The National Institute on Drug Abuse (NIDA) and other components of the National Institutes of Health are conducting research to determine the possible role that active chemicals in marijuana, like tetrahydrocannabinol, cannabidiol, or other cannabinoids may play in treating autoimmune diseases, cancer, inflammation, pain, seizures, substance use disorders, and other psychiatric disorders.¹³ DEA supports these, scientific research efforts by providing Schedule I research registrations to qualified researchers. In fact, DEA has never denied a marijuana-related research application to anyone whose research protocol had been determined by the Department of Health and Human Services to be scientifically meritorious.

Perhaps one of the most effective tools DEA has in this fight is our ability to target the financial infrastructure of major drug trafficking organizations and members of the financial community who facilitate the laundering of their proceeds. By seizing drug proceeds, DEA prevents drug

<http://www.medicalnewstoday.com/articles/250404.php>; “Teen Cannabis Use Linked to Lower IQ.” Christian Nordqvist. Medical News Today. August 28, 2012. <http://www.medicalnewstoday.com/articles/249508.php>.

¹⁰ Defined as having used on average 18,000 times and a minimum of 5,000 times in their lives.

¹¹ Gruber AJ, Popp HG, Hudson JI, Yurgelun-Todd D. Attributes of long-term heavy cannabis users: A case control study. *Psychological Med* 33(8):1415–1422, 2003. Available: <http://www.ncbi.nlm.nih.gov/pubmed/14672250>

¹² “Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine.” U.S. Food and Drug Administration, April 20, 2006.

<<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm/108643.htm>>.

¹³ National Institute on Drug Abuse. DrugFacts: Is Marijuana Medicine? Available: <http://www.drugabuse.gov/publications/drugfacts/marijuana-medicine>

trafficking organizations from using these funds to fuel the next round of drug production or other nefarious activity to include terrorism. Between FY 2005 through the end of FY 2013, DEA has denied drug trafficking organizations approximately \$25.7 billion in revenue, including \$3.5 billion in FY 2013 alone. To put that in perspective, DEA's total appropriated budget over that same time period totaled \$16.9 billion.

Looking forward, DEA will continue to build on the progress we have made both domestically and internationally. With our state and local partners we target traffickers who significantly impact communities across the nation, frequently bringing with them associated gang activity and violence. These investigations complement and support our international partnerships, allowing DEA to target the world's "Most Wanted" drug traffickers who manage sophisticated criminal organizations with operations that span the globe. Due to the very nature of the threat, it is clear that the antidrug mission this agency carries out is an essential element to the national health and security of the U.S. and our interests abroad.

These comprehensive efforts reflect our historic commitment to bringing drug traffickers to justice. And nowhere is this commitment more evident than in Mexico with the February 22, 2014 arrest of Joaquin "El Chapo" Guzman Loera, the head of the Sinaloa Cartel, by Mexican authorities. This was a significant achievement for Mexico and a major step forward in our shared fight against transnational organized crime, violence, and drug trafficking. We congratulate the Mexican people and their government on this capture. The DEA and Mexico have a strong partnership, and we will continue to support Mexico in its efforts to improve security for its citizens and continue to work together to respond to the evolving threats posed by transnational criminal organizations.

Enforcement strategies such as these, which target major drug trafficking organizations and their proceeds, are one element in the Administration's comprehensive national drug control strategy. Drug trafficking and abuse harms our citizens and endangers future generations of Americans. Today's drug traffickers exploit new and evolving technologies to communicate, launder ill-gotten gains, and facilitate the smuggling of drugs and weapons. DEA must use every tool in the toolbox to combat these organizations through strategic enforcement.

Moving forward, DEA will continue to build upon these gains and focus on emerging threats. Additionally, we will keep working alongside Members of this Committee and other leaders to advance legislation to strengthen the Controlled Substances Act, to ensure the law keeps pace with changes in technology, illicit drug manufacturing, and the discovery of new substances that can be abused.

Targeting the world's most prolific and dangerous drug traffickers is a dynamic and evolving mission, and with it comes a myriad of challenges. But throughout our history, DEA has met those challenges and produced impressive results. Using a blend of ingenuity, dedication and drive, our

agency has time and again targeted the world's most infamous criminals and brought them to justice. DEA plays an important role in our country's holistic strategy of prevention, treatment, and enforcement.

Thank you for the opportunity to appear before you today to discuss the activities of the DEA. I would be happy to answer any questions you may have.

**Statement Of Senator Patrick Leahy (D-Vt.),
Chairman, Senate Judiciary Committee
Hearing On Oversight Of The Drug Enforcement Administration
April 30, 2014**

I welcome Administrator Michele Leonhart of the Drug Enforcement Administration to the Senate Judiciary Committee. In recent years, the Committee has held numerous hearings exploring issues related to drug abuse and drug-related crimes, but today marks the first appearance by Administrator Leonhart before this Committee.

This hearing comes at an important time. Our nation continues to struggle with an old and persistent problem – the seemingly unrelenting addiction to powerful controlled substances. Yet much about this problem is changing. The drugs of choice are evolving, along with the path to addiction for many Americans. Prescription drug abuse has reached epidemic levels, and overdoses from prescription opioids now account for more than half of all drug-related deaths.

State laws are evolving, too. After decades of treating marijuana the same as cocaine and heroin, some states have sought solutions that reach beyond the criminal justice system. Vermont has decided to allow the use of marijuana by patients with debilitating conditions, like cancer and multiple sclerosis. Vermont also has decriminalized marijuana, imposing civil fines on users instead of criminal sanctions and jail. Other states have gone further.

Around the country, law enforcement is now demonstrating a strong commitment to creative approaches to combating drug abuse and addiction. No one questions that disrupting trafficking networks is necessary to reduce the flow of illegal drugs. But we have seen that enforcement alone is not enough. No amount of arrests or seized drugs can truly break America's drug habit. Despite our efforts, supply relentlessly chases demand. A comprehensive approach is needed – one that includes prevention, treatment, and reentry services.

A month ago I brought the Senate Judiciary Committee to Rutland, Vermont. Rutland, like rural towns across the country, has seen a surge in addiction to heroin and other opioids. But the community has come together to respond in remarkable ways. The police department almost functions as a community organizer, helping to shape community-driven strategies through Project VISION. They partner with early intervention coordinators, social workers, and even building inspectors, to address addiction from every angle and to send a clear message that drugs will not be tolerated. Communities in Vermont have also developed successful diversion programs to keep offenders out of the criminal justice system when the underlying issue is a treatable addiction.

I am encouraged to see that the Justice Department is similarly committed to a comprehensive approach. Through its "Smart on Crime" initiative, the Department is supporting prevention and reentry efforts and promoting fairer sentences for low-level offenders. Smart on crime does not mean weak on crime – serious offenders still deserve serious punishment. But it does mean ensuring that finite resources are devoted to law enforcement priorities that are proven effective.

The DEA, too, is committed to addressing drug abuse through prevention. The DEA has long supported educational programs and community-based initiatives that aim to reduce demand for drugs. I view in the same light the Office of Diversion Control, which controls the distribution of prescription drugs. Time and again, we have seen Americans slide into addiction after using powerful prescription opioids. Some even turn to heroin. Heroin has now crept into rural communities once thought unimaginable, and my home state of Vermont has not been spared.

The Office of Diversion Control must maintain a watchful eye over the distribution process and prescribing practices and encourage responsible disposal of unused prescription drugs through drug take-back initiatives. I was pleased to see that, in conjunction with the DEA, authorities in Vermont last Saturday recovered over 3,300 pounds of unused prescription drugs through a take-back event. That means hundreds of thousands of unwanted pills are no longer sitting on shelves and susceptible to abuse. Effective diversion control means effective addiction prevention. As powerful new prescription opioids continue to enter our markets, this work is more important than ever, and I am committed to supporting the DEA's efforts in this regard.

I also believe that the DEA's traditional criminal enforcement authorities still play an essential role. The DEA has enjoyed great success targeting those who profit from the illegal drug trade. There was no bigger target than the Mexican drug kingpin known as "El Chapo." His recent arrest was the result of an extraordinary investigation and pursuit by the DEA and our counterparts in Mexico. And just last week, the Mexican drug trafficker who ordered the 2010 murders of a U.S. consulate employee and her husband was sentenced to life in prison. Much closer to home, I have seen how effective the collaboration is between the DEA and the Vermont Drug Task Force. The Task Force has been able to break up significant trafficking rings that might otherwise have gone undetected.

While the DEA is doing critically important work in many areas, I do want to raise with the Administrator today my concerns about some of its tactics.

I have concerns about some of the DEA Special Operation Division's investigative techniques. Given the sensitivity of these matters, I have raised these concerns privately. But this is an area where additional oversight is needed, and I trust that the Administrator will ensure the DEA's cooperation with this oversight.

I also have repeatedly sought answers regarding the DEA's involvement in a 2012 counter-narcotics operation in Honduras, in which four Honduran civilians were killed including a 14-year-old boy, and in which others were severely injured. I am disappointed that I have only just this week received a response to a letter I sent in October on this matter. I remain concerned about factual inconsistencies in the DEA's description of the operation. In addition, the DEA must make changes to ensure this type of tragedy does not happen again. If not, I will have difficulty supporting DEA's participation in such operations in the future.

Thank you, Administrator Leonhart, for your testimony today. I am eager to hear your ideas for how the DEA can best approach drug policy in a careful, comprehensive way.

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*U.S. Senator Chuck Grassley • Iowa
Ranking Member • Senate Judiciary Committee*



<http://grassley.senate.gov>

Statement of Ranking Member Grassley of Iowa

U.S. Senate Committee on the Judiciary

Hearing on Oversight of the Drug Enforcement Administration

Wednesday, April 30, 2014

Mr. Chairman, thank you for holding today's oversight hearing focusing on the Drug Enforcement Administration. I welcome Administrator Leonhart. There are many issues to discuss about DEA's important work.

The DEA is facing many challenges as it strives to keep our nation safe from dangerous drugs that prevent so many Americans from leading healthy, productive, fulfilling lives. Unfortunately, too many of those challenges are coming from the Obama Administration itself.

The United States is experiencing an epidemic of opioid (OH-pee-oyd) abuse, including abuse of both heroin and prescription pain killers. The 2012 National Survey on Drug Use and Health estimates that nearly 700,000 Americans reported using heroin in the past year, a number that has been steadily increasing.

The effects of this epidemic have been devastating. For example, deadly heroin overdoses increased 45% from 2006 to 2010. The media recently focused attention on the death of acclaimed actor Philip Seymour Hoffman from a heroin overdose. But anyone's death from a drug overdose is a tragedy.

Law enforcement, including the DEA, has a critical role to play in responding to this epidemic. Of course, we can't arrest our way out of it. But we can maintain the current law enforcement tools that help the DEA go after those who are trafficking heroin into our communities.

Unfortunately, the sentencing bill the Obama Administration supports does just the opposite. The proposed Smarter Sentencing Act that recently passed out of this committee cuts the mandatory minimum sentences for those who manufacture, import, or distribute heroin in half. These are penalties for dealers, not users. In the midst of a heroin epidemic, this makes no sense.

But don't take my word for it. In opposing the bill, federal prosecutors themselves wrote that the current system of penalties is the "cornerstone" of their ability "to infiltrate and dismantle large-scale drug trafficking organizations and to take violent armed career criminals off the streets." I don't want to remove this cornerstone, least of all now.

Another challenge for the DEA that I hope to discuss is the mixed message that the Obama Administration is sending young people about the dangers of marijuana use. The Department of Justice declined to challenge state laws that have legalized marijuana, despite the obvious conflict with federal law. In an interview, the President also stated that it was "important" that these states "go forward" with legalization. This has caused confusion and uncertainty about whether using marijuana is really something to be discouraged.

But a recent scientific study served as a reminder of how dangerous marijuana can be. A paper published earlier this month in the Journal of Neuroscience concluded that even casual marijuana use was associated with potentially harmful changes to the brains of young people.

The Department of Justice apparently concluded that so long as the states that legalize marijuana create effective regulatory schemes, federal enforcement priorities wouldn't be undermined. Those priorities include the prevention of violence, increased use among minors, and diversion of marijuana to other states. But what is happening on the ground doesn't reflect an effective regulatory scheme at all.

In fact, what is unfolding in Colorado is severely endangering public safety and health. On March 11, a college student jumped to his death from a Denver hotel balcony after eating a marijuana-laced cookie that apparently caused him to hallucinate. On April 14, a Denver man shot and killed his wife while she was frantically calling 911 for help after he ate marijuana-laced candy that again apparently caused hallucinations. And just last week, on April 21, a Greeley, Colorado fourth grader was caught selling marijuana that he got from relatives.

As a result, it is hardly surprising that a senior DEA official recently told the Senate Caucus on International Narcotics Control that what was happening in these states is “reckless and irresponsible.” At this point, those words apply equally to the Department of Justice’s policy that has permitted states to legalize a drug for recreational purposes that Congress has chosen to make illegal.

As the above examples attest, marijuana is being combined with cookies and candy in Colorado in a way that is attractive to young people, including children. I hope to discuss the legislation Senator Feinstein and I introduced last year, the Saving Kids From Dangerous Drugs Act of 2013, that we hope can help deter this kind of marketing. But no law matters unless it is permitted to be enforced.

Another challenge for the DEA is the ongoing threat of synthetic drugs. This has been an issue of concern to me for some time, since my constituent, David Rozga, committed suicide after smoking synthetic marijuana.

Just last year, news reports linked a synthetic form of ecstasy called “Molly” to the deaths of at least four young people in Boston, New York, and here in Washington.

Synthetic drugs are a special challenge, both for policymakers and law enforcement. These drugs are the products of traffickers’ efforts to

circumvent the law by slightly altering the chemical structure of actual controlled substances. A change of a molecule or two to a banned drug is sometimes enough to make a new and legal alternative. This is a difficult problem without easy solutions.

So we need to think creatively to find answers. For example, the State of Iowa, led by a Democrat Attorney General, recently initiated a potentially groundbreaking fraud lawsuit against the owners of a convenience store that sold synthetic drugs. This approach may prove to be a valuable complement to federal law enforcement efforts directed at the sources of these drugs.

I look forward to discussing these and a variety of other issues with you, time permitting. Thank you.

Questions for the Record from Senator Dianne Feinstein
For Michele M. Leonhart, Administrator, Drug Enforcement Administration
Senate Committee on the Judiciary

April 30, 2014

Transnational Drug Trafficking Act

It is my understanding that drug traffickers in Peru and Colombia often contract with other criminal groups to move their drugs through Central America and Mexico en route to the United States. This can sometimes make it difficult to prosecute the South American traffickers, as they can claim that in delivering drugs to intermediaries, they did not know that their narcotics were destined for the United States. I believe that we cannot allow these criminals to avoid prosecution by utilizing new, more complex trafficking strategies. I have introduced legislation, the Transnational Drug Trafficking Act of 2013, to address this problem.

- Given the current dynamics of the drug trade in Latin America, would lowering the knowledge threshold for drug traffickers from knowing to having reasonable cause to believe that their illicit drugs were destined for the United States assist in the extradition and prosecution of high level drug traffickers?

Synthetic Drugs

Synthetic drugs like K-2, Spice, and Bath Salts have been of major concern in recent years, prompting a number of efforts to combat these substances. However, when Congress outlawed several of these synthetic drugs last year, traffickers did not stop producing them. Instead, they slightly altered the chemical structure of illegal drugs to produce what we call “controlled substance analogues,” which mimic the effects of drugs like ecstasy, cocaine, PCP, and LSD.

I have introduced a bill – The Protecting Our Youth from Dangerous Synthetic Drugs Act – that would give law enforcement the tools they need to address this issue by authorizing the federal government to establish and maintain a list of unlawful controlled substance analogues. Through this list, the government could quickly respond to a new synthetic analogue by placing it on the list, thus making that analogue drug illegal.

- **Would legislation that enabled the federal government to maintain a list of controlled substance analogues be helpful to address the challenges posed by synthetic drugs?**

Illegal Drugs Marketed to Kids

In January of last year, the DEA busted two phony medical marijuana dispensaries in San Diego that grossed an estimated \$3.5 million annually. DEA agents found drinks, cookies, brownies, and candies that were laden with THC and had names such as “Reefers Peanut Butter Cup,” “7 High,” and “Root Buzz.” With names such as these — and the fact that most of the people running the dispensaries were between the ages of 18 and 22 — it seems clear that the illegal dispensaries’ intended audience included minors.

- **Could you describe the threat that you see of illegal drugs being marketed to kids?**
- **What are some of the tactics that drug manufacturers and dealers use to market illegal drugs to kids?**

Ryan Haight Act

I authored the Ryan Haight Act, which established a regime for selling controlled substances over the Internet, including the requirement that controlled substances be dispensed only after an in-person medical visit has been conducted.

- **I understand that the sale of controlled substances by illegitimate online pharmacies based in the United States has decreased significantly since the Ryan Haight Act was enacted. Is that your understanding?**
- **As illegitimate online pharmacies have moved their base of operations overseas, what steps are you taking to prevent them from illegally shipping drugs into the United States?**
- **Does the training process for DEA agents include education on rogue online pharmacies? If it does, do you have adequate resources to support your efforts? If not, what tools would you need to implement such training?**
- **Do you need additional authorities to stop the illegal flow of controlled substances into the United States that were purchased over the Internet?**

"DEA Oversight"
Senate Committee on the Judiciary
April 30, 2014

Written Questions for the Record for Administrator Michele Leonhart
Submitted by Senator Sheldon Whitehouse

As you know, I have been requesting a briefing on sensitive DEA Special Operation Division programs for several months. It is my understanding that, for at least a portion of that time, DEA and the Department of Justice delayed that briefing based on the fact that the Department of Justice had suspended one of the programs and was reviewing its legality and appropriateness. These delays continued after I had clearly communicated to DEA and the Department of Justice that the suspension and review had no bearing on my interest in the programs.

- **Is it your position that agency suspension or review of law enforcement programs limits congressional oversight of those programs?**
- **If so, what is the constitutional or statutory basis for this position?**
- **Can you give your assurance that I will now receive a briefing on these matters in a timely manner?**

QUESTIONS SUBMITTED TO HON. MICHELE M. LEONHART BY SENATOR BLUMENTHAL

“Oversight of the Drug Enforcement Administration”

April 30th, 2014

Senator Blumenthal

Questions for the Record

Last August, Reuters published an article regarding a DEA’s Special Operations Division or SOD. According to the article, DEA personnel have been using information from foreign intelligence intercepts to build domestic criminal cases, while simultaneously concealing from the court the use of those intercepts. I know DEA has questioned some of what was written in that article, but I want to focus on what I consider the crux of the issue.

- 1. Can you tell me with certainty that DEA personnel do not utilize foreign intelligence intercepts when building domestic criminal cases, and if DEA personnel do engage in such conduct, is that fully reported to the judge that ultimately tries the targeted criminal defendant?**
- 2. The end of the Reuters article refers to the DEA conducting a review of the program. Can you tell me if that review is complete, and if so, what it has found?**
- 3. Would you agree with me that foreign intelligence intercepts should not be used to build cases against U.S. persons except as authorized by law?**

- 4. Would you agree that judges should have the information to determine whether the cases that come before them have been built in a way that conforms with the law?**
- 5. And would you further guarantee this Committee that your agents are ensuring that prosecutors have full knowledge of all evidence against a defendant as well as the origins of that evidence?**

Senate Committee on the Judiciary**"Oversight of the Drug Enforcement Administration"****April 30, 2014****Questions for the Record from Ranking Member Charles E. Grassley****Administrator Michele Leonhart****1. Proposed Saving Kids From Dangerous Drugs Act of 2013**

Senator Feinstein and I introduced this legislation in November of last year. The bill would amend the Controlled Substances Act to make it unlawful for any person at least 18 years of age to: (1) knowingly or intentionally manufacture or create a Schedule I or II controlled substance that is combined with a beverage or candy product, marketed or packaged to appear similar to a beverage or candy product, or modified by flavoring or coloring; and (2) know, or have reasonable cause to believe, that the combined, marketed, packaged, or modified controlled substance will be distributed, dispensed, or sold to a person under 18 years of age. It also imposes enhanced criminal penalties for violations (not more than 10 years for a first offense or 20 years for a subsequent offense, involving the same controlled substance and schedule).

- a. Are you familiar with this legislation? Given what we are seeing in Colorado and elsewhere, do you think it would be helpful to you if it were to become law?

2. Naloxone

There has been much publicity recently concerning the promise of the overdose drug Naloxone and how it can save lives.

- a. Please tell us about the effectiveness of this drug and the safety issues associated with it.
- b. To whom do you believe it should be made available?
- c. Do you have any concerns that if it were widely available to the public, its effectiveness could encourage more abuse of heroin or prescription drugs?

3. FinCEN Marijuana Guidance

On February 14, 2014, the Treasury Department's Financial Crimes Enforcement Network (FinCEN) issued guidance on "how financial institutions could provide services to Marijuana-related businesses."

- a. Did FinCEN discuss this guidance with DEA before it was issued?

- b. If so, when did FinCEN first contact DEA and what did FinCEN discuss with DEA?
- c. Did DEA raise any concerns about FinCEN's guidance?
- d. Were the suggestions made by DEA incorporated into FinCEN's guidance? If so, what were those suggestions?
- e. What effects, if any, has DEA seen regarding money laundering as a result of this guidance?

4. Counternarcotics Efforts in Afghanistan

On June 7, 2014, Afghanistan will hold a runoff election to choose a new president. It is my understanding that both candidates have stated they support U.S. Government programs in the country and, if elected, would sign the bilateral security agreement. DEA plays a key role in providing training and technical assistance to the Counternarcotics Police of Afghanistan (CNPA), Afghan Threat Finance Cell (ATFC), the National Interdiction Unit (NIU), and the Sensitive Investigative Unit (SIU). The effectiveness of these operations is still largely dependent on the availability of U.S. military forces for security. Poppy cultivation has already increased dramatically over the last year.

- a. Assuming a bilateral security agreement is signed, what personnel levels and programs will DEA be able to support in Afghanistan going forward? What would you expect would be the effect of these changes on counternarcotics efforts in Afghanistan?
- b. What steps are being taken by DEA to prepare for the possibility that a bilateral security agreement is not signed, and the U.S. is forced to completely withdraw forces from Afghanistan? What would you expect would be the effect of a total withdrawal of U.S. forces on counternarcotics efforts in Afghanistan?

5. Cocaine Trafficking in the Caribbean

In a recent meeting with my staff, DEA confirmed reports that the amount of cocaine transiting through the Eastern Caribbean has doubled, and maybe even tripled, since last year. Less than fifteen years ago, it was estimated that forty percent of South American cocaine made its way to the United States through the Caribbean. That figure had then dropped to just five percent.

Drug trafficking organizations are adept at shifting their operations and trafficking routes to the paths of least resistance. When law enforcement cracked down on the drug traffickers in Mexico, they increased their presence farther south in the countries of Central America, and now the same may be occurring in the Eastern Caribbean. The United States, through the Caribbean Basin Security Initiative (CBSI), is providing security assistance to the region.

- a. What programs, either inside or outside the CBSI, have proven to be the most effective in addressing this shift?

- b. Going forward, what else does DEA believe is needed to address the shift?
- c. What steps, if any, are being taken by DEA to address the increase in drug trafficking that is originating in Venezuela?

6. Operation Bahamas, Turks and Caicos (OPBAT)

OPBAT is a combined Coast Guard, DEA and Government of Bahamas partnership to combat drug smuggling to and from the Bahamas. The OPBAT Operations Center is responsible for initiating and prosecuting law enforcement cases in the Bahamian area of responsibility. The OPBAT assets regularly assist with counternarcotics and search and rescue missions throughout the region. In 2012, Senator Feinstein and I wrote a letter to DEA in support of the OPBAT mission and the need for adequate helicopter coverage to carry out crucial counternarcotics work in the region.

- a. How have OPBAT efforts and assets been adjusted, if at all, in response to the increased drug trafficking in the Caribbean?

7. DEA's Treatment of Daniel Chong

On May 4, 2012, I sent a letter to you regarding reports of the alleged mistreatment of Daniel Chong, a University of California-San Diego college student, by DEA. On May 14, 2012, DEA responded to my letter. DEA's response was inadequate, however, because it did not address the substance of a single one of my questions. I re-asked these questions for the record in connection with DEA testimony at a May 16, 2012, hearing before the Senate Caucus on International Narcotics Control. On June 28, 2013, DEA again failed to answer some of my questions, citing an ongoing Office of Inspector General (OIG) review. I incorporate by reference my questions posed in the above-referenced documents.

- a. Can you assure me that promptly after that OIG review is completed, you will respond to my remaining questions on this topic?

8. Access to Schedule II Pain Medications by Patients in Long Term Care Facilities

Problems with prompt access to Schedule II pain medications for seniors in nursing homes may soon become a pressing issue, with hydrocodone combination drugs likely moving to Schedule II. I believe a dialogue between DEA and the long-term care community is important to ensure that the needs of legitimate users of pain relief drugs, like nursing home patients, are taken into account as this process moves forward. Are you and your colleagues at the DEA willing to meet with stakeholders in the long-term care community to discuss this issue?

9. Research Related to Schedule I-Based Medicines

In your written testimony you state, “The National Institute on Drug Abuse (NIDA) and other components of the National Institutes of Health are conducting research to determine the possible role that active chemicals in marijuana, like tetrahydrocannabinol, cannabidiol, or other cannabinoids may play in treating autoimmune diseases, cancer, inflammation, pain, seizures, substance use disorders, and other psychiatric disorders. DEA supports these, scientific research efforts by providing Schedule I research registrations to qualified researchers.” However, 21 U.S.C. Section 822(d) states that the Attorney General can issue a waiver for Schedule I research registrations to any manufacturer, distributor, or dispenser if he finds it consistent with public health and safety.

- a. Please explain the process in which a registration waiver is granted.
- b. How common is it for the Attorney General to issue a registration waiver for research into Schedule I substances?
- c. Please provide a list of waivers granted or in effect within the last 30 years and for which substance the registration waiver was granted.
- d. Is the Attorney General considering or has he considered granting a waiver for any marijuana-related drugs or medicines? If so, please provide a list of the medicines considered for a registration waiver.

QUESTIONS SUBMITTED TO HON. MICHELE M. LEONHART BY SENATOR HATCH

"Oversight of the Drug Enforcement Administration"
Questions for the Record Submitted by
Senator Orrin G. Hatch

- 1) In January I shared with the DEA a copy of a letter I sent to the FDA expressing my concern that FDA not dismantle controls on GHB < the date rape drug. We passed the Date Rape Drug legislation in 2000 working with many parties, including FDA but also DEA. If FDA is considering changing the controls on GHB, will DEA coordinate with FDA and ensure no changes are made that will increase the risks of diversion or abuse, including facilitated sexual assault, of GHB?
- 2) Ensuring the development new treatment options and timely patient access to new therapies has been a priority of mine and many other member of the Committee. However, I am concerned about delays in DEA scheduling newly approved FDA drugs that are preventing patients from gaining access to needed therapy options. When the FDA approves a new drug that contains a new molecular entity (NME), it is required to provide the DEA a recommendation on which schedule the drug should be placed if it has been shown to have a potential for abuse. The fact that is a new molecular entity by definition means that it has never been marketed in the United States.

In section 201(b) of the CSA, it states that DEA is bound by the medical and scientific recommendations of the FDA when determining the appropriate schedule of a drug or substance, is that correct?

To your knowledge has the DEA ever deviated from the FDA's recommendation for a newly approved New Molecular Entity?

Does the agency have an internal timeline for making final schedule determinations for a new molecular entity of an FDA approved product and process timelines to ensure the DEA makes its internal deadlines? If so, why has the agency not released the timeline?

- 3) More than 150 million use dietary supplement annually, and the responsible industry believes that these products should be regulated, made to high quality standards and above all be safe and beneficial. However, some unscrupulous manufacturers have taken to adding illegal anabolic steroids, which provide attributes outside of what a dietary supplement would do. For example, to promote fast muscle growth. These products are being marketed as dietary supplements. Not only is the confusing, but it is dangerous to the consumer. I have introduced the Designer Anabolic Steroid Control Act (DASCA) with Sen. Whitehouse in effort to give DEA more authority to pursue and stop these bad actors and their products. Do you believe DASCA's enactment will give DEA the tools to list designer anabolic steroids and stop these bad actors from falsely marketing spiked and adulterated steroid products to unsuspecting consumers?
- 4) How many anabolic steroids have been scheduled since the Anabolic Steroid Control Act of 2004 - the last time Congress amended the CSA? As you may know, this amendment that I introduced with former Sen. Biden (now Vice President) was to allow DEA to administratively classify

additional compounds as anabolic steroids. What are the practical problems DEA encounters when you try to go after bad actors that are spiking products with illegal anabolic steroids?

- 5) The Designer Anabolic Steroid Control Act would give DEA the authority to address concerns that designer anabolic steroids are masquerading in some dietary supplements. All five of the dietary supplement trade associations (American Herbal Product Association – AHPA; Consumer Healthcare Products Association – CHPA; Council for Responsible Nutrition – CRN; Natural Products Association – NPA; and, United Natural Products Alliance – UNPA) support this legislation, as well as many consumer, sports and athletic groups. What enhancements to DEA's authority would allow DEA to keep up with the bad actors in this area? Would DASCA solve the current problems that exist with DEA listing designer anabolic steroids on the Controlled Substances list?

**Senator Jeff Sessions
Questions for the Record
Administrator Michele Leonhart**

1. In his August 2013 memo to U.S. Attorneys, Deputy Attorney General Cole announced that the Justice Department would essentially cease prosecutions in states that had legalized marijuana, as long as those states have “strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests.” What input did you provide to Attorney General Holder and Deputy Attorney General Cole regarding that policy memo?
2. In your testimony, you mentioned the recent arrests of major international criminals such as Afghan drug lord Haji Baghco, Colombian drug trafficker Daniel Barrera-Barrera, and the head of the world’s largest drug trafficking organization, Joaquin “El Chapo” Guzman Loera. In these or other similar cases, please describe whether the DEA was able to secure the cooperation of defendants in lower-level roles in these organizations to pursue higher level targets by using the prospect of a mandatory minimum sentence.
3. In a 1986 *Wall Street Journal* article entitled “Lessons of the First Cocaine Epidemic,” David F. Musto wrote “as cocaine’s effects become more obvious – and crack is speeding up this process – a similar outrage against cocaine will lead to reduced demand, more effective law enforcement, and a new public memory regarding cocaine, a form of social immunization that will last at the very least for a generation or two.” Do you see any similarities between the cocaine and crack epidemics and the current heroin epidemic?
4. According to the 2013 study, “Monitoring the Future,” (MTF) published by the University of Michigan Institute for Social Research and sponsored by the National Institute on Drug Abuse:

“In the late 20th century, young Americans reached extraordinarily high levels of illicit drug use by U.S. as well as international standards. . . . In 1975, when MTF began, the majority of young people (55%) had used an illicit drug by the time they left high school. This figure rose to two thirds (66%) in 1981 before a long and gradual decline to 41% by 1992—the low point. After 1992—in what we have called the “relapse phase” in the epidemic—the proportion rose considerably to a recent high point of 55% in 1999; it then declined gradually to 47% in 2009, before rising slightly to 50% by 2013.”

What do you believe is the reason for this recent increase and what do you believe should be done to reverse it?

Questions for the Record of Senator John Cornyn for DEA
Administrator Michele Leonhart

May 7, 2014

1. As you know, the Judiciary Committee recently debated legislation that would reduce mandatory minimum sentences for a majority of Controlled Substance Act offenders convicted in the federal criminal justice system.
 - a. In your experience, does DEA refer low-level Controlled Substances Act offenders for federal prosecution? If so, what percentage of total DEA prosecution referrals under the Controlled Substances Act are made against low-level offenders?
 - b. What threshold rules, requirements, or factors does DEA consider before referring a Controlled Substances Act offense for federal prosecution?
 - c. Do you consider mandatory minimum sentences for Controlled Substances Act offenses to be a fair and effective tool for DEA in the investigation of transnational criminal organizations and drug trafficking networks?
2. I have heard from several of my constituents who suffer from epilepsy regarding their concerns with the unpredictable and often lengthy DEA process for the scheduling of new FDA approved epileptic medications. It is my understanding that since 1999, DEA review time has increased from an average of 49 days to an average of 238 days. What steps is DEA taking to ensure that FDA approved medications are being reviewed for scheduling in a timely manner to ensure that patients have access to potentially life-saving medications?
3. It appears from the data in the proposed rule to reclassify hydrocodone that a majority of hydrocodone prescriptions and diversion occur in the community, not in hospitals. Can DEA provide the number of cases of narcotics diversion involving a Skilled Nursing Home Facility in the past 5 years?
4. In July of 2012, I wrote you a letter concerning DEA's continued interpretation of the Controlled Substances Act definition of "dispense" that requires a pharmacist to deliver controlled substances only to the "ultimate user," even in situations where the prescribing physician has made a determination that it is medically necessary for the drug to be administered by the doctor in an office or clinical setting. DEA has taken this position despite the plain language of the definition of "dispense" in the Controlled Substances Act, which allows for "constructive delivery" of controlled substances. Sixteen months later, in November of 2013, DEA's Office of Congressional and Public Affairs sent a response.
 - a. Why did it take the agency 16 months to respond to a letter from eleven U.S. Senators, many of whom are members of the Judiciary Committee, which has

jurisdiction over the DEA? Does the agency consider this an acceptable response time for congressional inquiries?

- b. In the response, DEA suggests that rulemaking is not necessary because a pharmacist can “distribute” controlled substances to practitioners for dispensing to patients under 21 CFR 1307. Is the agency aware that in the case of compounded controlled substances, this position would put a pharmacist in violation of Section 503A of the FDCA as recently re-codified by the Drug Quality and Security Act, which requires a patient-specific prescription to avoid the manufacturing standards of the FDCA?
- c. Does DEA take the position that a pharmacist dispensing a controlled substance directly to a patient’s prescribing physician, after a determination that it is medically necessary for the drug to be administered in a clinical setting to the named patient on the prescription, presents a greater risk of controlled substance diversion than a pharmacist dispensing a controlled substance directly to the patient or a member of the patient’s household? If so, please explain.

QUESTIONS SUBMITTED TO HON. MICHELE M. LEONHART BY SENATOR FLAKE

Written Questions of Senator Jeff Flake
U.S. Senate Committee on the Judiciary
Oversight of the Drug Enforcement Administration
May 7, 2014

1. There have been a number of drug tunnel discoveries in the news this month. One such discovery was by the Nogales Tunnel Task Force in Arizona. The tunnel was approximately 449 feet long, with approximately 60 feet in Mexico and 389 feet in the U.S. According to ICE, who works on the Task Force along with the DEA, a total of 101 cross-border tunnels have been discovered in Nogales since 1990, including four so far in fiscal year 2014. In 2011, Congress attempted to address the border tunnel problem by passing the Border Tunnel Prevention Act. The legislation gave the DEA, as well as your counterparts, additional tools in combatting the problem of border tunnels.
 - a. Do you still continue to see an increase in the number and complexity of border tunnels along the U.S. – Mexico border?
 - b. How have you utilized the additional tools provided in the Border Tunnel Prevention Act to better combat this problem?
2. According to press reports, when the task force discovers these tunnels, it fills them with cement from the entrance to the border fence location. I understand this is an expensive endeavor, costing up to \$20,000 to \$30,000 per tunnel. Given this large cost, it is important to ensure it is successful. However, according to press reports, on the Mexico side “authorities often throw trash and other debris in the tunnel’s entrance, cover it with plywood, and then add concrete on top. Beyond the entrance of the tunnel, it remains untouched on the Mexico side.” As a result, diggers in Mexico can open the tunnel from another starting point and then work around the concrete at the border thereby negating U.S. efforts to close the tunnel.
 - a. Is the DEA working with Mexican officials to ensure these tunnels are taken fully out of commission on the Mexico side of the border?
3. On March 28, 2014, several news sources reported that the Drug Enforcement Agency’s New York Organized Crime Drug Enforcement Strike Force will lease 56,000 square feet of prime office space in Brookfield Place, a newly renovated office building in lower Manhattan. Brookfield Place recently underwent a \$250 million renovation, creating retail space for high-end retail shops, a 25,000 square foot French inspired marketplace, as well as five waiter service restaurants.
 - a. The Strike Force offices are currently located at 85 10th Avenue. Could you please explain the selection process in deciding to relocate to the 10th floor of Brookfield Place, including why you are leaving your current office and any difference in price between your current office space and the Brookfield location?



Statement
Of
The National Association of Chain Drug Stores
For
United States Senate
Committee on the Judiciary

Hearing on:

“Oversight of the Drug Enforcement Administration”

April 30, 2014
10:00 a.m.
226 Dirksen Senate Office Building

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NACDS Statement on "Oversight of the Drug Enforcement Administration"
April 30, 2014
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The National Association of Chain Drug Stores (NACDS) thanks Chairman Leahy, Ranking Member Grassley, and Members of the Committee on the Judiciary for the opportunity to share our perspectives on "Oversight of the Drug Enforcement Administration." Among its many duties, the Drug Enforcement Administration (DEA) is responsible for regulating prescription drugs that may be subject to diversion and abuse, as well as practitioners and pharmacies that prescribe and dispense these medications to our nation's patients. An ongoing challenge for DEA, health care providers, and our nation as a whole, is combating the diversion and abuse of prescription drugs. NACDS and the chain pharmacy industry are committed to partnering with DEA, as well as other federal and state agencies, law enforcement personnel, policymakers, and others to work on viable strategies to prevent prescription drug diversion and abuse. Our members are engaged daily in activities aimed at preventing drug diversion and abuse.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

Background

First enacted in 1970, the federal Controlled Substances Act (CSA) regulates the manufacture, importation, possession, use, and distribution of prescription drugs that have a potential for diversion and abuse and are collectively known as "controlled substances." The CSA creates a closed system of distribution for controlled substances; DEA often refers to this as "cradle-to-grave" control over controlled substances. DEA has implemented a very tight and comprehensive regulatory regime pursuant to the CSA.

States have followed this lead and have implemented similar, sometimes duplicative regimes. This matrix of regulation has created a multi-layered system of checks and balances to protect Americans from the dangers of prescription drug abuse. Pharmacists and other pharmacy personnel are all trained to understand and comply with this complex regulatory matrix.

Chain Pharmacy Initiatives

To comply with DEA's "cradle to grave" regulatory regime, chain pharmacies have created a variety of loss prevention and internal security systems that are in place from member prescription drug distribution centers right down to the point of dispensing to the patient. Our members undertake initiatives to ensure that prescription drugs are accounted for in every step along the way. Some of those initiatives could include conducting background checks before hiring personnel who have access to prescription drugs, training about controlled substance laws and regulations within 30 days of hire, maintaining electronic inventories of controlled substances, and conducting random audits. Our members work closely with law enforcement to see that perpetrators of crimes relating to controlled substances are brought to justice.

Specifically, at the pharmacy level, examples of the member initiatives include training pharmacy personnel on how to handle suspect prescription drug orders, and exception reporting, in which exceptionally large or unusual orders of controlled substances will trigger an internal investigation. Chain pharmacies also may maintain perpetual inventories of controlled substances that are randomly audited by internal security personnel. Pursuant to DEA and state regulations, pharmacy and chain distribution centers are required to be highly secured with physical barriers, heavy duty safes, secure cages, and complex alarm systems. Some pharmacy chains also utilize cameras and closed-circuit television surveillance to ensure compliance with policies and procedures. Some pharmacies require employees to read and sign "codes of conduct," which commits them to compliance. Some member pharmacies will conduct drug testing, including random, for cause, and pre-employment testing.

Chain pharmacies are committed to ensuring that prescription drugs remain under tight control for the purposes of providing care to their patients, and are not diverted for nefarious purposes. Our members' efforts are evidence of this commitment.

The Role of DEA and Improving DEA Transparency

According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility also rests with the pharmacist who fills the prescription. 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 section 309 of the CSA (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the CSA.

Community pharmacists are front-line healthcare providers and are one of the most accessible members of a healthcare team. As such, the CSA requires pharmacists to take on diverse and sometimes conflicting roles. On the one hand, pharmacists have a strong ethical duty to serve the medical needs of their patients in providing neighborhood care. On the other hand, community pharmacists are also required to be evaluators of the legitimate medical use of controlled substances.¹ As briefly mentioned above, the CSA requires that a pharmacist, prior to dispensing any controlled substance, make the following determinations—whether the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a “legitimate medical purpose” “by a prescriber acting in the usual course of his or her practice.”² The former obligation is called “corresponding responsibility,” and if the two elements are not met, the prescription is not valid. DEA interprets a pharmacist’s corresponding

¹ In order for a prescription for a controlled substance to be valid, federal law (21 C.F.R § 1306.04(a)) requires that the prescription be issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her practice. The rule places a ***corresponding responsibility*** upon the dispensing pharmacist to establish the validity of the prescription by ensuring the prescription is written for a legitimate medical purpose.

² 21 C.F.R. 1306.04(a).

responsibility "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'"³

Pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacies strive to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse while still achieving our primary goal of assisting patients who need pharmacy services.

DEA's enforcement activities include conducting inspections of the entities that are subject to its regulatory oversight. Although such enforcement activities are essential to its mission, DEA has been criticized for an alleged lack of transparency in its inspection and other enforcement actions, and even inconsistency among the actions of its numerous field offices. Such opaqueness and inconsistency impose challenges on the compliance efforts of DEA registrants.

To help address the problems of DEA opaqueness and inconsistency, we support efforts to promote accountability and transparency with respect to DEA's inspection and enforcement programs. The following recommendations drawn from Food and Drug Administration transparency and oversight and enforcement initiatives could serve as a model for DEA:

1. Development of a Comprehensive DEA Investigation Program, Corresponding Inspector Manual & Compliance Policy Guides: Specifically, DEA would set forth guidance for its oversight of regulated facilities inspections that provide clear and firm direction.

³*East Main Street Pharmacy*, 75 FR 66149, 66163 (Oct. 27, 2010).

NACDS Statement on "Improving Predictability and Transparency in DEA and FDA Regulation"
April 30, 2014
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2. Accountability & Consistency among Field Offices: DEA would ensure the uniformity and effectiveness of its inspection program and oversight over field offices. DEA would provide public training for inspectors, and develop an audit process to ensure that inspections are carried out consistently across field offices.
3. Transparency & Communication - DEA Inspection Observations: DEA would provide substantive and timely feedback to inspected regulated facilities regarding agency observations and facility compliance. Specifically, DEA would provide regulated facilities with substantive written feedback upon completion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the CSA and implementing regulations. Without receiving such information, it is difficult, if not impossible, for regulated facilities to implement requisite facility and process improvements and take corrective actions where necessary.
4. Public Disclosure - Oversight of Inspections: An important mechanism of accountability is public disclosure of information. Disclosure of final inspection reports of regulated facilities would provide the public with a rationale for DEA enforcement actions and the industry with transparency into agency decision-making, allowing them to make more informed actions to enhance facility compliance.
5. Ombudsman Office: An ombudsman office would address complaints and assist in resolving disputes between companies and DEA regarding interactions with the Agency on inspections and compliance issues.

We believe these recommendations would greatly increase predictability and transparency in DEA regulation. The adoption of such recommendations would greatly enhance the compliance efforts of DEA registrants, thus leading to more effective DEA regulation and oversight. Enhanced compliance efforts by DEA registrants and more

effective DEA regulation and oversight would have highly beneficial impacts on efforts to combat prescription drug diversion and abuse.

A related challenge for pharmacies is whether the DEA registration number of a prescriber is valid and/or valid for the class of medication that has been prescribed. We support efforts to enhance the verification of prescriber data provided by DEA. It would be most helpful if DEA could provide reliable, consistent, and clear data that serves as the ultimate source for the status of a prescriber. Ideally, this database would include information about the status of the prescriber's license from the state issuing authority, such as the state medical board. Moreover, we request that there be a mechanism for DEA to provide clear guidelines on the expiration of prescribers' DEA registrations. This is currently a protracted process and it can be unclear to pharmacy personnel whether a lapsed prescriber registration (such as due to a late renewal) is still valid or, in fact, expired and invalid.

Better Focusing Resources

In the recent past, it is our understanding that DEA has been taking a harder look at the problem of prescription drug abuse in the U.S. DEA has placed increased scrutiny on both wholesale distributors and pharmacies. Since the mid-2000's, DEA has taken action against wholesale distributors that it deems are inappropriately distributing controlled substances to pharmacies, including shutting down a number of their wholesale distribution centers. More recently, DEA has focused its attention on chain pharmacies, shutting down such chain pharmacy distribution centers that it deems are distributing controlled substances inappropriately, as well as shutting down a number of chain pharmacies that it believes are dispensing medications to patients inappropriately.

Additionally, we are hearing that DEA and other enforcement actions may be imposing arbitrary limits on the distribution and dispensing of prescription pain medications, causing problems with patients' ability to access much needed prescription pain medications. Different groups are pointing fingers at each other as the source of the

problems of prescription drug abuse and for legitimate patients having difficulty accessing their prescription pain medications. Pointing fingers of blame is not a helpful exercise and usually causes more harm than good, especially when lives are at stake. NACDS and chain pharmacies avoid assigning blame for the complex prescription drug abuse issues that we all need to address.

Since NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription pain medications, we are pleased to support H.R. 4069, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2013." By establishing the "Combating Prescription Drug Abuse Working Group," this legislation would better focus government resources on solving the problems of prescription drug abuse and ensuring that legitimate patients are not harmed.

We believe that bringing together stakeholders to address the problems associated with prescription drug abuse in this manner would provide better solutions than have been developed to date. Improved collaboration and coordination among federal agencies and other stakeholders would benefit all, including the patient, whose legitimate access to medication must be preserved in order for any potential solution to be successful.

NACDS is committed to efforts to curb prescription drug abuse and ensure patient access to prescription medications. We know that for some patients, access to necessary prescription drugs to control their chronic pain may be limited due to efforts to thwart prescription drug abuse. Even in the news media, we see coverage about the effects of prescription drug abuse, but the patient access challenges are conspicuously missing. However, the pharmacy trade publication, *Drug Store News*, has created a microsite on its website to raise awareness about patients living with chronic pain. The site focuses on the challenges that real patients face if unable to access prescription pain medications due to laws or regulations designed to curb prescription drug abuse. In collaboration with the U.S. Pain Foundation, *Drug Store News* conducted a series of interviews, including an

audio segment with a patient who has been living with chronic pain for 20 years. In addition, profiles of four patients living with chronic pain are included on the microsite.

Electronic Prescribing and Prescription Monitoring Programs

Since DEA issued regulations to allow for the electronic prescribing of controlled substance (EPCS) prescription medications, NACDS has aggressively pursued state legislation and regulations to allow all controlled substances to be prescribed electronically. We believe that EPCS will mitigate forgeries associated with written and oral prescriptions, and provide a deterrent effect for prescribers. Most importantly, EPCS holds promise to create a robust database of real-time information that could be used by industry stakeholders and enforcement officials that may assist with the proactive identification of drug abuse. Now that most states allow EPCS, we urge the states to require that all controlled substance prescriptions be issued electronically.

On a parallel track, NACDS and chain pharmacies support controlled substance prescription drug monitoring programs to help combat prescription drug abuse. Currently, 48 states have operational monitoring programs and one more is in the stages of program implementation. Recognizing the important role these programs have in helping to prevent drug abuse and diversion, chain pharmacies actively support these programs. Pharmacies submit information on the controlled substances they dispense on a weekly or daily basis depending on the particular state's program requirements. This information includes data on the patient, prescribed drug dosage and quantity, and the prescriber. This information allows the state to conduct confidential reviews to determine any patterns of potential abuse or diversion.

NACDS and chain pharmacies support these programs as one of many strategies to help curb prescription drug abuse and diversion. We support these programs and believe they have greater potential. To this end, we have developed a number of recommendations to improve them. Since prescriber access to the information in prescription monitoring programs can be challenging to obtain (and, in some states, is not even permitted under a

particular state's laws,) we support initiatives to facilitate and mandate prescriber use of the program data. These programs contain a wealth of data that could assist prescribers in making determinations about whether to issue a prescription for an addictive medication.

Unfortunately, many state programs are not connected with each other. Connected state prescription monitoring programs would allow prescribers to access patient data from other states, which is critically important in any metropolitan area that extends across state lines. Consequently, we support efforts to standardize and interconnect all states' prescription drug monitoring programs.

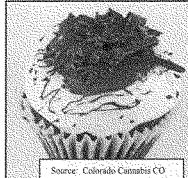
Law Enforcement-Authorized Programs for Return and Disposal of Unwanted Prescription Drugs

Another important strategy to curb drug diversion and abuse is to provide consumers with appropriate means to return unwanted prescription drugs for disposal. Finding a workable law enforcement-authorized means for consumer disposal of unused and expired drug products is critical to reducing drug abuse. While varying policy options have been proposed, NACDS supports protecting patient health and safety by maintaining a physical separation between pharmacies and locations that take back consumers' unwanted drugs. For example, drug take-back events sponsored by DEA provide for such separation and avoid the potential for returned medications to re-enter the drug distribution supply chain. In addition, we support policies where consumers have a reliable and readily available means to return their unwanted medications, such as mail-back envelope programs that are sanctioned by law enforcement or the DEA. Finally, we have commented on DEA's proposed regulations to allow consumers to properly dispose of unused, unwanted prescription drugs, and look forward to DEA's final rule.

Conclusion

NACDS thanks the Committee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.

<p>19 March 2014</p>  <p>Colorado Information Analysis Center</p> <p>***Alert Bulletin Marijuana Infused Edibles***</p>	<p>UNCLASSIFIED // FOR OFFICIAL USE ONLY</p> <p>CIAC Report 14-65046</p>
<p>(U//FOUO) Marijuana Infused Products and Edibles</p> <p>(U//FOUO) The State of Colorado legalized medical marijuana in 2012 and recreational marijuana in 2014. There has been an increased amount of marijuana infused products sold to the public. The products range from <i>fruit chewz</i>, <i>gummiez</i>, cupcakes, truffles, rice krispy treats, butter, and banana bread. It is extremely difficult to differentiate between marijuana infused products and non-infused products if the original packaging is not with the product.</p> <p>(U//FOUO) A new Colorado law signed 17 March 2014 extends the same packaging requirements to medical marijuana products as they exist for recreational pot.¹ This is part of an effort to keep marijuana edibles away from minors. Critics say it is too easy for someone to confuse infused products with their non-infused products, or to ingest higher quantities of THC, the psychoactive component of marijuana, than they intend. There have been concerns about the accuracy of testing and labeling of edibles. On 1 May 2014 all edibles sold from businesses must be tested for potency.²</p> <p>(U//FOUO) In March 2014 there were two documented cases of marijuana infused edibles being consumed by minors. The first case involved a middle school student who took marijuana infused candies to school and shared them with friends. The students were unaware the candy was infused with marijuana. The second case involved an 18 year old who ate a marijuana infused candy bar that was not in its package. The 18 year old did not realize it was infused with marijuana and was treated for marijuana overdose. The effects associated with edibles are comparable to smoking marijuana however the effects are known to take longer to feel but last longer because the edibles are digested rather than processed through the lungs.³</p> <p>(U//FOUO) Beyond Mars^{USBUS} is one website that has a list of their edible products and the production information for the edible. The website describes the treats as adult favorites but with a twist. The <i>sticky ickies</i> are made with melted butter, marshmallows, rice krispies, and clean pure cannabis Huxley's^{USBUS} oil.⁴</p> <hr/>	
<p>UNCLASSIFIED // FOR OFFICIAL USE ONLY</p> <p>Production Number: 023</p>	



(U) Marijuana infused Black Forest cupcake



(U) Serving Size 1; THC 50 mg per serving; Potency: High; Oil Type: Whole Bud Oil



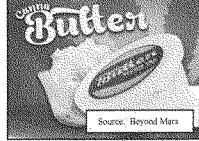
(U) Serving Size 10 MG; THC 100 MG; Potency: Medium; Oil Type: Butane Hash Oil



(U) Serving Size 1 Gummiez; THC 100-200 MG; Potency: High; Whole Bud Oil

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CIAC Report 14-65046

(U//FOUO) There are numerous websites and dispensaries that sell marijuana infused products and edibles. Infused products such as butter, honey, oils⁵, apple butter, and marinara sauce make it possible to cook marijuana infused edibles that do not have to be labeled with a THC warning. This makes regulating these products almost impossible. Marijuana infused products and edibles can be brought in to establishments such as schools, jails, offices, military bases and hospitals without being detected. This is a cause for concern for public health and safety.



(U) Serving Size 10 MG; THC 200 MG-800 MG; Potency Medium, High & Very High; Whole Bud Oil
Source: Beyond Mars

(U//FOUO) With Colorado leading the way in the legalization of retail marijuana sales, it is expected that additional laws will be passed to address problems or loopholes as they are identified. Marijuana infused edibles and products are an easy alternative to smoking and are more attractive to those who have an interest in trying marijuana but prefer to be discreet. The popularity of marijuana infused edibles will increase the likelihood that someone will ingest it unintentionally as well as allow the products to be brought into locations where marijuana is not allowed and can go undetected.

(U//FOUO) If you or your agency has any cases or incidents involving these types of products, please contact Trooper Pam Webster at pam.webster@state.co.us or (720) 219-3403.

(U//FOUO) This report addresses the following CIAC Standing Information Needs: CIAC-SIN-3

¹ <http://www.csmonitor.com/USA/2014/0318/Colorado-wrestles-with-how-to-keep-edible-marijuana-away-from-kids-video>

² <http://www.csmonitor.com/USA/2014/0318/Colorado-wrestles-with-how-to-keep-edible-marijuana-away-from-kids-video>

³ <http://www.csmonitor.com/USA/2014/0318/Colorado-wrestles-with-how-to-keep-edible-marijuana-away-from-kids-video>

⁴ http://beyondmarsedibles.com/?page_id=65

⁵ <http://www.foodchannel.com/articles/article/marijuana-dispensaries-going-gourmet/>

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U. S. Department of Justice
 Drug Enforcement Administration
 Office of Congressional and Public Affairs

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The Honorable Patrick Leahy
 Chairman
 Committee on the Judiciary
 The United States Senate
 Washington, DC 20510

Dear Mr. Chairman:

We write to clarify one issue addressed in testimony at the April 30, 2014, hearing before the Committee regarding oversight of the Drug Enforcement Administration.

During the hearing, responding to a question about trafficking trends related to marijuana in Colorado, Administrator Michele Leonhart stated, "...we've talked to our partners in Kansas and they've already been seeing a 61 percent increase in marijuana seizures coming from Colorado." To clarify, the Administrator was referring to a report drafted after the passage of the Colorado law that showed during the seven-month period, from April through October 2013, 61 percent of Kansas Highway Patrol-related seizures of marijuana originated from Colorado.

We hope this information is helpful, and ask that this letter be included in the official hearing Record. Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter.

Sincerely,

Eric J. Akers, Deputy Chief
 Office of Congressional and Public Affairs

cc: The Honorable Charles E. Grassley, Ranking Member

