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EXAMINING THE FEDERAL GOVERNMENT'S RESPONSE TO THE PRESCRIPTION DRUG ABUSE CRISIS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JUNE 14, 2013

Serial No. 113–55

Printed for the use of the Committee on Energy and Commerce

energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

85–445 WASHINGTON : 2014

For sale by the Superintendent of Documents, U.S. Government Printing Office
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EXAMINING THE FEDERAL GOVERNMENT'S RESPONSE TO THE PRESCRIPTION DRUG ABUSE CRISIS

FRIDAY, JUNE 14, 2013

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

The subcommittee met, pursuant to call, at 9:32 a.m., in room 2123 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Whitfield, Rogers, Murphy, Gingrey, Cassidy, Guthrie, Griffith, Bilirakis, Ellmers, Capps, Schakowsky, Green, Butterfield, and Castor.

Staff present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Paul Edattel, Professional Staff Member, Health; Brad Grantz, Policy Coordinator, O&I; Sydne Harwick, Legislative Clerk; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and the Economy; Heidi Stirrup, Health Policy Coordinator; Alli Corr, Democratic Policy Analyst; Eric Flamm, Democratic FDA Detailee; Elizabeth Letter, Democratic Assistant Press Secretary; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; Anne Morris Reid, Democratic Professional Staff Member; and Rachel Sher, Democratic Senior Counsel.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The subcommittee will come to order. The chair will recognize himself for an opening statement.

Today's hearing is the first in a series of hearings this subcommittee will hold on the subject of prescription drug abuse, which has been described by the Centers for Disease Control and Prevention as an epidemic in the United States.

In 2010, 7 million individuals aged 1.2 or older—that is 2.7 percent of this population—were current nonmedical users of prescription, or psychotherapeutic, drugs, and over one million emergency department visits that year involved nonmedical use of pharma-

ceuticals. Nearly all of these drugs were originally prescribed by a physician.

According to the National Institute on Drug Abuse, prescription drug abuse is most prominent among young adults age 18 to 25. NIDA also reports that in 2010, almost 3,000 young adults died from prescription drug—mainly opioid—overdoses, which is more than the total number of people that died from overdoses of any other drug, including heroin and cocaine combined.

Opioid pain relievers, such as Vicodin and OxyContin, are the largest class of abused prescription drugs, followed by stimulants for treating attention deficit hyperactivity disorder—ADHD—such as Adderall or Ritalin, and central nervous system depressants for relieving anxiety, such as Valium and Xanax.

According to the National Survey on Drug Use and Health, published by the Substance Abuse and Mental Health Services Administration (SAMHSA), of those individuals who used prescription painkillers non-medically in 2010 and 2011, nearly ¾ received the drugs from a friend or relative, either for free, that is 54.2 percent; through a purchase, that is 12.2 percent; or by stealing the drugs, 4.4 percent.

Today's hearing focuses on the Federal Government's response to the prescription drug abuse epidemic. It should be noted that this committee has played a key role in facilitating Prescription Drug Monitoring Programs by authorizing the National All Schedules Prescription Electronic Reporting Act (NASPER), co-sponsored by Representative Whitfield and Ranking Member Pallone. NASPER, which is housed at the Department of Health and Human Services, was signed into law on August 11, 2005, to assist States in combating prescription drug abuse of controlled substances through the PDMP.

It provides grants to set up or improve state systems that meet basic standards of information collection and privacy protections that will make it easier for States to share information. PDMPs enable authorities to identify prescription drug abusers, as well as the "problem doctors" who either overprescribe or incorrectly prescribe prescription drugs.

While NASPER is an excellent step in the right direction, the program has not been funded since fiscal year 2010, although HHS continues to fund state PDMPs through grants to support interstate interoperability and integration of PDMPs with electronic health records and to improve the timeliness of access to PDMP data.

It is abundantly clear that the prescription drug abuse epidemic is a crisis in the U.S. However, while we discuss this complicated and dynamic issue we need to keep in mind that many of these medications that so many are abusing are critical for many patients living with chronic pain.

The Institute of Medicine estimates that there are more than 100 million adults in the U.S. living with chronic pain. It is critical as we move forward that we remember that these medications are vital for many Americans experiencing such pain.

This hearing will help us better understand and define the various components of the issues and the challenges we face. In addi-

tion, this subcommittee will learn about the programs we currently have in place and their level of effectiveness.

Today's witnesses represent the Office of National Drug Control Policy, the FDA, and the Substance Abuse and Mental Health Services Administration. I look forward to hearing their testimony. Thank you.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

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Today's witnesses represent the Office of National Drug Control Policy, the FDA, and the Substance Abuse and Mental Health Services Administration, and I look forward to their testimony.

Thank you, and I yield the balance of my time to Rep. _____.

Mr. PITTS. And does anyone seek time? I guess I don't have time. Thank you. I yield the balance of my time and now recognize the gentlelady Ms. Schakowsky for 5 minutes for an opening statement.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

First, I would like to ask if I could put the opening statement of Mr. Waxman into the record.

Mr. PITTS. Without objection, so ordered.

[The prepared statement of Mr. Waxman follows:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN

Prescription drug abuse is a serious and growing problem in America. The number of deaths due to unintentional overdoses with prescription drugs dwarfs the number of deaths from illegal drugs, and almost doubled between 2000 and 2007. According to the Centers for Disease Control and Prevention, there were over 16,650 deaths in 2010 due to overdose with prescription painkillers.

Although these drugs can cause harm if abused, they can also offer tremendous relief to patients, such as those with cancer or with chronic pain that responds poorly to other medications. The challenge, then, is to identify the means to prevent abuse while preserving access to these drugs by those who truly need them. I hope our witnesses today will provide information that can help us meet this challenge.

Clearly, there is no silver bullet, or any single simple approach that will solve the problem. However, there are a number of avenues that may be worth pursuing, many of which are reflected in the Administration's prescription drug abuse plan.

First: Providers should be better educated on the use and potential abuse of these drugs, so they can be more effective in recognizing developing problems of abuse, and, in turn, more effective in educating and treating their patients. Studies show that even brief interventions by health care providers can be successful in reducing or eliminating substance abuse by patients who have begun abusing prescription opioids but have not yet become addicted to them.

There are a number of potential mechanisms that could enhance provider education. For example, Congress or possibly the Drug Enforcement Administration could include among the eligibility standards for DEA registration, a requirement that physicians receive adequate and appropriate training in the prescribing and use of controlled substances. FDA could also require that pharmaceutical companies develop educational materials and physician training programs as part of a Risk Evaluation and Mitigation Strategy (REMS) tied to opioid drug approval.

Second: We must educate patients on the risks of abuse of these drugs, and the need to properly store and dispose of them. According to a 2009 national survey by the Substance Abuse and Mental Health Services Administration, over 70% of people who abused these drugs got them from friends or relatives, rather than from drug dealers or over the internet. If we can reduce inappropriate access to these drugs, we can also reduce the incidence of their abuse.

A third approach involves efforts of drug companies to develop abuse-deterrent formulations of controlled drugs—making them difficult or impossible to crush or dissolve, for example, so they cannot be taken by inhalation or injection for an enhanced effect. FDA is supportive of such activities, and recently released a draft guidance to assist industry in developing new formulations of opioid drugs with abuse-deterrent properties. The guidance describes FDA's current thinking about the studies companies would be expected to conduct to demonstrate the abuse-deterrent properties of a specific formulation, including the process by which FDA would evaluate such studies as well as the labeling claims FDA might approve based on the results.

This is a positive development and I applaud FDA for making this guidance a top priority. But I am concerned about the increasing evidence that brand companies are using abuse-deterrent technologies as a tool to thwart generic competition.

Indeed, the brand manufacturers of opioid drugs appear to be timing the release of their new abuse-deterrent formulations to coincide with the expiration of their patents and periods of marketing exclusivity. Upon FDA approval of the new formulations, the companies remove the old formulations from the market, claiming that they are no longer safe. If FDA agrees the brand formulations were removed for

safety reasons, FDA is precluded from approving generic competitors without comparable abuse-deterrent formulations.

When a brand manufacturer's new formulation truly deters abuse, there is no question FDA should not approve a generic version without comparable abuse-deterrent properties. In making that evaluation, however, FDA must be careful to ensure that the claimed abuse-deterrent properties are effective enough to justify a decision that the original version is no longer an acceptably-safe product.

To be clear: Abuse deterrence should not become a new "work-around" through which brand companies avoid generic competition. Instead drug manufacturers should engage in this area in accordance with both the letter and the spirit of the law. Towards that end, FDA should also provide guidance to companies on what they are expected to do to obtain approval of abuse-deterrent generic formulations.

No doubt, we need to address the growing problem of prescription drug abuse in this country. But we must do so through means that recognize and preserve the critical role opioid pain medications play in improving the quality of life of those with otherwise intractable and chronic pain. I hope our hearing today will enable us to make progress towards this goal.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you.

I am happy that we are having this hearing on drug abuse in the United States and I am glad that we can work together in a bipartisan manner to tackle this problem. I want to welcome all of our witnesses today.

This hearing provides an opportunity to raise awareness and discuss action that we can take to end a crisis that is truly destroying lives, hurting families and communities across the country.

My constituent, Peter Jackson, tragically lost his 18-year-old daughter Emily to this epidemic. While visiting family, Emily's cousin offered her an OxyContin tablet that had belonged to her uncle, who had recently died of cancer. After taking the OxyContin tablet while drinking, Emily went to sleep and never woke up. She died from respiratory depression; she stopped breathing.

While Emily's story of dying after taking a single un-prescribed OxyContin tablet may be extremely rare, death from the abuse and misuse of prescription opioid drugs are not. Prescription opioid drugs were involved in 16,650 overdose deaths in 2010, accounting for more deaths than from overdoses of heroin and cocaine combined. This represents a 313 percent increase in deaths over the past decade.

In addition to those tragic deaths, there are other negative health consequences that result from prescription drug abuse. For every overdose death in 2010 there were an additional 10 abuse treatment admissions, 26 emergency department visits, 108 people with abuse or dependence, and 733 nonmedical users of those drugs.

In addition to the human toll, there are financial costs associated with prescription drug abuse that our health care system simply cannot afford. The direct health care cost of prescription drug abuse exceeds $70 billion each year. Research has found that, on average, opioid abusers generate direct costs 8.7 times higher than non-abusers each year. It is a national imperative that we work to end this crisis. Reducing the prevalence of prescription drug abuse will save lives and save money.

There are actions underway that are helping to combat this problem at the federal level. Last year, we passed several provisions as part of the Food and Drug Administration's Safety and Innovation Act to combat prescription drug abuse, including a requirement that the FDA hold a public meeting on the scheduling of hydrocodone and issue guidance on developing abuse-deterrent products. Federal agencies are also operating programs to combat prescription drug abuse, including developing and supporting efforts to educate providers and populations at risk for prescription drug abuse.

While federal efforts are critical, we must partner with States if we are to be successful in ending prescription drug abuse due to States' responsibility to license and train the health care professionals that prescribe and dispense these drugs. We must also build on current efforts by identifying additional steps that we can take to tackle such abuse. We must make drugs containing hydrocodone schedule II drugs. While it will be important to take steps to ensure this change does not limit access to patients with legitimate medical needs, this change is needed to adequately reflect the potential risk these drugs pose to public health.

We should also take steps necessary to restrict the use of oxycodone pain relievers to severe pain, rather than moderate to severe pain, in order to prevent the overprescribing of these powerful medications.

I look forward to hearing from our witnesses about the Federal Government's efforts to combat prescription drug abuse, to learn additional steps we can take to stop the abuse and misuse of opioid drugs, and I would appreciate any comment on the suggestions that I made it my testimony.

And I yield back.

Mr. PITTS. The chair thanks the gentlelady and now recognizes the vice chairman of the subcommittee, Dr. Burgess, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the Chairman for the recognition.

Now, the fact of the matter is that we lose more people in this country to the drug overdoses than we do to automobile accidents. And of those drug overdoses, ⅔ of them are prescription drug overdoses. So we have got a plenty big problem. The good news is there is plenty we can do about it. But unfortunately, the agencies and lawmakers have, so far, not taking anything other than a short-term approach. We really need a broad-based, comprehensive strategy that is focused on going after the bad actors.

So to start we could go after the pill mills. They may be hard to find, but maybe not. They advertise, so we are very fortunate. They tell us where they are, what their hours are, they tell us their charges. So if I can find them, how come the Board of Pharmacy can't? How come law enforcement can't? And take a hard look at this.

Look, I ran a medical practice for 25 years, never once did I advertise a free initial visit, dispensing onsite, discounts off meds,

coupon included. This warrants a hard look. It just doesn't fit a normal type of medical practice.

We should reauthorize and fight to fund NASPER. This committee reauthorized it in the past. It is the only authorizing legislation that encourages state Prescription Drug Monitoring Programs. NASPER was a product of this committee, bipartisan, drafted with medical providers, States and patients in mind.

We should encourage qualitative drug screening and reject contrary Medicare policies. We should encourage abuse deterrent formulations and reward investment in these technologies. We might also work with Canada to align our policies in approving and reimbursing these technologies. We should look at and examine the personal use exemption to see if it encourages bringing controlled substances into the country. We should do more to shutdown the rogue internet pharmacies at home and abroad.

It boils down to this: right now, you can go to a publication; you could go on the internet and buy a controlled substance by pointing and clicking at two things, two statements you have to make: one, I need the drug; and two, I ain't lying. Most people can meet that bar.

I am open to discussing provider education if it does not subvert medical judgment. We have allowed a few bad actors to jeopardize a doctor's ability to offer pain care and care for the patients out of fear for patient abuse and diversion. And this is an important point. Being someone who has written prescriptions, I do have a perspective on this that says we have got to stop the diversion but we also need to be careful that our—whatever we do is not so prescriptive that it prevents people who have a legitimate need and use of this medication to not obtain it.

So pain costs are estimated at more than $100 billion yearly and they are the cause of 25 percent of sick days. Prescription medications may be an important part of pain therapy. If we don't stop the bad actors, we are going to hurt the people who have legitimate uses for these medications. The bad actors cannot be allowed to jeopardize a doctor's ability to alleviate human suffering.

Again, there is much we should do. I understand why this may be a series of hearings and, Mr. Chairman, obviously I look forward to working with you. We need to involve doctors; we need to involve patients as witnesses.

Thank you, Mr. Chairman, for the consideration and I will yield the balance of the time to Dr. Gingrey.

Mr. GINGREY. I appreciate my OB/GYN colleague from Texas for yielding to me because I agree with so much of what he said.

You know, the problem is a huge problem in not only the cost of the legal dispensation or prescribing of these types of medications, pain medications, anxiolytics, antidepressants, whatever. But, just think about the cost of decreasing productivity in individuals that maybe are a little bit, just a little bit overmedicated. You know, this might sound a little harsh, but honestly, I think maybe a little pain or a little anxiety in our lives is a good thing. It can be a productive thing and make you appreciate that you have to work through that. And that if you try to completely eliminate each of those things, then that is where you get to the dependency, the addiction, the decreased productivity, or the cost to society.

So I think physicians have a big role to play in this, and even the ones that are prescribing legally. And I am not talking here about the pill mills. The State's doing, I think, a good job of trying to crack down on that.

But finally, we must take a close look at how we as a society support treatment and recovery for patients struggling to overcome addiction. We must look for new and innovative treatment plans which treat this dependence and leave the abuser without new addictions, where they are on some other medication that is supposedly helping them and they are almost just as addicted as they were before.

Mr. Chairman, I yield back and I thank you for the time.

Mr. PITTS. The chair thanks the gentleman.

That concludes the opening statements. The Committee has one panel before us today and I will introduce those members at this time: Mr. Gil Kerlikowske, Director, Office of National Drug Control Policy is with us; secondly, Dr. Throckmorton, Deputy Director of Regulatory Programs, Center for Drugs Evaluation and Research, U.S. Food and Drug Administration; finally, Dr. Westley Clark, Director, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration.

Thank you for coming. Your written testimony will be made part of the record. You will be each given 5 minutes to summarize your testimony.

Mr. Kerlikowske, you are recognized for 5 minutes for your opening statement.

STATEMENTS OF R. GIL KERLIKOWSKE, DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE PRESIDENT; DR. DOUG THROCKMORTON, DEPUTY DIRECTOR FOR REGULATORY PROGRAMS, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; AND DR. H. WESTLEY CLARK, DIRECTOR, CENTER FOR SUBSTANCE ABUSE TREATMENT, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

STATEMENT OF R. GIL KERLIKOWSKE

Mr. KERLIKOWSKE. Thank you, Chairman Pitts and representative Schakowsky and members of the subcommittee, and thank you for the opportunity to address the important issue of prescription drug abuse in this country.

Preventing prescription drug abuse has been a major focus of our office since my confirmation now 4 years ago. We have worked very collaboratively with a number of federal agencies throughout government to address what the CDC has rightly termed an epidemic. My position allows me to raise the public awareness and take action on drug issues that affect the Nation, and the Administration recognizes that addiction is a disease, that prevention, treatment, and smart law enforcement all have to play a part of a comprehensive strategy to reduce drug use, to give help to those who need it, and to ensure public health and safety.

And we are here today because the prescription drug abuse as a devastating consequences for public health and safety in the country. Increases in treatment admissions for substance use dis-

orders, emergency department visits, and, sadly, the deaths that are attributable to prescription drug overdoses place an enormous burden upon communities across the country.

In 2010 alone, more than 38,000 Americans died from a drug overdose; 22,000 of those overdose deaths were attributable to prescription medications; and most of those deaths, almost 17,000, were attributable to prescription painkillers. And in response the Administration released a comprehensive program called Prescription Drug Abuse Prevention Plan.

The plan brings together a variety of federal, state, local, and tribal partners to focus on the four major priority areas dealing with this: education, monitoring, proper disposal, and enforcement, and the plan promotes mandatory education and safe prescribing and addiction practices for prescribers and dispensers.

Current training for health care providers on safe opioid prescribing and addiction can be an adequate and inconsistent. Medical school students receive an average of only 11 hours of training on pain education. Most schools do not offer specific training on opioids at all. Several States including Iowa, Massachusetts, and Utah passed mandatory prescriber education legislation. And we have come a long way in educating the general public about prescription drug abuse. We have worked with a wide array of state government leaders, medical associations, public health and safety organizations to prioritize prescription drug abuse and overdose prevention.

The second pillar of the plan focuses on strengthening the Prescription Drug Monitoring Programs. In 2006, only 20 States had PDMPs. Today, 49 States have authorized legislation, 46 States have operational PDMPs. There are currently 14 States that are able now to share data across state lines and we are supporting that expanded interoperability.

The Administration has worked with Congress to allow the Department of Veterans Affairs to share prescription drug data with PDMPs and we are pleased to say that the VA's rulemaking process is nearing completion, and VA has authorized its health care providers to access those state PDMPs when consistent with state laws.

And third, the Administration has continued to expand safe and proper disposal of unused and expired medication. Since 2010, the Drug Enforcement Administration has partnered with thousands of local law enforcement agencies and our Drug-Free Communities coalitions to hold six national take-back days collectively, safely disposing of over 2.8 million pounds of unused medication.

Lastly, the Administration plan focuses on improving law enforcement capabilities to reduce diversion. The National Methamphetamine and Pharmaceutical Initiative, funded through our office of high intensity truck trafficking areas, has trained more than 2,500 law enforcement and criminal justice professionals on pharmaceutical crime investigations and prosecutions. The federal law enforcement continues to partner with state and local agencies around the country to reduce the pill mills and prosecute those that are responsible for improper or illegal prescribing.

The Administration is working to expand access to naloxone, an emergency overdose reversal medication for first responders who

may encounter overdose victims and can help prevent a fatal opioid overdose. And we are also addressing many of the other consequences of the epidemic, including the emerging issues like neonatal abstinence syndrome and indications of increased heroin use in other places throughout the country.

In closing, let me recognize that none of these things would be possible if my executive branch colleagues and I want to accomplish for this Nation without the ongoing support of Members of Congress. And thank you for the opportunity to testify.

[The prepared statement of Mr. Kerlikowske follows:]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

"Examining the Federal Government's Response to the Prescription Drug Abuse Crisis"

Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

Friday, June 14, 2013
9:30 a.m.
2123 Rayburn House Office Building

Written Statement
of
R. Gil Kerlikowske
Director of National Drug Control Policy

Chairman Pitts, Ranking Member Pallone, and distinguished members of the Subcommittee, thank you for this opportunity to address prescription drug abuse in our country. The Office of National Drug Control Policy (ONDCP) was established by Congress with the principal purpose of reducing illicit drug use, manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. As a component of the Executive Office of the President, our office establishes policies, priorities, and objectives for the Nation's drug policies. We also evaluate, coordinate, and oversee the international and domestic anti-drug efforts of Executive Branch agencies and ensure such efforts sustain and complement state and local drug policy activities.

As Director of National Drug Control Policy and chief advisor to the President on drug policy matters, I am charged with producing the *National Drug Control Strategy*, the Administration's primary blueprint for drug policy, along with a national drug control budget and guidelines for cooperation among Federal, state, local, and tribal entities. My position allows me to raise public awareness and to take action on drug issues affecting our Nation. The Obama Administration recognizes that addiction is a disease, and that we need an evidence-based public health and safety approach to reduce drug use and its consequences.

The Administration's 2013 *National Drug Control Strategy* represents a 21st century approach to drug policy. This science-based plan, guided by the latest research on substance use and substance use disorders, contains more than 100 specific actions to support our work to protect public health and safety in America. The *Strategy* contains a specific policy focus area devoted to preventing prescription drug abuse, which has been a signature initiative of my tenure as Director of National Drug Control Policy.

The considerable public health and safety consequences of prescription drug abuse underscore the need for action, which is why the Administration released its comprehensive *Prescription Drug Abuse Prevention Plan (Plan)* in 2011. The *Plan*, a companion to the *National Drug Control Strategy*, brings together a wide range of stakeholders to reduce diversion and abuse of prescription drugs while also ensuring legitimate access. The *Plan* focuses on four major pillars, each designed to intervene at a critical juncture in the process of diversion and abuse: education for prescribers, patients, and parents; prescription drug monitoring programs; proper medication disposal; and effective enforcement.

There are signs that the national effort to reduce and prevent prescription drug abuse is working. The latest survey data show the number of people 12 and older currently abusing prescription drugs has decreased significantly from 7.0 million in 2010 to 6.1 million in 2011, a 12 percent decrease.[1] We also know that past month non-medical use of prescription drugs among young adults ages 18 to 25 was significantly lower in 2011 (5.0 percent) compared to just one year

[1] Substance Abuse and Mental Health Services Administration. *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2012]. Available: http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#Fig2-2

earlier (5.9 percent), a trend that is also true for the abuse of pain relievers among this age group.[2] However, while these trends are promising, we know there is much more to do.

The Epidemic of Prescription Drug Abuse

The misuse and abuse of prescription medications have taken a devastating toll on the public health and safety of our Nation. Increases in substance abuse treatment admissions, emergency department visits, and, most disturbingly, overdose deaths attributable to prescription drug abuse place enormous burdens upon communities across the country.[3,4,5] So pronounced are these consequences that the Centers for Disease Control and Prevention (CDC) has characterized prescription drug overdose as a public health epidemic,[6] a label that further underscores the need for urgent policy, program, and community-led responses.

The numbers paint a grave picture. In 2010 alone, more than 38,000 Americans died from drug overdose. Drug overdose deaths have become the leading cause of death due to injury in the United States, with drug overdose deaths outnumbering both motor vehicle (35,000) and firearm (31,000) deaths in the United States in 2010.[7] This means that on average more than 100 Americans die from drug overdoses every day in this country.

Just over 22,000 of these overdose deaths were attributable to prescription medications, and most of those deaths – almost 17,000 [16,651] – were attributable to prescription opioids – nearly four times the number just a decade earlier. Opioid pain relievers are now involved in far more overdose deaths than heroin and cocaine combined.[8]

The abuse of prescription opiates also is associated with increased morbidity. In 2011 alone, 1.2 million emergency department visits involved the non-medical use of prescription drugs—more than double the estimate from 7 years earlier and about equaling the number of visits involving all other illicit drugs combined (1.2 million vs. 1.3 million).[9] Data also show a nearly six-fold

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[2] Substance Abuse and Mental Health Services Administration. *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings.* U.S. Department of Health and Human Services. [September 2012]. Available: http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#Fig2-8

[3] Substance Abuse and Mental Health Services Administration. Treatment Episode Data Set (TEDS) 1999-2009, National Admissions to Substance Abuse Treatment Services. U.S. Department of Health and Human Services. [2011]. Available: www.samhsa.gov/data/2k12/TEDS2010N/TEDS2010NWeb.pdf

[4] Substance Abuse and Mental Health Services Administration. Highlights of the 2010 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. U.S. Department of Health and Human Services. [July 2012]. Available: http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm

[5] CDC. National Center for Health Statistics. Underlying Cause of Death 2000-2010 on CDC WONDER Online Database. Extracted October, 2012.

[6] CDC grand rounds: prescription drug overdoses - a U.S. epidemic.
Centers for Disease Control and Prevention (CDC).
MMWR Morb Mortal Wkly Rep. 2012 Jan 13;61(1):10-3.PMID: 22237030 [PubMed - indexed for MEDLINE]

[7] Warner M, et al. State Variation in Certifying Manner of Death and Drugs Involved in Drug Intoxication Deaths. Acad Forensic Pathol 2013 3 (2): 231-237.

[8] Jones CM et al. Pharmaceutical Overdose Deaths, United States, 2010. JAMA 2013;309(7):657-659.

[9] Substance Abuse and Mental Health Services Administration. Highlights of the 2010 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. U.S. Department of Health and Human Services. [July 2012]. Available: http://www.samhsa.gov/data/2k12/DAWN096/SR096EDHighlights2010.pdf

increase in addiction treatment admissions for individuals primarily abusing prescription pain relievers from 2000 to 2010.[10]

The ease of access to prescription drugs, combined with a low perception of risk, make reducing prescription drug abuse especially difficult, particularly among youth. We all recognize that these drugs can be just as dangerous and deadly as illicit substances when misused or abused.

The Federal Response

Two years ago, with input from our partners in the Federal Government, including the Food and Drug Administration and the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services (HHS), who are represented here today, the Obama Administration released the first comprehensive action plan to combat the prescription drug abuse epidemic, the *Prescription Drug Abuse Prevention Plan*.

The **first pillar** of the *Plan* outlines the Administration's support for expanded education for the public, patients, and prescribers. As many health care providers would agree, managing a patient's pain is a crucial and often very difficult task. However, research indicates that students in medical school receive on average only 11 hours of training on pain and pain management, and most schools do not offer specific training on opioids, substance abuse and addiction, or clinical decision making.[11] A 2011 Government Accountability Office report on education efforts related to prescription pain reliever abuse found that "most prescribers receive little training on the importance of appropriate prescribing and dispensing of prescription pain relievers, on how to recognize substance abuse in their patients, or on treating pain."[12] It is clear that training can prepare our health care providers to adequately address pain management, substance abuse, and responsible prescribing practices.

For these reasons, the *Plan* includes a core action to promote mandatory education on proper prescribing and addiction potential for prescribers and dispensers of these controlled substances. Training is an important public health measure, and the Administration continues to support mandatory education for prescribers, as reiterated in the 2013 *National Drug Control Strategy*. Several states, including Iowa,[13] Massachusetts,[14] and Utah,[15] have passed legislation requiring prescriber education on this subject.

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[10] Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Substance Abuse Treatment Admissions by Primary Substance of Abuse. According to Sex. Age Group. Race, and Ethnicity , United States* [2000 and 2010 tables]. U.S. Department of Health and Human Services. [2012]. Available: http://wwwdasis.samhsa.gov/webt/tedsweb/tab_year.choose_year_web_table?t_state=US

[11] Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.

[12] U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: http://www.gao.gov/assets/590/587301.pdf

[13] Iowa Board of Medicine. "New rules require physicians to complete training on chronic pain, end-of-life care." State of Iowa. [August 2011]. Available: http://medicalboard.iowa.gov/Board%20News/2011/New%20rules%20physicians%20to%20complete%20training%20chronic%20pain_08182011.pdf

[14] Executive Office of Health and Human Services. "PMP and Mandatory Educational Requirements for Prescribers." Commonwealth of Massachusetts. [October 2011]. Available: http://www.mass.gov/eohhs/provider/licensing/occupational/dentist/pmp-and-mandatory-educational-requirements-for-pre.html

[15] Utah Division of Occupational and Professional Licensing. *Utah Controlled Substances Act. 58-37-6.5*. State of Utah. [May 2012]. Available: http://www.dopl.utah.gov/laws/58-37.pdf#page=24

ONDCP worked with the National Institute on Drug Abuse at the HHS National Institutes of Health to develop two free online continuing education training tools for health care professionals who prescribe opioid analgesics. Since these tools became available in October 2012, clinicians have completed nearly 50,000 hours of continuing medical education courses on the abuse potential of these medications and management of patients to whom they are prescribed.

We are also working to educate the general public. ONDCP's National Youth Anti-Drug Media Campaign provides teen exposure to anti-drug messages through a combination of advertising (e.g., social media, Internet, and cinema) and public communications. The Media Campaign's "Above the Influence" brand (www.abovetheinfluence.com), which is being transitioned to the Partnership at Drugfree.org, is an important national tool for educating young people and their parents about the dangers of prescription drug abuse, among its many other drug prevention messages. ONDCP also manages the Drug Free Communities (DFC) Support Program, which provides grants to nearly 700 local drug-free community coalitions, enabling them to increase collaboration among community partners, including local youth, parent, business, religious, civic, law enforcement, and other groups, to prevent and reduce youth substance use, including prescription drug abuse and misuse. Since DFC coalitions have identified prescription drug abuse as a growing problem and a priority for their communities, the DFC Program recently modified its four core measures to include prescription drug abuse prevention. Through prevention strategies, DFC coalitions use comprehensive approaches to address prescription drug abuse, such as raising awareness for prescribers, parents, and youth; organizing prescription drug disposal events; and developing systems for safe disposal of prescription drugs.

The **second pillar** of the *Plan* focuses on strengthening Prescription Drug Monitoring Programs (PDMPs), state-administered databases that monitor the prescribing and dispensing of controlled substances. Information contained in PDMPs may be used by prescribers and pharmacists to identify patients who may be doctor shopping (seeing multiple doctors to obtain prescriptions), need substance abuse treatment, or are at risk for overdose. In accordance with state laws, PDMP information may also be used by state regulatory and law enforcement officials to pursue cases involving "pill mills," prescribers or pharmacists operating outside the bounds of proper practice, and other sources of diversion. In 2006, only 20 states had PDMPs. Today, 49 states have laws authorizing PDMPs; only Missouri and the District of Columbia are without legislation authorizing PDMPs, and 46 states have operational programs.

But these important programs can function more effectively. For example, as of today, only 14 state PDMPs can share data with other PDMPs. We are working with our Federal partners to make these systems more user-friendly, so physicians and pharmacists can access them quickly and easily. For instance, SAMHSA and the HHS Office of the National Coordinator for Health Information Technology worked with health care facilities across the country to better integrate PDMPs into provider workflow, making these critical tools more accessible to those who need them. Ongoing support from the Bureau of Justice Assistance at the Department of Justice, through the Harold Rogers PDMP Program, is facilitating ongoing efforts to enhance interoperability among state systems.

These systems must continue to mature, and the Administration continues to invest and focus on expanding interstate data sharing, streamlining PDMP operations, and ensuring that data from prescribers in Federal agencies, such as the Department of Defense, Department of Veterans Affairs, and the Indian Health Service, are shared with state PDMPs.

The **third pillar** of our plan focuses on safe disposal of unused and expired medications. Research shows that over 70 percent of people misusing prescription pain relievers in the past year report getting them from a friend or relative the last time they abused them.[16] Safe and proper disposal programs allow individuals to dispose of unneeded or expired medications in a safe, timely, and environmentally responsible manner.

Since September 2010, the Drug Enforcement Administration (DEA) has partnered with hundreds of state and local law enforcement agencies and community coalitions, as well as other Federal agencies, to hold six National Take-Back Days. Through these events, DEA has collected and safely disposed of more than 2.8 million pounds of unneeded or expired medications. As part of the Secure and Responsible Drug Disposal Act of 2010, DEA recently published proposed regulations that, once finalized, will expand the safe and effective disposal of prescription drugs nationwide. ONDCP will work with Federal, state, local, and tribal stakeholders to identify ways to establish disposal programs in their communities upon completion of the rulemaking process.

The **final pillar** of the Administration's plan focuses on improving law enforcement capabilities to reduce diversion. Federal law enforcement is partnering with state and local agencies across the country to reduce pill mills and prosecute those responsible for improper or illegal prescribing practices. The National Methamphetamine and Pharmaceuticals Initiative (NMPI), funded through ONDCP's High Intensity Drug Trafficking Areas (HIDTA) program, provides critical training on pharmaceutical crime investigations to law enforcement agencies across the country. In FY 2012 alone, NMPI provided training to nearly 6,600 law enforcement and criminal justice professionals. Also in 2012, NMPI helped convene five statewide prescription drug summits. These efforts disseminate critical knowledge to law enforcement and criminal justice professionals.

Collaboration on this issue has included a broad range of stakeholders. We have worked with a number of associations and groups, including the National Governors Association, the National Association of Attorneys General, the American Medical Association, the American Dental Association, the National Safety Council, the National Conference of State Legislatures, the National Association of Boards of Pharmacy, the Association of State and Territorial Health Officials, state medical boards, and countless community groups in states, localities, and tribes across the country.

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[16] Substance Abuse and Mental Health Services Administration. *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings.* U.S. Department of Health and Human Services. [September 2012]. Available: http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#Fig2-14

All of these groups and the constituencies they represent have recognized the urgency of this national problem and are helping to bring about the changes we need to prevent more abuse, more arrests, and more deaths.

There are signs that the national effort to reduce and prevent prescription drug abuse is working. The latest survey data show the number of people 12 and older currently abusing prescription drugs has decreased significantly from 7.0 million in 2010 to 6.1 million in 2011, a 12 percent decrease.[17] We also know that past month non-medical use of prescription drugs among young adults ages 18 to 25 was significantly lower in 2011 (5.0 percent) compared to just one year earlier (5.9 percent), a trend that is also true for the abuse of pain relievers among this age group.[18] However, while these trends are promising, we know there is much more to do, particularly to address increasing rates of chronic nonmedical use of pain relievers. The frequency of chronic nonmedical use of pain relievers (nonmedical use of 200 days or more in the past year) among all users in the past year increased roughly 75 percent between 2002-2003 and 2009-2010. This equates to almost 1 million people in the United States who reported using opioid analgesics nonmedically each year.[19]

The Administration is focused on addressing some of the most pronounced consequences of this epidemic, including overdose deaths and emerging issues like maternal addiction and neonatal abstinence syndrome (withdrawal symptoms due to a mother's substance use). The need for further partnerships on overdose prevention is underscored by evidence of increased heroin use in some areas of the country and increasing heroin treatment admissions among 18- to 25-year-olds (from approximately 43,000 in 2000 to approximately 68,000 in 2010).[20]

With the recent rise in overdose deaths across the country,[21] it is increasingly important that we make certain everyone know overdoses can be prevented and that deaths can be avoided. We are working to expand access to naloxone, an emergency overdose reversal medication, for first responders who encounter overdose victims.

For example, the Police Department in Quincy, Massachusetts, has partnered with that State's health department to train and equip police officers to resuscitate overdose victims using naloxone. Since October 2010, officers in Quincy have administered naloxone in more than 160 overdose events, almost all of them resulting in successful overdose reversals.[22]

Naloxone is only one element in the broad range of overdose prevention efforts. The odds of surviving an overdose, much like the odds of surviving a heart attack, depend on how quickly the victim receives treatment. We are also closely examining Good Samaritan laws, which immunize

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[17] Substance Abuse and Mental Health Services Administration. *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2012]. Available: http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#Fig2-2

[18] Substance Abuse and Mental Health Services Administration. *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2012]. Available: http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#Fig2-8

[19] Jones CM. Frequency of prescription pain reliever nonmedical use: 2002-2003 and 2009-2010. Arch Intern Med. 2012;172(16):1265-1267

[20] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010. Drug Alcohol Depend. 2013 Feb 11. pii: S0376-8716(13)00019-7. doi: 10.1016/j.drugalcdep.2013.01.007.

[21] Jones CM et al. Pharmaceutical Overdose Deaths, United States, 2010. JAMA 2013;309(7):657-659.

[22] Quincy (MA) Police Department Reporting.

from criminal prosecution individuals who are overdosing and witnesses on the scene who seek medical aid for these individuals. These laws eliminate any potential fear of prosecution for drug use and thus facilitate seeking prompt medical attention if an individual is overdosing. Several states—including California,[23] Illinois,[24] and New Mexico[25]—have passed Good Samaritan laws. As these laws are implemented, the Administration will carefully monitor their effect on public health and public safety.

The Administration also recognizes that people who need treatment should have timely access to a broad array of services, especially access to medication assisted treatments for opioid addiction. Fortunately, we have an array of proven interventions and medications to treat addiction.

The Affordable Care Act will also help expand treatment services. The Affordable Care Act will extend access to and parity for mental health and substance use disorder benefits for an estimated 62 million Americans and help integrate substance use treatment into mainstream health care.[26] The health care law, therefore, gives many more Americans in need an opportunity to be treated.

Conclusion

We continue to work with our Federal, state, local, and tribal partners to accomplish all the goals of the *Prescription Drug Abuse Prevention Plan* and address other emerging issues, such as the transition from prescription drugs to heroin, ensuring treatment for opioid abuse and misuse for pregnant women, and neonatal abstinence syndrome.

Together with all of you, we are committed partners, working to reduce the prevalence of substance use disorders through prevention, increasing access to treatment, and helping individuals recover from the disease of addiction.

Thank you for the opportunity to testify here today, and for your ongoing commitment to this issue. I look forward to continuing to work with you on this pressing public health matter.

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[23] California Legislative Information. *AB-472 Controlled substances: overdose: punishment.* Available: http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201120120AB472

[24] Illinois General Assembly. *Bill Status of SB1701.* Available: http://www.ilga.gov/legislation/BillStatus.asp?DocNum=1701&GAID=11&DocTypeID=SB&SessionID=84&GA=97

[25] Justia.com U.S. Law. *2011 New Mexico Statutes: Chapter 30: Criminal Offenses: Article 31: Controlled Substances, 30-31-1 through 30-31-41. Section 30-31-27.1: Overdose prevention: limited immunity.* Available: http://law.justia.com/codes/new-mexico/2011/chapter30/article31/section30-31-27.1/

[26] Berino, K., Rosa, P., Skopec, L. & Glied, S. (2013). Affordable Care Act Will Expand Mental Health and Substance Use Disorder Benefits and Parity Protections for 62 Million Americans. *Research Brief.* Assistant Secretary for Planning and Evaluation (ASPE). Washington, DC (Citation: Abstract of the Brief found at http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm)

Mr. PITTS. The chair thanks the gentleman.

Dr. Throckmorton, you are recognized for 5 minutes for an opening statement.

STATEMENT OF DOUG THROCKMORTON

Dr. THROCKMORTON. Mr. Chairman and members of the subcommittee, I am Dr. Douglas Throckmorton, Deputy Director for Regulatory Programs in the Center for Drug Evaluation and Research at the FDA. Thank you for your opportunity to be here today to discuss the misuse and abuse of prescription drugs, especially prescription opioids.

The importance of this problem is hard to overstate. Beyond the sobering statistics are individuals and their families whose lives have been shattered by prescription opioid misuse, abuse, and addiction. It is a crisis that affects us all, and meaningful and enduring solutions will require all of our collective efforts.

Balancing the needs of patients suffering from pain with the need to combat opioid misuse, abuse, and addiction is a priority for the FDA and for me personally. In seeking this balance, FDA has pursued a targeted, science-based approach aimed at critical points in the development and use of opiod medications. While additional work remains to be done, I would like to mention some of the activities FDA is doing now.

First, we are a science-based agency and are focusing on improving the safe use of pain medicines. These activities include recent work we have done to encourage the development of abuse-deterrent drug formulations for opioids. The FDA believes the development of these new formulations to successfully deter abuse is an important part of our efforts to improve their safe use.

For example, in January of this year, the FDA issued a draft guidance document for industry outlining the development of abuse-deterrent opioid drug products. And in the fall, the FDA will participate in a public meeting to discuss the issues addressed in that draft guidance, as well as issues surrounding the development of abuse-deterrent formulations for generic drug products.

In addition, the FDA has taken recent regulatory actions concerning two opioid products, OxyContin and Opana ER, that were reformulated with the intention of making the products more difficult to manipulate and abuse. The data for these two products were reviewed carefully and independently by FDA scientists and resulted in a change in the labeling for OxyContin. Our decisions relied on the totality of the evidence for the particular drug at hand, and given where we are in the evolving science of abuse deterrence, were made on a case-by-case basis.

A second critical area where we have devoted time and resources is the development of effective patient and prescriber education. The interaction between prescribers and patients plays a critical role in improving the safe use of these drugs and the FDA has taken a number of steps to improve the educational materials that are available for patients and prescribers.

For example, in July of 2012 we approved a risk evaluation and mitigation strategy, known as REMS, for manufacturers of over 20 extended-release and long-acting opioids. Under this REMS, manufacturers are required to support the development of effective pre-

scriber training programs offered by accredited continuing education providers and to make them available at little or no cost to health care professionals. The training is based on a syllabus developed by the FDA with input from other stakeholders. We are currently posting those educational materials on our Web site to make them easier for prescribers to find and make use of.

A third critical area where we have devoted time and resources is on ways to prevent the overdose deaths associated with prescription opioids by improving the treatment of overdose. Naloxone is an injectable medication that is the standard treatment to rapidly reverse the overdose of either prescription or illicit opioid. And when given quickly, it can and does save lives.

At a public meeting the FDA convened last year with several other parts of the Federal Government, stakeholders encouraged the exploration of new ways to administer naloxone that may be easier than currently available, such as auto-injectors or via intranasal administration. In this area, FDA is working to provide regulatory priority assistance to manufacturers, who are working on assessing these new ways to give naloxone.

To finish my remarks, our society faces two important challenges. We must balance efforts to address the misuse, abuse, and addiction that harms our families and communities and the need for appropriate access to pain medications for patients that need them. There can be no doubt there is much to be done and that we must act now. These are not simple issues and there are no easy answers. Given the complexity of the issues surrounding this problem, real and enduring progress will require a multifaceted approach combined with the dedication, persistence, and full engagement of all parties.

FDA continues to prioritize our efforts in this area to combat this significant public health crisis. We welcome the opportunity to work with Congress, our federal partners, the medical community, advocacy organizations, patients, and families to turn the tide on this devastating epidemic.

Thank you for your continued interest in this important topic and for the opportunity to testify regarding FDA's contributions on this issue. I am happy to answer any questions you have.

[The prepared statement of Dr. Throckmorton follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

DOUGLAS C. THROCKMORTON, M.D.

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"EXAMINING THE FEDERAL GOVERNMENT'S RESPONSE TO THE PRESCRIPTION DRUG ABUSE CRISIS"

June 14, 2013

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman, Ranking Member Pallone, and Members of the Subcommittee, I am Dr. Douglas Throckmorton, Deputy Director for Regulatory Programs in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the epidemic of misuse, abuse, and diversion of prescription drugs, especially prescription opioids, in the United States.

This is a problem that has cast a terrible shadow across our nation and led to a public health crisis of devastating proportions. It is a crisis that has affected us all, and meaningful and enduring solutions will require all of our collective efforts.

Many of us are all too familiar with the numbers associated with this epidemic. According to the latest estimates from the Centers for Disease Control and Prevention (CDC), in 2010, prescription opioid drugs were involved in 16,650 overdose deaths, a 313 percent increase over the past decade. And the Substance Abuse and Mental Health Services Administration (SAMHSA) reports that for each death, there are an additional nine treatment admissions,[1] 32 emergency department visits,[2] and 734 non-medical users of these drugs.[3] Although the problem partly is attributable to inappropriate or illicit use, such as sharing

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[1] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2000-2010. National Admissions to Substance Abuse Treatment Services.* DASIS Series S-61, HHS Publication No. (SMA) 12-4701. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

[2] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, SAMHSA, Drug Abuse Warning Network, 2010 available at *http://www.samhsa.gov/data/dawn/nations/Nation_2011_AllMA.xls.*

[3] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Results from the 2011 National Survey on Drug Use and Health:* detailed table 1.1A (HHS Publication No. SMA 12-4713, NSDUH Series H-44). Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

medication with family and friends or theft of the drug from home medicine cabinets, legitimate use of medications for pain may also lead to unnecessary adverse events, addiction, and death for some patients. Beyond these grim statistics, we find individuals and their families whose lives have been shattered by prescription opioid abuse, misuse, and addiction.

We play a critical role in the development, review, and approval of drugs. FDA reviews applications for opioid medical products, requires accurate drug prescribing information, and monitors how these products are used once they go to market—and a balance must be struck between their benefit in treating patients and the risks associated with misuse, abuse, and addiction to those patients and to others.

Combating opioid misuse, abuse, and addiction has long been a priority for the Agency, and FDA has taken many steps to address this problem over the last few decades. We have taken action to build upon existing initiatives and develop new ones, including establishing a task force to focus on this critical issue.

Over the last decade or so, FDA has worked to pursue a targeted, science-based, multi-pronged approach that addresses misuse, abuse, and addiction at critical points in the development of an opioid product and in its use throughout the health care system. This comprehensive approach includes five broad areas:

- Encouraging scientific work into the development of safe and effective treatments for pain and into the most appropriate uses of pain medicines;
- Encouraging the development of abuse-deterrent drug formulations for opioids;
- Working to improve the appropriate use of opioids to treat pain through prescriber and patient education;

- Evaluating opioid labeling, and
- Improving the availability of products that treat abuse and overdose.

Research, Scientific, and Development Needs

As a scientific and public health regulatory agency, FDA's approach to regulation of prescription opioids must be grounded in science; specifically, we must bring to bear the best available knowledge and understanding concerning both the treatment of pain and potential adverse consequences of opioid use. FDA has long been committed to obtaining the best information possible about the appropriate and safe use of opioid drugs in pain management. For example, we held a joint meeting with the National Institutes of Health last May on what is known scientifically about the efficacy of opioids in treating chronic non-cancer pain. And we are continuing to work with academics and other scientists to ensure that we have reliable data to guide FDA's decision-making on these complex and challenging issues.

The Food and Drug Administration Safety and Innovation Act (FDASIA, Pub. Law 112-144) required FDA to "hold a public meeting to solicit advice and recommendations to assist in conducting a scientific and medical evaluation in connection with a scheduling recommendation to the Drug Enforcement Administration (DEA) regarding drug products containing hydrocodone, combined with other analgesics or as an antitussive." That meeting took place on January 24-25, 2013. The Advisory Committee was provided data and heard presentations from various experts, and then the majority of the Committee voted to recommend rescheduling hydrocodone combination products from Schedule III to Schedule II.

FDA also received and is in the process of reviewing 768 comments from the public—patients, parents, and health care professionals such as dentists, nurse practitioners, ophthalmologists and physicians—expressing their views on rescheduling. The data provided at the meeting, public comments, and the Committee's recommendation will help inform FDA's scheduling recommendation.

Abuse-deterrent Formulations

The continued development of opioids that are specifically formulated to deter abuse is an important component of our twin goals of minimizing abuse and misuse of prescription opioids while maintaining and improving access to these medications for patients who need them. Abuse-deterrent formulations target known or expected routes of abuse, such as crushing the product or extracting the active ingredient from the product to facilitate rapid release of the opioid following swallowing, snorting, or injection.

FDA is working to encourage the development of abuse-deterrent forms of opioid medicines. First, in January of this year, FDA issued a draft guidance document on the development of abuse-deterrent opioid drug products, as required by FDASIA. The draft guidance sets forth FDA's current thinking regarding the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies will be evaluated by FDA, and what labeling claims may be approved based on the results of those studies. FDA will participate in an upcoming public meeting to discuss the issues addressed in the draft guidance on September 30 and October 1, 2013.

FDA has also recently taken regulatory actions regarding two opioid products—OxyContin and Opana ER—that were reformulated with the intention of making the products

more difficult to manipulate for purposes of abuse. The regulatory implications have been the subject of independent, extensive consideration by FDA experts over the course of many months. Our decisions took into account the totality of the evidence for the particular drug at issue and were made on a case-by-case basis.

First, on April 16, 2013, FDA approved updated labeling for Purdue Pharma L.P.'s reformulated OxyContin that describes its abuse-deterrent properties; specifically, the new labeling indicates that the product has physical and chemical properties that are expected to make abuse via injection difficult and reduce abuse via the intranasal route (snorting). The Agency also decided that the company's original formulation had been withdrawn for safety or effectiveness reasons, because it posed an increased potential for abuse by snorting and injecting, compared to reformulated OxyContin. As a result, FDA will not approve any generic versions of the original formulation of OxyContin.

Second, on May 10, 2013, FDA determined that the original formulation of Opana ER was *not* removed from the market for safety or effectiveness reasons, because the available evidence was insufficient to conclude that the original formulation had an increased potential for abuse compared to reformulated Opana ER. While there is an increased ability of the reformulated Opana ER to resist crushing relative to the original formulation, study data show that the reformulated version's extended-release features can be compromised when subjected to other forms of manipulation, such as cutting, grinding, or chewing, followed by swallowing. As a result, FDA will not take steps to remove existing generic versions of the original formulation from the market and will continue to approve such generics, so long as they meet all applicable requirements.

Although these actions had different outcomes based on the science presented, they demonstrate that FDA can and will act in this area to exercise our regulatory authority to protect the public health. While we intend to take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent products, we will be driven by science and the data presented to us for each product to ensure that products that claim to be abuse-deterrent actually deter abuse.

While we recognize that abuse-deterrent formulations are not a panacea, they are an important part of a multi-faceted approach to the epidemic of prescription drug abuse.

Prescriber and Patient Education

Prescribers and patients both play a critical role in preventing the abuse and misuse of opioids, and FDA has taken a number of steps to educate these groups. On March 1, 2013, FDA issued an open letter asking all prescribers of opioids to ensure that they have a thorough knowledge of the FDA-approved product labeling for the opioids they prescribe and to ensure that they have adequate training in opioid therapy. The letter was supported by the American Medical Association, American Academy of Family Physicians, and other leading health professional groups.

The Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Amendments Act of 2007, authorizes FDA to require sponsors to develop and comply with risk evaluation and mitigation strategies (REMS) when necessary to ensure that the benefits of a drug outweigh the risks. In July 2012, after a three-year effort, FDA approved a REMS for manufacturers of over 20 extended-release and long-acting (ER/LA)

opioids. This REMS acknowledges that our nation's front-line health care professionals play an important role in efforts to reduce the abuse and misuse of opioids.

It is also critically important to improve prescribers' knowledge about the best uses of opioids, including knowing when these products should be used and by which patients. Thus prescriber education is an important element of this REMS for ER/LA opioids. Under the ER/LA opioid REMS, manufacturers are required to ensure that prescriber training programs—offered by accredited continuing education providers—are made available for all U.S.-licensed prescribers, using a syllabus developed by FDA with input from many stakeholders. As a part of our assessment of this REMS, these courses will be audited to ensure that they are unbiased and accurate.

The first of these voluntary prescriber training programs was rolled out on March 1, 2013, and others will soon follow. Training is an important public health measure, and the Administration continues to support mandatory education for prescribers, as called for in the 2013 National Drug Control Strategy.

Finally, FDA tries to use its platform as a public health agency to educate patients and prescribers about the appropriate use and potential risks of drugs. In addition to training for prescribers, patients also need access to educational materials to help guide the use of opioid medicines. Under the REMS for ER/LA opioids, manufacturers have developed a patient-friendly counseling tool for prescribers to give to every patient, when they write a prescription for an ER/LA opioid. The REMS also includes a product-specific Medication Guide to be provided to the patient when they pick up their prescription. Included in these materials is information on how to safely store medications, while it is still in use, and what to do with the leftover supply, when it is no longer needed. Given the importance of educating patients, we

are also partnering with other groups. For instance, FDA and SAMHSA are working with the National Council on Patient Information and Education in a patient education campaign aimed at teenagers and college students.

Opioid Labeling

The primary tool that FDA uses to inform prescribers about the approved uses of medications is the approved product labeling (or package insert). The approved information is based on scientific and clinical information gathered about the drug, including clinical pharmacology studies, animal studies, clinical studies and post-market experience. It is important to note that FDA does not regulate the practice of medicine, and how an opioid product is prescribed is dependent on the prescriber's assessment of the benefits and risks to a particular patient based on factors, including the patient's pain management needs.

Over the past several years, FDA has made many changes to opioid product labeling in an effort to improve their proper use and to reduce their misuse and abuse. Today these labels have some of the most restrictive language that can be found in drug labeling, including a boxed warning about their potential for abuse, which calls attention to serious or life-threatening risks. In response to calls to further restrict the indications for these products and make changes to the labeling, we have held public meetings as recently as February of this year to get input on opioid labeling and identify what data exist that could inform further review of the labeling. We are currently reviewing that information and comments from stakeholders to determine whether additional changes are appropriate.

Finally, with regard to improving the labeling for opioids, FDA agrees that opioid exposure from misuse or abuse can create significant problems for mothers and infants and

that the labeling needs to be accurate. Current FDA-approved labeling for opioid medications addresses the effects of *in utero* exposure on neonates and advises against the use of opioids in women during and immediately prior to labor and delivery. Labeling also addresses the effects of opioid exposure to newborns of mothers who continue to use opioids while nursing. Recently, the dangers of opioid withdrawal in infants born to mothers who were using opioids have been raised, and FDA is reviewing the labeling of opioids to ensure that it accurately reflects the available data on the effects of opioid exposure in pregnant and nursing women and their infants.

Products to Treat Overdose and Abuse

Finally, FDA has been working with many other stakeholders to explore the best ways to treat overdoses of opioids, including overdoses of FDA-approved opioid medications. In 2009 and 2010, over 15,000 people died from an overdose involving opioid medications. Naloxone is an injectable medication that is the standard treatment to rapidly reverse the overdose of either prescription (e.g., oxycodone) or illicit (e.g., heroin) opioids. Naloxone is most commonly used by trained medical personnel in emergency departments and on ambulances. There is a growing interest by prescribers and patients in exploring the broader uses of naloxone, including its use in non-medical settings such as nursing homes.

FDA, working with other parts of the Federal Government, is looking at how naloxone may be delivered safely in ways that are potentially easier to use and do not require needles or syringes. Any such product would be subject to FDA review. FDA is providing priority regulatory assistance to manufacturers who are working on new ways of giving naloxone,

using autoinjectors or intra-nasally, that would be easier to use in non-medical settings. FDA approval would be contingent on the safety and effectiveness of the new product.

CONCLUSION

In summary, we face an ongoing challenge and a dual responsibility—we must balance efforts to address misuse, abuse, and addiction that harm our families and communities against the need for appropriate access and the pain management needs of patients who rely on these important medications. There can be no doubt that there is much to be done—and we must act now. In my testimony I have discussed some of the many activities that FDA is working on in this area. These are not simple issues and there are no easy answers. Given the complexity of the issues surrounding the abuse, misuse, and addiction to prescription painkillers, real and enduring progress will require a multi-faceted approach combined with the dedication, persistence, and full engagement of all parties. We welcome the opportunity to work with Congress, our Federal partners, the medical community, advocacy organizations, and the multitude of interested communities and families to turn the tide on this devastating epidemic.

Thank you for your continued interest in this important topic and for the opportunity to testify regarding FDA's contributions to progress on this issue. I am happy to answer any questions you may have.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman, Dr. Clark, for 5 minutes for an opening statement.

STATEMENT OF H. WESTLEY CLARK

Dr. CLARK. Good morning, Chairman Pitts, Congresswoman Schakowsky, and members of the subcommittee. I am Dr. H. Westley Clark, and I am the director of the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration. Thank you for inviting me to testify today regarding SAMHSA's role in preventing non-medical use of prescription drugs and treating individuals who abuse those drugs.

SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. We envision a nation that acts on the knowledge that behavioral health is essential for our health, prevention works, treatment is effective, and people recover.

The challenge of prescription drug misuse and abuse is a complex issue that requires epidemiological surveillance, interventions, prescriber education, access to effective treatment services, and continued research by the private and public sectors. SAMHSA's strategy to reduce prescription drug misuse and abuse aligns with the four-part strategy of ONDCP. We work across the U.S. Department of Health and Human Services by participating in the Behavioral Health Coordinating Committee's Prescription Drug Abuse Subcommittee. We are in active partnerships with the CDC, the FDA, the Office of the National Coordinator of Health Information Technology (NIH), and others aimed at preventing and treating prescription drug misuse and abuse.

According to our 2011 National Survey on Drug Use and Health, nonmedical use of prescription drug ranks as the second-most common illicit class of drugs in the United States. You have mentioned these data and there is no need for me to repeat it, but it is important to know that there was a slight decline in nonmedical use between 2010 and 2011, which suggests that the national, state, and local efforts to reduce prescription drug misuse may be having an impact, but there is still much work to be done.

State Prescription Drug Monitoring Programs, or PDMPs, are an important component in government efforts to prevent and reduce drug diversion and abuse. PDMPs monitor and analyze scheduled prescription drugs with the goal of preventing prescription drug misuse and abuse, as well as illegal diversion.

In 2005, the National All Schedules Prescription Electronic Reporting Act, or NASPER, created a Department of Health and Human Services grant program administered by SAMHSA for States to implement or enhance PDMPs. NASPER received funding from Congress in fiscal years 2009 and 2010, which resulted in SAMHSA providing 26 grants to 14 States. However, in fiscal years 2011 and '12, Congress did not appropriate funding for the NASPER program.

In 2011, SAMHSA funded the enhanced access to PDMPs through Health IT Project which was managed by ONC in collaboration with SAMHSA's CDC and ONDCP. The project was unlike the NASPER grants in that its purpose was to use health IT to increase timely access to PDMP data.

In 2012, the PDMP Electronic Health Record Integration and Interoperability Expansion program was funded by SAMHSA. This program complements existing federal efforts by improving real-time access to PDMP data through the integration of PDMPs into existing technologies such as electronic health records.

SAMHSA has also engaged in the efforts to prevent and treat prescription drug misuse and abuse through education programs for prescribers and future prescribers, prevention and early intervention programs, treatment of prescription drug abuse, as well as through regulation. We support the education of current prescribers through continuing medical education courses and other less formal efforts such as webinars.

The Screening, Brief Intervention, and Referral to Treatment program is an important tool for the early identification of persons who might be at risk for opioid abuse and other substance use. SAMHSA provides grants to States, territories, and tribal organizations to implement SBIRT for adults in primary care. We have a residency grant program through SBIRT to address future prescribers and include screening for prescription drugs.

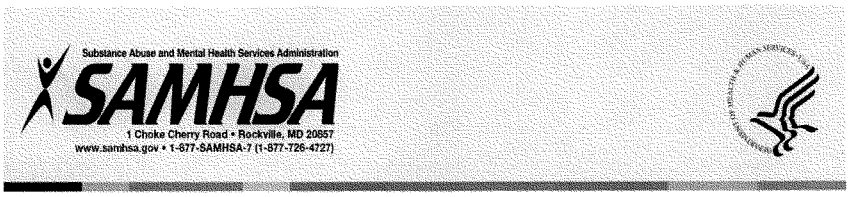
We support prevention and early intervention through several other grant programs. Our block grant program is targeted toward funding to States and territories for their prevention and treatment and services efforts. The Strategic Prevention Framework Partnerships for Success program is designed to address two of the Nation's top substance abuse prevention priorities, including underage drinking and prescription drug misuse and abuse among persons aged 12 to 25.

We work with ONDCP on our Drug-Free Communities efforts in collaboration to make sure that communities can prioritize prescription drug abuse. We are working with other federal agencies to explore telemedicine to address the need for increased access in rural settings. Our strategy to reduce prescription drug misuse includes the expansion of improved access to treatment, the Drug Addiction Treatment Act of 2000 permits qualified physicians to prescribe certain medications for the treatment of opioid addiction in outpatient settings.

We also regulate opioid treatment programs that use methadone and buprenorphine approved by FDA to treat patients with opioid dependence. We are working in collaboration with the DEA.

Through these and other efforts, SAMHSA is working daily to address the issue in order to reduce the significant long-term impacts of this serious public health problem. Thank you for the opportunity to testify regarding SAMHSA's efforts in this area and I welcome any questions that you might have.

[The prepared statement of Dr. Clark follows:]



Testimony Before the

The Energy and Commerce Subcommittee on Health

on Prescription Drug Abuse

June 14, 2013

Statement of H. Westley Clark, M.D., J.D., MPH

Director, Center for Substance Abuse Treatment

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

Good morning Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee. My name is Dr. H. Westley Clark, and I am the Director of the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS). I am pleased to address SAMHSA's role in preventing non-medical use of prescription drugs, and treating individuals who abuse prescription drugs.

SAMHSA's Role

SAMHSA was established in 1992 and is directed by Congress to effectively target substance abuse and mental health services to the people most in need of them, and to translate research in these areas more effectively and more rapidly into the general health care system. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA strives to create awareness that:

- Behavioral health is essential for health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

SAMHSA serves as a national voice on mental health and mental illness, substance abuse, and behavioral health systems of care. It coordinates behavioral health surveillance to better understand the impact of substance abuse and mental illness on children, adults, and families, as well as the costs associated with treatment. SAMHSA helps to ensure dollars are invested in evidence-based and data-driven programs and initiatives that result in improved health and resilience.

The challenge of prescription drug misuse and abuse is a complex issue that requires epidemiological surveillance, distribution chain integrity, interventions, prescriber education, access to effective treatment services, and more research by the private and public sectors. Thus, no organization or agency can address the problem alone; a coordinated response is required. The Federal Government, medical partners, public health administrators, state governments, and international organizations all are needed to implement educational outreach and intervention strategies targeted to a range of discrete audiences , including physicians, pharmacists, patients, educators, parents, high school and college students, adults at high risk, older adults, and many others. Outreach to physicians as well as pharmacists needs to be complemented by education, screening, intervention, and treatment services for those misusing or abusing prescription drugs.

SAMHSA's strategy to reduce prescription drug abuse and assist individuals who misuse or abuse prescription drugs is in alignment with the Office of National Drug Control Policy's (ONDCP) four-part strategy: education for prescribers, patients, and the public; prescription monitoring; safe drug disposal; and effective enforcement. SAMHSA works across the Department of Health and Human Services through the Behavioral Health Coordinating Committee's (BHCC) Prescription Drug Abuse Subcommittee. As a result, SAMHSA has partnerships with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health, the Centers for Medicare &

Medicaid Services, the Office of the National Coordinator for Health Information Technology (ONC), the Office of the Assistant Secretary for Health, and the Office of the Assistant Secretary for Planning and Evaluation aimed at preventing and treating prescription drug misuse and abuse. SAMHSA is represented on the ONDCP Interagency Workgroup on Prescription Drugs.

Prevalence of Non-medical Prescription Drug Use

SAMHSA's National Survey on Drug Use and Health (NSDUH) is an integral part of our national surveillance of non-medical use of prescription drugs. According to 2011 NSDUH data, nonmedical prescription drug use ranks as the second most common class of illicit drug use in the United States.[1] The NSDUH found that in 2011, 1.9 million persons aged 12 or older initiated non-medical use of prescription pain relievers in the preceding year. Marijuana was the only illicit drug with more initiates in 2011.[2] The 2011 NSDUH also found that males were more likely than females to report non-medical prescription pain reliever use in the preceding year, and young adults (18 to 25) had the highest rate of reported prior-year non-medical use.[3]

The 2011 NSDUH also revealed that an estimated 54 percent of the prior-year non-medical users of prescription pain relievers obtained the drugs for free from a friend or relative. The next most common source was a single doctor (18 percent), followed by individuals who bought or took drugs from a relative or friend (17 percent). Other less-frequent sources included buying drugs from a drug dealer or other stranger, obtaining them from more than one doctor, and less than one percent reported getting them from the internet.[4]

Recent data indicate that the rate of non-medical use declined slightly between 2010 and 2011[5] and suggest that national, state, and local efforts to reduce prescription drug misuse may be beginning to have an impact. However, with an annual average of 15.7 million people aged 12 or older having misused prescription drugs between 2005 and 2011, there is still much work left to be done.

State Prescription Drug Monitoring Programs

State prescription drug monitoring programs (PDMPs) are an important component of government efforts to prevent and reduce controlled substance diversion and abuse. State PDMPs collect, monitor, and analyze scheduled or controlled prescription drugs, with the goal of preventing prescription drug misuse and abuse and illegal diversion. Forty-six states operate PDMPs; three states (Georgia, New Hampshire, and Maryland) have enacted PDMP-establishing

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[1] Center for Behavioral Health Statistics and Quality. (2012). *Results from the 2011 National Survey on Drug Use and Health: Summary of national findings* (HHS Publication No. SMA 12-4713, NSDUH Series H-44). Rockville, MD: Substance Abuse and Mental Health Services Administration. The survey defined "non-medical use" as use without a prescription of the individual's own or use simply for the experience or feeling the drugs caused.
[2] Id.
[3] Id.
[4] Id.
[5] Id.

legislation but do not yet operate PDMPs; and one state (Missouri) and the District of Columbia have not enacted legislation.[6]

The National All-Schedules Prescription Electronic Reporting Act of 2005 (NASPER) created a grant program administered by SAMHSA for states to implement or enhance PDMPs. SAMHSA received NASPER funding from Congress in Fiscal Year (FY) 2009 and FY 2010, and provided 26 grants to 14 states. In FYs 2011 and 2012, Congress did not appropriate funding for NASPER.

In FY 2011, SAMHSA also funded the Enhancing Access To PDMPs Through Health Information Technology Project, which was managed by ONC in collaboration with SAMHSA, CDC, and ONDCP. This project stems from joint efforts of public sector and private industry experts that participated in the White House Roundtable on Health Information Technology and Prescription Drug Abuse in June 2011. In turn, the BHCC Prescription Drug Abuse and Health Information Technology Subcommittees created the "Action Plan for Improving Access to Prescription Drug Monitoring Programs through Health Information Technology."[7] The project's purpose is to use health information technology (health IT) to increase timely access to PDMP data for three types of medical professionals within a variety of care settings:

- Ambulatory clinic healthcare providers (*e.g.*, physicians, nurses, nurse practitioners);
- Emergency Department physicians; and
- Dispensing pharmacists.

The project set out to investigate and develop the standards necessary to utilize existing technologies, the health information exchanges, and the PDMPs to improve, with appropriate privacy protections, the tracking of opioid use by implementing pilot studies and establishing work groups. The first part of the project involving the work groups was completed, and a report was published summarizing the work groups' findings, in August 2012.[8] The second part of the project identified, developed, and implemented six pilots that tested new technology that links state PDMPs and providers' electronic health record (EHR) systems. The results demonstrated the value-add of increased access to state PDMP data at the point of care. For example, , pilot participants reported that the functionality streamlined their clinical workflows, made PDMP data easier to access, and helped better inform clinical decisionmaking.

In FY 2012, SAMHSA and ONC extended the project, scaled up some of the existing pilots (*i.e.*, increased the number of pilot sites or of states supplying PDMP data), and launched new pilots to test new types of data integration. In total, seven pilots were launched or expanded. Additionally, a website, "PDMPConnect" was developed that will serve as a nexus of resources for prescribers, dispensers, health IT developers, and PDMP-related organizations. PDMPConnect will be launched in the near future to provide ongoing information to the prescriber and dispenser communities about the types of data connectivity programs underway, identify and provide the resources needed to create PDMP/health IT connections, and provide

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[6] *Status of Prescription Drug Monitoring Programs (PDMPs)*, PDMP Training & Technical Assistance Center, available at http://pdmpassist.org/pdf/pmpprogramstatus2013.pdf (last revised June 5, 2013).

[7] http://www.healthit.gov/sites/default/files/rules-regulation/063012-final-action-plan-clearance.pdf.
[8] http://www.healthit.gov/sites/default/files/rules-regulation/063012-final-action-plan-clearance.pdf.

video stories, articles, and news flashes to educate and build awareness about the field. Moreover, the technical framework for PDMP integration is being examined to address challenges in interoperability through the Standards and Interoperability Framework.

In FY 2012, SAMHSA established the PDMP Electronic Health Record Integration and Interoperability Expansion program, with $4 million in funding from the Prevention and Public Health Fund. Working collaboratively with the Harold Rogers Prescription Drug Monitoring National Training and Technical Assistance Program at the Department of Justice (DOJ), this program complements existing Federal efforts by improving real-time access to PDMP data through integration into existing technologies, like EHRs, to improve the ability of state PDMPs to reduce the nature, scope, and extent of misuse. The program also strengthens currently-operational state PDMPs by providing resources to make the changes necessary to increase the PDMPs' interoperability. Nine states received funding to allow for system modifications to expand interoperability; EHR and pharmacy system enhancement; adoption of specifications for exchanging PDMP reports; and modification of EHR and pharmacy systems to permit new linkages. CDC will evaluate the program and report on the best practices developed and how they can be utilized by other states working to link PDMPs to other health IT systems.

In FY 2013, SAMHSA, using budget authority, anticipates awarding up to eight grants for EHR and PDMP data integration. Unlike the FY 2012 grants, the FY 2013 program will not focus on state-to-state interoperability. The purpose of this program is to reduce prescription drug misuse and abuse by providing healthcare providers with access to PDMP data to make sound clinical decisions without disturbing their regular clinical workflow.

Finally, SAMHSA staff participates in projects with other agencies to increase PDMP use to identify emerging prescription drug abuse problems.

Additional Efforts in Preventing and Treating Prescription Drug Misuse and Abuse

Education

Current prescribers: SAMHSA supports the education of prescribers through formal continuing medical education courses and other less formal efforts, *e.g.,* webinars hosted by SAMHSA's opioid prescriber clinical support system (PCSS) grantee (the American Academy of Addiction Psychiatry). SAMHSA has prioritized these prescribing courses for states with the highest rates of opioid-related mortality (*e.g.,* New Mexico, West Virginia). The PCSS—Opioids is a national mentoring network offering support (*e.g.*, clinical updates, evidence-based outcomes, and training) to physicians and other medical professionals in the appropriate use of methadone and other opioids for the treatment of chronic pain and opioid addiction. This program also addresses the nation's rise in opioid-associated morbidity and mortality that has been spurred by misuse/abuse, and fatal drug interactions involving methadone and other prescription medications, over-the-counter medications, and illicit drugs.

SAMHSA also supports the Medical Education and Supporting Services for Opioid Treatment Program to educate and prepare opioid treatment programs (OTPs) to achieve accreditation by SAMHSA's approved accreditation organizations. Accreditation has been shown to improve treatment outcomes and access to treatment for patients and provides the opportunity for OTPs to

incorporate best practices in their treatment programs. Other goals include improving OTP administration and management, increasing staff retention, providing more OTP staff training, increasing availability of comprehensive services and emergency services, and improving patient outcomes.

SAMHSA also works with ONDCP to provide outreach and disseminate educational materials to various sectors of our society that encounter this class of drugs.

Educating future prescription drug prescribers: SAMHSA's Screening, Brief Intervention, Referral to Treatment (SBIRT) program is an important tool for early identification of persons who might be at risk for opioid dependency and other substance use disorders. SAMHSA's SBIRT Residency grant program addresses future prescribers and includes screening for prescription drug abuse, and more recently has emphasized the use of state PDMPs.

The SBIRT program was established to engage health professionals in the identification, counseling, referral, and ongoing medical management of persons with substance use disorders. Through SBIRT, states, territories, and tribal organizations are eligible to receive grants to implement screening, brief intervention and referral to treatment services for adults in primary care and community health settings, for substance misuse and substance use disorders. This program is based on research showing that by simply asking questions regarding unhealthy behavior and conducting brief interventions, patients are more likely to avoid the behavior in the future and seek help if they believe they have a problem. In 2011, over 213,000 clients were served by the SBIRT Program. The percentage of clients reporting abstinence at follow-up tripled compared to the percentage reporting abstinence at baseline.

Prevention and Early Intervention

Substance Abuse Prevention and Treatment Block Grant Prevention Set-Aside:
The Substance Abuse Prevention and Treatment Block Grant (SABG) is a formula-based grant provided to states and territories to provide financial support for its prevention and treatment programs and services. Federal statute requires states and territories to direct at least 20 percent of the SABG toward substance abuse prevention services. For many states and territories, this funding represents the vast majority of their substance abuse prevention budget. Under the SABG states are requested to identify the categories of substances, including prescription drugs, they intend to address with the 20 percent set-aside for prevention based on data collected and analyzed from statewide and local needs assessments.

Strategic Prevention Framework/Partnerships for Success: The Strategic Prevention Framework/Partnerships for Success (SPF/PFS) is designed to address two of the nation's top substance abuse prevention priorities, including underage drinking and prescription drug misuse and abuse among persons aged 12 to 25. Under this program, states and jurisdictions are funded to implement a strategic planning process and to use data to identify which of the two priorities will be addressed with this grant's funding. The majority (85 percent) of grant funding must be allocated to communities of high need, which then use the funds to enhance their community-level infrastructures using the strategic planning process; leverage, redistribute, and/or realign funds for prevention activities; implement a comprehensive prevention approach, including a mix of evidence-based programs, policies, and practices that best address selected prevention

priorities; identify technical assistance and training needs and develop responsive activities; and collect and report community-level data. The program is based on the premise that changes at the community level will, over time, lead to measurable changes at the state level. By working together to foster change, states and their SPF/PFS funded communities of high need can more effectively begin to overcome the challenges underlying their substance abuse prevention priorities and achieve the goals of the SPF/PFS.

Drug-Free Communities: The Drug-Free Communities (DFC) program is a collaborative effort directed by ONDCP and administered by SAMHSA. DFC has two goals:

1. Establish and strengthen collaboration among communities, public and private non-profit agencies, and Federal, state, local, and tribal governments to support the efforts of community coalitions working to prevent and reduce substance use among youth.

2. Reduce substance use among youth and, over time, reduce substance abuse among adults by addressing the factors in a community that increase the risk of substance abuse and promoting the factors that minimize the risk of substance abuse.

Grantees funded under DFC target prescription drug misuse and abuse if the data collected and analyzed in their respective communities indicate it is a problem that needs to be addressed.

Prevention of Prescription Drug Abuse in the Workplace Technical Assistance: The Prevention of Prescription Drug Abuse in the Workplace (PAW) program provides technical assistance to SAMHSA grantees, employers, unions, and other communities and collaborates with partner organizations. PAW educational/technical assistance resources include fact sheets, online products, occupational-specific screening and assessment tools, presentations, trainings, and literature reviews. Topics such as developing specific workplace prescription drug abuse policies; integrating prescription abuse messaging into current programs and community outreach activities; and prescription drug abuse evaluation activities and metrics are addressed.

Tribal Prescription Drug Summit: In response to tribal leaders' concerns about an increase in the use and abuse of prescription drugs in American Indian communities, SAMHSA co-sponsored a Tribal Prescription Drug Abuse Summit in June 2012. The summit brought together tribal leaders and representatives of the Health Resources and Services Administration, SAMHSA, area Indian Health Service providers, behavioral health directors, and representatives of the Great Lakes and National American Indian and Alaska Native Addiction Technology Transfer Centers. The goal of the summit was to discuss the tribal perspective on prescription drug abuse and the Federal efforts and programs to address the issue and to create an action plan to move forward. Topics focused on four pillars of the action plan: education, monitoring, disposal, and enforcement. Participants continue to assess the effectiveness of the four pillars of the action plan against prescription drug abuse.

Prescription Drug Abuse Treatment

Treatment of opioid dependence/addiction is a critical element of SAMHSA's strategy and includes psychotherapeutic approaches such as cognitive behavioral therapy, as well as expanding and improving access to the three FDA-approved medical treatments: (1) methadone,

which is regulated by FDA, SAMHSA, and DOJ's Drug Enforcement Administration (DEA); (2) buprenorphine, for which SAMHSA and DEA together process waivers enabling physicians in outpatient settings to prescribe products for opioid dependence; and (3) oral and extended-release injectable naltrexone. SAMHSA also has been working with other Federal agencies to explore "telemedicine" enabling treatment in rural settings. SAMHSA is continuously educating providers and consumers about these medical treatments through educational efforts, the PCSS model referenced above, and interactions with provider communities. SAMHSA works with the FDA to ensure that the safety of these medications is continuously monitored and analyzed. For example, SAMHSA convened expert panels and work groups with the FDA to assess methadone's safety for cardiac health; methadone-overdose-related mortality; the risk of pediatric exposure to buprenorphine; and diversion of these medications for illicit or inappropriate use. SAMHSA convened a similar meeting to develop guidelines for the medicine Vivitrol, an injectable medicine indicated for monthly administration to treat opioid dependence.

SAMHSA provides direct funding for the treatment of substance abuse, including prescription drug abuse. The SABG is the largest program; the President's FY 2014 Budget includes $1.8 billion for this program, of which 80 percent is for treatment (the other 20 percent is directed to prevention).

Regulation and Certification

SAMHSA regulates OTPs that use methadone and buprenorphine products approved by FDA to treat patients with opioid dependence (42 CFR Part 8). SAMHSA carries out this responsibility in coordination with DEA, states, the District of Columbia, and territories by enforcing regulations that established an accreditation-based system.

The Drug Addiction Treatment Act of 2000 (DATA) permits qualified physicians to prescribe certain opioid treatment medications for the treatment of opioid addiction in the outpatient setting. Under DATA, qualifying physicians are "certified" to obtain waivers from the requirement under 21 U.S.C. § 823(g) to obtain approval from SAMHSA as OTPs. As of June 1, 2013, there are 23,000 active DATA-certified doctors eligible to prescribe buprenorphine products, and 6,440 active physicians may prescribe for up to 100 patients.

Conclusion

As I stated earlier in my testimony, prescription drug misuse and abuse is a complex issue. It requires a concerted effort by many. SAMHSA's prevention and treatment strategies to address drug misuse and abuse are both targeted specifically to the prescription drugs themselves and to programs that support prevention, intervention, and treatment of addictions, which can have a significant long-term impact on this serious public health problem.

Thank you for this opportunity. I welcome any questions that you may have.

Mr. PITTS. The chair thanks the gentleman. The chair apologizes; we are trying to get the jackhammer to stop, but until that time, if you will please speak directly into the mike, we would appreciate it.

Thank you for your testimony. I will begin the questioning and recognize myself for 5 minutes for that purpose.

Director Kerlikowske, the ONDCP oversees and coordinates the many agencies involved in prescription drug abuse. Please describe the advantages and challenges that come with having so many agencies and departments involved in the fight against prescription drug abuse.

Mr. KERLIKOWSKE. Congress clearly recognized the need for coordination, the fact that there are 15 primary federal agencies that all have a role in the drug issue. I don't think anything is more complex or challenging than the prescription drugs. It is not like an issue where it is coming across the border; it is coming right out of our own medicine cabinets. The mere fact that it was not recognized as a significant problem except by subject matter experts in the health field, people that ran treatment programs, but generally, the public did not even begin to understand the magnitude of the prescription drug problem.

We worked to bring everybody together to sit at the table and to develop a plan knowing that any one component, whether it was the law enforcement agencies, whether it was the regulatory agencies, that any one component would not be able to solve or at least significantly reduce this problem.

Our partners, two of which are here, but a number of them are out as part of our program, all came together with one goal, and that is to reduce this tragedy not only in the loss of life but the expense, so we couldn't be more pleased with 1) their cooperation, and 2) at least the inkling, as Dr. Clark said, of some success in this area.

Mr. PITTS. Thank you. Dr. Throckmorton, generic versions of long-acting opioids without abuse-deterrent properties entered the market in January of this year. Does the Agency intend to monitor real-time data in order to evaluate whether such entry affects opioid abuse and how well real-time data like this will be utilized by the Agency now and in the future when the FDA is evaluating the science regarding claims of abuse deterrents?

Dr. THROCKMORTON. Mr. Chairman, the goal that our agency has set is to incentivize the development of successful abuse-deterrent formulations and find ways to move them onto the market. Our intent is to set forth a roadmap that makes that successful, makes that happen in good time. Following up on that, we need to work to develop ways to move generics that also have abuse-deterrent technologies, make them possible to come onto the market as well.

You asked about monitoring of the response of the marketplace to those sorts of decisions. We do watch that information. We have an Office of Epidemiology that focuses on marketing issues, as well as post-marketing safety issues. We use that information as we look at individual decisions to understand the impact that a decision that ours might have with regard to the use of products in the market.

Mr. PITTS. And to follow up, the FDA has committed, through the user fee process, to increase transparency and predictability around the drug review and approval process. Earlier this week, we wrote to DEA regarding delays in reviewing FDA scheduling recommendations for new drug approvals containing controlled substances. Does the Agency have recommendations on improving this process to address the issue of DEA delays?

Dr. THROCKMORTON. It is an important question that we make sure that we have timely access to new medicines that are recommended for controlling, but we need to remember that the final decision about the controlling is made by the Drug Enforcement Administration under the Controlled Substances Act. My focus in the Center for Drugs has been to make certain that there is a timely scientific assessment from the FDA that can in fact work to inform that decision by the Drug Enforcement Administration. So what we have been doing is looking back at our process to make sure that it is as efficient and timely and scientific as possible so we get our recommendations in good order to the Drug Enforcement Administration through our Office of Assistant Secretary for Health, which is at the Health and Human Services level.

Mr. PITTS. Thank you. Dr. Clark, can you discuss your relationship with the 46 States that operate Prescription Drug Monitoring Programs?

Dr. CLARK. We are working in concert with the Department of Justice, the Harold Rogers program. We have, through our special initiatives, reached out to as many jurisdictions as possible so that we can link the PDMPs with electronic health records.

As you know, as I mentioned, the NASPER program, which was targeted toward grants to States, has not been funded, so we have shifted our focus from that effort to looking at other technologies so that we can address the public health aspect of this by linking electronic health records to PDMPs so that we can have real-time data so that the practitioner in the clinic or in the emergency room has access to information about the client sooner than some of the delays associated with current State PDMP programs.

We can't wait 2 weeks to inform the clinician. We would like to be able to get that clinician real-time access to information so that they can make appropriate decisions about the care. Sometimes, it is someone who is running a scam on the doctor; sometimes, it is a patient who is having a reaction to the medication. So it is really useful to have real-time access to the clinical context of using prescription drugs.

Mr. PITTS. The chair thanks the gentleman. My time is expired. And the chair recognizes the gentlelady from California, Mrs. Capps, for 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman.

And I am so glad we are here today having a hearing on an issue that really clearly cuts across party lines.

Prescription drug abuse is a real and pervasive problem, and while it clearly impacts families and communities across our Nation, it also affects our health care system. However, I want to make sure that efforts to address this issue, important as they are, do not cause other problems, especially those regarding people with chronic pain. This is a delicate balancing act in a way.

Americans' struggle with pain has been an important issue for me for many years. In 2007, I introduced the National Pain Care Policy Act and was pleased to see the part of it was included with the Affordable Care Act. As a result, the Institute of Medicine was directed to do a study on pain, and what they found is that pain is the most common reason people seek medical care. Over 160 million US adults suffer from chronic pain. The severity, duration, and disabling consequences of pain vary from person to person, as does the response to treatment. But pain accompanies a range of other clinical conditions, as all of you know, including cancer, diabetes, arthritis, and on and on. Access to medications is critical for these patients and survivors in order to complete other prescribed treatments and maintain other activities of daily living. And many medications prescribed to patients for acute pain, as well as chronic pain contain hydrocodone. So Dr. Throckmorton, as FDA reviews the potential rescheduling of hydrocodone-containing medications, does sufficient data and analysis exists about the potential impacts rescheduling could have on patient access to hydrocodone-containing medications?

Dr. THROCKMORTON. Thank you, Congresswoman. First, let me say I agree with you. Finding a balance between the necessary access for pain medicines for patients that require them and addressing this crisis of abuse is absolutely essential, something that the FDA keeps in mind as we are thinking about our regulatory activities. With regard to assessing access to pain medicines, it is something we have worked on internally; it is something I have discussed with outside groups extensively. I know there are a number of people looking at better ways to measure that.

There is a part of our REMS implementation that we put in place last year. For instance, we required to the manufacturers to assess the impact of that REMS on access to pain medications because we understand that it is an important aspect of our regulatory activities and whatever we end up deciding to do in the future.

With regards to hydrocodone, Congress, in the recent Food and Drug Administration Safety and Innovation Act directed us to hold public hearing on hydrocodone and up-scheduling, and in that direction included language directing us to talk to patients and groups that had experience on the impact that this might have with regards to the up-scheduling of hydrocodone. We held that meeting. We have over 700 comments to the docket about that meeting that we are currently looking at. A large number of them comment on the effects that different activities might have as regards to access, something that we are reviewing as we think about making our decisions.

Mrs. CAPPS. Thank you. And if there are access problems, could you elaborate—I know there is not much time left—but on the process available to individuals who are rightfully prescribed these medications but encounter problems accessing them?

Dr. THROCKMORTON. The reason why they are having trouble getting the medicine would be important to understand. So if there is a drug shortage, for instance, and their challenge is getting a drug that is not available anywhere in their area, FDA has a drug shortage staff that I supervise, and we would love to hear from you. We

have a Web site. We would want to work with you to find other ways to make that pain medicine available to you.

If it is due to lack of availability at a pharmacy or pharmacies near you, you know, because of concerns over scheduling or something like that, those things I would have a less clear answer on but I would suggest the Boards of Pharmacy or other local area groups like that might be somewhere to talk to.

Mrs. CAPPS. Thank you. And, Mr. Chairman, I am about out of time and I didn't even get to ask the other 2 members of the panel. This is such an important topic I think for us to be discussing, and I would certainly hope that this is just one hearing, that we have many more because I wanted to get into prevention, and that is a whole other topic and involved may be some other people, too, but you certainly are experts on this. We could certainly use some more hearings on this topic in my opinion. So thank you very much for scheduling this one.

Mr. PITTS. The chair thanks the gentlelady, and this is just the first in a series of hearings we plan.

The chair now recognizes the vice chairman of the Subcommittee, Dr. Burgess, for 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

And Mr. Kerlikowske, you sent a letter—you heard me reference the alignment of our policies with those to our neighbor to the north and you sent a letter about this. And you got Dr. Throckmorton over there diligently working on abuse deterrents and OxyContin, but how do we align our policies with Canada to prevent the older generic form from coming across the border? Because I, probably as we speak about this, I can see someone developing a business plan that would involve the importation of large amounts of generic OxyContin that didn't have an abuse deterrent.

Mr. KERLIKOWSKE. It is an important issue because the United States has done a lot to reduce the easy availability and also the fact that the opiod prescription painkillers here are not as easily manipulated, but the fact that Canada has that was of great concern to us. So early on, before they hit the market, we had written to the Health Minister. The Health Minister from Canada replied that she actually didn't have the authorities within Canadian law to limit this, but she had not only heard from us; she had also heard from the provinces who were also concerned that this would be widely and easily available within the provinces.

So we notified Customs and Border Protection first to identify and be aware of this in case they see these coming through. So far in Milwaukee that is the only location that we have received a report of seeing some of these, and it was not a great number of them.

We have a meeting scheduled in July with our Canadian counterparts who will be here in Washington, D.C., and I will be traveling to Ottawa hopefully with a colleague from the Food and Drug Administration to also work with them.

Mr. BURGESS. So you will be monitoring it?

Mr. KERLIKOWSKE. Absolutely.

Mr. BURGESS. And would you be averse to providing periodic reports to the staff of this committee——

Mr. KERLIKOWSKE. I would be happy to.

Mr. BURGESS [continuing]. About that ongoing effort? You know, let me just ask you on your four pillars in your testimony you talked about, the last pillar was the enforcement piece. And despite the salacious nature of the covers of this magazine, I submit to you that I can help you locate the bad actors. They advertise and it is not hard to pick them out of a crowd. So I hope you are focusing some efforts on disrupting the supply chain because, again, these people are not shy about telling you who they are and where they are and their hours of operation, their prices, and a discount coupon.

Mr. KERLIKOWSKE. You can see certainly Broward County, Florida, was the kind of epicenter of this. They had 90 of the top 100 prescribing and dispensing——

Mr. BURGESS. This magazine is from Broward County——

Mr. KERLIKOWSKE [continuing]. Opioids.

Mr. BURGESS [continuing]. So I wasn't going to identify the location, but since you did—Dr. Throckmorton, let me just ask you. Are there any efforts at the FDA to make naloxone an over-the-counter preparation like an inhaler or an autopen?

Dr. THROCKMORTON. We think it is important to first understand how best to use the naloxone, so we are working as a part of a much larger group of federal agencies to understand the best uses of naloxone. As a regulator, my job in that discussion is not to decide as a policy how naloxone should be used, and instead, it is to lay out the regulatory pathway should a firm be interested in developing one of those products. So we have met regularly with the makers of autoinjector products, makers of inhalational products to lay out the pathways that are necessary for them to get approval as prescription products.

At the meeting that we held last year, attended by NIDA, attended by the Office of National Drug Control Policy and SAMHSA, we heard loud and clear that there was a broad interest in moving naloxone to over-the-counter status.

Mr. BURGESS. Yes, let me just interrupt you. I am not sure I agree with that, but we live in a world where levonorgestrel now is available over-the-counter with the Tootsie Rolls and Snickers bars. If interdiction and abstinence is not going to work in other areas, you know, maybe this is something that needs to be looked at because anyone who has ever seen the dramatic reversal of an amp of NARCAN on an opiate overdose will understand that you go from crisis to normal in the space of 26 seconds, and it is dramatic.

Again, I am not saying that I advocate that, but I just wonder in this brave new world that we have entered, is that a consideration? So I hear that you are in fact entertaining that.

Mr. Kerlikowske, I also have to mention about drug diversion, and you mentioned the 11 hours in medical school. You do learn a lot in your very first years in residency and practice, and I just recall very vividly when I was a resident at Parkland Hospital moonlighting at community hospitals, and someone would come in with a textbook description—in fact, they probably memorized the textbook—but a textbook description of renal pain—renal colic pain and were savvy enough to bite their lip and spit in the cup before they collected a specimen for you so they had blood in their urine

and fit the bill pretty quickly. And I know what it is, Doctor; I have an appointment with my urologist. I just need something to get me through the night. And about the fourth time you hear that story, you think, there is something fishy here.

Of course, doctor shopping is a big problem and the doctors who are just leaving training and getting into practice, this is where a lot of that educational activity could do a lot to prevent diversion.

Thank you, Mr. Chairman. I will yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentlelady from Florida, Ms. Castor, for 5 minutes for questions.

Ms. CASTOR. Thank you, Mr. Chairman.

And thank you, gentlemen, very much. I am especially grateful to Director Kerlikowske because you have given us such great guidance in the State of Florida where, colleagues, it has been a horrendous problem in the State of Florida. You would not believe, you could drive by some of these pain management clinics and see lines of people early in the morning, and we would often hear from our colleagues in Kentucky, in Virginia, in Tennessee about how folks would just travel down to Florida, find a pain management clinic that would prescribe, give them onsite hundreds of pills, go back.

And this pipeline, fortunately, has been squeezed now. Florida finally adopted a prescription drug database. We have some stops and starts with that. I am concerned their physicians and pharmacists are not using it; it is voluntary. I am a little bit concerned the State hasn't provided a long-term commitment to make it work, and I would like you all to address that.

But local law enforcement, they are seeing some improvements from where we would have at least one death per day in our community from prescription drug abuse. They say now with county ordinances on these pain management clinics new requirements to go after the docs, arrests of doctors and prosecutions. But I know local law enforcement can't do it all.

Can you all tell how is the State of Florida doing because I know it has been, unfortunately, one of the worst in the country? And then at the federal level what can we do to provide greater tools to local law enforcement? And then one of my local sheriffs says it is not up to local law enforcement; this is an addiction and we have go to do more.

Director?

Mr. KERLIKOWSKE. As a graduate of the University of South Florida, I had a special affinity for the problems in Florida in particular. But I can tell you that Florida is doing markedly, remarkably better. The leadership of the attorney general, Pam Bondi, on this issue has been very good. We have worked hard with a number of groups there and Florida has actually reduced the problem I think from seven overdose deaths a day. They have been able to make progress.

I think from the federal government's standpoint what we need to be able to do is to make sure that these prescription drug monitoring plans are interoperable. Fourteen States now can share data but we saw a moment of some of the physicians that were suspect, as the vice chair mentioned, from Florida to other States, and so

that information needs to be done. So that is one thing the federal government can continue to do.

Ms. CASTOR. You know, our database is voluntary and it hasn't been up and running for very long, but still, there is some frustration that you only have 10 percent of pharmacists that are using it and not many doctors. So if we have interoperability between States, that still doesn't get to the problem of incentivizing pharmacists and doctors, prescribers to use that. How do we better incentivize the use of the database?

Mr. KERLIKOWSKE. And we are actually seeing significant improvements. One is that the electronic health records system, which eventually will be compatible with these kind of systems so that you don't have one PDMP standalone system, and then you have got your other electronic health records.

The other is the e-prescribing that has taken hold. Physicians are not very happy about being able to prescribe electronically a large number of different types of drugs, but when it comes to controlled substances, they go back to paper and pencil. All of these things are kind of underway, but I think the amount of education and information that is being made to the physicians is a result of using a PDMP and the stories that they have told and the fact that we are strongly encouraging mandatory prescriber education will be helpful. Thank you.

Ms. CASTOR. OK. And, gentlemen, can you all tell me—I am a cosponsor of a bill, H.R. 1285 by Congressman Buchanan from the Sarasota area and Congressman Markey from the Energy and Commerce Committee. It would amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug. Do you all support that? Could you just say yes or no because my time is limited?

Mr. KERLIKOWSKE. I don't believe the Administration has taken a position and we have strongly encouraged the science-based evaluation for the scheduling. So I wouldn't be able to tell you right now.

Ms. CASTOR. OK. Doctor?

Dr. THROCKMORTON. He is speaking for the Administration.

Ms. CASTOR. OK. And same answer, Dr. Clark?

Dr. CLARK. Speaks for the Administration.

Ms. CASTOR. OK. Thank you all very much for your efforts in this area.

Mr. PITTS. The gentlelady's time is expired.

At this time I request unanimous consent to include a statement from the National Association of Chain Drug Stores into the record.

Without objection, so ordered.

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

Mr. PITTS. The chair now recognizes the gentleman from Illinois, Mr. Shimkus, for 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. And I just have two brief questions.

One is I understand in Europe 85 percent of their prescription drugs is in blister packaging. Whether that is correct or not, that is what I have been informed. Do you think that would have any positive effect on some of these specific prescription type drugs, especially for those that might be going to, you know, families or

families who are taking care of seniors and really the accountability and the inability to really just disburse that without breaking up the package?

Dr. THROCKMORTON. I think it is a very good question, and the use of innovative packaging and storage techniques to make a difference in this particular crisis, one of the things that we have not had an opportunity to think through as fully as we would like to.

I have formed a group within the FDA to start looking at these issues. I have a part of my center that focuses on packaging and labeling and those things, and I have asked them to look at issues like this.

One of the challenges about requiring blister packs for one kind of drug is that it spills over to requiring blister packs potentially for other kinds of drugs that have similar kinds of dangers, and there is a concern about access and impact in other ways on health care system. So we need to look broadly at how these packaging more creatively than we have, I believe.

Mr. SHIMKUS. Anyone else want to add? No. We were talking about some of the—and I am not a medical doctor so I don't remember all the names and stuff of the various drugs or the drugs to remediate the drug effect, but I am curious as to how much coordination there is between each of you when there is a development of a promising treatment which could help address the national priority of abating the drug abuse crisis? And I do know the FDA really has the approval though, but are you all involved with them, especially in this case, Dr. Clark?

Dr. CLARK. Yes, not only the FDA has the leadership in that but we work in collaboration with ONDCP, NIH, and others, as the literature, which as Dr. Throckmorton mentioned, that the science-based literature produces new ideas. We have this ongoing dialogue. We have working groups that are multiagency, multi-department to examine the implications. We also work with the organized medicine and the various medical societies to address these issues. We try to track these developments so that we can decide whether they can be moved into clinical practice.

Mr. KERLIKOWSKE. We spend more time with each other than our family.

Mr. SHIMKUS. That is true up here, too, many times, unfortunately.

So, Mr. Chairman, that is all I have. I yield back the balance of my time. Thank you.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I wanted to also reinforce my view. I think I do have something as a comment that is already in the record, and when it comes to the changing the scheduling of hydrocodone from its current schedule III to schedule II of the Controlled Substance Act, that was one of the suggestions that came from my constituent who lost his daughter.

The other was he suggested—and I don't know if this is under consideration—take steps necessary to restrict the use of oxycodone pain relievers to severe pain rather than moderate to severe pain, so that would change the packaging in order to prevent the over-

prescribing of these powerful medications. I wonder if any—actually, whoever knows best.

Dr. THROCKMORTON. Yes, that is something that I can comment on. There are citizens' petitions, there are requests for action before my agency about the changes in labeling that you are referring to, so I won't be able to talk in great specific about the changes in what is called the moderate-to-severe language that is in current opioid indications.

I mean I will say, however, that the FDA has always had an interest in making sure that our labels are accurate and fair and include all of the information that we know to be scientific.

I had a public meeting earlier in this year where I posted a series of questions to academics, advocates, family members asking for their help in understanding how our current labeling for opioids might be improved, in general asking them for suggestions, and we got a number of comments and we are in the process of looking at those comments, looking at other ways to make sure those labels say what they need to. We believe educating prescribers begins with the approved labeling, which outlines how the products are best used based on our scientific judgment, and we need to make those as fully accurate as we can.

Ms. SCHAKOWSKY. I wonder if part of the customer, the consumer education includes encouraging families with children between 12 and 18 to have a lockbox for certain drugs so that they keep them out of the hands of children, Dr. Clark?

Dr. CLARK. Yes, we do believe that prescription drugs should be treated very carefully. Lockboxes are good ideas. As Chairman Pitts pointed out, a lot of prescription drugs are shared between friends and family, so you have got this cultural dynamic that we also have to deal with. So consumers and family members need to be brought in.

And our prevention efforts include not only take-back programs that Mr. Kerlikowske mentioned but the idea of promoting of the appropriate management of description drugs in the home. So lockboxes is our one strategy; making sure we have an informed consumer, another strategy; making sure that the delivery system educates the consumer about the potential risk of misuse and diversion of the medications, yet another strategy.

And, as was pointed out, we need to reach out to consumer groups and parent groups and consumer coalitions so that we can promote this cultural shift in attitudes about these medications.

Ms. SCHAKOWSKY. OK. I have one more question. It appears there is a new trend of manufacturers seeking approval of new abuse-deterrent formulations near the time of the expiration of their patents and marketing exclusivity, so they then withdraw the original formulation from the market claiming it is no longer safe in light of the availability of the abuse-deterrent formulations. And if the FDA agrees that the original formulation was removed for safety reasons, then the FDA is precluded from approving generic competitors without comparable abuse-deterrent formulations. And in the absence of generic versions, then patients are forced to pay higher monopoly prices for extended time periods, which in turn has the potential to decrease patient access to these drugs. Have you heard about this?

Dr. THROCKMORTON. Yes. And this is back to the discussion of the balances, you know, that need to be kept in mind as we think about addressing this abuse crisis. So in this case we have the necessary balance between incentivizing the development of abuse-deterrent formulations that work. We want to have opioids in formulations that deter abuse. I believe that is in everyone's best interest to find a way to incentivize that while at the same time recognizing the impact and importance of the generics in the U.S. market, currently well more than 75 percent of the total prescriptions, et cetera.

Accomplishing that balance is something that the FDA is thinking and working very hard on. Our first action was earlier in the year when we put out the guidance laying out how we would try to incentivize the development of new formulations. Following up on that, we are now thinking about ways to develop guidance on abuse deterrent formulations to generics to allow them to come on the market as well.

In other places and in this place I would expect our focus would be on the performance of those generics and not on the technology that was used to make that generic. So we would require that the generics demonstrate they are abuse-deterrent, the thing that we would all want to have rather than that they used the same technology. We think that would incentivize the development of appropriate generics, generics that work, while recognizing the important role that the innovator plays here in terms of developing new innovative products.

Mr. PITTS. The chair thanks the gentlelady and now recognizes the gentleman from Louisiana, Dr. Cassidy, for 5 minutes for questions.

Mr. CASSIDY. Thank you, Mr. Chairman.

Mr. Kerlikowske, what percent of docs write what percent of narcotics?

Mr. KERLIKOWSKE. Congressman, I actually don't know. I know that the information about the doctors said to prescribe, for instance, oncologists write a large number of the——

Mr. CASSIDY. So oncologists, pain doctors?

Mr. KERLIKOWSKE. The pain doctors, et cetera. And I think Dr. Throckmorton probably can also help me. I just play a doctor on TV. I am with a real doctor.

Dr. THROCKMORTON. And I won't be able to give you specific numbers; we can certainly get that. The majority of pain medications are actually written by primary care doctors and——

Mr. CASSIDY. No, that is the majority——

Dr. THROCKMORTON. Yes.

Mr. CASSIDY. But if we look at those who write an extraordinary amount, those that are two standard deviations out, by definition if you are two standard deviations out, you are 5 percent, right? So intuitively, if we are looking at the folks who we are concerned about, I am suspecting that it is going to be a small percent writing a lot of the inappropriate prescriptions. You are nodding your head. Do you think that intuition is correct?

Dr. THROCKMORTON. It depends on where you cut that line off is 5 percent or it is something like that. But there is clearly a minor-

ity of physicians that are writing for large amounts of these opioids. I agree with that.

Mr. CASSIDY. Now, I am not sure to whom this would go; I think one of the two of you because I am not sure this is SAMHSA's gig, but I know if you got 46 States that have a Prescription Drug Monitoring Program, I am a doc; I have a DEA number. Every time I write that number it a goes into a database and they know if I have written an prescription. I think, although I was not able to confirm, these databases and likewise have patient information. Now, I keep on wondering if our goal is to find that small percent of docs who are writing inappropriately and we have a unique identifier for whom that doc is and we can look up in the phone book and see where their practice is, why don't we just turn it over to Google and let them data mine and tell us who are the crooks? Do you follow what I am saying?

Aside from being tongue-in-cheek, if we have all these unique identifiers and all these databases are real-time data, what is the challenge in figuring out which docs are the bad actors?

Mr. KERLIKOWSKE. There are a couple challenges that really do come up. One is that things can change, particularly in rural areas, pretty dramatically if a physician leaves a practice and is gone and suddenly that physician taking his or her place has to write a lot more prescriptions because they have actually taken over.

Mr. CASSIDY. But as we look at the data, I mean knowing that the urban setting is where most of this is happening, but even if it is rural, what you describe is a little kind of codicil that is still broad sweep. It seems as if we have got a unique identifier, you have got a real-time database, and you have got 46 States with it; it doesn't seem like this should be such a challenge.

Mr. KERLIKOWSKE. You are right, but also the real devastation has been in the rural areas. Kentucky, southern Ohio——

Mr. CASSIDY. I will accept that as well, but again, you have got a unique identifier, you have got a real-time database; what is the great challenge?

Mr. KERLIKOWSKE. I think the other challenge is that because these are individual state programs, some are within the law enforcement component, some are within the medical practice component, and each State uses those individually to determine——

Mr. CASSIDY. So does DOJ have access to these Prescription Drug Monitoring Programs?

Mr. KERLIKOWSKE. Those who have access?

Mr. CASSIDY. Department of Justice or do you or does the executive branch?

Mr. KERLIKOWSKE. No.

Mr. CASSIDY. So it is entirely state jurisdiction?

Mr. KERLIKOWSKE. Exactly.

Mr. CASSIDY. Now, we mentioned interstate compacts. I presume in these interstate compacts the States are communicating one to the other as to, listen, this fellow just dropped out; he moved to your State. He is someone you should watch for. Dr. Clark, do you have a thought?

Dr. CLARK. Well, we are moving toward that position. It is really important to recognize that the electronic health record integration and interoperability activity is moving toward that position. Some

jurisdictions are in fact trying to come up with algorithms where you can identify the outliers in terms of pain medication——

Mr. CASSIDY. Well, it just seems like a sort.

Dr. CLARK. It is a little more complicated than that, as Dr. Throckmorton pointed out, in part because you do in fact pull in the cancer doctors or the arthritis doctors——

Mr. CASSIDY. But I know that. But you know who the cancer doctors are. If there are 100,000 docs, there is going to be 5,000 who are cancer and 5,000 who are legitimate pain docs, and then there is going to be somebody who you know just moved to this state from that state to the state.

Dr. CLARK. Indeed. And that is what the electronic health records and interoperability——

Mr. CASSIDY. Now, see, it concerns me that your electronic medical record, because really I don't want the government snooping in my electronic medical record. On the other hand, if we have a real-time database your Prescription Drug Monitoring Program, that is the subset of folks who are writing prescriptions and it is centered upon the physician, and you can look and see here is my top thousand writers, 500 are oncologists or pain docs or ortho, and here is—do you see what I am saying?

Dr. CLARK. Yes, well, HHS has actually done a survey looking at part D programs and it discovered it was a little more complicated because indeed trying to pigeonhole a practice isn't as simple as all that. But you are right with the advent of increasing monitoring capability and big data, we will be able to make some kind of reasonable assessment of a practitioner and at least explore that practitioner, what he or she is doing.

Mr. CASSIDY. OK. I yield back. Thank you.

Mr. PITTS. I thank the gentleman and now recognize the gentleman from North Carolina, Mr. Butterfield, for 5 minutes for questions.

Mr. BUTTERFIELD. Thank you so very much, Mr. Chairman, and thank you for convening this hearing and thank the three witnesses for their testimony here today.

Prescription drug abuse is certainly a serious problem that impacts an estimated 12 ½ million Americans and now is considered a health epidemic by the Centers for Disease Control. And so it is a serious problem. This hearing today is very appropriate. This is a conversation that we must have and we must do something about it if we can.

In the last Congress I served as ranking member of the Commerce, Manufacturing, and Trade Subcommittee under the then-leadership of Chairwoman Mary Bono. The issue of prescription drug abuse is one that was and continues to be very important to her and to me. Our subcommittee held several hearings on prescription drug abuse last Congress, and so I have a somewhat keen understanding and interest in stemming the growing problem.

The chair then and I shared a deep concern for individuals' well-being, especially young people who gain access to an abuse prescription drugs. The multiple hearings that we had on this issue during the last Congress made very clear to me that drug manufacturers and the drug supply chain are not the problem. With Purdue Pharma developing next-generation crush-resistant drugs, the in-

dustry is playing an increasing role in stopping illicit use. Nefarious black markets and drug diversion at the end-user stage are the problem.

And so the question is how do we address this problem while avoiding burdensome regulations on your manufacturers and others along the supply chain?

And so I just want to follow up just a bit on Ms. Schakowsky's line of questioning a few moments ago. Abuse-deterrent drugs are a fairly new addition to the market, and so what impact have abuse-deterrent drugs had on the illegal and illicit use of prescription drugs? And so just thinking out loud, I would just imagine that if one drug is made abuse-deterrent, the person would just find another drug that is not abuse-deterrent that produces a similar result, shifting but not reducing the abuse.

And I guess I can go to Dr. Throckmorton on this one. Should the FDA remove roadblocks to manufacturers who want to produce abuse-deterrent drugs so that they can speed the new formula to market to reduce overall abuse?

Dr. THROCKMORTON. Yes, we should. And we are working to do exactly that. I view the development of abuse-deterrent technologies and encouraging their use in opioids as an incremental process. We are beginning now to walk a road where I had hoped to see a broad majority of opioids in abuse-deterrent formulations. That is going to help address your concern, the squeezing the balloon if you will, people moving from abuse-deterrent formulations to another formulation that is easier to abuse.

In the short-term here, I think we would be fooling ourselves if you imagine that wasn't going to happen, so my job—I think our agency's job is to incentivize the development of those new technologies broadly and to make certain that those technologies demonstrate that they work. So we should be developing abuse-deterrent formulations that successfully reduce abuse through reviewing of the data—I believe the FDA plays a critical role there—and then rewarding those new formulations in labeling, rewarding them in ways that will encourage their use by physicians and by patients with a long-term goal of having a broad range of opioids that are in abuse-deterrent formulations.

Mr. BUTTERFIELD. Let me now go to Dr. Clark if I can.

Dr. Clark, how can we educate health care providers to spot the warning signs of frequent flyers who might not have a legitimate need for powerful prescription drugs? Do you think the implementation of interoperable electronic medical records—you mentioned that earlier—would help to flag these individuals who are doctor-surfing only to get more and more prescriptions that they need to sell?

Dr. CLARK. Indeed. We think that the interoperability between electronic health records and the prescribing is very important. We are working with the Office of the National Coordinator for Health Information Technology to achieve that. We think that educating practitioners is important. We work with the FDA and the National Institute of Drug Abuse. We both have training programs, NIDAMED for the National Institute of Drug Abuse and SAMHSA has a training program associated with Boston University. We have trained over 13,000 prescribers. We work with state medical

societies. SAMHSA sponsors state medical society training, and we have, as a result of this broader effort that the Congress has mobilized, we are fighting.

More and more practitioners are showing up at our conferences to listen and learn about prescription drug abuse, to listen and learn about adequate pain management strategies, to listen and learn how to monitor for deviant behaviors and also while maintaining a good balance of care because indeed pain is a problem. So we want to continue that effort here and we think that is a useful effort.

Mr. BUTTERFIELD. Thank you, Dr. Clark. My time is expired.

I didn't get to Mr. Kerlikowske and I spent considerable time rehearsing your name and I won't be able to use it. But I yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Virginia, Mr. Griffith, for 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman. I appreciate it.

Dr. Throckmorton, can you please update the Committee as to where the Agency stands related to requirements of the Food and Drug Administration's Safety and Innovation Act pertaining to public meetings surrounding the scheduling of combination hydrocodone products? Now, I know you mentioned in your testimony that a public meeting had been held and I think in one of the answers to the earlier questions you said you all were relying on science instead of going straight to rescheduling some of the drugs.

But can you tell us, you know, what you hope for or we are hoping for an update on what you think is the process going forward on this rescheduling?

Dr. THROCKMORTON. Sure. I won't be able to talk in any detail because we have not yet formed a recommendation about what, you know, the matter. Our task was to respond both to the science, the request from the Drug Enforcement Administration to reconsider our recommendation from 2008, as well as respond to the language that Congress gave us in FDASIA directing us to hold the meeting that included membership to solicit input on things like the impact of up-scheduling. We are taking those two things very seriously.

As I mentioned previously, that meeting elicited 760 some comments, over 100 of them making specific recommendations for us to consider instead of up-scheduling, so making recommendations for other activities. We are trying to work through all of those to form the best science-based recommendations——

Mr. GRIFFITH. Any idea of a timeline on when you think something might come out?

Dr. THROCKMORTON. I am afraid I can't give you a timeline. I can tell you that I understand your frustration. I understand that this is an important issue that we want to move forward. My people are doing everything that we possibly can to do it right.

Mr. GRIFFITH. I appreciate that. Thank you.

Now, it may come as a surprise to some of you all that Virginia actually has the oldest medicinal marijuana law on the books dating back to the 1979 act. That was, however, unlike some of those States that have said, you know, if it makes you feel good, do it.

Virginia actually requires that there be a medical reason and there be a prescription, which is not currently allowed.

Wouldn't you agree with me, Dr. Throckmorton, that we need to have a discussion about the legitimate uses of medicinal marijuana and freeing it up so that Virginia can exercise its will so that doctors can actually prescribe it in those areas that are authorized by the Virginia law?

Dr. THROCKMORTON. My own personal views aside, the FDA would not have a clear role in responding to issues around medicinal marijuana. We do have a role in the scheduling of marijuana in a somewhat similar fashion that we have a role to play in hydrocodone. So there is a recommendation process that the DEA requests of us. That is regarding the development of marijuana-related drugs.

Mr. GRIFFITH. But you would agree that we probably ought to be having a public discussion about legitimate medicinal marijuana usage?

Dr. THROCKMORTON. I think I am not going to be able to comment on that, sir.

Mr. GRIFFITH. All right. I appreciate that.

The Center for Substance Abuse Treatment recently released an RFA for Physician Clinical Support System, Medication-Assisted Treatment to support physician educational on the use of medications to treat opioid addiction. My understanding is that a number of treatments have been approved by the FDA to directly treat opioid abuse. One such drug that I am aware of is—and I am probably going to mispronounce it—Vivitrol. How does CSAT plan to expand its efforts to increase awareness and knowledge about these new medications, Doctor—or either one of you?

Dr. CLARK. One of the things that we are doing is working with medical societies, working with the treatment programs so that they are very much aware of the existence of medication. We have promulgated advisories so that people can understand them and we are also meeting with the manufacturers so that we have a better understanding of what their strategies are. So we think this is an important issue.

We work with the FDA and ONDCP so that we can promulgate increased access to treatment because that is one of our concerns, making sure that people have access to new treatments as they develop and the consumers have access to those.

Mr. GRIFFITH. I thank you.

I would point out, Mr. Chairman, that I have heard a lot today about electronic medical records, and Dr. Cassidy issued a concern, a warning, a broad interpretation of the Smith v. Maryland case upon which the NSA relies on in its current standing would say that if you shared your medical records with a third party insurance company, you may also not require—I don't agree with that interpretation, but you may also not require a search warrant to get those records. I don't think that is right but that is another day.

Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Pennsylvania, Dr. Murphy, for 5 minutes for questions.

Mr. MURPHY. Thank you, Mr. Chairman. I appreciate the panel being here.

I want to follow up on some of the questions here about drugs used to treat opioid addiction. The current published information published by the FDA—and I address this to Dr. Throckmorton and Clark—allows for the use of generic buprenorphine, which is Suboxone, in the context of the doctor-patient joint decision. However, there is a concern from psychiatrists who treat persons with addictions that the published indications are vague enough to allow for misinterpretation. Now, I have heard from doctors in my district that there is misinformation about when a doctor can prescribe generic buprenorphine versus the branded Suboxone strip. And so it is leading to access issues because pharmacists are concerned about prescribing the generic.

Are any of you aware of a problem with this issue? And if not, is that something you can get back to me on or we can communicate on later? I am not trying to trip you up. I am just trying to see if we can start a dialogue on that.

Dr. THROCKMORTON. It would probably be better if we had a little bit more specifics about that one.

Mr. MURPHY. Thank you.

Dr. THROCKMORTON. There were recent issues about generic and innovator Suboxone. There was a citizens' petition that was submitted to our agency that we responded to. I am not sure if that is exactly it but we would be happy to follow up and——

Mr. MURPHY. I would appreciate it if we can talk directly.

Let me also ask about this. Now, we are aware of all the overdoses and how much they have killed with prescription painkillers. We know that States are collecting information on prescriptions but how this helps is still a concern. One person can go to 10 different pharmacies with 10 different prescriptions and collect those, and the States can sometimes then pick up if it is the same person. But, of course, John Doe can also say, oh, I am filling a prescription for my grandmother, my aunt, and other things, and the question is can we find that person in the current system who may be using legitimate prescriptions or the next step is false names, et cetera?

How does this collecting information by the States help us in finding such persons? Could some of you comment on that? Yes, sir.

Mr. KERLIKOWSKE. Congressman, the two important parts of these PDMPs, which are then run by the state Boards of Licensure, one is that a physician can have that instant access to, say, to a new patient or, you know, the number of doctors that that patient has also seen because these require, when they fill these prescriptions, identification. The other is that a Board of Licensure and the States regulate medicine, not the Federal Government, can use that to identify a prescriber who may be above and beyond and then take appropriate steps for inquiry.

I think that people do look at innovative ways around this but the States—and I would recognize Kentucky as an example—that have the most knowledgeable people running their PDMPs have been pretty successful in bringing this down. And of course the other part of that goal then is to get somebody into treatment to reduce the problem.

Mr. MURPHY. Well, let me add another element to this. A couple years ago Congress passed a law saying that people were picking up Sudafed had to show a photo ID, et cetera.

Mr. KERLIKOWSKE. Right.

Mr. MURPHY. And our concern is in terms of what you understand very well, for all of you, is that one person picking up multiple prescriptions for themselves we can pretty much identify that may be an abuse and that person can be picked up by the PDMPs, et cetera. One person who may be legitimately gathering prescriptions to pick them up for other family members we have to somehow identify who is a person with the problem, who is not. Can any of you comment on the concept of perhaps extending that, that requiring a photo ID so that person's name could also be checked if they are picking up more?

Mr. KERLIKOWSKE. I would certainly be happy to tell you what the state PDMPs are seeing as a result of that question. I would be glad to do that.

Mr. MURPHY. Any others have any comments on thoughts that agencies may have about extending that?

Dr. THROCKMORTON. Well, one agency that is not here would be the Drug Enforcement Agency, and I think there are limitations on how people can fill prescriptions that are not written directly to them. And it would be important just to look into that. And I don't know those details so wouldn't want to, you know, try to answer.

Mr. MURPHY. Dr. Clark, do you have any comments?

Dr. CLARK. And while we are thinking about this in a more formal way, I do know that many pharmacies, especially the chain pharmacies, are requiring photo ID on presentation even for the person for whom the prescription is written, and whoever picks up the drug, the photo ID is required. So I know that people are concerned about the issue.

Mr. MURPHY. And I understand the chain drugstores then, they will begin to raise questions themselves by contacting the doctor, and obviously, we want to stop the illegality of this and we want to help the people in need. So I hope that is an area where we can move toward some—this is a concrete action that Congress can take on this and I look forward to talking with you more about that.

Thank you very much, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Texas, Mr. Green, for 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman, and thank you for having the hearing today.

Dr. Clark, you spoke about SAMHSA's effort to prevent prescription drug abuse in the first place and you have also described SAMHSA's treatment activities when addiction disorders rise. Treatment of addiction to prescription drugs is crucial in importance and, as we all know, promising behavioral and medical approaches exist to treat this form of addiction.

The Affordable Care Act builds on bipartisan legislation cosponsored and supported by many members of this committee, the Mental Health Parity and Addiction Equity Act of 2008, to ensure that more individuals suffering from substance abuse use disorders receive the care they need.

My first question is how do you anticipate the Affordable Care Act will impact access to services for people who are addicted to prescription drugs or have other substance use disorders?

Dr. CLARK. One of the things that is in the Affordable Care Act is in fact the provision of services for mental health and substance use disorders, which means that individuals who have no coverage currently and that has been one of the barriers for people seeking treatment, that barrier would be removed. So the Affordable Care Act will allow health coverage for individuals who cannot afford the cost of care and therefore would be able to engage in care.

It will also allow for a broader reach for using the structures like Accountable Care Organizations so that we can identify individuals early before they develop full-blown addiction issues, risky behavior if you will, so that we will be able to intervene at an earlier point in time.

Mr. GREEN. So Medicaid and the marketplace exchanges, whether they are state or national exchanges, will expand the population for those who receive substance abuse treatment?

Dr. CLARK. Indeed.

Mr. GREEN. OK. It is clear from your comments the Affordable Care Act made it possible for many people with substance use disorders, whether it is addiction to prescription drugs or illicit drugs, to access treatment.

Mr. Chairman, I know we have had differences over the Affordable Care Act but I hope we all share the goal of providing more robust treatment to those who are working to overcome prescription drugs.

Director Kerlikowske—close enough, I hope—with your name like Green it is not hard to pronounce—how do you track the progress in completing action items identified in the Administration's plan in meeting the goals you have set?

Mr. KERLIKOWSKE. When we put together the prescription drug plan, we brought everyone to the table for a number of months, and all of the agreements that are in there continue into an interagency work group. So we set some specific goals and then we bring that where those people that are closest to the problem and on the ground and had a responsibility for each of their agencies together on a quarterly basis to go over their progress.

So we are starting to see—and I come from a profession that isn't known for its optimism in law enforcement, but I can tell you that seeing the changes that Dr. Clark and the chairman talked about from 2010 to 2011, I think we are starting to turn the corner on this prescription drug problem.

Mr. GREEN. Good. Dr. Clark, I am interested in hearing more about SAMHSA's coordination with the Centers for Disease Control and Prevention on surveillance activities. For example, you testified that SAMHSA funds the annual national survey on drug use and health which collects data on nonmedical use of prescription drugs, among other things. SAMHSA also oversees Drug Abuse Warning Network, or DAWN, surveillance activities of drug-related emergency department visits and drug deaths. Is that partnership going to continue and if you have any more to share with the Committee on that partnership because obviously we like agencies to work together?

Dr. CLARK. And indeed we are working together. I think the Assistant Secretary for Health Howard Koh and my immediate boss Pamela Hyde chairing the Behavioral Health Coordinated Committee, the objective is to make sure that we are working together, and Ms. Hyde works very closely with the director of the CDC to make sure that there is no duplication of effort but there is collaboration and coordination.

And we have our data teams working together. The director of the Center for Behavioral Health Statistics and Quality, Dr. Pete Delaney, is working with the National Center for Health Statistics to make sure that we get the best data possible dealing with the epidemiology of substance abuse.

Mr. GREEN. Thank you. Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Kentucky, Mr. Guthrie, for 5 minutes for questions.

Mr. GUTHRIE. Thank you, Mr. Chair. And I thank you all for coming.

These first couple of questions are for Dr. Throckmorton. And I have been a strong proponent—I am from Kentucky and we have been real aggressive with trying to deal with the drug problem in our area, prescription drug problem. And the tamper-resistant technology has been important. In your written testimony you talked about there were two recent determinations from the FDA on different formulations for OxyContin and for Opana ER, and can you take a minute to explain why there were two different determinations of those two cases about the drug-resistant technology?

Dr. THROCKMORTON. Sure. I will speak in general terms. In both cases we looked at the available data on that product and specific the new formulation and then looked at it in comparison with the earlier formulation, the formulation that had been originally developed and asked questions about whether or not the new technology promised to reduce abuse. We think it is terribly important that this bar, this bar of concluding something is abuse-deterrent be high enough to be worth developing, make it an incentive, make it something that we can reward in labeling terms to make those products attractive for manufacturers to take the time and money to develop.

In the case of OxyContin when we looked at the data, there were important aspects of the new formulation that really did predict it was going to be harder to abuse. One particular one is when people tried to make it ready to inject, it turns into a gel that is just physically impossible to inject into someone's arm. You know, some of that testing involved using people who are addicts trying to, you know, do things that, you know, that would allow this to be used and they were unable to do it.

Now, so those sorts of evidence strongly suggest that a product with those formulation characteristics is going to have reduced attractiveness to abusers in the real world. We are tracking that real-world experience now going forward. On the other hand, when we looked at the totality of the data around the Opana ER product, we didn't see data of that same kind, data that suggested that that product was really going to be meaningfully harder to abuse, meaningfully meaning we would see less abuse——

Mr. GUTHRIE. I want to ask you another one and I got one more that I want to ask, but thank you for that. And on Capitol Hill there has been a lot of discussion about whether generic prescription opioids must have identical abuse-deterrent technology or whether it must simply be comparable or meet or exceed of the other drug. Can you discuss your perspective on this debate and what you are doing to ensure the process remains science-based and technology-neutral?

Dr. THROCKMORTON. Absolutely. And I think it is a very important question. We are going to be talking about—we are working internally on and we are planning on talking about it at a public meeting at the end of September and early October. What I anticipate is that we are going to rely on the generics demonstrating they are abuse-deterrent, not that they use the same technology. That would be the approach that we have used in other places.

And so the testing that we will lay out, the testing that we will develop will be to decide whether or not the new formulation, however it is made, is abuse-deterrent to the level that it needs to be compared with the innovator, not that it used the same technology.

Mr. GUTHRIE. Because I would like to ask Mr. Kerlikowske a question or just bring this up. A very good friend of mine—his name is Tommy Loving—he is head of our drug task force. Do you know Tommy? And very aggressive in this and we get together quite—I will see him in the morning actually for coffee probably.

And he brought it to me a few months ago that heroin has really shown itself in an alarming statistic. And I said why is that kind of—you know, heroin, that seems like something that was 1970s, I guess? He said because our legislature has been so aggressive with the pharmacies, with the tamper-resistant, so now the prescription drugs are more difficult to get than heroin.

And I just want to see—I know you are aware of that, just the strategy with that. The prescription drug abusers are now finding an outlet easier to get heroin than prescription drugs because we have been so good in our State of trying to control it.

Dr. THROCKMORTON. And that has been going on for a while. The anecdotal evidence across the country is that there is an increase in heroin and some of the survey instruments are also showing that we have a younger population.

There is another component about this, too, and that is that young people are heroin-naïve. Older people really have an understanding of the dangers of heroin. Young people believe that it is not that powerful, that as long as they smoke it or snort it that they won't become an injecting drug user, and of course within a few weeks they do become an injecting drug user at the same time that prescription drugs are being made less available through all of the things that you have heard about today and the cost. And heroin is much less costly. So we have some real concerns about the heroin issue, and I couldn't agree with the drug task force commander more.

Mr. GUTHRIE. Thank you and I yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Kentucky, Mr. Whitfield, for 5 minutes for questions.

Mr. WHITFIELD. Thank you, Mr. Chairman. And thank you all for being with us today.

I want to give a little bit of historical perspective on the Prescription Drug Monitoring Program, and since my facts are oftentimes wrong, if I am wrong, you all can correct me. And then I want to just ask a couple of questions.

Kentucky, as my understanding in 1998, started a Prescription Drug Monitoring Program. In 2002, Hal Rogers started the Prescription Drug Monitoring National Training and Technical Assistance Program at the Department of Justice. Now, that was an unauthorized program because this committee has the jurisdiction.

Since that time, it has received an average of 7 or $8 million a year, and we all acknowledge and say that it has been an effective program. I don't think anyone would dispute that. But in 2005, this committee that does have jurisdiction recognizing the success of that program initiated NASPER. Now, the only difference is that the Hal Rogers program was centered at the Department of Justice and NASPER was over at HHS.

NASPER received funding in 2011, and '12 I believe did not get funding. And, as a matter of fact, someone at the Appropriations Committee in the report language in the Omnibus Bill even specifically said no money will be spent on NASPER, which I thought was a little bit mean-spirited myself.

But regardless of that, you three fellows are the experts in the area and I would ask you the question, do we need NASPER anymore? Maybe we should just eliminate NASPER and let's just focus on the Hal Rogers program. Or should we try to combine them? Or should we try to reauthorize NASPER?

You know, I think a lot of the problems we have in the Federal Government on a lot of programs is that Congress does not have a coherent, organized approach to dealing with the problem. So would you all just give us—because I mean our committee does have jurisdiction. Maybe we should reauthorize it and try to start over, but I would just ask for your guidance on this issue. And if each one of you would comment, I would appreciate it.

Mr. KERLIKOWSKE. I know that NASPER was designed to have a bit of a different take on the program versus the high technology of the Hal Rogers PDMPs. We are pleased that there is still money, as you said 7 to $8 million each year that is made available to the States to start up these PDMPs. And I would be happy to sit down with not only representatives from Congress but also some of these inner-agency people and provide some level of our expertise and what we have seen as to NASPER. We would be glad to do that.

Dr. CLARK. I agree with Director Kerlikowske. There needs to be, shall we say, a convening of minds to look at what it is that we are trying to achieve and how best can we achieve it. The specific program may not be the issue; it is the technologies that exist and it is bridging some of the limitations. And it is also dealing with some of the conflicting imperatives associated with both programs.

So our focus on linking Prescription Drug Monitoring Programs with electronic health records, working with the Office of National Coordinated Health Information Technology and with the support of ONDCP in order to give practitioners real-time access, the amount of money and PDMPs just hasn't been a large amount of

money in the first place, so the strategy might be how do we best use limited resources to enhance our efforts to deal with the prescription drug abuse problem without compromising the health of people who suffer from pain or other conditions requiring controlled substances.

Mr. WHITFIELD. Yes. Now, Mr. Chairman, I might just suggest that—and maybe in a private setting—some of our staff could work with these three gentlemen and their staff to determine what can we do to make this program even more effective? I mean maybe all of the effort should be generated that the Hal Rogers program or maybe that there would be a combination or maybe there is something we can do. But since our program has expired, looking at reauthorization, I think it would be helpful to have these discussions. Thank you.

Mr. PITTS. We will pursue that. Thank you.

The chair now recognizes the gentlelady from North Carolina, Mrs. Ellmers, for 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman. And thank you for holding this subcommittee hearing. Thank you to our panel.

I have a couple of questions in regard to patient safety for those who truly are in need of pain medication and how, as we are trying to make the system more effective for, you know, identifying abusers and how to use and work on that problem, how do we protect those patients as well?

You know, the first thing that comes to my mind is the Sudafed issue and how an individual has to basically show their license, their identification, and I know why that has been put in place. I am curious as to why that approach was taken. Is it because it was an over-the-counter drug initially, and because it is used to formulate other drugs? Dr. Throckmorton, can you tell us a little bit about that approach? Because I am concerned that we might take an approach like that into the future with others.

Dr. THROCKMORTON. I want to make sure that I understand the question you are asking. So with pseudoephedrine—Sudafed itself is not abused. It is——

Mrs. ELLMERS. Correct.

Dr. THROCKMORTON [continuing]. Obviously, what it is being used to create——

Mrs. ELLMERS. Correct.

Dr. THROCKMORTON [continuing]. Highly dangerous, you know, methamphetamine. And, you are right, it was over-the-counter and, you know, Congress felt that there were additional restrictions that were necessary to ensure the safe use of that product.

That is different than the conversation we are having around hydrocodone where——

Mrs. ELLMERS. Right.

Dr. THROCKMORTON [continuing]. It in and of itself is a product that has the potential for abuse——

Mrs. ELLMERS. Addictive abuse.

Dr. THROCKMORTON [continuing]. One that is already under some control for the Drug Enforcement Administration, the schedule III already has a——

Mrs. ELLMERS. So basically, the difference being that the Sudafed was an agent that was used to——

Dr. THROCKMORTON. Create.

Mrs. ELLMERS [continuing]. Create another, and so therefore——

Dr. THROCKMORTON. That is the——

Mrs. ELLMERS [continuing]. The idea was to find out who was—make sure that those individuals who were actually purchasing it were identified.

The other issue is what other protections is the FDA putting in place to ensure that patients who really are in need of those critical pain medications for, whether it be chronic pain or acute pain, what protections are in place so that again we might—I hate when the pendulum swings one way when really what we need to do is kind of come up with a real balance.

Dr. THROCKMORTON. Well, we think there are several things to do. So first and foremost, we have been listening carefully. So I have been now working on the opioids and, you know, for a substantial fraction of my time for the last several years. And I have had the opportunity to sit down with hospice care workers. I have sat down with cancer survivors. I have sat down with groups to see the need for access to pain medicines for patients that need them. I have also sat down with groups, you know, that see the cost that prescription drug abuse is, you know, having in America. So to fully understand sort of the broad spectrum of views, we are trying to listen as carefully as we can.

At the end of the day, one of the things that we concluded was the better educated people were about how best to use these medicines—and that means both the prescribers and the patients—the more comfortable we believed they would be in making the right choices. And the right choices here could be not prescribing an opioid to avoid abuse, avoid misuse, or it could be to make a choice to prescribe it because they are now educated well enough to know how to do it well, how to monitor that patient well, how to spot the signs of abuse——

Mrs. ELLMERS. Sure.

Dr. THROCKMORTON [continuing]. And so they are not scared to use a word——

Mrs. ELLMERS. OK.

Dr. THROCKMORTON [continuing]. To use the opiates right.

Mrs. ELLMERS. And thank you because I think that is the best approach as well.

But if there is an individual right now—and I appreciate especially working with hospice and certainly that is an area where those medications are used and I can see that issue occurring—but if there is an individual who feels that their pain, for whatever purpose, whatever reason, has an issue with access and feels that they are having difficulty obtaining, is there a phone number? Is there a way—who does that individual reach out to? And any of you can comment on any of these things.

Dr. THROCKMORTON. Partly, it will depend on what the source of not being able to get the medicine is. So if it is a drug shortage, for instance, that the drug is not available the way, you know, sometimes drugs have gone into shortage recently and we have shortages with fentanyl, for instance, periodically or whatever, that is absolutely something the FDA wants to hear about. I have a staff that work on that 24/7 trying to understand, prevent, mini-

mize those shortages. And we have a Web site at the FDA to allow people to report.

If it is a pharmacy not carrying the drug, those are decisions that the FDA doesn't have a clear role in and I would suggest Boards of Pharmacy or some other local authorities would be the place to talk to.

Mrs. ELLMERS. Thank you. Thank you. I apologize, Mr. Chairman. My time ran over. Thank you very much.

Mr. PITTS. The chair thanks the gentlelady and now recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it very much. And thank you for holding this hearing. And I thank the panel for their testimony.

Along with many Floridians, I am concerned about the alarming increase in prescription drug abuse and illegal sales of prescription medications. I believe that issues concerning both overprescribing and the illegal use and sale of these drugs should be addressed. Prescription drug abuse is both a federal and state issue, and I have worked with both local and federal officials to take on this issue.

In my district, Pasco and Pinellas Counties have had some of the highest oxycodone causes of death with 197. Hillsborough County, this is in the Tampa Bay area, was fourth in Florida with 128 deaths from oxycodone. Sadly, Pasco and Pinellas Counties also led the state in methadone deaths and hydrocodone deaths. The number of ER-related visits from misuse or abuse of prescription drugs has nearly doubled in the past 5 years.

Recently, there was a drug summit in Pasco County where both health officials discussed the growing problem of babies born addicted to prescription drugs. Pinellas County ranks first in the state for babies born addicted. Florida has taken some positive steps to fight prescription drug abuse such as legislation to eliminate pill mills in 2011.

Florida currently runs four drug tracking programs in addition to the Controlled Substance Reporting System. The number of doctors on the DEA's list of top 100 purchasers of oxycodone declined by 97 percent in a single year and pain management clinic registration decreased by 36 percent. This is a good start but there is much more work to be done. I am sure you will agree. That is why I have instructed my office to look into issues of prescription drug abuse and developing, of course, future legislation. And again, Mr. Chairman, I really appreciate you holding this hearing.

I have a couple questions. Mr. Kerlikowske, I talked a bit about this of course, the growing problem of babies born addicted to prescription drugs such as oxycodone. This is a serious problem in our communities. I would like to have you come down if you will to the Tampa Bay area and meet some of the local officials, the health officials and providers who are dealing with this growing problem.

I want to ask you a question. Are there any funds or programs available for the local community to tap into to help with the problem either on the prevention or treatment side? And I also want to ask Dr. Clark, are there resources for my community, of course, from SAMHSA? So those are the questions.

Mr. KERLIKOWSKE. Congressman, we fund the Drug-Free Communities program, these grassroots communities programs that do prevention, and of course oftentimes that local voice is more powerful and more important to people about prevention. And we have worked with them to help them understand and become more knowledgeable.

We fund almost 700 of them around the country to become more knowledgeable about this neonatal abstinence syndrome because we are seeing in a number of States, Florida, who is—and I attended the first meeting of the advisory committee that has worked so hard under the Attorney General to reduce that problem. It is a complex problem because there are women in pain that are also pregnant and are being treated. There are women in drug programs at the same time, and so there has to be a very careful balance.

But I would also tell you I would be happy to visit the Tampa Bay area with you and examine this more closely.

Mr. BILIRAKIS. Well, thank you very much. I appreciate that. I welcome that.

Anyone else wish to comment on the panel?

Dr. CLARK. We have Targeted Capacity Expansion grants that are available to the States so the States can use their block grants to help promote education. We are developing an internal strategy to deal with NES. We recognize it is much broader than the prescription opioids. It involves heroin. But, as you know, that any time a woman has to take medication while she is pregnant, there is some associated risk for the neonate, and so what we will try to do is promote adequate education of consumers and practitioners so that we can address these issues.

We have a Pregnant and Postpartum Women's program that allows women who have addiction problems to get into treatment. During the time that they are pregnant and when they deliver, we can deal with both the mom and the child. And the data do show that the outcomes of the birth are much more positive when we have those kinds of programs.

But the most important thing is having this concerted effort involving multiple layers at the State level, at the local level, community level involving practitioners as well as consumers.

Mr. BILIRAKIS. Thank you. Thank you very much. I yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

The House is voting on the floor. There are less than 10 minutes left to vote.

That concludes the questions from the members. There might be other questions. We will submit those to you in writing if you would please respond promptly. And members should submit their questions by the close of business on Friday, June 28.

So thank you very much to the witnesses, to the members for attending.

Without objection, the subcommittee is adjourned.

[Whereupon, at 11:23 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

According to the Centers for Disease Control and Prevention, prescription drug abuse is an epidemic. And unfortunately it is a growing problem that is affecting too many American families.

Data from the National Survey on Drug Use and Health (NSDUH) show that about 15.7 million people aged 12 or older used prescription-type drugs non-medically in the past year, and that 2.5 million of these individuals reported using prescription-type drugs non-medically for the first time.

Particularly alarming is the fact that many people, especially teenagers, believe prescription drugs are safer than illegal drugs because they are prescribed by a healthcare professional and dispensed by a pharmacist. But with more than 20,000 deaths occurring each year due to the misuse and abuse of prescription drugs, we must ensure that our research, education, and prevention efforts are addressing this major public health and safety concern.

The federal government has undertaken a number of positive initiatives. The National All-Schedules Prescription Electronic Reporting Act (NASPER), which I coauthored with my colleague Ed Whitfield from Kentucky, was enacted in 2005 to provide grants to states to establish prescription drug monitoring programs, so that these potentially dangerous substances are used only for intended purposes with legitimate prescriptions. The program, administered by the Substance Abuse and Mental Health Services Administration (SAMHSA), helped ramp up state efforts to reduce abuse and diversion of prescription drugs. It is critical that we continue to support this program through federal funding.

There is also a great deal of work being done right now by the Food and Drug Administration (FDA) to implement provisions related to prescription drug abuse that were included in the Food and Drug Administration Safety and Innovation Act (FDASIA), which Congress passed last summer. FDA has been tasked with thoroughly reviewing all Federal programs regarding prescription drug abuse and treatments for those with prescription drug dependence and identifying any gaps. That report is due out this summer and I think will be useful in the work of this Subcommittee. In addition, as we will hear from FDA today, they have issued guidance on developing abuse-deterrent products.

The Administration has also made prescription drug abuse a priority, setting out a plan to address this health epidemic. I support those efforts, but it is clear that we still have an unsolved problem that needs further attention.

I hope our witnesses today can help us navigate how we can find innovative approaches to combating prescription drug abuse while recognizing the critical use that many of these drugs have for patients across the country.

Thank you.

Statement

Of

The National Association
of Chain Drug Stores

For

U.S. House of Representatives
Energy and Commerce Committee

Subcommittee on Health

Hearing on:

"Examining the Federal Government's
Response to the Prescription Drug Abuse
Crisis"

June 14, 2013
9:30 a.m.
2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd, Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Subcommittee on Health for the opportunity to submit a statement for the hearing on "Examining the Federal Government's Response to the Prescription Drug Abuse Crisis." NACDS and the chain pharmacy industry are committed to partnering with federal and state agencies, law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug abuse. Our members are engaged daily in activities with the goal of preventing drug abuse.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their over $1 trillion in annual sales. Every $1 spent in these stores creates a ripple effect of $1.81 in other industries, for a total economic impact of $1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

NACDS and the chain pharmacy industry share the Subcommittee's concerns with the problem of prescription drug abuse. We believe that there are a variety of ways to help

curb prescription drug abuse, and chain pharmacies actively work on many initiatives to reduce this problem.

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, addiction and abuse, 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 diversion and 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 our prescription drug distribution centers right down to the point of dispensing to the patient. We 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, and maintaining electronic inventories of controlled substances and conducting random audits. The tools we utilize to secure our facilities and operations can include camera surveillance, heavy duty safes, secure cages, and complex alarm systems. We work closely with law enforcement to see that perpetrators are brought to justice.

Specifically, at the pharmacy level, examples of the initiatives our members have undertaken 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, every pharmacy is highly secured with physical barriers and complex alarm systems. Some pharmacies also utilize cameras and closed-circuit television 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.

In addition to developing, implementing, and maintaining our own policies and procedures, we support numerous other initiatives to mitigate and reduce prescription drug abuse. Chain pharmacies participate in state controlled substance prescription drug monitoring programs. NACDS and our member companies support policies that work to prevent illegitimate Internet drug sellers from selling or offering to sell drugs to U.S.

consumers in violation of federal and state laws. We also support efforts to provide patients with means for disposal of their unwanted medications in ways that are authorized by law enforcement.

The Role of FDA

Six years ago, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided the FDA the authority to impose risk management plans on prescription drugs, known as Risk Evaluation and Mitigation Strategies (REMS). A REMS will be imposed if FDA finds that a REMS is necessary to ensure that the benefits of a drug product outweigh the risks of the drug product. Among the numerous REMS that FDA has implemented is a REMS for long-acting and extended release opioid products ("LA/ER opioid drugs"). These are pain relieving medications that have an elevated potential for abuse. The central component of this "Opioid REMS" is an education program for prescribers (e.g., physicians, nurse practitioners, physician assistants) so that LA/ER opioid drugs can be prescribed and used safely. NACDS agrees that prescribers should be properly educated about the risks and benefits of prescription drugs, including those that have elevated abuse potential like LA/ER opioid drugs. It is critical that all prescribers understand the nature of addiction and abuse before issuing prescriptions for these medications. NACDS supports FDA's Opioid REMS.

In addition, FDA recently implemented a REMS for another class of drugs with elevated abuse potential: transmucosal immediate-release fentanyl (TIRF) products. NACDS and

other industry stakeholders have worked closely with FDA over the past few years to design and implement this REMS. We are appreciative of this collaborative effort spearheaded by FDA. If this REMS proves successful, we are hopeful that it could serve as a model for future REMS for products similar to TIRF products.

As we pursue solutions to the problem of prescription drug abuse, it is critical that we do not place undue burdens on legitimate patients who require prescription medications. As FDA has recognized through the REMS program, the risks of medications must be mitigated relative to their benefits. However, we cannot mitigate risks to the point that legitimate patients cannot receive medications' benefits. We believe that FDA has struck a proper balance thus far.

Controlled Prescription Monitoring Programs

NACDS and chain pharmacies support controlled substance prescription monitoring programs to help combat prescription drug abuse. Currently, about 44 states have operational monitoring programs and another five states are in various 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 monthly, weekly, and daily depending on the particular state's program requirements. This information includes information 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.

These monitoring programs offer many benefits to aid in curbing prescription drug abuse. For example, they aid in identifying, deterring, or preventing drug diversion and abuse. These programs encourage appropriate intervention to determine if a person may have a drug addiction, so that treatment may be facilitated. The programs also provide public information on trends in drug abuse and diversion.

NACDS and chain pharmacies support these programs as one of many strategies to help curb prescription drug abuse and diversion. We believe that these programs have proven useful in preventing drug abuse and diversion at the prescriber, pharmacy and patient levels.

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 the following principles for proper return and disposal of consumers' unwanted medications. These include 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. The state of Maine has operated a DEA-authorized drug mail-back program, funded through federal grants, where consumers are provided with pre-paid, mail-back envelopes distributed at pharmacies and other locations, to mail in their unwanted medications. In addition, at various locations across the U.S., law enforcement partners with pharmacies to provide drug take-back events to give consumers means to return their unwanted medications. These programs help prevent teens and others from accessing and using prescription drugs in dangerous and potentially deadly ways. We 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.

The Role of DEA

DEA holds the primary authority to implement and enforce the CSA. NACDS and our members vigorously support the mission and efforts of DEA. We seek to work with DEA and other law enforcement bodies on a routine basis.

Pharmacies 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 must 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 regulations provide that physicians and other prescribers are responsible for ensuring that prescriptions for controlled substances are issued for legitimate medical purposes within the prescribers' usual course of professional practice. According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility 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.

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.

In addition, DEA has been visiting states nationwide and providing day-long presentations to pharmacists to apprise them of DEA's expectations.

Better Focusing Government Resources

Unfortunately, DEA's enforcement actions are causing problems with patients' ability to access much needed prescription pain medications. To better focus government resources on solving the problem of prescription drug abuse, NACDS urges Congress to create a commission or advisory group to bring together all stakeholders to address the problems of prescription drug diversion and abuse. The activities and recommendations of the advisory group should be broad in scope; however the recommendations should include specific direction for federal agencies to carry out. Most importantly, there should be an agreement from all participants to support this collaborative result.

The appropriate participants include key government agencies, patient groups, pharmacy groups, prescriber and other provider groups, prescription drug wholesaler groups, pharmaceutical companies, public policy experts, state attorneys general, and law enforcement officials including groups representing local law enforcement.

The policy areas that should be reviewed include:

- Improving controlled substance monitoring programs to avoid duplication and provide access to all relevant stakeholders
- Shutting down illegal Internet prescription drug sites
- Shutting down "pill mills"

- Facilitating proper disposal of prescription drugs through take-back programs
- Identifying hot spots of prescription drug abuse
- Better collaboration among federal agencies, especially FDA and DEA, on drug abuse issues to suggest guidelines for DEA action
- More resources for law enforcement
- Better education of providers, patients, parents and youth
- Development of abuse-resistant products
- Recommendations for reducing robberies, burglaries, and cargo theft
- The recommendations should be broken down by state and federal recommendations with respect to what is appropriate federally versus the individual states

We believe that bringing together stakeholders to address the problems of 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 access to critical medication must be preserved in order for any potential solution to be successful.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments on efforts to address the problem of drug abuse. We are committed to the health and welfare of our patients, as well as all Americans, including ensuring that they can still access critical pain medications while we tackle the problem of prescription drug abuse.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
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July 9, 2013

The Honorable R. Gil Kerlikowske
Director
Office of National Drug Control Policy
Executive Office of the President
750 17th Street, N.W.
Washington, D.C. 20503

Dear Mr. Kerlikowske:

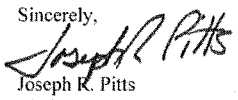
Thank you for appearing before the Subcommittee on Health on Friday, June 14, 2013, to testify at the hearing entitled "Examining the Federal Government's Response to the Prescription Drug Abuse Crisis."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, July 23, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

RESPONSES TO
QUESTIONS SUBMITTED FOR THE RECORD TO
R. GIL KERLIKOWSKE
DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY

FOLLOWING JUNE 14, 2013, HEARING ENTITLED,
"EXAMINING THE FEDERAL GOVERNMENT'S RESPONSE TO THE PRESCRIPTION DRUG ABUSE CRISIS"
SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Joseph R. Pitts

1. In 2012, the FDA, in partnership with other regulatory and law enforcement agencies, undertook Operation Pangea V and took action against more than 4,100 internet pharmacies. Operation Pangea V resulted in the shutdown of more than 18,000 illegal pharmacy websites and seized approximately $10.5 million worth of pharmaceuticals worldwide. This operation illustrates the magnitude of the internet pharmacy problem. Online Pharmacies have proven to be very problematic and dangerous as they often do not require any prescription. How is ONDCP combating online pharmacies?

ANSWER: While research shows that less than one percent of individuals abusing or misusing prescription drugs obtain them from Internet sales, the Federal Government has taken steps to reduce the role of illegal Internet pharmacies in diversion of opioid pharmaceuticals[1]. The Ryan Haight Online Pharmacy Consumer Protection Act requires Internet pharmacies dispensing controlled substances to obtain a special Drug Enforcement Administration (DEA) registration and report monthly to DEA, to disclose detailed information on their home page, and to not provide such pharmaceuticals to individuals who have not had at least one face-to-face evaluation by a prescribing medical practitioner, subject to limited exceptions for telemedicine practice. It is designed to allow DEA to better monitor unlawful Internet pharmacy operations, and reduces the number of Internet pharmacies distributing controlled substances illegally. Pharmacies that are lawfully registered with DEA and whose dispensing of controlled substances via the Internet consists of filling or refilling prescriptions for Schedule III-V controlled substances (as specified in 21 U.S.C. § 802(55) and (56)) are exempt from the Ryan Haight Act definition of "online pharmacy." Those online pharmacies and websites that continue to unlawfully sell opioid pharmaceuticals and other controlled substances are typically located outside the United States, and to date, DEA has not registered any online pharmacies pursuant to the Ryan Haight Act.

[1] Substance Abuse and Mental Health Services Administration. *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings.* U.S. Department of Health and Human Services. [September 2012]. Available: http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#2.16

Within the Office of National Drug Control Policy (ONDCP), the High Intensity Drug Trafficking Areas (HIDTA) program provides designated areas around the country with funds to establish multi-agency task forces to address drug enforcement issues within their respective areas. Of the 28 HIDTAs, 19 (including 4 of the 5 regions comprising the Southwest Border HIDTA) have identified Internet pharmacies as a growing threat to their area.

Most investigations conducted by HIDTA task forces focus on poly-drug organizations and not specifically on Internet sales of illegal drugs. Given the role the Internet has played in the illegal distribution of pharmaceuticals, however, some HIDTAs have specifically targeted them.

For example, the Nevada HIDTA funds a task force called Pharm-Net that specifically targets pharmaceuticals purchased over the Internet. This unique task force has been in place since 2006. The Pharm-Net task force focuses on sources of supply, including on-line pharmacies, and drug trafficking organizations that divert pharmaceutical controlled substances. Many of the targeted organizations involve medical professionals such as doctors, pharmacists or other health care workers with access to controlled substances or prescriptions to obtain controlled substances.

ONDCP will continue to work with DEA, the Food and Drug Administration (FDA), and other agencies to address online operations illegally diverting these medications and will continue to partner with international, state, and local law enforcement agencies to further suppress illegal online sources of prescription drug diversion.

2. How does the ONDCP allocate its funds to address prescription drug abuse?

ANSWER: ONDCP partners with several agencies to coordinate funding for the action items listed in the 2011 *Prescription Drug Abuse Prevention Plan (Plan)* under the National Drug Control Budget. For example:

- The Administration has requested $7 million in FY 2014 for the Prescription Drug Monitoring Program of the Department of Justice's Office of Justice Programs to enhance the capacity of regulatory agencies and health care providers to collect and analyze controlled substance prescription data;
- The DEA's Diversion Control Program (DCP), with a request of $360.9 million in FY 2014, aids in preventing the diversion of pharmaceutical controlled substances;
- The National Institute on Drug Abuse (NIDA) supports research to better understand the patterns and motivations underlying prescription drug abuse, the development and testing of prevention programs, pain medications with reduced abuse potential, and treatments for prescription drug abuse and opioid overdose. NIDA released findings in 2013 in the following areas: Problem Behaviors Can Signal Risk in Prescribing Opioids to Teens; Preclinical trials of an Oxycodone Vaccine successful; Thoughts of Suicide May Persist Among Nonmedical Prescription Opiate Users; and Few Teens With Prescription Opioid Use Disorders Receive Treatment; and
- The Substance Abuse and Mental Health Services Administration (SAMHSA) is reviewing applications for up to approximately $2.8 million in Cooperative Agreements

for Electronic Health Record and Prescription Drug Monitoring Program Data Integration grants. SAMHSA is also awarding up to $750,000 to help enable opioid treatment programs to develop electronic health record systems.

In FY 2012, ONDCP spent $1 million from HIDTA's discretionary funding to support investigations to disrupt and dismantle drug trafficking organizations suspected of violating Federal, state, or local statutes pertaining to the diversion of licit pharmaceutical controlled substances. The investigations also targeted rogue pain clinics, physicians who prescribe scheduled drugs without a valid medical reason, and pharmacies that illegally dispense or divert controlled drugs.

With a request of $85.6 million in FY 2014, ONDCP also funds nearly 700 Drug Free Communities (DFC) Support Program coalitions across the country. Many of these community coalitions have prevention initiatives geared toward reducing prescription drug abuse and misuse. Coalitions supported by the DFC program, which is administered by SAMHSA, work with youth, parents, schools, law enforcement, business professionals, media, local, state and tribal government, and other community members to identify and address local youth substance use problems and create sustainable community-level change. Through the use of environmental prevention strategies, DFC coalitions use comprehensive approaches to address prescription drug abuse such as raising awareness for prescribers, parents, and youth; organizing prescription drug take-back events; and developing systems for safe disposal of prescription drugs. DFC grantees have identified prescription drug abuse as a priority for their coalitions.

3. How does the CDC, FDA and ONDCP work together during the development of a promising treatment which could help address the national priority of abating the drug abuse crisis? While obviously approval of any new medication is under the purview of the FDA, I'd like to know more about the extent to which each of your agencies provide your expertise to one another when a therapy with this potential is under review.

ANSWER: As acknowledged, there are very strict rules governing the review and approval of medications, including restrictions on the role Federal agencies outside the FDA can play in these processes. However, as part of the overall effort to curb prescription drug diversion and abuse, the Administration has established clear objectives to promote the development of promising treatments.

One aspect of the Administration's *Plan* relates to the development of abuse deterrent formulations of opioids. The Plan has two specific action items to advance this work. The first item, led by the Department of Health and Human Services (HHS), calls for expediting research through grants, partnerships with academic institutions, and priority New Drug Application review by the FDA to develop treatments for pain with no abuse potential as well as the development of abuse-deterrent formulations of opioid medications and other drugs with abuse potential. NIDA is funding grants for the development of such medications.

The second action item, also led by HHS, calls for providing guidance to the pharmaceutical industry on developing abuse-deterrent drug formulations and on post-market assessment of their

performance. In January 2013, FDA issued draft guidance on the development of abuse-deterrent opioid drug products, as required by the Food and Drug Administration Safety and Innovation Act. Recent actions by FDA concerning abuse-deterrent formulations of well-known prescription opioid drugs demonstrate that FDA is using the available scientific information to make its determinations concerning the marketing by drug manufacturers of purported abuse-deterrent formulations.

NIDA has prioritized the development of medications to treat substance use disorders. To accelerate the progress of medications development, NIDA has increased collaboration with pharmaceutical industry and biotech companies, is evaluating compounds with relevant mechanisms that have been "de-risked", awarding larger grants for shorter duration to obtain quicker results, and having the flexibility to prioritize projects as needed. NIDA is also funding a promising approach to treat substance use disorders that uses anti-drug enzymes or antibodies to neutralize the substance while it is still in the bloodstream, keeping it from entering the brain. NIDA scientists also review the eight factor evaluation of abuse liability required under the Controlled Substances Act (CSA) for scheduling of medications, once the evaluations are performed by the FDA.

The Centers for Disease Control and Prevention (CDC) regularly works with FDA on efforts to improve understanding of abuse and overdose risks, public health implications of abuse, and how safer products or those with abuse-deterrent properties might impact the public health burden. CDC is also engaged with FDA to improve surveillance capacity to better evaluate the impact or potential impact of products under development.

One other aspect of sharing between FDA, CDC and ONDCP that has been valuable has been exchange of information about prescription drug use and misuse. Both FDA and CDC scientists are working hard to track this epidemic and share this information where possible and needed with ONDCP and other parts of the Federal Government. While new medications continue to be developed, broader adoption of existing medicines to manage substance use disorders is necessary. In one important step, working with interagency partners, the Department of Defense is currently working on rulemaking to allow for TRICARE coverage of treatment of substance use disorders through medication-assisted treatment, such as methadone or buprenorphine.

ONDCP will continue to work with NIDA, FDA, CDC, and other Federal interagency partners to help ensure innovative treatments are developed and tested safely and efficiently, and that existing treatment modalities are widely available to those that need them. There is significant potential in medication-assisted treatment, and we must ensure that these options are widely available, particularly in underserved communities in rural and other areas with limited treatment infrastructure. ONDCP continues to urge the medical research and substance abuse treatment fields to develop new therapies and more fully incorporate existing, evidence-based treatment modalities into health care.

Full implementation of the Affordable Care Act includes treatment for substance use disorders as one of the ten Essential Health Benefits, as well as application of the Mental Health Parity and Addiction Equity Act of 2008 to these benefits, so that substance use disorders are treated the same as other chronic health disorders. ONDCP continues to work with its Federal partners to

ensure that clinically effective and cost effective substance use disorder services are integrated into the U.S. healthcare system.

4. How do you measure the success of the *Prescription Drug Abuse Prevention Plan*?

ANSWER: The Administration has established a number of specific goals to help gauge success of the *Plan* and ongoing efforts to reduce and prevent abuse of prescription drugs. The overarching five-year goal, as outlined in the *National Drug Control Strategy*, is a 15 percent reduction in non-medical use of prescription-type psychotherapeutic drugs in the past year among people 12 years of age and older.

ONDCP has established a multi-pronged approach to assess progress on these goals. From a strategic level, the Performance Reporting System (PRS) is a monitoring system that assesses interagency progress toward achieving the Goals and Objectives of the *Strategy*. The *Strategy* addresses the importance of both prevention and early intervention. Three PRS measures address non-medical use of prescription drugs: (1) percent of respondents in the past year using prescription-type drugs non-medically, age 12 – 17; (2) percent of respondents in the past year using prescription-type drugs non-medically, age 18 – 25; and (3) and percent of respondents in the past year using prescription-type drugs non-medically, age 26+. From an operational perspective, the ONDCP Delivery Unit tracks progress on action items that support achieving the Goals of the *Strategy*, including supplemental strategies such as the *Prescription Drug Abuse Action Plan*.

Historic strides have been made in preventing doctor shopping by working with states to expand the use of prescription drug monitoring programs (PDMPs). In 2006, only 20 states had PDMPs. Today, 49 states have laws authorizing these databases, and 47 states have operational programs. Each day, these programs are helping to rein in the diversion of prescription drugs for non-medical use by enhancing the ability of prescribers, pharmacists, and state authorities to prevent abuse.

ONDCP has worked extensively with medical professionals to provide training on how to properly prescribe painkillers. In conjunction with NIDA, ONDCP has made available two free online training tools for healthcare professionals who prescribe these powerful drugs. Already, nearly 60,000 clinicians have completed these training courses in less than a year. Moreover, FDA now requires manufacturers of extended-release and long-acting painkillers to make available free or low-cost continuing education to prescribers under the Risk Evaluation and Mitigation Strategy for extended-release and long-acting (ER/LA) opioid analgesic drugs (ER/LA Opioid Analgesic REMS). The FDA expects companies to train at least 60 percent of the approximately 320,000 prescribers of these drugs within the next four years.

Through support of DEA's National Prescription Drug Take-Back Day initiatives, communities have reasonable ways to dispose of unneeded or expired medications languishing in home medicine cabinets. These events have already collected and safety disposed of almost three million pounds of medications, draining a key source of drugs that are often diverted for abuse.

Progress has been made under all four pillars, and there are signs in recent years that this national effort is working. One example is non-medical prescription drug use among young adults. The rate of non-medical use of prescription drugs among young adults (18 to 25 years old) in 2012 was 5.3 percent. While this rate is similar to rates seen in 2010 and 2012, it is lower than the rate in the years 2003 through 2007 and 2009 (which ranged from 5.9 to 6.5 percent).[2] While not definitive, these new data underscore the need for ongoing focus on reducing and preventing prescription drug abuse.

5. Why has ONDCP prioritized reauthorizing NASPER?

ANSWER: When the Administration released the *Plan* in 2011, the number of states that had PDMPs was significantly less than today, and those PDMPs were only beginning to commence operation, let alone work with each other. At that time, there were two Federal programs: the Harold Rogers Prescription Drug Monitoring Program (HRPDMP) grants, administrated by the Bureau of Justice Assistance (BJA) in the Department of Justice; and the National All Schedules Prescription Electronic Reporting (NASPER) program, administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS. As originally conceived, HRPDMP grants could be used to plan a state PDMP, but to be eligible for a NASPER grant a state needed to have PDMP legislation in place. During the initial years of NASPER's authorization, there was still a need to support widespread establishment and implementation of PDMPs, as well as ensuring that states would make their PDMPs more interoperable and use them as a public health tool, not primarily a law enforcement tool.

Given that 49 states now have legislation authorizing PDMPs and 47 states have operational programs, the focus in supporting PDMPs has shifted from getting PDMPs started to improving the utility of existing PDMPs and enhancing their interoperability, both with other state PDMPs and with other health information technology systems.

We are committed to working with SAMHSA and BJA to ensure a streamlined Federal approach to provide support for state PDMPs. We continue to support both BJA's efforts to fund and enhance PDMPs through the HRPDMP and SAMHSA's efforts through its PDMP and EHR Integration grants.

6. Are you investigating a strategy involving drug packaging?

ANSWER: In April 2013, FDA announced approval of updated labeling for reformulated OxyContin® (oxycodone hydrochloride) stating that the product has physiochemical properties that are expected to make abuse via injection difficult and are expected to reduce abuse via the intranasal route (snorting). This is the first time that FDA has approved labeling that

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[2] Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings.* U.S. Department of Health and Human Services. [September 2013]. Available: http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch2.3

characterizes a product's abuse-deterrent properties. Including information about a product's abuse-deterrent properties in labeling is important to inform health care providers, patients, and the public about the product's predicted or actual abuse potential. FDA continues to encourage pharmaceutical manufacturers to seek approval of proposed product labeling that highlights product safety and other properties and appropriately characterizes the abuse-deterrent properties of a product. The FDA's guidance around such labeling notes that labeling language regarding abuse deterrence should describe the drug's specific abuse-deterrent properties, as well as the specific routes of abuse that the drug has been developed to deter.

7. In the document *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, one of the primary action items is educating prescribers. You note that you would like to amend Federal law to require the training. In conjunction with this legislative approach has your agency talked to medical, nursing, and pharmaceutical schools about including this in the curriculum?

ANSWER: Yes, the Administration is working with a number of health care practitioner organizations and associations, as well as medical colleges and faculty to promote the widespread adoption of this safe prescribing and substance abuse content by medical educators. For example, ONDCP is working with the American Dental Association to ensure that safe prescribing education is properly tailored to dental students and professionals. Additionally, ONDCP leadership has met with a host of medical and pharmacy school deans and faculty, including a keynote address and a private meeting at the 2012 American Association of Colleges of Pharmacy Annual Meeting in Orlando, FL, and staff-level engagements with the Association of American Medical Colleges, encouraging these associations and their members to strengthen and expand curricula around safe prescribing, abuse-potential of medications, and recognizing the signs and intervening with patients with substance use disorders. These messages are reinforced in work with state Medical and Pharmacy Boards, as well as their national counterparts. All of these efforts inform education, not only in medical, nursing, dental, and pharmacy schools, but also continuing education over the course of health care professional careers.

In 2011, ONDCP convened a meeting with leaders in pharmacy education to encourage pharmacy schools to expand educational offerings. The Administration has also taken a number of steps to promote expanded continuing medical education for prescribers, so that current prescribers receive further training in prescribing controlled substances, particularly opioid pain relievers. The Administration is committed to making convenient, free or low-cost tools and training available to a broad spectrum of prescribers and dispensers of these controlled substances.

ONDCP worked with NIDA to develop two free online continuing education training tools for healthcare professionals who prescribe opioid analgesics. Since these tools became available in October 2012, nearly 60,000 clinicians (primarily physicians and nurses) have completed coursework eligible for continuing medical education credit—as well as training on the abuse potential of these medications and management of patients to whom they are prescribed.

SAMHSA is providing training on prescription drug abuse for physicians and other health professionals both online and in-person in 20 states with particularly high rates of opioid dispensing. In addition, the FDA has developed a Risk Evaluation and Mitigation Strategy for ER/LA opioids analgesics. Approved in July 2012, the ER/LA Opioid Analgesic REMS requires all manufacturers of ER/LA opioids to make available training for prescribers of these medications.[3] The training must include information that prescribers can use when counseling patients about the risks and benefits of opioid use. The FDA expects the training to be provided free or at low-cost by continuing education providers and at least 60 percent of the approximately 320,000 active prescribers of ER/LA opioids to be trained within four years from when training is available.[4] A number of these education programs are already available or will be available to health care providers in the near future.

8. It is clear that the prescription drug abuse crisis is extremely complicated and constantly changing. Has the ONDCP altered the prescription drug abuse plan to accommodate for the evolving epidemic? If so, how has the plan changed?
a. What caused the changes in strategy?
b. What have been the strongest and most effective parts of the strategy?

ANSWER: ONDCP regularly engages with partners at the Federal, state, and local levels to adapt and respond to emerging issues related to prescription drug diversion and abuse. ONDCP also works with interagency partners to examine the latest research and data to better inform ongoing work to reduce prescription drug abuse and its consequences. The Administration is focused on addressing some of the most pronounced consequences of this epidemic, including overdose deaths and emerging issues like heroin use as well as neonatal abstinence syndrome and maternal addiction.

With recent rises in overdose deaths across the country,[5] ONDCP has increased its focus on comprehensive overdose prevention, recognizing that overdoses can be prevented, antidotes are available, and treatment is imperative. ONDCP is working with Federal partners and state and local authorities to expand access to naloxone, an emergency opioid overdose reversal medication, for first responders who encounter overdose victims. The agency is also closely examining Good Samaritan laws, which provide limited protections for individuals who call 911 in overdose situations, to remove perceived barriers to calling for help. These steps are critical as part of a larger effort to inform the public, law enforcement, and health care professionals about the nature of prescription drug abuse, addiction, and overdose prevention.

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[3] Food and Drug Administration. Extended Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS). U.S. Department of Health and Human Services. [August 2012]. Available: http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf

[4] Food and Drug Administration. Extended Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS). U.S. Department of Health and Human Services. [August 2012]. Available: http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf

[5] CDC/Wonder; data extracted on January 28, 2013.

Another area of expanded focus is the nexus between prescription drug abuse and heroin use. The number of primary admissions for heroin treatment services among 18 to 24 year olds increased from 37,000 in 2000 to 60,000 in 2011.[6] Epidemiologists in all regions of the United States report increases in heroin use among young adults and those outside of urban areas.[7] Research also indicates that injection-drug users report prescription opioid use predates their heroin use, and increased tolerance to prescription opioids and lower costs motivate them to try heroin.[8] ONDCP and researchers with the CDC are closely monitoring these trends to determine whether there is a relationship between prescription drug initiation and transition to heroin use, particularly among young people. The Administration is also ensuring that comprehensive overdose prevention properly considers the role of heroin in overdose, and is underscoring the importance of getting individuals abusing prescription drug into treatment before their tolerance leads to injection drug use.

The Administration is also taking steps to understand and address the clinical and policy issues related to maternal addiction, including neo-natal abstinence syndrome (NAS), the withdrawal symptoms exhibited by some infants born to mothers exposed to illicit drugs and certain medications during pregnancy. Many hospitals with little experience caring for drug exposed newborns prior to the prescription drug abuse epidemic are now witnessing increases in births requiring additional hospital resources. Between 2000 and 2009, the rate of hospitals billing for NAS increased from 1.2 to 3.4 per 1,000 hospital births per year.[9] This translates to roughly one infant per hour born with signs of drug withdrawal. In August 2012, ONDCP hosted a national leadership meeting that focused on NAS and evidence-based treatment and prevention options for maternal addiction. The conclusions reached at this meeting are reflected in a renewed emphasis on maternal addiction and neonatal abstinence syndrome in the *National Drug Control Strategy*.

The Administration's efforts around PDMPs and health information technology (IT) have also progressed. In support of the *Plan,* ONDCP convened a Roundtable on Health IT and Prescription Drug Abuse shortly after the *Plan's* release. Over 30 attendees from the public and private sectors discussed integrating these innovative technologies with PDMPs so that prescribers and pharmacists can more easily and effectively access and use the PDMP data. They agreed on nine pilot studies, and HHS contracted with the MITRE Corporation to facilitate the development of some of these pilots.[10]

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[6] Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Treatment Episode Data Set (TEDS). Data extracted as of October 15, 2012.
[7] Proceedings of June 2012, NIDA CEWG (Unpublished Data from NIDA).
[8] Lankenau SE, et al. (2012). Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012 Jan;23(1):37-44. Epub 2011 Jun 20.
[9] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. "Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009" JAMA. 2012 May 9;307(18):1934-40. Available: http://www.ncbi.nlm.nih.gov/pubmed/22546608
[10] Prescription Drug Abuse and Health Information Technology Workgroup, Behavioral Health Coordinating Committee, U.S. Department of Health and Human Services. "Action Plan For Improving Access to Prescription Drug Monitoring Programs Through Health Information Technology." June 30, 2011.

The pilots, which were completed in 2012 and early 2013, yielded encouraging results.[11] For example, one of Indiana's health information organizations, the Indiana Network for Patient Care, leveraged its hospital network to offer information from the State PDMP along with a "narcotic score" alert (using a formula to determine high risk based on the number of prescriptions) to emergency room doctors as part of their normal view of a patient's record. In Kansas, a secure e-mail protocol called "DIRECT" was used to send a PDMP report securely from the PDMP to a provider's electronic health record (EHR) when a certain threshold was met, such as when the patient sought to fill five prescriptions from five providers during one calendar quarter. Finally, in Michigan, a vendor of an electronic prescribing (e-prescribing) module worked with that State's PDMP to pull information from the PDMP when a provider electronically prescribed a medication using the module. This allowed providers to receive alerts concerning previous prescriptions of controlled substances before submitting a new prescription.

The mechanisms developed for these pilots and others conducted during the two year process remain in place in their respective states. While preliminary evidence and prescriber reaction were positive, wider implementation and more research will be needed to prove the effectiveness of these methods in increasing prescriber use of PDMP data, leading to appropriate interventions when drug-seeking behavior is discovered. To further encourage the development of innovative health IT integration with PDMPs, SAMHSA awarded nine two-year grants in FY 2011 and is in the process of awarding up to $2.8 million in grants to states this year.[12] As part of these health IT integration efforts, SAMHSA and Office of the National Coordinator for Health IT (ONC) are working with states to explore data standards that would allow PDMPs and health IT systems to be more interoperable. This work is aimed at allowing EHRs to use PDMP data more effectively for clinical purposes.

These and other efforts build upon the foundational 2011 *Plan*, and ONDCP and Federal interagency partners continue to respond to emerging issues, and identify new opportunities to prevent the diversion and abuse of prescription medications.

9. In your testimony, you note that 49 states have laws authorizing PDMPs. Why do Missouri and the District of Columbia not have legislation authorizing PDMPs?

a. Which states have the best PDMP programs?
b. What makes PDMPs effective?
c. Are all PDMPs built upon a similar model?
d. Are there any outstanding PDMPs that have proven to be more successful than others?
e. Would you please explain the importance of state PDMPs being interoperable with other states; PDMPs?

ANSWER:

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[11] MITRE. Connecting Prescribers and Dispensers to PDMPS through Health IT: Six Pilot Studies and Their Impact. 2012. http://www.healthit.gov/sites/default/files/pdmp_pilot_studies_summary_0.pdf

[12] Substance Abuse and Mental Health Services Administration. Cooperative Agreements for Electronic Health Record (EHR) and Prescription Drug Monitoring Program (PDMP) Data Integration. RFA No. TI-13-013. 2013 http://www.samhsa.gov/grants/2013/ti-13-013.pdf.

Missouri and District of Columbia

ONDCP has engaged in discussions with leaders in both the Missouri and the District of Columbia governments about potential legislation to authorize PDMPs in their jurisdictions. Missouri's legislature considered multiple bill proposals during the past legislative session to authorize a PDMP. Two such bills were considered in the Missouri Senate Committee on Veterans' Affairs and Health on March 7, 2013.[13,14] The two bills both included provisions to address concerns expressed by members of the legislature about maintaining the privacy of individuals who are filling prescriptions for controlled substances. The 2013 Missouri legislative session ended on May 17. My office will continue discussions with State leadership in Missouri about the importance of PDMPs in preventing prescription drug abuse and will support their efforts to pass legislation in the 2014 legislative session.

With advice and encouragement from ONDCP, the Washington D.C. Department of Health and the Mayor's office have worked with the Washington D.C. City Council to develop a proposal that would authorize a District-wide PDMP. As a result of their efforts, City Council Chairman Mendelson introduced legislation in February 2013 that would authorize a PDMP.[15] The Council's Committee on Health held a public hearing on July 12 and heard extensive witness testimony in support of the legislation.[16] We are hopeful that the District of Columbia will soon authorize the creation of a PDMP.

PDMP Models

All state PDMPs are built upon a general model. They collect information reported electronically by dispensers of controlled medications to a database managed by the state. PDMPs give certain persons or agencies access to the information, often through a web portal, in order to deter the over-dispensing of prescription drugs.

However, there are some important variations within this common state PDMP structure. States have different requirements about how frequently dispensers must report to the state PDMP, ranging from real-time reporting to monthly reporting.[17,18] Importantly, state PDMPs also vary in terms of which agency they assign to house and manage the database. Some states house their PDMP in one of their law enforcement divisions, such as their Bureau of Narcotics[19] or their

[13] Missouri Senate, Missouri Senate Bill 233, Bill Status. http://www.senate.mo.gov/13info/BTS_Web/Bill.aspx?SessionType=R&BillID=17590490

[14] Missouri Senate Bill 146, LR Number 0976S.01I. http://www.senate.mo.gov/13info/BTS_Web/Bill.aspx?SessionType=R&BillID=17254382

[15] Council of the District of Columbia, Legislative Information Management System, Legislation, Legislation No. B20-0127. http://dcclims1.dccouncil.us/lims/legislation.aspx?LegNo=B20-0127.

[16] Council of the District of Columbia. Council Hearing Archive. Committee on Health, Public Hearing, Yvette M. Alexander, Chairperson, July 12, 2013. http://dccouncil.us/granicus/archive/.

[17] Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obndd/Prescription_Monitoring_Program/

[18] Alaska Prescription Drug Monitoring Program. Dispenser Information. http://www.alaskapdmp.com/dispenser/

[19] Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obndd/Prescription_Monitoring_Program/

Attorney General's office.[20] Other states house their database in the Department of Public Health,[21] the State Board of Pharmacy,[22] or State medical licensing boards.[23]

States also vary in how they obtain funds for running their PDMP. Some states rely solely on Federal grant monies and private donations, expressly prohibiting the use of State funds.[24] In addition to Federal grants, states fund their PDMPs with general funds, licensure fees, and civil and administrative recoveries. BJA recently released a technical assistance document on funding options for state PDMPs developed by the Prescription Drug Monitoring Program Training and Technical Assistance Center.[25] This document provides helpful tips to states on ways that other states have supported their PDMPs with funding.

Effective PDMPs and State Examples

New research shows that relative to states without PDMPs, states with PDMPs mitigate the prevalence of prescription opioid abuse and misuse in both the general population and among those in opioid treatment programs.[26] Although some states' PDMPs have existed for several years, many are early in the establishment and implementation process. As a result, there is a paucity of available research on effectiveness and outcomes of implementing specific PDMP features. In September 2012, the Prescription Monitoring Program Center of Excellence at Brandeis University, a BJA-funded program, published a paper of PDMP best practices.[27] This paper examined observations about PDMPs from peer-reviewed journals and developed 35 potential best practices for PDMPs. However, the authors noted that there are major gaps, such as a lack of randomized control trials, systematic reviews, or meta-analyses that need addressing in future research.[28] Based on Brandeis's analysis and the underlying research on PDMPs, the following list represents what the ONDCP believes are promising practices, which, if enacted, would improve the utility of PDMPs as public health tools. The ensuing discussion includes examples of state PDMPs that illustrate these practices:

1. Access to and regular consultation of PDMPs by prescribers and other healthcare professionals;

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[20] State of California Dept. of Justice, Office of the Attorney General. CURES/PDMP. http://oag.ca.gov/cures-pdmp

[21] Rhode Island Department of Health. Prescription Drug Monitoring Program. http://www.health.ri.gov/programs/prescriptionmonitoring/

[22] Health Information Designs. Colorado Prescription Monitoring Program. http://www.hidinc.com/copdmp

[23] State of Indiana Professional Licensing Agency. Indiana Scheduled Prescription Electronic Collection and Tracking Program (INSPECT). http://www.in.gov/pla/inspect/index.htm

[24] Revised Statutes of the State of New Hampshire (Title XXX, Ch. 318-B) § 318-B:32: "II. All costs incurred by the board for the implementation and operation of the program shall be supported through grants, gifts, or user contributions. The board may charge a fee to individuals who request their own prescription information. The amount charged for an individual's request for his or her prescription information shall not exceed the actual cost of providing that information. III. There shall be no state general funds appropriated for the implementation or operation of the program."

[25] PDMP Training and Technical Assistance Center. Funding Options for Prescription Drug Monitoring Programs. 2013 http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf

[26] Reifler LM, Droz D, Bailey JE, Schnoll SH, Fant R, Dart RC, Bucher Bartelson B. Do prescription monitoring programs impact state trends in opioid abuse/misuse? Pain Medicine 2012; 13: 434–442.

[27] Clark T, Eadie J, Kreiner P, Strickler G. Prescription Drug Monitoring Program Center of Excellence. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. September 20, 2012, http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf.

[28] *Ibid* at 64

2. Real- or near-real-time collection and reporting of prescription drug data;
3. Unsolicited reporting of prescription drug use information to prescribers and pharmacists;
4. Access by researchers and medical examiners to individual-level PDMP data for surveillance/research;
5. Interstate data sharing/harmonization and interoperability of data across states.

Access to and consultation of PDMPs by prescribers and other healthcare professionals: Not all states currently allow or encourage prescribers and/or dispensers to access the data. In Pennsylvania, for example, State law does not allow prescribers to access the PDMP; it is solely used as law enforcement tool.[29] States that do allow access approach giving access differently. In some states, registration and access are completely optional.[30] In other states, such as Kentucky, access is mandatory before prescribing or dispensing controlled substances.[31] Regardless of whether or not states require checking the PDMP, states will not experience the full benefit of these databases unless prescribers and pharmacists use the data as an opportunity to intervene and help individuals get treatment for addiction. As mentioned previously, states that are working to improve prescriber access to their PDMPs through electronic health records have had some success in making access to the information a part of the prescriber's existing workflow. These technological developments will continue to be important both in states where access is required to prescribe certain controlled substances and in states where access to the data remains optional.

Some states only give PDMP access to providers who have controlled substance prescription privileges. PMDP legislation in Maryland, Indiana, North Dakota, Utah, and Colorado authorizes PDMP access to providers other than prescribers.[32,33,34,35,36] Providers who do not

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[29] Title 28 PA Consolidated Statute, Chapter 25, Subchapter A, Section 25.131 available at http://www.pacode.com/secure/data/028/chapter25/chap25toc.html#25.131. See also http://www.attorneygeneral.gov/drugs.aspx?id=5946

[30] Criminal Offenses (720 ILCS 570), Illinois Controlled Substances Act. http://www.ilga.gov/legislation/ilcs/ilcs5.asp?ActID=1941&ChapterID=53

[31] Kentucky (Title 18, Chapter 218A) § 218A.202: "(2) A practitioner or a pharmacist authorized to prescribe or dispense controlled substances to humans shall register with the cabinet to use the system provided for in this section and shall maintain such registration continuously during the practitioner's or pharmacist's term of licensure and shall not have to pay a fee or tax specifically dedicated to the operation of the system . . . . (1) Prior to the initial prescribing or dispensing of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a practitioner shall: . . . (b) Query the electronic monitoring system established in Section 4 of this Act for all available data on the patient;"

[32] Maryland (Title 21, Subtitle 2A) § 21-2A-06: "(b) The Program shall disclose prescription monitoring data, in accordance with regulations adopted by the Secretary, to: . . . (5) A rehabilitation program under a health occupations board, on issuance of an administrative subpoena Maryland Senate Bill Page 13 line 30 linked to May 24, 2012. http://mlis.state.md.us/2011rs/bills/sb/sb0883t.pdf

[33] Indiana (Title 35, Article 48, Chapter 7) § 35-48-7-11.1: "(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons: . . . (8) A substance abuse assistance program for a licensed health care provider who: (A) has prescriptive authority under IC 25; and (B) is participating in the assistance program

[34] North Dakota (Title 19, Chapter 19-03.5) § 19-03.5.03: "3. Unless disclosure is prohibited by law, the board may provide data in the central repository to: . . . j. A licensed addiction counselor for the purpose of providing services for a licensed treatment program in this state

[35] Utah CONTROLLED SUBSTANCE DATABASE ACT 58-37f-301. 2. Access to database.(i) a mental health therapist, if: (i) the information relates to a patient who is: (A) enrolled in a licensed substance abuse treatment program; and (B) receiving treatment from, or under the direction of, the mental health therapist as part of the

prescribe controlled substances, such as counselors, may use PDMP data to identify patients who are continuing to access controlled substances while they are pursuing treatment, and intervene appropriately.

Real- or near-real-time collection and reporting of prescription drug data:
As health providers, dispensers, and others begin to use PDMPs and are given better access to them, it is important for states to ensure that they have access to as accurate a list of the prescriptions dispensed as possible. Any lag time between the prescription being dispensed, and being recorded in the PDMP presents an opportunity for pill mills and doctor shoppers to evade detection. State law mandates that dispensers report prescribing data to the PDMP anywhere from instantaneously to monthly.[37,38] Oklahoma was the first state to require "real time" reporting, or within 5 minutes of delivery of the substance, starting in January 2012.[39] While it is too early to measure the effectiveness of real time reporting, prescribers have voiced concern with relying on PDMP data when there is substantial lag time. As a result, real-time reporting may provide another incentive for prescribers and dispensers to check and use the PDMP data.

Unsolicited reporting of patients' prescription drug use information to prescribers and pharmacists:
States report data from their PDMPs to those authorized to see it in two different ways: "solicited" and "unsolicited." Solicited reports are those that the PDMP returns upon an authorized request. For example, a prescriber might log on to the PDMP through a web portal and type in identifying information about a patient to retrieve the list of controlled substances dispensed to that patient. Unsolicited reports are sent from the PDMP, either manually or in an automated fashion, to specific persons authorized by State law when a pre-determined threshold of excessive dispensing is met. While it is very important for PDMPs to offer solicited reports, unsolicited reports provide a way to inform prescribers, dispensers, licensing board employees, and other users about excessive prescribing and dispensing even if they do not check the PDMP regularly. States such as Nevada have created an automated mechanism to trigger the creation of an unsolicited report to a prescriber when a patient exceeds a pre-established threshold for the number of providers and pharmacies visited within a given time period.[40] A study of Wyoming's

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patient's participation in the licensed substance abuse treatment program described in Subsection (2)(i)(i)(A);(ii) the information is sought for the purpose of determining whether the patient is using a controlled substance while the patient is enrolled in the licensed substance abuse treatment program descried in Subsection (2)(i)(i)(A); and (iii) the licensed substance abuse treatment program described in Subsection (2)(i)(i)(A) is associated with a practitioner who: (A) is a physician, a physician assistant, an advance practice registered nurse, or a pharmacist; and (B) is available to consult with the mental health therapist regarding the information obtained by the mental health therapist, under Subsection (2)(i), from the database http://www.dopl.utah.gov/programs/csdb/58-37f_2012-01-01.pdf

[36] Colorado (Title 12, Article 22, Part 7) § 12-22-705: "(3) The program is available for query only to the following persons or groups of persons:. . . (c) Practitioners engaged in a legitimate program to monitor a patient's controlled substance abuse

[37] Alaska Prescription Drug Monitoring Program. Dispenser Information. http://www.alaskapdmp.com/dispenser/Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obndd/Prescription_Monitoring_Program/

[38] Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obndd/Prescription_Monitoring_Program/

[39] Ibid.

[40] Prescription Monitoring Program Center of Excellence at Brandeis, Notes from the Field 2.5 Nevada's Proactive PMP: The Impact of Unsolicited Reports http://www.pmpexcellence.org/sites/all/pdfs/nevada_nff_10_26_11.pdf

PDMP showed that unsolicited reports can increase the frequency with which practitioners request solicited reports from the PDMP, suggesting that unsolicited reporting raises awareness about the database and its usefulness to providers.[41]

Access by researchers and medical examiners to individual-level PDMP data for surveillance/research:
PDMP data, particularly when combined with data from other sources, can provide researchers and state officials with valuable information about the scope and location of prescription drug abuse. For example, epidemiologists in Utah matched individual patient death records and poison control center data to individual PDMP records to identify a range of issues, including the source of the medication involved with overdose deaths.[42] Researchers in New Mexico similarly used PDMP data to show that some types of controlled prescription drugs presented a higher risk of overdose than others and that certain doses or combinations of controlled medications were also particularly risky.[43] Access to individual-level PDMP data, consistent with applicable privacy safeguards, permits a fuller understanding of the extent of the prescription drug abuse problem.

State Interoperability
While prescription drug monitoring programs have shown positive effects within states, doctor shoppers and pill mills can evade detection by doing business across state lines. A recent study showed that "shoppers" of opioids travelled a median of over 83 miles to obtain their prescriptions in 2008. Almost 20% of these individuals travelled across state lines.[44] The study concluded that effective data sharing between state PDMPs may improve program effectiveness in reducing opioid shopping behavior.

BJA, the Office of the National Coordinator for Health Information Technology (ONC) at HHS, and private entities, such as the National Association of Boards of Pharmacy (NABP) and the Alliance of States with Prescription Monitoring Programs, have worked on architecture and standards to allow the interoperability needed for interstate data sharing. There are currently 15 states that are sharing information through the PMP InterConnect hub, established by the NABP using the standards developed with the support of BJA and the Alliance of States with Prescription Monitoring Programs.[45] In addition to the data being shareable across state lines, it is essential that practitioners be allowed by state law to access the prescription information from states in which they are not licensed. Some state PDMP laws currently do not allow the sharing PDMP data to prescribers in other states.

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[41] PMP Center of Excellence, "Trends in Wyoming PMP prescription history reporting: evidence for a decrease in doctor shopping?" 2010. http://www.pmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf.
[42] Sims SA, Snow LA, Porucznik CA. Surveillance of methadone-related adverse drug events using multiple public health data sources. J Biomed Inform. 2007 Aug;40(4):382-9
[43] Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG, Harvey W, Loring LD. A history of being prescribed controlled substances and risk of drug overdose death. Pain Med. 2012 Jan;13(1):87-95
[44] Cepeda MS, Fife D, Yuan Y, Mastrogiovanni G, Distance Traveled and Frequency of Interstate Opioid Dispensing in Opioid Shoppers and Nonshoppers. J Pain. 2013 Jun 19. pii: S1526-5900(13)00992-9. "Shoppers" was defined in the study as individuals who fill more than three opioid prescriptions from multiple doctors in at least three different pharmacies with at least one day of overlap.
[45] National Association of Boards of Pharmacy. NABP PMP Interconnect Map. June 28, 2013. http://www.nabp.net/system/redactor_assets/documents/569/_Set_41__WI_and_NE_6-28-13.pdf.

Conclusion

Improving PDMP quality, harmonization, and interoperability and, in some cases, establishing PDMPs authorized by newly-passed state laws will ensure they provide maximal utility as surveillance and public health clinical decision support tools, augmenting their initial use as enforcement tools.

The Honorable Bill Cassidy and H. Morgan Griffith

An L.A. Times investigation recently uncovered that a small number of doctors were responsible for most of the prescription drug overdose deaths between 2006 and 2011 in Los Angeles, Orange, Ventura and San Diego counties of California. The investigation consisted of examining publicly available cause-of-death, toxicology reports and other information in county coroners' files, including lists of prescription medications found at death scenes. If an L.A. Times reporter can uncover provider-specific data on inappropriate prescribing of prescription drugs from publically available data, why can't the federal or state governments do so as effectively with even more robust data monitoring tools?

ANSWER: The recent *Los Angeles Times* investigative report did much to bring the Nation's attention to the problem of prescription drug overdose. Unfortunately, many of the data sources used by the *Times*' reporters are not consistently collected or uniformly available to the public across jurisdictions. For reporting on overdose deaths, the Federal Government relies upon cause of death data compiled by the Centers for Disease Control and Prevention (CDC) from death certificates prepared by local coroners and medical examiners. These death certificates do not routinely provide the level of detail, such as specific drugs that may have been involved in a death, which was reported in the *Times*. This is especially true with respect to scene of death investigations and provider-specific data on inappropriate prescribing, and these sorts of data have been proven to be of great value in determining the extent of this problem. In 2009, the CDC and local public health and safety officials investigated overdose deaths in West Virginia and found results similar to those reported by the *Times*.[46] However, such special investigations are labor intensive, costly, and dependent upon close collaboration with local authorities and access to the data.

The Administration is committed to working with partners at the state and local level to identify and address all pathways of diversion, including "pill mills" and improper prescribing. Innovative enforcement strategies, particularly those involving collaboration across Federal, state, and local agencies, are helping many communities shut down these illegal operations.

In accordance with state laws, prescription drug monitoring program (PDMP) information may also be used by state regulatory and law enforcement officials to pursue cases involving prescribers or pharmacists operating outside the bounds of proper practice, "pill mills," and other sources of diversion. But these important programs can function more effectively. We are working with our Federal partners and states to make these systems more user-friendly so that agencies tasked with detecting fraud, such as medical boards and licensing agencies can access or receive PDMP information more quickly and easily. Additionally, the Drug Enforcement Administration makes its registrant database available to any state, without a fee, for use in their PDMP or other state agency charged with investigating health care fraud or controlled substance diversion.

[46] Paulozzi LJ, Logan JE, Hall AJ, McKinstry E, Kaplan JA, Crosby AE. A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia. Addiction 2009;104(9):1541-8.

Also, increased reporting and access to PDMP information from entities outside of law enforcement and prescribers can be useful. Some states have allowed medical examiners to access individual level PDMP data. This access allows them to make comparisons to other information, such as death records, which can help in determining a cause of death and detecting "pill mill" operations.

In addition, the National Institute of Justice awarded three new grants in FY 2012 to promote research on illegal prescription drug market interventions: Identifying High Risk Prescribers Using PDMP Data: A Tool for Law Enforcement; Non-Medical Use of Prescription Drugs: Policy Change, Law Enforcement Activity, and Diversion Tactics; and Optimizing Prescription Drug Monitoring Programs to Support Law Enforcement Activities. These grants are enabling Federal, state, and local law enforcement agencies to better use data and share best practices to shut down sources of diversion.

Further, CDC is analyzing various data sources to identify appropriate metrics for outlier prescribers. CDC is also working with Brandeis PDMP COE to validate these metrics using various state and national data sources.

The Honorable Gus Bilirakis

1. Recently, there was a drug summit in Pasco County, FL where public health officials were talking about the growing problem of babies born addicted to prescription drugs. The Pasco-Pinellas area ranks first in the state for babies born addicted. What tools, programs and grants are available for my community to combat this problem?

ANSWER: The Federal Government supports state and local efforts to help prevent and treat the growing problem of babies born exposed to prescription drugs. The Attachment lists grant programs awarded to state and local groups in Florida in FY 2012 that could be used in part to help reduce drug use. Highlighted below are a few specific Federal programs that target prescription drug abuse and treatment of prescription drug dependence both in the mothers and their newborns:

Department of Health and Human Services

- **Administration for Children and Families - Promoting Safe and Stable Families Program:** Provides competitive grants for regional partnerships to provide services and activities to work with children and families impacted by a parent's or caretaker's substance abuse.

- **Center for Medicare and Medicaid Services - Medical Assistance Program - Grants to States for Medicaid:** Shares the cost for Medicaid services which may include the treatment of prescription drug dependence both in the mothers and their newborns.

- **Health Resources and Services Administration - Healthy Start Initiative -** provides for universal risk screening of pregnant women and newborn infants to identify those at risk of poor birth, health and developmental outcomes. Healthy Start includes targeted support services that address identified risks including prevention and treatment of prescription drug dependence both in the mothers and their newborns.

- **National Institutes of Health - Drug Abuse and Addiction Research Programs:** Provides research into the prescription drug abuse and prevention and treatment of prescription drug dependence both in the mothers and their newborns.

- **Substance Abuse and Mental Health Services Administration (SAMHSA) - Block Grants for Prevention and Treatment of Substance Abuse:** Provides states with flexible funding which can be allocated to localities for the prevention and treatment of prescription drug dependence both in the mothers and their newborns.

- **SAMHSA - Projects of Regional and National Significance - Cooperative Agreement for the Physician Clinical Support System for the Treatment of Substance Use Disorders with Buprenorphine:** The SAMHSA-funded Physician Clinical Support System (PCSS) is designed to assist practicing physicians, in accordance with the Drug Addiction Treatment Act of 2000, in incorporating into their practices the treatment of prescription opioid and heroin dependent patients using buprenorphine.

- **SAMHSA - Projects of Regional and National Significance - Cooperative Agreement for the Physician Clinical Support System for Medication Assisted Treatment.** The SAMHSA-funded Physician Clinical Support System (PCSS-MAT) is designed to assist physicians interested in incorporating into their practice the treatment of prescription opioid addicted patients using Food and Drug Administration approved medications (buprenorphine, methadone and naltrexone (oral and extended release).

- **SAMHSA - Projects of Regional and National Significance - Screening, Brief Intervention and Referral to Treatment:** Supports a health system-level approach to screening and brief intervention within primary care, general medical and community settings—including physician offices, hospitals, educational institutions, and mental health centers including screening for prescription drug dependence both in the mothers and their newborns.

- **SAMHSA - Projects of Regional and National Significance - Pregnant & Postpartum Women Residential Treatment for Pregnant and Postpartum Women and Residential Treatment for Women and their Children:** Provides cost effective, comprehensive, coordinated systems of care to improve outcomes for the entire family that can be sustained over time. To accomplish this comprehensive service system, it is necessary to partner with multiple systems of care. These partnerships include agencies/organizations such as local public housing authorities (for permanent housing for families), child welfare, health, mental health, family court, criminal justice, employment, education programs, and child-serving agencies.

More information on each of these efforts is available on the agency web sites.

2. What changes can we make to our prescription drug laws to make it harder for people to improperly obtain and abuse prescription drugs?

ANSWER: It is clear that we are not doing enough to prepare our health care providers to adequately address pain management, substance abuse, and use safe prescribing practices. As many healthcare providers would agree, managing a patient's pain is a crucial and often very difficult task. However, research indicates that students in medical school receive on average only 11 hours of training on pain education, and most schools do not offer specific training on opioids, substance abuse and addiction, or clinical decision making.[47] A 2011 Government Accountability Office report on education efforts related to prescription pain reliever abuse found that "most prescribers receive little training on the importance of appropriate prescribing and dispensing of prescription pain relievers, on how to recognize substance abuse in their patients, or on treating pain."[48]

[47] Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.
[48] U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: http://www.gao.gov/assets/590/587301.pdf

For these reasons, the Administration continues to support mandatory education on proper prescribing and addiction potential for prescribers and dispensers of these controlled substances, including for prescribers working for the Federal Government. Several states, including Iowa,[49] Massachusetts,[50] and Utah,[51] have passed mandatory prescriber education legislation, and we strongly encourage other states to explore this as an option.

[49] Iowa Board of Medicine. "New rules require physicians to complete training on chronic pain, end-of-life care." State of Iowa. [August 2011]. Available: http://medicalboard.iowa.gov/Board%20News/2011/New%20rules%20physicians%20to%20complete%20training%20chronic%20pain_08182011.pdf

[50] Executive Office of Health and Human Services. "PMP and Mandatory Educational Requirements for Prescribers." Commonwealth of Massachusetts. [October 2011]. Available: http://www.mass.gov/eohhs/provider/licensing/occupational/dentist/pmp-and-mandatory-educational-requirements-for-pre.html

[51] Utah Division of Occupational and Professional Licensing. *Utah Controlled Substances Act, 58-37-6.5*. State of Utah. [May 2012]. Available: http://www.dopl.utah.gov/laws/58-37.pdf#page=24

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July 10, 2013

Dr. Doug C. Throckmorton
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Throckmorton:

Thank you for appearing before the Subcommittee on Health on Friday, June 14, 2013, to testify at the hearing entitled "Examining the Federal Government's Response to the Prescription Drug Abuse Crisis."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, July 24, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 26 2013

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the June 14, 2013, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Examining the Federal Government's Response to the Prescription Drug Abuse Crisis." This letter provides responses for the record to questions posed by you and one of the Committee Members, Congressman Bilirakis, which we received on July 10, 2013.

If you have further questions, please let us know.

Sincerely,

Sally Howard
Deputy Commissioner
Policy, Planning, and Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking member

We have restated your questions below in bold, followed by our responses.

The Honorable Joseph R. Pitts

1. **FDA has taken a number of steps this year to encourage the development of abuse-deterrent opiates and to protect the public from being inundated with non-abuse-deterrent versions of those safer products once they have been introduced to the market. There remains the threat, however, that drug makers continue to seek approval of new opiate products that have no abuse-deterrent features. Last December, one such product was brought before an FDA advisory panel which voted 11 to 2 against approving the product, in part because it would have been readily crushable and abusable just as OxyContin used to be. An agency spokesperson at the meeting (Rappaport), however, expressed uncertainty whether the FDA is legally empowered to refuse to approve a new opiate drug product on the ground that it lacks abuse deterrent features.**

    a. **Has the agency, since last December, decided whether it has the legal authority to accept its own expert advisory panel recommendation and refuse to approve a new opiate drug product on the ground that it lacks abuse deterrent features considered necessary to the safety of the drug?**

    FDA shares your concerns regarding prescription drug abuse, including the abuse of opioid analgesics. Your question references the December 7, 2012, meeting of the Anesthetic and Analgesic Drug Products Advisory Committee, which focused on a specific pending application. Under applicable statutory and regulatory provisions, we are generally prohibited from disclosing information about any pending new drug application (NDA).

    FDA is strongly committed to finding ways to reduce abuse and misuse of opioid medications. As part of our ongoing mission to protect the public health, we often seek advice from advisory committees on a wide range of medical and technical issues. Advisory committees are comprised of outside experts with a broad range of expertise and different backgrounds. Advisory committee recommendations are not binding on the Agency; however, they are considered carefully. When considering whether to approve a proposed new opioid drug product, FDA must determine if the product meets the statutory approval standard, which is whether the product has been shown to be safe and effective. In addition, the Agency considers the known risks associated with the drug along with the potential benefits the drug will provide. While we consider the views of advisory committee members, ultimately FDA must review and evaluate the science and determine whether the product that is the subject of a given new drug application meets this approval standard.

b. Is there a need for legislation to clarify that FDA has this authority?

The Administration has taken no position on the need for legislation in this area.

2. FDA provided guidance in January on the development and testing of new abuse-deterrent opiate drugs. However, my understanding is that it has so far chosen not to develop guidance on the requirements for approval of generic versions of abuse-deterrent drugs.

a. Why did the agency choose not to issue guidance on the development and testing of abuse-deterrent generic drugs?

It is correct that FDA has not issued guidance on the development and testing of generic versions of drugs with abuse-deterrent properties. However, FDA is actively working on the scientific and regulatory issues surrounding the development and evaluation of abuse-deterrent generics, and we may address this topic in future guidance documents.

Providing guidance in this area needs to be a sequential process, beginning with guidance on the development of abuse-deterrent products by innovators. We understand the critical role generics play in our health care system and that the issues around the development of generics that are abuse-deterrent need to be addressed.

b. How is the agency assuring that generic versions of abuse-deterrent drugs have the same abuse-deterrence features as the innovator products they would substitute for?

FDA has been working internally on the scientific and regulatory issues surrounding development and evaluation of abuse-deterrent generics. In addition, FDA will be presenting at an upcoming meeting focused on issues concerning development and evaluation of abuse-deterrent generics. The public meeting, "Abuse Deterrent Formulation Science Meeting on the FDA Draft Guidance," has been organized by Cross Company Abuse Liability Consortium and will be held on September 30-October 1, 2013.[1]

FDA may also address this topic in future guidance documents.

c. How does the agency intend to publicize the requirements for abuse-deterrent generic drugs so that generic drug makers can design and test their products accordingly and the public can have confidence that appropriate standards are being applied?

FDA may address this topic in future guidance documents.

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[1] See *www.adfsciencemeeting.com*

3. **As you are aware, DEA's current strategy of attempting to curb prescription drug abuse is what they call a "chokepoint" approach, in which they are targeting prescription drug wholesalers and chain pharmacies with enforcement actions to restrict the amount of controlled substances being provided to patients. I am hearing that this is causing significant problems for patients with chronic pain to access their critical pain medications. What is your agency doing to ensure that patients continue to have access to critical pain medications? If people who use these medications legitimately are having problems accessing them, to whom should they report the information?**

   Under the Controlled Substances Act (CSA), the authority for quota-setting for controlled substances is vested with the Drug Enforcement Agency (DEA), not FDA. However, FDA provides DEA with information to aid in the process. FDA determines annual estimates of medical need for the drugs listed in Schedule II of the CSA.

   The estimates of medical needs for each Schedule II active pharmaceutical substance are provided to DEA to assist them in setting manufacturing and production quotas. The estimates of medical need for each substance are derived from previous years' sales data. In addition to projecting estimates, FDA also provides information it has received that relates to newly approved drug products on the market as well as discontinued drug products that are no longer available. In this way, DEA will have current, up-to-date information to assist them in setting the appropriate quotas for each substance.

   If FDA is informed about a possible shortage of a drug, FDA informs DEA so that DEA can revise the quota, if appropriate. If patients are experiencing difficulty obtaining their prescribed medications because of a shortage of the drug, FDA's Drug Shortage Staff (DSS) may be contacted at drugshortages@fda.hhs.gov. DSS will provide information about how to obtain the drug if it is available and, if there is a shortage, will work to address it with the manufacturer.

   In addition, individuals can contact the Board of Pharmacy in their state to report problems accessing medications.

4. **How is interagency development of REMS for controlled substances coordinated? For example, how is DEA brought in to ensure that a REMS will not conflict with DEA's regulations? Does FDA consult with SAMHSA and/or the HHS-Office of Civil Rights on REMS compliance with HIPAA and other privacy laws regarding information about controlled substances? Finally, how is it ensured that controlled substance REMS do not put pharmacists in the untenable position where compliance with a REMS would require violating state controlled substance or state pharmacy laws?**

   FDA has and will continue to consult with other agencies as needed to ensure that a Risk Evaluation Mitigation Strategy (REMS) will not conflict with other Federal

laws, such as the CSA. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) participated in reviewing the syllabus for the prescriber education programs under the REMS for extended-release and long-acting (ER/LA) opioids. As part of the Office of National Drug Control Policy (ONDCP), National Drug Control Strategy, FDA and SAMHSA have been working together with other Federal partners to explore mandatory prescriber education.

FDA strives to craft REMS in a way that is specific enough to ensure that the benefits of a drug outweigh its risks, but general enough to avoid conflict with state pharmacy or other laws.

The Honorable Gus Bilirakis

1. **What changes can we make to our prescription drug laws to make it harder for people to improperly obtain and abuse prescription drugs?**

Combating opioid misuse, abuse, and addiction has long been a priority for the FDA. As a scientific and public health regulatory agency, FDA's approach to regulation of prescription opioids must be grounded in science; specifically we must bring to bear the best available knowledge and understanding concerning both the treatment of pain and the potential adverse consequences of opioid use.

Over the last decade or so, under its existing authorities within the FD&C Act, FDA has worked to pursue a targeted, science-based, multi-pronged approach that addresses misuse, abuse, and addiction at critical points in the development of an opioid product and in its use throughout the health care system.

We would like to highlight three areas of recent activity within a broader comprehensive approach:

Abuse-deterrent formulations: FDA is committed to finding ways to reduce abuse and misuse of opioid medications. As part of our ongoing mission to protect public health, FDA has concluded that if the Agency determines that a formulation of an extended-release opioid drug product has abuse-deterrent properties, the Agency has authority under the FD&C Act to require generic versions of the product to have abuse-deterrent properties also. In addition, we have the authority to refrain from approving non-abuse-deterrent formulations of that drug and to initiate procedures to withdraw non-abuse-deterrent versions already on the market.

FDA recently made a determination regarding a drug reformulated with the intention of deterring misuse and abuse: OxyContin ER (oxycodone hydrochloride). After an extensive, science-based review, on April 16, 2013, FDA approved product labeling describing reformulated OxyContin's properties that are expected to make abuse via injection difficult and to reduce abuse via the intranasal (snorting) route. The Agency also concluded that the benefits of the earlier formulation that lacks abuse-deterrent properties no longer outweigh its risks, and that the earlier formulation of OxyContin

was withdrawn from the market for reasons of safety or effectiveness. That determination precludes approval of generic versions of the earlier formulation of OxyContin.

This decision was the subject of extensive consideration by FDA experts over the course of many months. FDA's decision took into account the totality of the evidence for OxyContin.

Improving appropriate use of opioids through prescriber education: It is critically important to improve prescribers' knowledge about the best uses of opioids, including knowing when these products should be used and by which patients. Thus, prescriber education is an important element of FDA's REMS for ER/LA opioids. Under the ER/LA opioid REMS, manufacturers are required to ensure that prescriber training programs—offered by accredited continuing education providers—are made available for all U.S.-licensed prescribers, using a syllabus developed by FDA with input from many stakeholders. As a part of our assessment of this REMS, these courses will be audited to ensure that they are unbiased and accurate. The first of these voluntary prescriber training programs was rolled out on March 1, 2013.

While voluntary training is an important public health measure, a new law requiring mandatory training would go even further to help ensure the safe use of opioid drugs. That is why the Administration stated in *Epidemic: Responding to American's Prescription Drug Abuse Crisis*[2] that it will work with Congress to amend Federal law to require practitioners who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registering and receiving their license to prescribe a controlled substance.

Improving the availability of products to treat abuse and overdose: FDA has been working with many stakeholders to explore the best ways to treat overdoses of opioids, including overdoses of FDA-approved opioid medications. Each year, prescription opioid medications are involved in over 15,000 deaths. Naloxone is an injectable medication that is the standard treatment to rapidly reverse the overdose of either prescription (e.g., oxycodone) or illicit (e.g., heroin) opioids. Naloxone is most commonly used by trained medical personnel in emergency departments and on ambulances. There is a growing interest by prescribers, patients, and advocates in exploring the broader uses of naloxone, including its use in non-medical settings such as nursing homes and hospices.

FDA, working with other parts of the Federal Government, is looking at new ways of giving naloxone that are potentially easier and do not require needles or syringes. The goal of this work is to expand the availability of naloxone in the places patients might overdose, and make it easier to administer to save lives. For example, FDA can grant priority review to products that involve new ways of delivering naloxone, such as using autoinjectors or intranasally, that would be easier to use in non-medical settings.

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[2] *http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf*

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July 9, 2013

Dr. H. Westley Clark
Director
Center for Substance Abuse Treatment
Substance Abuse and Mental Health
Services Administration
1 Choke Cherry Road
Rockville, MD 20857

Dear Dr. Clark:

Thank you for appearing before the Subcommittee on Health on Friday, June 14, 2013, to testify at the hearing entitled "Examining the Federal Government's Response to the Prescription Drug Abuse Crisis."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, July 23, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Dr. H. Westley Clark, Director, SAMHSA Center for Substance Abuse Treatment
Responses to Questions for the Record
Energy and Commerce Committee, Subcommittee on Health Hearing
June 14, 2013
"Examining the Federal Government's Response to the Prescription Drug Abuse Crisis"

The Honorable Joseph R. Pitts

1. **The Center for Substance Abuse Treatment (CSAT) recently released an RFA for a "Physician Clinical Support System – Medication Assisted Treatment" to support physician education on the use of medication to treat opioid addiction. The RFA states "...the number of people who have been inducted to extended release injectable naltrexone remains relatively low" and that "...training in the appropriate use and indications for extended release injectable naltrexone is highly needed." How does CSAT plan to expand its efforts to increase awareness and knowledge about this medication?**

   The new Substance Abuse and Mental Health Services Administration (SAMHSA) Physician Clinical Support System - Medication Assisted Treatment (PCSS-MAT) grant will increase prescribers' awareness and knowledge about extended release naltrexone (Vivitrol ®) by providing training opportunities that utilize several different formats including online modules, case studies, webinars and others. These activities are expected to reach approximately 30,000 physicians over the three years of the grant period.

2. **Earlier this year SAMHSA reported that "Hospital emergency department visits linked to buprenorphine have increased 10-fold from 2005 to 2012 with 52 percent of these emergency room cases involving non-medical (illicit) use." Likewise, the DEA's Office of Diversion Control reports that buprenorphine is now the 3rd most diverted prescription opioid today, surpassing methadone, and second only to oxycodone and hydrocodone. Given these unintended and other unwelcomed and unanticipated consequences, what is CSAT doing to help reduce the illicit use of this medication?**

   Buprenorphine abuse and diversion are measureable; however, the levels of actual abuse (not adjusted for rate of use) and diversion are noticeably less than other opioids. In addition, certain peer-reviewed studies looking at buprenorphine diversion and nonmedical use indicate that some of this use is occurring because people do not have access to substance abuse treatment.

   SAMHSA is currently updating the agency's buprenorphine curriculum. The new curriculum has a specific section addressing the issue of non-medical (illicit) use. The revised curriculum, titled "The DATA 2000 Waiver Course," will emphasize the importance of using state prescription drug monitoring programs prior to and over the

course of treatment as well as appropriate use of buprenorphine products in the treatment of opioid dependence. The importance of toxicology screening, of requiring psychosocial treatment in addition to medication use, appropriate dose determination, and methods of monitoring progress in treatment which should be considered in setting frequency of office visits and amount of prescribed medication that is provided to a patient will also be emphasized in the curriculum.

3. **SAMHSA supports a number of web-based treatment locators for the professional community and the general public. We found one that lists methadone clinics and one that lists physicians who offer buprenorphine treatment. Does SAMHSA have a similar locator for patients who are seeking extended release naltrexone? What plans does SAMHSA have to provide, on an equal basis, information for accessing all FDA-approved medications to treat opioid dependence?**

   SAMHSA's Behavioral Health Treatment Services Locator (Locator)[1] currently allows referring professionals and the general public to search for facilities that provide medication-assisted opioid therapy with methadone and buprenorphine. The information in the Locator is collected by the National Survey of Substance Abuse Treatment Services (N-SSATS), an annual census of specialty substance abuse treatment facilities. A question on Vivitrol (extended-release injectable naltrexone) was added to the N-SSATS 2013 survey. Thus, the next time the Locator is updated, currently scheduled for early 2014, it will allow visitors to identify facilities that provide treatment with Vivitrol.

4. **In Administrator Hyde's testimony before the Energy and Commerce Committee on Oversight and Investigations Hearing on May 22, 2013, she stated that much of SAMHSA's funding goes to the block grants, which are passed on to the states to fund substance abuse treatment- which is about $1.8 billion for substance abuse prevention and treatment. We understand that a significant portion of addicted individuals relapse to drug use. Further, we understand that for the treatment of opioid dependence, SAMHSA dedicates a great deal of funding, time and effort on the development and delivery of education training activities with respect to substitution, or replacement therapies. Is it within the authority of SAMHSA to provide stronger guidance to states to use some percent of their block grant funds on FDA-approved non-addictive medications?**

   The statute (42 U.S.C. §§ 300x-21 through 300x-66) and implementing regulations (45 CFR 96.120 through 96.137) governing the Substance Abuse Prevention and Treatment Block Grant (SABG) program provide states and jurisdictions with the flexibility to plan, carry out and evaluate activities to prevent and treat substance abuse according to the needs in that state. SAMHSA has provided guidance to the states on the services and levels of care that constitute a full continuum of care which includes medication-assisted treatment. The statute and regulation do not include any prescriptive language regarding any specific service, including pharmacologic therapies. However, in

[1] http://findtreatment.samhsa.gov.

the application guidance for the block grant application (Table 4, page 30), under the heading "SAPT Projected Expenditures for Treatment and Recovery" SAMHSA has clarified that up to 10 percent of the funds available can be used for medication management, pharmacotherapy (including all FDA-approved medications for treating substance use disorders), and laboratory services.

5. **Over the last two fiscal years, SAMHSA has reduced funding of its Opioid Treatment Programs from $12.8 million in FY 2012 to $8.746 million in FY 2014- including a proposed $200,000 reduction in the coming fiscal year. While we applaud the fiscal restraint, we are concerned that funding is being reduced from the opioid Treatment Programs initiatives in particular. Is there a rationale for this particular reduction in light of the prescription drug epidemic and increasing number of opioid overdose deaths?**

   The funding for Opioid Treatment Programs (OTP) in FY 2012 totaled $12.9 million, of which $8.9 million came from SAMHSA budget authority and $4 million from the Prevention and Public Health Fund. In FY 2013, SAMHSA's budget authority for all programs was reduced by 5 percent due to sequestration. However, given the Department of Health and Human Services' priority on prescription drug abuse prevention and treatment, SAMSHA reallocated funds within its appropriation as displayed on its FY 2013 operating plan to include $12.4 million for OTPs.

6. **According to the Drug Abuse Warning Network (DAWN) report released by SAMHSA in July of 2012 emergency department visits for drugs misuse and abuse for pharmaceuticals rose 115% between 2004 to 2010, would you talk about this data and the reason for the increase?**

   Over 80 percent of the annual increase of about 720,000 emergency department (ED) visits for misuse and abuse of pharmaceuticals from 2004 to 2010 is due to increases in the misuse and abuse of two types of medications: prescription opiates and opioids, and benzodiazepines. According to the Centers for Disease Control and Prevention (CDC), this increase in ED visits is paralleled by an increase in opioid and benzodiazepine related overdose deaths. Misuse and abuse of prescription opiate and opioid medications (approximately 350,000 more visits in 2010 than in 2004, an increase of about 175 percent) and benzodiazepines (approximately 235,000 more visits in 2010 than in 2004, an increase of about 140 percent) have caused increasing concern over the last decade. Opiates and opioids and benzodiazepines are safe and effective medications when they are used as directed by the people for whom they are prescribed. However, they are also addictive substances with potential for abuse. It is likely that there are multiple causes contributing to the increase in misuse and abuse of these medications. Some portion may be associated with the greater number of prescriptions being written, making prescription drugs more accessible and able to be diverted and used for nonmedical purposes.

7. **SAMHSA's National Survey on Drug Use and Health revealed an estimated 54% of the prior-year non-medical users of prescription pain relievers obtained the drugs**

for free from a friend or relative where less than 1% reported receiving them from the internet. How do we solve a problem that is primarily happening at home?

SAMHSA has partnered with the National Council on Patient Information and Education on the "Not Worth the Risk – Even If It's Legal" campaign to develop and distribute a comprehensive range of educational and outreach messages encouraging parents to talk to their teens about preventing prescription drug abuse. In addition, SAMHSA has partnered with the Community Anti-Drug Coalitions of America (CADCA) to host Community Prevention Day where participants receive training and technical assistance that is specific to substances abuse prevention including prevention of prescription drug abuse. SAMHSA works with CADCA to get the message out to patients, parents, family members and other involved persons in communities to promote the responsible use of pain medications and other prescription drugs.

SAMHSA's Strategic Prevention Framework – Partnerships for Success II (SPF-PFS II) grant is designed to address two of the nation's top substance abuse prevention priorities: (1) underage drinking among persons aged 12 to 20; and (2) prescription drug misuse and abuse among persons aged 12 to 25. The program promotes the alignment and leveraging of prevention resources and priorities at the federal, state, and community levels. SAMHSA's Drug-Free Communities Support Program grants, in partnership with the Office of National Drug Control Policy (ONDCP), provide funding to support established community-based youth substance use prevention coalitions capable of effecting community-level change.

The SABG is a formula-based grant provided to states and territories to provide financial support for its prevention and treatment programs and services. Federal statute requires states and territories to direct at least 20 percent of the SABG toward substance abuse prevention services. For many states and territories, this funding represents the vast majority of their substance abuse prevention budget. Under the SABG, states are requested to identify the categories of substances, including prescription drugs, they intend to address with the 20 percent set-aside for prevention based on data collected and analyzed from statewide and local needs assessments.

Educating prescribers and dispensers of controlled substance pharmaceuticals on the potential abuse caused by these substances is also critically important as they will, in turn, provide patient education. SAMHSA funded the development of live and online CME courses on Prescribing Opioids for Chronic Pain for providers in consultation with the American Academy of Pain Medicine, Case Western Reserve University School of Medicine, and an independent panel of experts in medical education, pharmacology, pain management, regulation, and addiction. Variations of the course were developed to meet the needs of the Indian Health Service, the military and medical specialties such as emergency medicine.

SAMHSA is working with the Drug Enforcement Administration (DEA) on Take Back programs which provide a safe, convenient, and responsible means of disposing of

prescription drugs. SAMHSA is working with physician and pharmacy groups to promote the adequate education of patients and consumers.

Ultimately, the transformation of attitudes at the local level involves local people. SAMHSA, in conjunction with our colleagues at the National Institutes of Health, the Food and Drug Administration, CDC, and DEA can assist by providing technical assistance to local authorities and local organizations to aid in the shifting in attitudes about the appropriate use, storage and disposal of prescription drugs.

The Honorable Phil Gingrey

1. **Over the past decade, SAMHSA has expended substantial resources in the development and implementation of training, education and demonstration programs with respect to buprenorphine. What plans does SAMHSA have for comparable education and training programs on the injectable naltrexone?**

   The new PCSS-MAT grant will increase prescribers' awareness and knowledge about extended release naltrexone by providing training opportunities that utilize several different formats including online modules, case studies and webinars on the use of naltrexone in both oral and injectable formulations. These activities are expected to reach approximately 30,000 physicians over the three years of the grant period.

2. **On November 30, 2006, SAMHSA released a report entitled "Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators Final Report." At that time, the Summary of the Report stated "*The phenomenon [of diversion] may reflect lack of access to addiction treatment, as some non-medical use [of buprenorphine] appears to involve attempts to self-medicate with buprenorphine when formal treatment is not available.*" As of today, however, buprenorphine appears to be widely available, with well over a million people dosed and sales in the U.S over $1 billion annually. Given the recent reports by the DEA and others, do you agree that an updated review of buprenorphine diversion and abuse is warranted?**

   It is important to note that two publications[2] from 2009 address diversion and abuse of buprenorphine and arrived at essentially the same conclusions as the 2006 SAMHSA report. An updated review of diversion and abuse of buprenorphine is being considered by SAMHSA. At this time, SAMHSA notes that, to be most valuable, a review on diversion and abuse of buprenorphine would need to be designed to assess the degree to which previous recommendations have been implemented and the impact of such activity. Given the N-SSATS 2011 shows a significant unmet need for opioid addiction treatment, any new report should also assess the availability and impact of medication assisted treatment not only on diversion and abuse, but also on overdose fatalities.

3. **How many patients are currently treated each year with the three medications approved by the FDA for the treatment of opioid addiction: buprenorphine, methadone, and injectable naltrexone? Is the "exit strategy" for transitioning opioid dependent Americans who are currently being treated with opioid dependence therapies from physical dependence on opioids to opioids-free and medication-free?**

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[2] Johanson CE, Arfken CL, di Menza S, Schuster CR. Diversion and abuse of buprenorphine: findings from national surveys of treatment patients and physicians. Drug Alcohol Depend. 2012 Jan 1; 120(1-3):190-5. doi: 10.1016/j.drugalcdep.2011.07.019. Epub 2011 Aug 21.
Center for Substance Abuse Research (CESAR) at University of Maryland, "CESAR Fax Special Series: Buprenorphine," June 13, 2011 – September 12, 2011, available at: http://www.cesar.umd.edu/cesar/pubs/20110915%20Buprenorphine%20CESAR%20FAX.pdf.

According to N-SSATS 2011:

- 306,000 persons were receiving methadone for addiction treatment in 2011 through SAMHSA certified OTPs.
- 32,676 persons received buprenorphine through licensed treatment programs. This number includes 7,020 who were in treatment at OTPs and 25,656 who were in treatment at substance abuse treatment facilities that were not OTPs.[3]

SAMHSA does not collect information on how many individual patients are treated with buprenorphine outside of licensed treatment facilities or with injectable naltrexone.

SAMHSA sponsored programs provide education to physicians on clinical strategies to taper and discontinue opioids including opioid analgesics or heroin, but research consistently indicates high relapse rates after medical withdrawal. Similarly, relapse rates following discontinuation of opioid agonist therapy (methadone or buprenorphine/naloxone) for opioid dependence are very high and associated with significant morbidity and mortality. Research is needed to identify modifiable variables associated with relapse, positive predictors of ongoing remission of addiction after treatment with opioid agonists and optimal time-frames and dosing schedules for titration off of medication as well as the effectiveness of a transition to naltrexone following medical withdrawal.

4. **In December 2012, SAMHSA issued new regulations that expanded the use of buprenorphine in opioid treatment programs (OTPs), or what formerly were referred to as methadone clinics. In the section of this Regulations labeled "Costs and Benefits." It states "There may be additional diversion and abuse risks associated with the possible expansion of treatment, but the secretary believes that the benefits of increased flexibility and increased access to care in OTP settings outweighs these possible risks." Please elaborate on the risk/benefit analysis undertaken, as referred to in this regulation.**

   OTPs are highly regulated and are required by law to provide behavioral therapy and monitor patient toxicology screens which assure maximum benefit of treatment for the patient. To assure safety of the community, patients are not permitted to take medication home for unsupervised self-administration unless they meet specific criteria designed to establish their stability, progress in recovery, and ability to protect their medication from misuse or diversion (42 CFR 8.12(i)(2)). All of these stipulations continue to apply to patients receiving buprenorphine from an OTP. The rule published in December 2012 allows physicians who are treating OTP patients with buprenorphine to dispense buprenorphine for unsupervised self-administration without fulfilling the time-in-

[3] OTPs are certified by SAMHSA and are the only kinds of facilities that can legally dispense methadone or buprenorphine for the treatment of opioid addiction. Other substance abuse treatment facilities that are not SAMHSA-certified OTPs can prescribe buprenorphine if they have a specially qualified physician on staff, but they may not dispense buprenorphine or methadone. Only OTPs can dispense these drugs.

treatment requirements which continue to apply to methadone. Based on experience to date with the safety of buprenorphine provided via the less restrictive environment of office-based treatment, allowing earlier and more individualized consideration for take-home dosing was deemed an appropriate measure to reduce the cost of treatment to the patient. Relaxing the need to present daily at the OTP in order to receive buprenorphine reduces distance and time spent traveling and permits a more expeditious reintegration of the recovering individual to family and work life. Finally, as noted that it would in the Final Rule, SAMHSA is sending a formal guidance letter to all OTP Medical Directors encouraging them to complete buprenorphine training and obtain a waiver. In the letter, SAMHSA provided links to Web sites where OTP physicians can complete on-line qualifying training.

The Honorable Bill Cassidy and H. Morgan Griffith

In your oral testimony, you indicated that the federal government is moving toward using electronic health records (EHRs) to develop algorithms to identity outliers of physicians prescribing large amounts of controlled prescription drugs. Please define precisely how the federal government plans on using EHRs for this purpose, including the scope of information the federal government will have access to. Specially, what level of patient information will the federal government have access to?

In September 2011, the Centers for Medicare & Medicaid Services (CMS) began working on an approach to help health plans to identify and manage the most egregious cases of opioid overutilization. Comprehensive policy was set forth in a final Call Letter (April 2012) and in more detail in final supplemental guidance (August 2012). In September 2012, CMS issued a memorandum which provided supplemental guidance regarding the section of the Final CY 2013 Call Letter entitled, "Improving Drug Utilization Review Controls in Part D" which sets forth how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements (42 CFR 423.153 *et seq.*) to prevent overutilization of prescribed covered Part D drugs.

As noted in the Final CY 2013 Call Letter, Part D sponsors are, and have been, responsible for establishing reasonable and appropriate drug utilization management programs that assist in preventing overutilization of prescribed medications. Through discussions with the industry, CMS has determined that sponsors need to employ more effective concurrent and retrospective drug utilization review (DUR) programs to address overutilization of medications in order to protect beneficiaries, to comply with DUM requirements and to reduce fraud, waste and abuse in the Part D program. CMS is developing monitoring tools which will identify outliers in opioid use.

SAMHSA is beginning to work with CMS to explore ways to collaborate on addressing the issues of overutilization of opioids and utilizing the capabilities of health information technology (IT) and electronic health records (EHRs). In addition, SAMHSA has focused efforts on HIT to improve access to Prescription Drug Monitoring Programs (PDMPs).

In 2011, SAMHSA initiated the Enhancing Access to PDMPs Project with the goal of using health information technology to improve access to PDMPs in an effort to reduce prescription drug abuse, misuse and overdose in the United States. The project was funded by SAMHSA and managed by the Office of the National Coordinator for Health Information Technology (ONC) in collaboration with SAMHSA, CDC, and ONDCP. During the first part of this two-part project, workgroups of individuals representing state and federal governments as well as industry, trade and advocacy groups, convened to discuss problems related to the transport and use of PDMP data. Recommendations were developed with the aim of facilitating information sharing for healthcare providers in order to make better informed clinical decisions. The second part of the project identified, developed, and implemented pilots that tested linkages between PDMPs and provider EHR systems and pharmacy systems. The results demonstrated the value of increased access to PDMP data at the point of care.

In 2012, SAMHSA provided additional funding to ONC to extend the project for six months to increase the number of pilot sites or the number of states supplying PDMP data in existing pilots and also launch new pilots to test new types of integration. The next phase of the project began in early 2013 and will expand the number of sites (to test scalability) or the number of states supplying PDMP data. Additional pilot sites also tested new types of integration including connecting through a health information exchange and looking at how data can be sent in near real-time from a pharmacy to the PDMP. This phase also focused on work around the goal of creating and disseminating messaging to PDMP stakeholders, especially prescribers and dispensers. Additionally, a "PDMP Resource Center" was developed to enable the entire PDMP community to share its experiences in one location. The Resource Center includes information on an open source reference implementation on PDMP/EHR exchange that can be adopted by PDMPs.

In FY 2012, SAMHSA established the PDMP Electronic Health Record Integration and Interoperability Expansion program, with $4 million in funding from the Prevention and Public Health Fund. Working collaboratively with the Harold Rogers Prescription Drug Monitoring National Training and Technical Assistance Program at the Department of Justice, this program complements existing federal efforts by improving real-time access to PDMP data through integration into existing technologies, such as EHRs, to improve the ability of state PDMPs to reduce the nature, scope, and extent of misuse. CDC will evaluate the program and report on the best practices developed and impacts of PDMP-EHR integration and how they can be utilized by other states working to link PDMPs to other health IT systems.

In FY 2013, SAMHSA anticipates awarding up to eight grants for EHR and PDMP data integration. The purpose of this program is to reduce prescription drug misuse and abuse by providing healthcare providers with access to PDMP data to make sound clinical decisions without disturbing their regular clinical work.

The PDMP EHR grant cooperative agreement program addresses minimum requirements for security of the database, specifically: "information from the PDMPs must be stored and protected in an electronic manner and must, at a minimum, be equivalent to the standards set forth in regulations promulgated under section 262 of HIPAA. This would include the technical safeguards standards of the HIPAA Security Rule under 45 CFR 164.312. In addition, this program does not supersede the requirements of the Federal substance abuse confidentiality law (42 U.S.C. 290dd-2) and regulations under 42 CFR Part 2."

The Honorable Gus Bilirakis

1. **Recently, there was a drug summit in Pasco Country, FL where public health officials were talking about the growing problem of babies born addicted. What tools, programs and grants are available for my community to combat this problem?**

   The statute (42 U.S.C. § 300x-22; 42 U.S.C. §300x-27) and implementing regulations (45 CFR 96.124(c)(e) and 45 CFR 96.131) governing the SABG program requires states to focus preventative efforts on substance-using pregnant women and women with dependent children.[4] In the FY 2013 SABG report, prepared and submitted by the Substance Abuse and Mental Health Program Office of the Florida Department of Children and Families, the state obligated and expended $12.4 million for services designed for such women and their dependent children. During the state fiscal year 2011-2012, the state served 1,235 pregnant women. The Substance Abuse and Mental Health Program Office of the Florida Department of Children and Families distributes its SABG and state general revenue funds to the state's 20 circuits.

   The National Center on Substance Abuse and Child Welfare (NCSACW)[5] is an initiative of the Department of Health and Human Services and jointly funded by SAMHSA's Center for Substance Abuse Treatment and the Administration on Children, Youth and Families' Children's Bureau's Office on Child Abuse and Neglect. The center provides targeted technical assistance to states and community-based organizations to improve systems and practice for families with substance use disorders who are involved in the child welfare and family judicial systems. NCSACW's goals are to develop and implement a comprehensive program of information gathering and dissemination, to provide technical assistance and to develop knowledge and its application that promotes effective practice, organizational, and system changes at the local, state, and national levels.

   SAMHSA's Residential Treatment for Pregnant and Postpartum Women program expands the availability of comprehensive, residential substance abuse treatment, prevention, and recovery support services for pregnant and postpartum women and their minor children, including services for non-residential family members of both the women and children. This program approaches service delivery from a family-centered perspective, meets the multiple individual needs of the population of focus, and considers

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[4] In FY 1994, states were required to expend not less than five percent of the SABG funds to increase the availability of services for women. The women's set-aside is the requirement that states expend a percentage of their annual SABG funds on services designed for pregnant women and women with dependent children. For FY 1995 and subsequent fiscal years, states are required to expend for such services for women not less than an amount equal to the amount expended by states in fiscal year 1994. States are not required to establish additional new programs or expand existing treatment capacity above the capacity developed in FY 1994.

[5] http://www.ncsacw.samhsa.gov/.

the health and well-being of the family members within the context of their families and other important relationships. Most recently, grants were awarded in FY 2011. Depending upon funding availability, another grant announcement may be forthcoming in the future.

SAMHSA efforts to outreach to prescribers and to the public regarding safe and appropriate use of opioid medications also help to prevent the development of addiction and women of childbearing potential are an important focus group for these trainings and materials which are available to individuals and groups in your community.

Finally, the Maternal, Infant and Early Childhood Home Visiting program is authorized by the Affordable Care Act and funded for five years at $1.5 billion. The program is administered by the Health Resources and Services Administration, in collaboration with the Administration for Children and Families. The Florida Department of Health is the designated lead agency and is working in partnership with the Department of Children and Families to plan and implement the program. The program will identify and focus on communities that have high rates of: premature birth, low birth weight infants, infant mortality; poverty; crime; domestic violence; high school drop-outs; substance abuse; unemployment; and child maltreatment.

2. **What changes can we make to our prescription drug laws to make it harder for people to improperly obtain and abuse prescription drugs?**

In 2011, ONDCP released the action plan "Epidemic: Responding to America's Prescription Drug Abuse Crisis" on preventing and reducing prescription drug abuse. The action plan included the following action items that would require a change in Federal law:

- Work with Congress to amend Federal law to require practitioners (physicians, dentists, and others authorized to prescribe) who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration. This training would include assessing and addressing signs of abuse and/or dependence.

- Support reauthorization of the National All Schedules Prescription Electronic Reporting Act, which created a formula grant program administered by SAMHSA that funds state PDMPs. The program outlines specific, uniform criteria states must have in place to be awarded funding, which increases consistency among state PDMPs.

- Work with the Congress on legislation to authorize the Departments of Defense and Veterans Affairs to share patient information on controlled substance prescriptions with state PDMPs.