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H.R. 5710, THE NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING REAUTHORIZATION ACT OF 2010; AND H.R. 5809, THE SAFE DRUG DISPOSAL ACT OF 2010

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

JULY 22, 2010

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H.R. 5710, THE NATIONAL ALL SCHEDULES ELECTRONIC REPORTING REAUTHORIZATION ACT OF 2010; AND H.R. 5809, THE SAFE DRUG DISPOSAL ACT

THURSDAY, JULY 22, 2010

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

The Subcommittee met, pursuant to call, at 10:04 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [Chairman of the Subcommittee] presiding.

Members present: Representatives Pallone, Green, Barrow, Inslee, Shimkus, Whitfield, Pitts and Gingrey.

Staff present: Karen Nelson, Deputy Committee Staff Director for Health; Ruth Katz, Chief Public Health Counsel; Naomi Seiler, Counsel; Rachel Sher, Counsel; Stephen Cha, Professional Staff Member; Emily Gibbons, Professional Staff Member; Anne Morris, Professional Staff Member; Alvin Banks, Special Assistant; Ryan Long, Minority Professional Staff Member; and Clay Alspach, Minority Professional Staff Member.

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

Mr. PALLONE. I call the meeting to order.

Today we are having a hearing on NASPER and safe drug disposal, and I will recognize myself initially for an opening statement.

The two important pieces of legislation that we are addressing basically deal with the growing crisis of abuse of prescription medications. First is the reauthorization of the National All Schedules Prescription Electronic Reporting Act, or NASPERR. This is a bill that I believe the gentleman from Kentucky is the prime sponsor but myself and others on the subcommittee have been involved with it in the past. And secondly is the Safe Drug Disposal Act.

According to the 2010 National Drug Control Strategy put forth by the White House, prescription-drug abuse is the fastest-growing drug problem in the United States. Since 1999, deaths from drug use have more than doubled, surpassing homicide, suicides and gunshot wounds as causes of death, and this increase in drug overdose death rates is largely because of prescription opioid painkillers. Deterrence of prescription-drug abuse is complicated by the

fact that prescription drugs are often obtained with ease from those closest to the drug abuser. Studies show that upwards of 70 percent of people who use prescription drugs for non-medical purposes got them from a friend or relative for free, for money or by stealing them, sometimes unnoticed from the family's medicine cabinet, and many people, particularly teenagers, believe prescription drugs are safer than illicit drugs because they are prescribed by a health care professional.

The Office of National Drug Control Policy working with other federal, State and local community partners has taken a leadership role in promoting comprehensive strategies that ensure prescription drugs are only used for their intended purpose and that unused or expired medications are disposed of in a timely, safe and environmentally responsible manner. Ridding the family medicine cabinet of leftover prescription drugs is easier said than done for a variety of reasons.

I am therefore particularly proud of an initiative in my State, New Jersey, last year supported by the Administration called Operation Medicine Cabinet. This was the first in the United States where we had a statewide day of disposal of unused, unwanted and expired medicine. New Jersey residents in communities in all 21 countries participated in a public health initiative sponsored by the Drug Enforcement Administration, or DEA, in New Jersey. This was in the Office of the Attorney General and also in combination with the Partnership for a Drug-Free New Jersey.

I should note that the huge success of New Jersey's program led to the creation of the American Medicine Chest Challenge, which is a national day of prescription-drug disposal that will be held this November 13th.

Today we will hear from the Administration on their support for the Safe Drug Disposal Act, which will make necessary changes in the Controlled Substances Act to make it easier for people to return unwanted drugs through the drug take-back programs, and this bill is the product of the hard work of Representative Inslee and also Representative Bart Stupak.

Now, we are also going to hear from our distinguished panel today on their support to reauthorize the second bill, the NASPER bill. This law, which was originally enacted in 2005, created an HHS grant program administered by SAMHSA for States to establish prescription-drug monitoring programs. PDMPs track drug prescriptions with the goal of preventing overuse and illegal diversion. Approximately 40 States maintain PDMPs or have laws that authorize their establishment. Starting in fiscal year 2009, Congress appropriated funding to support NASPER grants in 13 States and the bill before us will reauthorize the program until 2013.

I mentioned that NASPER was an initiative that Representative Whitfield, who is here now, worked on in 2005. You also, Mr. Shimkus, Bart Stupak, were involved in this. I think it is a good program. It certainly needs to be reauthorized.

[The prepared statement of Mr. Pallone follows:]

Statement of Rep. Frank Pallone
Hearing on Pending Public Health Legislation
NASPER & SAFE DRUG DISPOSAL
July 22, 2010

Today, we convene a hearing on two pieces of important legislation that seek to address the growing crisis of abuse of prescription medications: the reauthorization of the "National All-Schedules Prescription Electronic Reporting Act" and the "Safe Drug Disposal Act."

According to the 2010 National Drug Control Strategy put forth by the White House, prescription drug abuse is the fastest growing drug problem in the United States. Since 1999 deaths from drug use have more than doubled, surpassing homicides, suicides and gunshot wounds as causes of death. This increase in drug overdose death rates is largely because of prescription opioid painkillers.

Deterrence of prescription drug abuse is complicated by the fact that prescription drugs are often obtained with ease from those closest to the drug abuser. Studies show that upwards of 70% of people who use prescription drugs for non-medical purposes got them from a friend or relative for free, for money or by stealing them—sometimes unnoticed from the family medicine cabinet. And many people, particularly teen-agers, believe prescription drugs are safer than illicit drugs because they are prescribed by a healthcare professional.

The Office of National Drug Control Policy, working with other federal, state and local community partners, has taken a leadership role in promoting comprehensive strategies that ensure prescription drugs are only used for their intended purpose, and that unused or expired medications are disposed of in a timely, safe and environmentally responsible manner.

Ridding the family medicine cabinet of leftover prescription drugs is easier said than done for a variety of reasons. I am therefore particularly proud of an initiative in New Jersey last year, supported by the Administration, called "Operation Medicine Cabinet. This was the first in the nation statewide day of disposal of unused, unwanted and expired medicine. New Jersey residents in communities in all 21 counties participated in, was part of a public health initiative sponsored by the Drug Enforcement Administration (DEA) New Jersey Division, the New Jersey Office of the Attorney General, and the Partnership for a Drug-Free New Jersey.

I should note that the huge success of New Jersey's program lead to the creation of the "American Medicine Chest Challenge," a national day of prescription drug disposal to be held on November 13, 2010.

Today, we will hear from the Administration on their support for the Safe Drug Disposal Act, which will make necessary changes in the Controlled Substances Act to make it easier for people to return unwanted drugs through "Drug Take-back" programs. This bill is the product of the hard work of Rep. Inslee and Rep. Stupak.

We will also hear from our distinguished panel today on their support to reauthorize The National All-Schedules Prescription Electronic Reporting Act (NASPER.) This law, which was originally enacted in 2005, created an HHS grant program administered by SAMHSA for states to establish prescription drug monitoring programs. PDMPs track drug prescriptions, with the goal of preventing overuse and illegal diversion. Approximately 40 states maintain PDMPs or have laws that authorize their establishment. Starting in FY2009 Congress appropriated funding to support NASPER grants in 13 states. The bill before us will reauthorize the program until 2013. NASPER is an initiative that

Rep. Whitfield, and I worked on in 2005, and again today with the support of Ranking Member Shimkus and Rep. Stupak.

And, now I would like to recognize the Ranking Member, Mr. Shimkus for an opening statement.

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111TH CONGRESS
2D SESSION

H. R. 5710

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.

IN THE HOUSE OF REPRESENTATIVES

JULY 1, 2010

Mr. WHITFIELD (for himself, Mr. PALLONE, Mr. SHIMKUS, Mr. STUPAK, Mr. ROGERS of Michigan, Mr. GENE GREEN of Texas, Mrs. BLACKBURN, Mrs. CHRISTENSEN, Mr. RADANOVICH, Mrs. MALONEY, Mr. BISHOP of Georgia, Mr. WILSON of Ohio, Mr. GINGREY of Georgia, Mr. GORDON of Tennessee, Mr. KAGEN, Mr. PITTS, and Mr. GONZALEZ) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2010".

SEC. 2. AMENDMENT TO PURPOSE.

Paragraph (1) of section 2 of the National All Schedules Prescription Electronic Reporting Act of 2005 (Public Law 109–60) is amended to read as follows:

"(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that—

"(A) health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

"(B) appropriate law enforcement, regulatory, and State professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and prescribing and dispensing practices of errant prescribers or pharmacists; and".

SEC. 3. AMENDMENTS TO CONTROLLED SUBSTANCE MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A), by striking "or";

(B) in subparagraph (B), by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(C) to maintain and operate an existing State controlled substance monitoring program.";

(2) by amending subsection (b) to read as follows:

"(b) MINIMUM REQUIREMENTS.—The Secretary shall maintain and, as appropriate, supplement or revise (after publishing proposed additions and revisions in the Federal Register and receiving public comments thereon) minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).";

(3) in subsection (c)—

(A) in paragraph (1)(B)—

(i) in the matter preceding clause (i), by striking "(a)(1)(B)" and inserting "(a)(1)(B) or (a)(1)(C)";

(ii) in clause (i), by striking "program to be improved" and inserting "program to be improved or maintained"; and

(iii) in clause (iv), by striking "public health" and inserting "public health or public safety";

(B) in paragraph (3)—

(i) by striking "If a State that submits" and inserting the following:

"(A) IN GENERAL.—If a State that submits";

(ii) by inserting before the period at the end "and include timelines for full implementation of such interoperability"; and

(iii) by adding at the end the following:

"(B) MONITORING OF EFFORTS.—The Secretary shall monitor State efforts to achieve interoperability, as described in subparagraph (A).";

(C) in paragraph (5)—

(i) by striking "implement or improve" and inserting "establish, improve, or maintain"; and

(ii) by adding at the end the following: "The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in

accordance with the formula described in subsection (a)(2)(B).";

(4) in the matter preceding paragraph (1) in subsection (d), by striking "In implementing or improving" all that follows through "with the following:" and inserting "In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) or (C) submit to the Secretary for approval a statement of why such compliance is not feasible and a plan for bringing the State into compliance, with the following:";

(5) in subsections (e), (f)(1), and (g), by striking "implementing or improving" each place it appears and inserting "establishing, improving, or maintaining";

(6) in subsection (f)—

(A) in paragraph (1)(B) by striking "misuse of a schedule II, III, or IV substance" and inserting "misuse of a controlled substance included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act"; and

(B) add at the end the following:

"(3) EVALUATION AND REPORTING.—Subject to subsection (g), a State receiving a grant under subsection (a) shall provide the Secretary with aggregate data and other information determined by the Secretary to be necessary to enable the Secretary—

"(A) to evaluate the success of the State's program in achieving its purposes; or

"(B) to prepare and submit the report to Congress required by subsection (k)(2).

"(4) RESEARCH BY OTHER ENTITIES.—A department, program, or administration receiving non-identifiable information under paragraph (1)(D) may make such information available to other entities for research purposes.";

(7) by redesignating subsections (h) through (n) as subsections (i) through (o), respectively;

(8) in subsections (c)(1)(A)(iv) and (d)(4), by striking "subsection (h)" each place it appears and inserting "subsection (i)";

(9) by inserting after subsection (g) the following:

"(h) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving a grant under subsection (a) shall take steps to—

"(1) facilitate prescriber use of the State's controlled substance monitoring system; and

"(2) educate prescribers on the benefits of the system both to them and society.";

(10) in subsection (m)(1), as redesignated, by striking "establishment, implementation, or improvement" and inserting "establishment, improvement, or maintenance";

(11) in subsection (n)(8), as redesignated, by striking "and the District of Columbia" and inserting ", the District of Columbia, and any commonwealth or territory of the United States"; and

(12) by amending subsection (o), as redesignated, to read as follows:

"(o) AUTHORIZATION OF APPROPRIATION.—To carry out this section, there are authorized to be appropriated $15,000,000 for fiscal year 2011 and $10,000,000 for each of fiscal years 2012 through 2015.".

○

.....

(Original Signature of Member)

111TH CONGRESS
2D SESSION

H. R. _____

To amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. INSLEE (for himself, Mr. SMITH of Texas, Mr. STUPAK, and Mr. MORAN of Virginia) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safe Drug Disposal Act of 2010".

SEC. 2. DELIVERY OF CONTROLLED SUBSTANCES BY ULTIMATE USERS FOR DISPOSAL.

(a) REGULATORY AUTHORITY.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

"(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

"(A) the person receiving the controlled substance is authorized under this title to receive and dispose of the controlled substance; and

"(B) the delivery and disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

The regulations referred to in subparagraph (B) shall be consistent with the public health and safety. In developing such regulations, the Attorney General shall take into consideration the ease and cost of program implementation and participation by various communities.

"(2) The Attorney General shall, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to deliver for disposal con-

trolled substances on behalf of ultimate users in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

"(3) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.".

(b) CONFORMING AMENDMENT.—Section 308(b) of the Controlled Substances Act (21 U.S.C. 828(b)) is amended—

(1) by striking the period at the end of paragraph (2) and inserting "; or"; and

(2) by adding at the end the following:

"(3) the delivery of such a substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with section 302(g).".

SEC. 3. PUBLIC EDUCATION CAMPAIGN.

The Director of National Drug Control Policy, in consultation with the Administrator of the Environmental Protection Agency, shall carry out a public education and outreach campaign to increase awareness of how ultimate

users may lawfully and safely dispose of prescription drugs, including controlled substances, through drug take-back programs and other appropriate means.

SEC. 4. GAO REPORT.

The Comptroller General of the United States shall—

(1) collect data on the delivery, transfer, and disposal of controlled substances under section 302(g) of the Controlled Substances Act, as added by section 2; and

(2) not less than 4 years after the date of the enactment of this Act, submit findings and recommendations to the Congress regarding use, effectiveness, and accessibility of disposal programs.

SEC. 5. EPA STUDY OF ENVIRONMENTAL IMPACTS.

(a) STUDY.—The Administrator of the Environmental Protection Agency (in this section referred to as the "Administrator") shall—

(1) in consultation with relevant state and local officials and other sources of relevant technical expertise, conduct a study to—

(A) examine the environmental impacts resulting from the ultimate disposal of controlled substances in existing disposal systems;

(B) taking into consideration such impacts, the ease and cost of implementation of drug

take-back programs, and participation in such programs by various communities, formulate appropriate recommendations on the destruction or ultimate disposal of prescription drugs, including controlled substances; and

(C) identify any additional legal authority needed by the Administrator to carry out such recommendations; and

(2) not later than 18 months after the date of the enactment of this Act, submit a report to the Congress on the results of such study.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the Administrator's authority under other provisions of law.

Mr. PALLONE. So now I would recognize Mr. Shimkus for his opening statement.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman.

I want to welcome our panel this morning. I think these bills are another good example of what we can do when we work together. These two pieces of legislation will both aid in tackling drug safety issues in the United States.

First, we will do so by reauthorizing the NASPER. NASPER addresses use and access problems. By reauthorizing this, we will ensure funds remain accessible to strengthen existing State programs while new ones get off the ground. I was an original cosponsor, as you mentioned, along with yourself and our colleague from Michigan, Mr. Stupak, and I want to really congratulate my colleague from Kentucky, Mr. Whitfield, who is the lead sponsor and the champion of the bill. His leadership has been very, very helpful and I am also glad he made it here on time for the hearing.

We also have the Safe Drug Disposal Act, which will ease the cumbersome process of disposal of unused controlled substance. There is a system in place for safe distribution of controlled substances. It only makes sense that we establish the same for the disposal of these drugs. Pharmacies and many others on the State and local level stand ready to provide these services in their communities if given the ability.

The Safe Drug Disposal Act would create these avenues by working with existing framework of already up-and-running drug take-back programs. I support this legislation and thank the chairman for continuing to work with the minority to get language to a comfortable level for everyone. I also look forward to continuing to work together to help move both of these bills through the committee for consideration and by the House.

Finally, last week I mentioned the desire from our side to invite Dr. Berwick to testify before this committee. Obviously I haven't heard a response yet so we will be formalizing a letter to Chairman Waxman for a request to do that. We know that Dr. Berwick is now officially in his role as CMS director. He will serve in a key role. He had made some very interesting comments and we just need to have a chance to ask him about those comments or how he will operate in his new position or if there is some change as far as the rationing debate and how we will handle this new health care law. It is the biggest thing we have done since I have been here in Congress, and it is just time to start getting some questions answered on this.

I am not going to belabor the point, Mr. Chairman. You have heard it before. And I will yield back my time.

Mr. PALLONE. Thank you.

The gentleman from Georgia, Mr. Barrow.

Mr. BARROW. Thank you. I will waive.

Mr. PALLONE. The gentleman waives.

Next we have the gentleman from Kentucky. I think I should mention that he—oh, Mr. Pitts. Oh, I am sorry. The gentleman from Pennsylvania, Mr. Pitts.

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

Mr. PITTS. Thank you, Mr. Chairman.

There is no doubt that prescription-drug abuse and particularly abuse of controlled substances is a serious problem in our country. The cost to society is high in lost productivity and wasted lives but also in direct costs to many government programs.

In September of last year, GAO released a study on Medicaid fraud and abuse related to controlled substances. In just this one federal program in just five States surveyed, GAO found the following: "Tens of thousands of Medicaid beneficiaries and providers were involved in potential fraudulent purchases of controlled substances, abusive purchases of controlled substance or both through the Medicaid program in California, Illinois, New York, North Carolina and Texas. About 65,000 Medicaid beneficiaries in the five selected States acquired the same type of controlled substance from six or more different medical practitioners during fiscal years 2006 and 2007 with the majority of beneficiaries visiting from six to 10 medical practitioners."

These activities, known as doctor shopping, resulted in about $63 million in Medicaid payments and do not include medical costs, that is, office visits, related to getting the prescriptions. GAO even found that according to Social Security Administration data, pharmacies filled controlled substance prescription of over 1,800 beneficiaries who were dead at that time.

These examples come from just one government program and they represent just one facet of the problem. But today we are addressing a tool that can be used to cut down on the fraud and abuse associated with controlled substance. The National All Schedules Prescription Electronic Reporting Reauthorization Act, or NASPERR, allows doctors to access the controlled substances prescription history of their patients in an effort to detect and deter abuse. I am pleased to be a cosponsor of this commonsense piece of legislation which had it been in place and funded during the time GAO was doing this study might have reduced the amount of doctor shopping that went on, may have prevented some of these fraudulent prescriptions for controlled substances from being written and may have saved taxpayers millions of dollars.

I look forward to hearing from our witnesses. Thank you, and I yield back.

Mr. PALLONE. Thank you, Mr. Pitts.

Mr. Green, I know you just walked in. Would you to do an opening statement?

Mr. GREEN. What about my colleague?

Mr. PALLONE. I already tried him. He waived.

Mr. GREEN. Well, then I will give mine.

Mr. PALLONE. The gentleman from Texas is recognized.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing today. We actually have subcommittees dealing with health care

issues, one in our first-floor committee room, and I apologize for being late.

Thank you, Mr. Chairman, for holding this hearing on prescription-drug monitoring programs in the NASPER program, which Congress enacted in 2005. Our ranking member, Mr. Whitfield, was author of the National All Schedules Prescription Electronic Reporting Act, and I am proud to have been a cosponsor of this bill and supported it when it came through our committee in both the 108th and 109th and now again in the 111th.

The NASPER was clear to us then as it is now on both law enforcement level and drug safety level with safe prescription monitoring programs sporadic and not interoperable. It is relatively easy for individuals who abuse prescription drugs to doctor-shop for controlled substances or obtain prescription drugs illegally with little detection from physicians or law enforcement.

The Texas prescription-drug monitoring program called the Texas Prescription Program was established more than 25 years ago in 1981. Each year the Texas Prescription Program collects 3.3 million prescriptions and monitors schedule II prescription drugs. During the first year of the Texas Prescription Drug Program enactment, the number of schedule II prescriptions filled in the State fell by 52 percent. The program helped the State crack down on the pill mills and forged prescriptions but it is clearly a law enforcement program and housed at the Texas Department of Public Safety.

Without question, prescription-drug monitoring programs offer significant benefits for law enforcement but they should go hand in hand with drug safety and public health benefits. I am pleased that we are here to discuss reauthorizing the program and I fully support the legislation introduced by Mr. Whitfield, Mr. Stupak and Mr. Pallone.

Additionally, we discussed legislation introduced by Mr. Stupak and Mr. Inslee on drug take-back programs. I am an original cosponsor of Mr. Inslee's legislation, the Safe Drug Disposal Act, which amends the Controlled Substances Act to allow end users or caretakers of an end user to safely dispose of unused prescription drugs and over-the-counter drugs through the Drug Enforcement Agency approved State-run drug take-back programs. Current law and DEA enforcement of the Controlled Substances Act can make it extremely difficult for end users to turn over unused meds for safe disposal. DEA rules are very strict and controlled substance can only be passed into the possession of law enforcement, which means they must be present at collection sites and drives. This requires coordination of law enforcement as part of this effort and it is impossible to have law enforcement at every collection site.

There is also a lack of public awareness of this rule and on what constitutes a controlled substance. This is a barrier in properly disposing of unused medications. Today unused meds are becoming a gateway to drug abuse, and flushing down the toilet can be harmful to our environment. We want to assist States and localities by facilitating the safe disposal of prescription medication, and I know Mr. Stupak and Mr. Inslee have been working to combine their legislation. I look forward to supporting their efforts.

And again, I thank our witnesses for being here, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Green.

And now Mr. Whitfield. I should tell you that Mr. Whitfield talks about NASPER all the time and has been constantly trying to improve and implement the program since he first got involved. I recognize the gentleman.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Well, thank you, Chairman Pallone and Ranking Member Shimkus. I would like to thank also Gene Green and Bart Stupak as well as Chairman Pallone and John Shimkus because it did take a real effort to get this legislation where it is today, and I might add that there was a program initiated in the Appropriations Committee a number of years ago around 2002 and they appropriated money that went to the Justice Department, and that prescription-drug monitoring program was primarily focused on law enforcement, which is vitally important, but the program had never really been authorized, and the Energy and Commerce Committee did have jurisdiction and we were able to introduce the legislation. It has been passed. There is now a monitoring program in 40 States, and we think it has potential to do a great deal of good for the American people to provide information for physicians as they treat patients that go across State lines and will dramatically improve the safety and effectiveness of our medical system.

So I look forward to the hearing today. I know the markup is going to be later this afternoon. But all of us know how complex health care is and how difficult the issues are, and frequently when I am at home, people ask me, well, you don't know anything about health care so how can you be up there doing what you are doing. Fortunately, we have Dr. Gingrey, who is a doctor, and I guess Dr. Burgess, but also some of us are fortunate to have some advisors that came up here as interns sometimes, and we have one with us this morning that is working on our staff for a while, and it's Dr. Jason Pope, and he is right here. He is on the staff at Cleveland Clinic and he is an assistant professor of anesthesiology at Vanderbilt. So I do want you all to know that we feel like we have some good, competent advice on a lot of these issues and we are glad to have Dr. Pope with us for a while here in Washington, D.C.

And I yield back the balance of my time.

Mr. PALLONE. Thank you.

I should mention there has been a change in plans. I think we have notified the staff that our intention is to have the markup 15 minutes after the hearing, so I don't know when that is exactly going to be but we are trying to move things as quickly as we can, so I thought I would mention that.

The gentleman from Georgia, Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Mr. Chairman, thank you. I thank Mr. Whitfield for his kind remarks about me and Dr. Burgess. I thank God for Dr. Pope because our information is a little dated, and I am sure

that if Burgess was here, he would say well, Gingrey's is a lot more dated than mine.

In any regard, Mr. Chairman, thank you for holding the hearing today. Prescription-drug abuse is a major problem in this country. In my home State of Georgia, the fact that a number of pain clinics were charged with illegally prescribing strong narcotics to patients is but one reminder that our country is not doing enough to curb this startling trend.

Prescription drugs, when taken appropriately for a medical condition, can improve a patient's quality of life or help them cope with a debilitating illness. However, when they are improperly taken, they can lead to chemical dependency, certainly from these pain clinics, and subsequently great hardship, loss of job, loss of marriage, loss of home. I could go on and on.

The two pieces of legislation that we are going to consider this morning have been drafted hopefully to address this problem, and I would like to thank the sponsors for their work in this area. Of particular note, I want to thank Congressman Whitfield for his continued efforts in electronic prescribing reporting through NASPER. It has been 5 years since Congressman Whitfield first championed the legislation into law and I am proud that I was asked to be a cosponsor of these efforts here today. I believe that the reauthorization of NASPER is a necessary step in the fight to address prescription-drug abuse and it will give States the support that they need to help prevent the overuse and illegal diversion of prescription drugs, particularly pain medication.

In addition, I would like to commend the sponsors of the various pieces of legislation that the subcommittee will be marking up this afternoon, both those that I serve with here on the committee and those off of the committee for their efforts. Given the nature of today's dual hearings, I would like to take a moment and single out a few sponsors personally for their efforts. First, Chairman Stupak's legislation, H.R. 903, the Dental Emergency Responders Act of 2009, is a commonsense solution to a problem that could benefit many during a national emergency. Therefore, I want to thank Chairman Stupak for sponsoring this legislation and I look forward to supporting it today.

Dr. Tim Murphy, my colleague on the committee and a fellow co-chair of the GOP Doctors Caucus, has advocated tort protection for volunteer providers, physicians from this committee for a few years now and I know our peers in the medical community appreciate his efforts. I look forward to supporting that bill, H.R. 1745, in committee today, and as a cosponsor going forward.

To all my colleagues, I understand that the process that led us here today has been a bipartisan one, thank goodness, for a change. And for that, I would like to commend Chairman Pallone and Ranking Member Shimkus for their efforts, and Mr. Chairman, I will yield back now.

Mr. PALLONE. Thank you, Mr. Gingrey.

I think we are done with our opening statements. We will turn to our two witnesses. Let me introduce them at this time. First on my left is the Hon. Gil Kerlikowske, who is Director of the Office of National Drug Control Policy, and then we also have Joseph Rannazzisi, who is Deputy Assistant Administrator from the Office

of Diversion Control for the U.S. Drug Enforcement Administration. I can't believe I got those two right. Your names are so long.

We ask you to try to keep to 5 minutes, although you are the only two, so I am not going to be strict, and then you can submit comments if you wish for the record, and after the hearing you may get additional written questions from us beyond what we question you on today.

So we will start with Mr. Kerlikowske.

STATEMENTS OF HON. R. GIL KERLIKOWSKE, M.A., DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY; AND JOSEPH RANNAZZISI, J.D., DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION

STATEMENT OF R. GIL KERLIKOWSKE

Mr. KERLIKOWSKE. Thank you, Mr. Chairman and Ranking Member Shimkus and the distinguished members of the subcommittee. I think you have already made it very clear about the numbers, the information that has been provided as the CDC has said determined the epidemic and prescription-drug issues, so I will move past some of that.

But reducing prescription-drug diversion and abuse has been a major focus of the Office of National Drug Control Policy since my arrival a little over a year ago, and we have made it one of three signature initiatives within the office. The significant contributing factor to the diversion and abuse of prescription drugs is the widespread availability. Many people are not purchasing prescription drugs from a drug dealer on the street. In 2007 and 2008, among the persons aged 12 or older who used pain relievers non-medically in the past 12 months, approximately 70 percent report having obtained the pain relievers from a friend or a relative. So this problem doesn't lend itself to traditional interventions. These drugs are originally dispensed, as Dr. Gingrey mentioned, for legitimate purposes and too often the public's perception is that they are safe for uses other than those for which they are prescribed, and we have to help change that public perception and the societal norm to one where unused or expired medications are disposed of in a timely, safe and environmentally responsible manner.

One aspect of President Obama's National Drug Control Strategy relates directly to the disposal of unused or unwanted prescription drugs, and the family medicine cabinet is a significant source of diversion for those seeking to abuse prescription drugs. Yet the difficulty in disposing of such medications in a fashion that is simple, legal and environmentally responsible has been a challenge.

Currently, the federal government advises controlled-substance users to dispose of controlled substances in one of three ways: to throw them in the trash after taking proper precautions, to flush down the toilet in limited cases for the very dangerous drugs, or to participate in take-back programs, as had been mentioned earlier, oftentimes community-based with the approval of DEA and in conjunction with law enforcement.

This legislation that the subcommittee is considering today will facilitate the establishment of pharmaceutical take-back programs

around the country by making a statutory change to the Controlled Substances Act. This step is required before the Drug Enforcement Administration can fully implement the legitimate take-back of frequently abused prescription drug products containing controlled substances, and such a step will greatly improve the ability of consumers to legally, safely and securely dispose of drugs.

The strategy also calls for the expansion of prescription-drug monitoring programs. These statewide databases recording the controlled substances dispensed by doctors, nurse practitioners and prescribers is important, and reauthorization of H.R. 5710, the National All Schedules Prescription Electronic Reporting Reauthorization Act of 2010, will be a great step in that direction. Information contained in a PDMP can be used by prescribers to guard against prescribing two or more drugs that might have negative interactions, can be used by pharmacists or prescribers to identify patients who may be shopping for prescriptions to sustain a prescription-drug addiction, and under specific circumstances by regulatory and law enforcement officials when pursuing cases involving rogue prescribers or pill mills. Prescription-drug monitoring programs are authorized in 43 States but only 34 States' programs are fully operational.

Each State's PDMP authorizing legislation determines where and how the PDMP in that State will function. We must ensure every State has a functional PDMP in place, prescribers and pharmacists regularly use these databases, and that PDMPs are developed with the capability to share information across State lines.

If these two measures are approved that are under consideration today, I believe it will be a tremendous step in the direction of limiting the harmful consequences of prescription-drug abuse in this country. I look forward to working with this subcommittee and I look forward to answering any of your questions. Thank you.

[The prepared statement of Mr. Kerlikowske follows:]

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

"Hearing On Pending Public Health Legislation"

House Committee on Energy and Commerce
Subcommittee on Health

Thursday, July 22, 2010
10:00 a.m.
2322 Rayburn House Office Building

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

Chairman Pallone, Ranking Member Shimkus, distinguished members of the Subcommittee, thank you for providing me the opportunity to appear before you today to address the current state of prescription drug abuse and recommend action that can be taken to address this epidemic. I am encouraged by your Subcommittee's focus on this topic. Reducing prescription drug diversion and abuse has been a major focus for the Office of National Drug Control Policy (ONDCP) since my arrival, and I have directed all National Drug Control Program agencies to address these vital issues in our drug control efforts.

The Growing Problem of Prescription Drug Abuse

Prescription drug abuse is the fastest-growing drug problem in the United States and is a serious public health concern. In recent years, the number of individuals who, for the first time, consumed prescription drugs for a non-medical purpose, exceeded the number of first-time marijuana users.[1] Monitoring the Future, a study of youth attitudes and drug use, shows that seven of the most commonly used drugs reported by 12th graders are pharmaceutical drugs used non-medically.[2] From 1997 to 2007, there was a 400 percent increase in addiction treatment admissions for individuals primarily abusing prescription pain killers.[3] The increase in the percentage of admissions for abuse of pain relievers spans every age, gender, race, ethnicity, education, employment level, and region. The study also shows a more than tripling of pain reliever abuse among patients who needed treatment for opioid dependence. According to a Department of Defense survey in 2008, one in eight (12%) active duty military personnel reported past month illicit drug use, largely driven by the misuse of prescription drugs (reported by 11%).[4] It is noteworthy that the Department of Veterans Affairs (DVA) does not currently participate in state Prescription Drug Monitoring Programs, however, ONDCP has engaged the DVA in conversations about this issue and the DVA has provided a positive response to address factors that may inhibit its participation in state PDMPs.

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1 SAMHSA 2009 Results from the 2008 National Survey on Drug Use and Health: National Findings.

2 University of Michigan 2009 Monitoring the Future: A Synopsis of the 2009 Results of Trends in Teen Use of Illicit Drugs and Alcohol.

3 Highlights for 2007 Treatment Episode Data Set (TEDS) Table 1b Admissions by primary substance of abuse: TEDS 1997-2007 Percent distribution, http://www.drugabusestatistics.samhsa.gov/TEDS2k7highlights/TEDSHighl2k7Tbl1b.htm

4 Bray et al., 2008 Department of Defense Survey of Health Related Behaviors Among Active Duty Military Personnel. (2009). Research Triangle Institute, Research Triangle Park, NC.

Between 2004 and 2008, the estimated number of emergency department visits linked to the non-medical use of prescription pain relievers doubled. This dramatic rise in emergency department visits associated with the non-medical use of these drugs occurred among men and women of all age groups.[5]

One major difficulty in deterring prescription drug abuse is the relative ease with which these drugs are obtained. In 2007-2008, among persons aged 12 or older who used pain relievers non-medically in the past 12 months, 55.9 percent got the pain relievers they most recently used from a friend or relative for free, 8.9 percent bought them from a friend or relative, and 5.4 percent took them from a friend or relative without asking. Nearly one-fifth (18.0 percent) indicated they got the drugs they most recently used through a prescription from one doctor. About 1 in 20 users (4.3 percent) obtained pain relievers from a drug dealer or other stranger, and 0.4 percent bought them on the Internet. These percentages are similar to those reported in 2006-2007.[6] Most distressingly, more than 26,000 Americans died from unintentional drug overdoses in 2006, and prescription drugs—particularly opioid painkillers—are considered a major contributor to the total number of drug deaths; in 2006 they represented 42 percent of unintentional drug overdoses.[7] In 2006, the number of drug-induced deaths exceeded deaths from motor vehicle crashes in 16 states and the District of Columbia, including large States such as Illinois, Pennsylvania, New York, and Michigan.

As these statistics demonstrate, the abuse of prescription drugs is a problem of ever-increasing concern. Although beneficial when used as prescribed by a health professional for legitimate purposes, the relative ease of access to prescription drugs, coupled with a misperception of the potential harms resulting from their misuse and abuse, requires a comprehensive public health and public safety approach to reducing this problem.

We must change public perception so the societal norm shifts to one where prescription drugs are only used for their intended purpose, and unused or expired medications are disposed of in a

5 Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs — United States, 2004–2008. June 18, 2010.

6 SAMHSA Results from the 2008 National Survey on Drug Use and Health: National Findings, 2008.

7 CDC, National Center for Health Statistics, "National Vital Statistics Report", 2009.

timely, safe, and environmentally responsible manner. We envision a future where disposal of these medications is second-nature to most Americans. Creating a method for disposal of expired or unused prescription drugs could benefit public health, public safety, and the environment.

We also believe every state should have a prescription drug monitoring program. H.R. 5710, the National All Schedules Prescription Electronic Reporting Reauthorization Act of 2010, which the Subcommittee will consider this afternoon, would reauthorize one of two Federal programs that funds prescription drug monitoring programs. Prescription drug monitoring programs, also called PDMPs, are state-wide databases of the dispensed controlled substances prescribed by doctors, nurse practitioners, and other prescribers. Information contained in the PDMP can be used by prescribers to guard against prescribing two or more drugs that might have negative interactions; by pharmacists or prescribers to identify patients who may be shopping for prescriptions to sustain a prescription drug addiction; and, under specific circumstances, by regulatory and law enforcement officials when pursuing cases involving rogue prescribers or "pill mills". We must ensure every state has a PDMP in place, prescribers and pharmacists use these databases, and PDMPs are developed with the capability to share information across state lines.

While the realities of prescription drug abuse demand action, any policy response must be approached thoughtfully, as it must strike a balance between our desire to minimize diversion and abuse of pharmaceuticals and the need to maximize their legitimate benefits. As science has successfully developed valuable medications to alleviate suffering, such as opioids for cancer patients and benzodiazepines for anxiety disorders, it has also led to the unintended consequence of increased pharmaceutical abuse.

The 2010 National Drug Control Strategy

Recently, the Obama Administration released its inaugural *National Drug Control Strategy (Strategy)*. The *Strategy* is the result of a nine-month consultative effort with Congress, Federal agencies, state and local partners, and hundreds of individuals across the country. It serves as a bold call to action for all Americans who share in the desire and the responsibility to keep our

citizens -- especially our vulnerable youth -- safe, healthy, and protected from the terrible costs of substance abuse, while ensuring our seniors, as well as those who are ill or vulnerable, have access to the prescription drugs they need to reduce pain, mitigate disease, and preserve life.

This *Strategy* is balanced, comprehensive, and recognizes prevention, treatment, and enforcement are all essential components of an effective approach to addressing drug use and its consequences. Our efforts incorporate science and smarter strategies to better align policy with the realities of drug use and its consequences in communities throughout this country. Research shows addiction is a complex, biological, and psychological disorder. It is chronic and progressive, and negatively affects individuals, families, communities, and our society as a whole. In 2008, over 23 million Americans ages 12 or older were estimated to need treatment for an illicit drug or alcohol use problem.

The *Strategy* sets specific goals by which we will measure our progress. Over the next five years, working with dozens of agencies, departments, Members of Congress, State and local organizations, and the American people, we intend to make significant reductions in illicit drug use and its consequences.

The 2010 National Drug Control Strategy Addresses Prescription Drug Abuse

The *Strategy* specifically acknowledges that prescription drug abuse is the fastest-growing drug problem in the United States, and, therefore, outlines an approach to address the unique issues surrounding the growing problem. One aspect of our *Strategy* relates directly to the disposal of unused or unwanted prescription drugs. The family medicine cabinet (e.g., the pain pill prescription that was never finished, the tranquilizers that are used occasionally) is a significant source of diversion for those seeking to abuse prescription drugs. Yet, the difficulty in disposing of such medications in a fashion that is simple, legal, and environmentally responsible is a challenge. In some communities, law enforcement professionals, in conjunction with grassroots organizations, have held "take-back" events at which such medications are safely collected and disposed of according to state and Federal environmental standards.

The drug disposal legislation you are exploring today will facilitate the establishment of

pharmaceutical take-back programs around the country by making a statutory change to the Controlled Substances Act (CSA) (P. L. 91-513). This step is required before the Drug Enforcement Administration (DEA) can fully implement the legitimate take-back of frequently abused prescription drug products containing controlled substances.

The Closed System of the Controlled Substances Act

I am encouraged by the Subcommittee's intent to amend the CSA, to permit promulgation of more systematic policy responses. Currently, the CSA establishes a closed system of distribution to provide security and accountability for the Nation's controlled substance supply. Under this system, all controlled substances used in legitimate commerce may be transferred only between persons or entities who are DEA registrants or who are exempted from the requirement of registration, until they are dispensed to the ultimate user. After a DEA-registered practitioner, such as a physician or a dentist, prescribes a controlled substance to a patient (i.e., the ultimate user), the patient can fill that prescription at a retail pharmacy. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants to participate in the process.

Under the CSA, if an individual has been prescribed a controlled substance, he or she cannot legally transfer the controlled substance to a pharmacist or any other non-law enforcement person for any reason, even if the person intends to dispose of the drug. Consumers, therefore, often retain unused controlled substances in their homes, which can lead to diversion and abuse. As already discussed, the 2009 Monitoring the Future Study found that seven of the most commonly used drugs reported by 12th graders are pharmaceutical drugs used non-medically.[8] Another survey indicated that a majority of the youth surveyed said that they had obtained the drug from a friend or relative, either free, purchased, or taken without asking. Legislative action to amend the CSA will be a step forward in preventing drug abuse because it will allow the DEA to accommodate the growing desire at the community level to properly dispose of pharmaceuticals. This may serve to limit the potential for diversion, abuse, and decrease potentially negative environmental issues.

8 University of Michigan 2009 Monitoring the Future: A Synopsis of the 2009 Results of Trends in Teen Use of Illicit Drugs and Alcohol.

Community-based Efforts to Control Prescription Drug Abuse

We know legitimate prescriptions from the family medicine cabinet are often the source of drugs that get abused, and the difficulty in disposing of these medications contributes to this problem. Therefore, proper disposal of unused or expired medications must be made easier. Disposing of unused or expired medications in a fashion that is simple, legal, and environmentally responsible is a challenge. Currently, the Federal government advises controlled substance users to dispose of controlled substances in one of three ways – throw them in the trash, after taking proper precautions; flush them down the toilet, in limited cases of very dangerous drugs; or participate in a take-back event.

As discussed, one method of disposal is to flush controlled substances down the toilet. This method of disposal is only recommended for exceptionally dangerous drugs. The FDA advises this because it has determined that the misuse of these prescription drugs creates a high risk of immediate harm, and so their potential danger outweighs the potential environmental impact. These prescription drugs are very dangerous and can be lethal if used improperly, especially by youth.

Take-back or community drug disposal events are community-based activities that accept prescription drugs. If controlled substances such as Vicodin or OxyContin are accepted, the events must be conducted in accordance with DEA guidelines, with the permission of the DEA Special Agent in Charge for the region, and under the supervision of authorized law enforcement officials. Any methods utilized to destroy the collected controlled substances must comply with all applicable Federal and state laws and regulations.

Currently, there are three types of take-back programs designed to assist in the disposal and destruction of prescription drugs. Under the Controlled Substances Act, any type of take-back that accepts controlled substances requires a waiver from the DEA. Programs range from: permanent sites where unused medication is received; one day events at various locations, such as pharmacies or hazardous waste collection sites; and in Maine, a mail/ship back program where ultimate users send their unused drugs to a central location using a pre-issued label or through a private carrier, such as UPS or FedEx.

EPA has awarded two grants for pilot take-back programs. From January to December 2008, the Regional eXcess Medication Disposal Service (RxMEDs) project, managed by the Area Resources for Community and Human Services (ARCHS) in St. Louis, collected more than 10,000 bottles of over-the-counter and non-controlled prescription drugs during collection days held at pharmacies.[9] In addition, through a mail-back return envelope system, the Safe Medicine Disposal for ME (SMDME) program collected more than 2,300 lbs of drugs, including controlled substances.[10]

Several states and many localities have organized one-day take-back events in coordination with appropriate law enforcement officials. In 2009, New Jersey held one of the most ambitious take back efforts, called Operation Medicine Cabinet. Throughout all of New Jersey's 21 counties, over 440 local police and sheriff departments hosted collection sites. Over 9,000 pounds of prescription drugs (both controlled and non-controlled substances) were collected at the one day take-back event. This event was organized through the Special Agent in Charge DEA New Jersey Division, the New Jersey Office of the Attorney General (OAG), and the Partnership for a Drug-Free New Jersey.

In March of this year, Oregon organized a Statewide Prescription Drug Turn-In Day. More than 2,300 individuals took part, turning in more than 4,000 pounds of pills, tablets, and other drugs. The event was coordinated by the Oregon Medical Association Alliance, Community Action to Reduce Substance Abuse, and the Oregon Partnership. Several other States, including Montana and Missouri, have conducted similar take-back days.

By taking legislative action, you will allow DEA to rewrite its rules, and, consequently, make it easier for local communities to do the right thing – dispose of pharmaceuticals, including controlled substances. Just as the Federal government took on the challenge of changing societal attitudes about wearing seat belts, so, too, does this Administration need to change societal attitudes about proper and timely disposal of prescription drugs. EPA is an important partner in

[9] Prudent Disposal of Unwanted Medications (RxMEDS): Final Report, 2009, http://www.epa.gov/aging/grants/winners/rx-meds-technical-report508.pdf

[10] Executive Summary: Reducing Prescription Drug Misuse Through the Use of a Citizen Mail-Back Program in Maine, 2010, http://www.epa.gov/aging/RX-report-Exe-Sum/

the disposal of pharmaceuticals and will continue to be involved in any efforts to improve the methods by which Americans dispose of unused prescription drugs.

Prescription Drug Monitoring Programs

Beyond the issue of disposal of excess medications, ONDCP is also focused on other effective measures which can be implemented to curtail prescription drug abuse and its consequences. PDMPs are a focus for ONDCP because we believe they can be a highly effective tool for medical professionals, patients, the public health community, and law enforcement. PDMPs are state-level, controlled substance prescription data collection systems which allow authorized users (such as prescribers, pharmacists, regulatory and law enforcement entities, and professional licensing agencies) access to the data under certain conditions and with varying restrictions. PDMPs gather controlled substance prescription data from pharmacies within their states on regular intervals (1, 2, or 4 times monthly).

Generally, PDMPs can generate two different kinds of reports: solicited and unsolicited. Solicited reports, which can be done with most PDMPs, occur when authorized users query or obtain information from the PDMP system for information about controlled substance prescriptions for individuals.

Unsolicited reports are automatically generated when certain thresholds, which might indicate abuse of a controlled substance, doctor shopping, or errant prescribing practices, are reached. Different states and Federal agencies are experimenting with different thresholds. For instance, the Substance Abuse and Mental Health Service Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) proposes unsolicited reports be sent to prescribers and pharmacies when an individual has filled six or more controlled substance prescriptions of the same drug class, from six or more different prescribers, or six or more different pharmacies in a state, within a one month period. ONDCP believes all PDMPs should produce and disseminate unsolicited reports.

The bill the Subcommittee will consider this afternoon (H.R. 5710) reinforces Federal support for state controlled substance monitoring programs as invaluable public health and public safety tools. Specifically, it will:

1. authorize Federal funding to support state surveillance systems for an additional 5 years;
2. expand the allowable uses of funds to include program maintenance;
3. compel interoperability between state programs;
4. increase prescriber education about using the state systems to inform patient care; and
5. permit grant funding to Territories of the United States.

NASPER's interoperability requirement will further an important goal of ONDCP's efforts to decrease prescription drug abuse. Criminal activity does not respect state borders, and state PDMPs must allow for information sharing across state lines. Currently, information sharing is done on an *ad hoc* basis between states. The Department of Justice, including DEA, has invested considerable resources to develop the technology for states to share PDMP data via a hub (currently located at the Ohio Board of Pharmacy). Kentucky and Ohio have shared test data via this hub (transactions occurred within 30 seconds) and currently have a memorandum of understanding in place to exchange real data. It is anticipated this will start occurring regularly by the end of 2010. Other states will be able to implement this technology once it is tested and found to be operationally sound. ONDCP has also invested resources in ensuring other states have the technology needed to be able to interact with the hub and engage in interstate information sharing.

PDMPs are authorized in 43 States, but only 34 have programs that are operational. The PDMP authorizing legislation in each state determines where and how the PDMP in that state functions or will function. In some states, this is done by regulation. Recently, I traveled to Delaware, where Governor Jack Markell signed PDMP authorizing legislation, thereby making Delaware the 43rd State with such authority.

PDMPs can be effective in decreasing prescription drug diversion and abuse, and the Administration is seeking to ensure new and existing PDMPs are used effectively to help the

communities with access to the data to use the data. A study sponsored by DOJ indicated that PDMPs reduce the amount of prescription pain relievers and stimulants available for diversion, thus reducing the probability of abuse. Evidence also suggests states which are proactive in their approach to regulation are more effective in reducing the per capita supply of prescription pain relievers and stimulants than states which are reactive in their approach.[11] PDMPs can and should serve a multitude of functions, including serving as a: tool for patient care, drug epidemic early warning system (especially when combined with other data), drug diversion investigative tool (although PDMP data cannot be used as evidence in court), and an insurance fraud investigative tool. H.R. 5710 will help further these goals.

Conclusion

Prescription drug take-back programs, along with prescription drug monitoring programs, play an important role in a comprehensive effort to reduce prescription drug abuse. ONDCP has worked with DOJ, DEA, HHS, FDA, EPA, and Congress to further refine Federal laws and regulations to foster an expansion of comprehensive and cost-effective prescription monitoring and take-back programs across the country. To be effective, these programs must be consumer friendly and protect patients' privacy.

The *National Drug Control Strategy* provides a blueprint for reducing prescription drug diversion and abuse. Other equally important parts of the *Strategy* include prescriber and patient education; enforcement efforts against illegal Internet pharmacies; enforcement efforts to crack down on rogue pain clinics and pill mills, and public education efforts aimed at increasing the awareness of the dangers of prescription drug misuse.

I look forward to continuing to work with the Committee to address these challenging and important issues. I recognize that none of the many things ONDCP and my Executive Branch colleagues want to accomplish for the Nation are possible without the active support of Congress. Thank you very much for the opportunity to testify and for your support of these vital issues.

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[11] Ronald Simeone and Lynn Holland, "An Evaluation of Prescription Drug Monitoring Programs." Simeone Associates, Inc. [2006] http://www.simeoneassociates.com/simeone3.pdf

Mr. PALLONE. Thank you.
Mr. Rannazzisi.

STATEMENT OF JOSEPH RANNAZZISI

Mr. RANNAZZISI. Thank you, Chairman Pallone, Ranking Member Shimkus and distinguished members of the subcommittee. On behalf of Acting Administrator Michelle Leonhart and the nearly 10,000 members of the Drug Enforcement Administration, I am honored to appear before you today to provide testimony concerning two very important measures that will help stem the growing tide of pharmaceutical controlled substance diversion and abuse, the disposal of pharmaceutical controlled substances from our household medicine cabinets and the creation and utilization of prescription-drug monitoring programs. I would be remiss in not thanking Director Kerlikowske for his leadership in these initiatives and addressing the overall problem of drug abuse.

Addressing the diversion and abuse of pharmaceutical controlled substances continues to be one of the DEA's top priorities. One way to accomplish this goal is to help our communities dispose of unwanted, unused or expired controlled substances that remain in household medicine cabinets long after they are needed. The medicine cabinet provides easy and free access to controlled substances by drug seekers and non-medical users such as teenagers and increases the risk of accidental ingestion and poisoning of children and the elderly. The Controlled Substances Act provides for a closed system of distribution with stringent procedures on procurement, distribution and possession of controlled substances. As part of this closed system, all persons who possess controlled substances must either be registered with the DEA or be exempt from registration. Under the Controlled Substances Act, ultimate users or patients are exempt from the requirement of registration when they possess this drug for a legitimate medical purpose. Although exempt, this exemption does not allow ultimate users to transfer controlled substances to any entity, even if the sole purpose of that transfer is for disposal. Therefore, the ultimate user or household member is left to personally dispose of the controlled substance. In many cases, the drugs remain in the household indefinitely or disposed of in an inappropriate manner, potentially impacting the water supply and environment.

States, countries and municipalities have tried to develop pharmaceutical collection and disposal programs to address the problems resulting from unwanted or unused medicines in household medicine cabinets. These programs are beneficial in many ways but the Controlled Substance Act provides for the collection and disposal of controlled substances in very limited circumstances. DEA has provided technical guidance to various law enforcement agencies' efforts to conduct collection and disposal initiatives over the last several years but these operations were limited to specific cities or counties. As the chairman mentioned, in November 2009 DEA Newark in cooperation with the Partnership for Drug-Free New Jersey, State and local law enforcement partners and community coalitions initiated Operation Medicine Cabinet. In just 4 hours, over 9,000 pounds of unused, unwanted and expired meds

were collected at law enforcement-run community collection sites throughout the State.

In order to stop the diversion of pharmaceutical controlled substances from the medicine cabinet, there must be a means by which ultimate users can transfer these substances to other entities for disposal. There are several bills pending to address this issue. In May 2009, the Department of Justice issued a views letter in support of H.R. 1359, the Secure and Responsible Drug Disposal Act of 2009. This bill provides a means by which ultimate users may lawfully transfer controlled substances to other entities for disposal, affords the Attorney General discretion to promulgate regulations and provides the requisite flexibility to address collection and disposal in a comprehensive manner. Without this legislation, DEA does not have authority to create a regulatory infrastructure to support the transfer of controlled substances from ultimate users to others for disposal.

Another initiative to address diversion and abuse of pharmaceutical controlled substances is the implementation and utilization of State prescription-drug monitoring programs. Although these programs vary from State to State, in general PDMPs reduce prescription fraud and doctor shopping by providing doctors and pharmacists with information concerning a patient's prescription history while ensuring patient access to needed treatment. Doctor shopping by drug seekers is one of the most common ways individuals unlawfully obtain pharmaceutical controlled substances. A doctor shopper may or may not have a legitimate medical condition. He or she visits several doctors that ultimately prescribe controlled substances for the same medical condition. The acquired drugs are then used to feed addiction or for illegal sale and distribution.

When authorized, PDMPs can assist law enforcement agencies and State regulatory bodies in the investigation of individuals involved in doctor shopping or medical professionals or individuals involved in the division and illegal distribution of controlled substances. Approximately 34 States currently have operational PDMPs and the DEA supports the establishment of these programs in every State and urges the States to work together to promote sharing of this information from State to State.

In conclusion, the collection, removal and safe disposal of unwanted or unused medications from households and the expansion of PDMPs will reduce or even eliminate some potential avenues of drug diversion and ultimately limit the availability of medications to drug seekers and abusers. We look forward to working with Congress to establish a solid foundation for take-back disposal programs and support any effort to expand the implementation and utilization of PDMPs to minimize avenues for diversion while protecting the public health and safety.

I thank the subcommittee for the opportunity to appear before you today and welcome any questions you may have.

[The prepared statement of Mr. Rannazzisi follows:]

Department of Justice

STATEMENT FOR THE RECORD OF

JOSEPH T. RANNAZZISI
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OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES

HEARING ON PENDING PUBLIC HEALTH LEGISLATION

JULY 22, 2010

Statement for the Record
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Office of Diversion Control
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Energy and Commerce Committee, Subcommittee on Health
U.S. House of Representatives
Hearing on Pending Public Health Legislation
July 22, 2010

Chairman Pallone, Ranking Member Shimkus, and distinguished Members of the Subcommittee, on behalf of Acting Administrator Michele Leonhart and the more than 9,600 men and women of the Drug Enforcement Administration (DEA), I am honored to have the opportunity to appear before you today to provide testimony concerning the disposal of pharmaceutical controlled substances and prescription drug monitoring programs (PDMPs).

Addressing the growing problem of the diversion and abuse of controlled pharmaceuticals continues to be one of the top priorities of DEA. DEA has made great strides in dealing with this ever-changing, global drug issue. We continue to concentrate on identifying, targeting, and dismantling large-scale organizations that seek to divert and distribute controlled pharmaceuticals in violation of the Controlled Substances Act (CSA).

DEA's obligation under the law and to the public is to ensure that pharmaceutical controlled substances are prescribed and dispensed only for legitimate medical purposes in accordance with the Controlled Substances Act. By carrying out this obligation, DEA strives to minimize the diversion of pharmaceutical controlled substances for abuse while ensuring that such medications are fully available to patients in accordance with the sound medical judgments of their physicians. In this manner, DEA is committed to balancing the need for prevention, education, and enforcement with the need for legitimate access to these drugs.

Today's hearing is focused on two areas of concern related to sources of diversion: unused pharmaceutical controlled substances, and those fraudulently obtained through a practice known as "doctor shopping." The desire to provide the public with effective means to dispose of unused pharmaceutical controlled substances is based on two main concerns: (1) protecting the safety and welfare of the American people by preventing the diversion of such drugs into either licit or illicit channels for the purpose of abuse or profit; and (2) developing drug disposal methods that help prevent contamination of the nation's water supplies.

"Doctor shopping" by drug addicts is one of the most common ways that addicts unlawfully obtain pharmaceutical controlled substances. Generally, this term refers to the visit by an individual—who may or may not have legitimate medical needs—to several doctors, each of whom writes a prescription for a controlled substance. The individual will visit several pharmacies, receiving more of the drug than intended by any single physician, typically for the

purpose of feeding an addiction. Associated illegal activities may include the forgery of prescriptions, or the sale or transfer of the drug to others. Unfortunately, in many states, physicians and pharmacists have not been able to automatically cross-check multiple prescriptions given to the same patient.

To address this problem, Congress first appropriated funds to the Department of Justice in 2003 to promote the deployment of Prescription Drug Monitoring Programs (PDMPs) by States. That commitment continues as part of the Administration's National Drug Control Strategy for 2010. Expanding prescription drug monitoring programs is one of several steps outlined in the Strategy to combat prescription drug abuse. Currently, these programs are operating in 34 states. The Administration supports establishment of these programs in every state, and is seeking to ensure new and existing monitoring programs effectively use the data they acquire and share information across state lines. PDMPs help cut down on prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient's prescriptions for controlled substances. The Office of National Drug Control Policy (ONDCP) is currently working with interested agencies, state representatives and professional organizations to combine the best practices of existing programs to develop PDMP standards. DEA looks forward to working closely with ONDCP to promote these standards. The goal is for 26 states and territories to implement the PDMP standards over a five year period

While the specifics of these programs vary from state to state, they generally share the characteristic of allowing prescribers (for example, a physician) and dispensers (for example, a pharmacist) to input and receive accurate and timely controlled substance prescription history information while ensuring patient access to needed treatment. Many states have some mechanism for law enforcement to receive this information in cases where criminal activity is suspected. Some states also allow health care providers to use this information as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions. In other states the justice system can use this information to assist in the enforcement of laws controlling the sale and use of controlled substance prescription medication.

Unused Prescription Drugs as a Potential Source of Diversion

The diversion of pharmaceutical controlled substances is a significant problem in the United States, as all reliable indicators show that the abuse (non-medical use) of these drugs has reached alarming levels in recent years. (These indicators include, but are not limited to; the National Survey on Drug Use and Health, Monitoring the Future Study, Partnership Attitude Tracking Study, and Drug Abuse Warning Network (DAWN) data.) One factor that may contribute to the increased abuse is the availability of these drugs in household medicine cabinets. In many cases, dispensed controlled substances remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users for abuse, accidental ingestion, or to sell for profit. Accidental ingestion of medication, including a controlled substance, by the elderly and children, is more likely when the household medicine cabinet contains unused medications that are no longer needed for therapy. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to abuse medications. For example, the 2009 Partnership Attitude Tracking Study (PATS) noted that 62 percent of those teens surveyed believe that most teens get prescription drugs from their

own family's medicine cabinets.[1] The Administration recognizes the issue of prescription drug abuse as described in the 2010 National Drug Control Strategy. One of the action items set forth in the Strategy is to increase prescription return/take-back and disposal programs.[2]

Statistics concerning the abuse of pharmaceutical controlled substances and prescription medication also reveal disturbing trends. As recently as June 18, 2010, the Centers for Disease Control and Prevention released a morbidity and mortality report that showed increasing morbidity associated with non-medical use of pharmaceutical controlled substances.[3] Persons between the ages of 12 and 17 abuse prescription drugs more than cocaine, heroin, and methamphetamine combined.[4] In this age group, prescription drug abuse is second only to marijuana abuse.[5] The ease of access to prescription medication is a contributing factor in this growing trend of abuse.

Another factor that may contribute to the overall upward trend of abuse is that teenagers and young adults believe that prescription medications are safer than other drugs of abuse such as heroin, cocaine, marijuana and methamphetamine. The 2008 PATS study noted that 41 percent of teenagers mistakenly believe that prescription medications are "much safer" than illicit drugs.[6] Prescription medications are surrounded by a false sense of security because they are manufactured by pharmaceutical companies, prescribed by physicians and other medical professionals, and dispensed by pharmacies. This false sense of security can end in tragedy. In 2008, 4.7 million teens admitted to abusing prescription drugs at some point in their lives.[7]

In conjunction with the increased abuse of prescription medication, there has been an increase in the number of poisoning deaths related to prescription drug abuse. For the period 1999 to 2006, the Centers for Disease Control and Prevention reported a approximately 270 percent increase in the number of unintentional poisoning deaths (i.e., overdoses) in which opioid analgesics were mentioned..[8] The 2009 Monitoring the Future study reported that Vicodin, the most widely prescribed brand name pain reliever containing the narcotic hydrocodone, is one of the most commonly abused drugs among 12th graders: in 2009, 1 in 10 reported non-medical use in the previous year.[9] On average, every day, 2,500 12-17 year olds abuse a prescription pain reliever for the first time.[10]

Unused Prescription Drugs as a Potential Source of Contamination

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[1] Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATS) Teens 2009 Report. March 2, 2010..
[2] 2010 National Drug Control Strategy, p. 32
[3] Centers for Disease Control and Prevention, *Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs – United States, 2004-2008*, June 18, 2010.
[4] Substance Abuse and Mental Health Services Administration. Results from the 2008 National Survey on Drug Use and Health.
[5] Ibid, p. 20.
[6] Partnership for a Drug-Free America, 2008 Partnership Attitude Tracking Study, Key Findings.
[7] National Survey on Drug Use and Health, Table 1.17A, SAMHSA, Sept 2009
[8] Centers for Disease Control and Prevention, 2007 Unintentional Poisoning Deaths, United States,. March 19, 2010, figure 2. http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf
[9] 2009 Monitoring the Future Study. University of Michigan, Ann Arbor. December 2009 Press Release.
[10] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (October 18, 2007). The OAS Report: A Day in the Life of American Adolescents: Substance Use Facts. Rockville, MD.

Recent studies by EPA and others have detected pharmaceutical drugs in varying concentrations in our nation's water supplies. While drugs in waterways also result from normal excretion routes and metabolic process, there has been an increasing interest among the public in developing methods to dispose of unused pharmaceuticals to reduce their introduction into the water supply. The overwhelming majority (approximately 90 percent) of pharmaceuticals dispensed in the United States are non-controlled substances, which are not subject to the provisions of the Controlled Substances Act (CSA).[11] Any organized collection of unused pharmaceuticals will, in all likelihood, involve the collection of both pharmaceutical controlled substances and non-controlled substances, as the public is generally unaware of the distinctions between controlled and non-controlled substances. As explained below, when controlled substances are involved, the CSA provides stringent limitations on the circumstances in which it is lawful to procure, distribute and possess such drugs.

Current Statutory Requirements

Under the CSA, Congress established a "closed system" of distribution designed to prevent the diversion of controlled substances.[12] In furtherance of the closed system, no controlled substance may be transferred between two entities unless the entities are DEA registrants or exempt from registration. In addition, DEA registrants must maintain copious records of all transactions involving controlled substances. The closed system is monitored by a DEA system that accounts for all controlled substances received, stored, distributed, dispensed, or otherwise disposed.

To maintain the closed system, every entity that distributes controlled substances, or proposes to engage in the distribution of any controlled substance, must obtain a DEA registration authorizing such activity. 21 U.S.C. § 822(a). "The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance . . . ." 21 U.S.C. § 802(11). "The terms 'deliver' or 'delivery' means the actual, constructive, or attempted transfer of a controlled substance ..., whether or not there exists an agency relationship." 21 U.S.C. § 802(8).

"Ultimate users" are exempt from the requirement of registration if the ultimate user lawfully obtained the substance, and possesses the controlled substance for a specified purpose, i.e., for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household. 21 U.S.C. §§ 802(27), 822(c)(3). Most important, this statutory exception does not allow a patient to deliver a controlled substance to any another entity for any purpose, including disposal of the drug.

To summarize, the CSA specifically allows ultimate users to obtain and possess controlled substances for personal use only. The statute does not contemplate that ultimate users may need to dispose of unused pharmaceutical controlled substances. Under current law, an ultimate user is not authorized to deliver or distribute controlled substances for purposes of disposal. Any such distribution by an ultimate user, regardless of the purpose, is illegal.

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[11] Source: IMS Health.
[12] H.R. Rep. No. 91-1444 at 3 (1970).

As an interim measure, DEA offices throughout the country continue to provide technical assistance to law enforcement agencies that conduct community "take-back" programs that collect unused pharmaceutical controlled substances. These "take-back" programs involve duly authorized law enforcement officials collecting unused controlled substances from ultimate users. Upon receipt, the authorized law enforcement agency must maintain custody of the controlled substances up to and including destruction. The manner of destruction must comply with applicable federal and state laws including those related to the public health and environment.

In April 2009, a law enforcement collection program was conducted in North Carolina that included several local sheriffs' offices and the North Carolina State Bureau of Investigation. "Operation Pill Crusher" collected more than 144,000 dosage units of expired and unused prescription medications from local residents. All pills collected were hand-counted, recorded, and transported to an incineration unit for destruction.

In November 2009, DEA's Newark Field Division Office, in conjunction with state and local municipalities, conducted a state-wide take-back program entitled "Operation Medicine Cabinet". More than 440 municipalities in all of New Jersey's 21 counties participated in the event. Over 9,000 pounds of pharmaceuticals were collected and properly destroyed.

Though these programs were successful, they are only a stop-gap measure due to the current statutory constraints.

Current Guidance Pertaining to Unused Prescription Drugs

On February 20, 2007, the U.S. Office of National Drug Control Policy (ONDCP) announced guidelines for the disposal of ultimate user medications, including dispensed controlled substances. The guidelines were published by ONDCP in conjunction with the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA).[13] The guidelines advise the public to flush medications only if the prescription label or accompanying patient information specifically states to do so. For all other medications, ONDCP recommends mixing the drug product with an undesirable substance (e.g. coffee grounds or kitty litter) prior to disposal in common household trash or at community pharmaceutical "take-back" programs. The press release announcing the guidelines stated:

> The new Federal guidelines are a balance between public health concerns and potential environmental concerns. "While EPA continues to research the effects of pharmaceuticals in water sources, one thing is clear: improper drug disposal is a prescription for environmental and societal concern," said EPA Administrator Stephen L. Johnson. "Following these new guidelines will protect our Nation's waterways and keep pharmaceuticals out of the hands of potential abusers."

Due to concerns about public safety, the U.S. Food and Drug Administration has currently identified a small number of prescription drugs which contain one of 10 controlled substances for which the FDA currently recommends disposal by flushing. Primarily narcotics,

[13] Office of National Drug Control Policy, Executive Office of the President. Proper Disposal of Prescription Drugs. February 2007. http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf

these preparations have life-threatening capabilities if improperly handled or improperly ingested.

Regulatory Action

On January 21, 2009, DEA published an Advance Notice of Proposed Rulemaking in the Federal Register entitled *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration.* Through this Notice, DEA sought information from all interested members of the public concerning the safe and responsible disposal of controlled substances. A variety of interest groups were solicited including ultimate users; state and local law enforcement agencies; concerned interest groups; long-term care facilities; hospices and in-home care groups; pharmacies; reverse distributors;[14] state regulatory agencies; and other interested parties.

The public comment period expired on March 23, 2009. DEA received 158 comments from a wide variety of sources including: the general public; the pharmacy community; hospitals; long-term care facilities; and reverse distributors. The DEA cannot move forward with a regulatory proposal without legislation such as those described below.

Problems that the Public is Experiencing in Handling Substances to be Destroyed

Because the CSA currently does not authorize ultimate users to dispose of controlled substances, except under limited circumstances, the distribution of a controlled substance by an ultimate user to another person, regardless of the purpose, violates the CSA. At this time, most U.S. communities do not offer programs to properly dispose of excess controlled substances or waste medication. Many consumers keep the drugs in their possession because they do not know how to dispose of them.

Legislative Proposals

DEA strongly supports legislation that authorizes DEA to address this issue through its rulemaking authority. DEA notes that Congress has offered proposed legislation in both chambers. The legislative intent appears consistent: to provide DEA the regulatory authority to give citizens lawful means to safely dispose of controlled substances that prevents their diversion, while also allowing the destruction of those substances in an environmentally safe manner that is consistent with EPA objectives.

In May 2009, the Department of Justice issued a views letter in support of H.R. 1359, the Secure and Responsible Drug Disposal Act of 2009.[15] A second bill, H.R. 1191, has also been introduced, but DEA has concerns about the complexity of the regulatory scheme called for in that bill, as well as the fact that it does not properly assign responsibility for environmental considerations in implementing take back disposal programs. We have been encouraged by conversations with the bill sponsor regarding these concerns. Additionally, we are hopeful that

[14] Reverse distributors are registered by DEA and authorized to accept controlled substances for destruction only from other DEA-registered persons or companies.
[15] The Senate companion bill is S-1292.

the Energy and Commerce committee, which has jurisdiction over both H.R. 1359 and H.R. 1191, will work toward finding a compromise approach to this important issue. If DEA is given the necessary statutory authority, it will be in a position to promulgate regulations that set forth a comprehensive framework for communities and regulated entities to use as guides to establish secure disposal programs for unused controlled substances. Conceivably, a variety of models will be able to operate under the established regulatory framework.

H.R. 1359, and its companion measures, S.1292 and S.3397, affords the Attorney General discretion to promulgate regulations and provides the requisite flexibility to address this important issue in a comprehensive manner. It would provide a means by which ultimate users may lawfully distribute controlled substances to other persons for disposal. It would do so by amending section 302 of the Act (21 U.S.C. § 822), to clearly state that an ultimate user who has lawfully obtained a controlled substance may, without being registered, deliver the controlled substance to another person for the purpose of disposing of the controlled substance. The person receiving the controlled substance must be authorized under the CSA to engage in such activity. The disposal must take place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances. This provision is necessary because the CSA currently does not allow for ultimate users to deliver controlled substances to others for the purposes of disposal.

This proposed legislation would also amend section 302 of the CSA to add a new provision (section 302(g)(2)) authorizing the Attorney General to promulgate regulations that authorize long-term care facilities, as defined by the Attorney General to dispose of controlled substances on behalf of ultimate users. The disposal would occur in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety. This provision is necessary because nursing homes and other long-term care facilities sometimes gain possession of controlled substances that are no longer needed by patients, but the CSA currently does not allow such facilities, which are usually not registered under the Act, to deliver controlled substances to others for the purposes of disposal. Addressing the unique nature of long-term care facilities is consistent with the numerous regulations promulgated by DEA to address the needs of ultimate users in these facilities.

For consistency with the foregoing amendments, the legislation also amends section 308(b) of the Controlled Substances Act (21 U.S.C. 828(b)) to make clear that the written order form requirement, which is generally a prerequisite under the Act for distributing a schedule I or II controlled substance, does not apply to the delivery of a controlled substance for the purpose of disposal by an ultimate user or long-term care facility acting in accordance with new section 302(g) of the Act.

The authority proposed to be afforded to DEA in H.R. 1359 and its companion measures is straightforward, the ensuing regulations can be implemented uniformly throughout the nation, and the regulatory scheme is envisioned to allow a wide variety of disposal methods that are consistent with effective controls against diversion. In addition, H.R. 1359 and its companion measures would give DEA the flexibility to allow, by regulation, new methods of disposal if and when they are developed in the future.

Conclusion

DEA has the vital statutory responsibility of promulgating and enforcing regulations that will minimize the availability of pharmaceutical controlled substances to non-medical users and preserve the integrity of the closed system of distribution. The collection, removal, and safe disposal of unused medication from households and long-term care facilities is one method of preventing these drugs from getting into the hands of the non-medical user. DEA also supports EPA's mission to dispose of these substances in a manner that is consistent with federal, state, and local environmental laws and regulations. It removes a potential avenue of diversion, limits the availability of medications to drug seekers/abusers and decreases the potential for accidental ingestion/poisoning. It is a priority for this Administration.

The Administration's commitment to supporting the establishment of PDMPs is highlighted in the National Drug Control Strategy for 2010. Expanding prescription drug monitoring programs is one of several steps outlined in the Strategy to combat prescription drug abuse. The Administration supports establishment of these programs in every state, and is seeking to ensure new and existing monitoring programs effectively use the data they acquire and share information across state lines. PDMPs help cut down on prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient's prescriptions for controlled substances.

Chairman Pallone, Ranking Member Shimkus, and distinguished Members of the Subcommittee, I thank you for the opportunity to appear before you today to discuss this important issue and welcome any questions that you may have.

Mr. PALLONE. Thank you.

We will take questions now from the panel, and I will start with myself, and I wanted to ask these questions of Mr. Kerlikowske. Basically I wanted to ask about the National Drug Control Strategy first and then about interoperability, and both relate to NASPER.

With regard to your office, you recently released a new National Drug Control Strategy, and I want to know how State prescription-drug monitoring programs fit into that broader strategy and if you can describe how the office will promote prescription-drug monitoring programs through that strategy.

Mr. KERLIKOWSKE. We have been very supportive of PDMPs, particularly shortly after coming into office and having visited south Florida and looked at some of the problems that were occurring with so-called pill mills in that area, and then visiting with other States. The Department of Justice has been very good about holding the PDMP workshops, bringing people together, and of course in this legislation, it would require that the director of ONDCP be involved in the advertising to people about how PDMPs can be helpful and can be useful, and so we are supportive of them. We have seen them work. We have worked with our partners at the Drug Enforcement Administration and could not think more highly of them.

Mr. PALLONE. Okay. You know, Mr. Whitfield reminded me of the difficulties we have had over the years that he struggled with, you know how we had these sort of two different programs, and so my second question is if you agree that prescription-drug abuse needs to be considered a public health problem and not just a law enforcement problem, and what else is the office doing to reduce prescription-drug abuse?

Mr. KERLIKOWSKE. We made it a signature effort in several ways. The first was that it actually until—and many members of this subcommittee have been involved in this but it really hasn't been recognized for the dangerousness. When I was—and I will just give you a great example of my own lack of knowledge. I had been a police chief for a long time, and I actually think I keep up with the literature and really know this stuff inside out. When I was told at confirmation that more people are dying from drug overdoses than from gunshot wounds and that that was being driven by prescription drugs, I said well, you know, I really didn't know that. I tested a number of my colleagues, none of whom I will name, to ask them if they also recognize the dangerousness of prescription drugs that were out there. Quite frankly, they did not either. And when I talked to judges and when I talked to prosecutors, they didn't either. So first, getting this front and center with the American public about the dangers.

The second thing is, is working with the hospitals, the Joint Commission on Accreditation, to help them develop protocols. We also have visited a number of medical schools. Quite often we don't see an awful lot in the curricula for doctors throughout their training in recognizing dependence, in recognizing addiction and in understanding some of those problems. So those are just a few of the ways, and there are others that are highlighted in the drug control strategy.

Mr. PALLONE. Okay. And then on the interoperability issue, the bill sets a new requirement that States specify a timeline for achieving interoperability of their programs with bordering States that participate in the NASPER program and it also directs the Secretary to monitor States' efforts to achieve interoperability. I know that that is important. I know it also began because of some of the concerns, you know, what they had in Kentucky where people were just going to other States. So my understanding is that the office is not trying to encourage all States to have identical prescription-drug monitoring programs. Is that accurate? Well, let me say this. Why is interoperability so important? Is it true that the office is not trying to encourage all States to have identical programs but then can different States' programs achieve some level of interoperability even if they are not identical?

Mr. KERLIKOWSKE. Mr. Chairman, I think that Kentucky led the way in working with the State of Ohio to absolutely address that. These statewide databases are important, and the fact that so much of the regulatory work is done by the Boards of Pharmacy and the medical boards and having a one-size-fits-all is not something that we would recommend. That being said, the NASPER legislation is particularly helpful because it lays down essentially basic guidelines for what should be included. And so that exchange of information among the States would be the things that would be most useful according to the practitioners that use these in identifying this.

And lastly, I would tell you that again in our visit to the pill mills in south Florida, a number of arrests that occurred through the HIDTAs, which are part of ONDCP also, back in Kentucky, Tennessee and West Virginia, were people that were traveling from those three States to south Florida in order to obtain such things as OxyContin.

Mr. PALLONE. So, but, I mean, again, you don't see a problem in the fact that the programs aren't identical in order to achieve the interoperability?

Mr. KERLIKOWSKE. I don't, as long as there is some basic information that can be exchanged electronically so that those boards and those States that need that basic level of information can use them and utilize them to begin to slow down or even reverse this terrible problem that you have identified.

Mr. PALLONE. Okay. Thank you.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Mr. Director, a lot of my questions are similar to what the chairman mentioned, so obviously you feel that the prescription-drug monitoring program is an important aspect of this fight. That is question one. And we are talking about prescription drugs. A lot of the problems, even connecting—I border Mr. Whitfield's district and I also border southeastern Indiana. What about the whole meth issue and ingredients that are not prescription-drug issues? You have the same issue as States themselves are trying to limit and have lists to prohibit the pseudoephedrine purchase across State lines. Can you speak to that?

Mr. KERLIKOWSKE. I can. As you know, Mr. Shimkus, the Office of National Drug Control Policy was not as particularly attentive

to methamphetamine in its early years as I believe it should have been, and having spent 9 years in the West I clearly recognized the issue of methamphetamine. I don't intend for ONDCP to allow that to happen again, and we want to make sure that we are on top of it. So methamphetamine in the grand scheme of our national drug issues is not as high as some other issues. On the other hand, when your small areas in southern Illinois or places just outside Seattle were being devastated by methamphetamine, we should have been on top of it and moved more quickly. Congress did that through the Combat Meth Act.

Unfortunately, what we are seeing is that now the people who are so good at purchasing over-the-counter or behind-the-counter drugs through false IDs, et cetera, are circumventing the Combat Meth Act. We have seen two measures of success so far. One is in the State of Oregon, which has made pseudoephedrine a prescription only, and their numbers of methamphetamine problems are in single digits as far as laboratories. And then recently Governor Haley Barbour just signed into law in Mississippi similar legislation to make pseudoephedrine a prescription only. There is no definitive evaluation but certainly what we have seen in Oregon bears worth watching.

Mr. SHIMKUS. Thank you. I appreciate the focus and your expertise in having to deal with this.

Let me ask Mr. Rannazzisi, do you think the drug take-back bill allows DEA to mandate that registered entities implement or establish a drug take-back program, current registered entities? Your evaluation, what do you think this legislation does to them?

Mr. RANNAZZISI. I think the legislation provides us with the opportunity to create a framework for drug disposal. When we create regulations for something like drug disposal, we don't try and specify who, what or where. What we try and do is create a framework and allow people to fit within that framework.

Mr. SHIMKUS. And just to follow up, the concern would be through regulations, mandates being placed on entities that currently don't have mandates and then they will have the funds to be able to implement that, so that is the focus of this question and that is why I asked that.

Mr. RANNAZZISI. I don't think I could comment on how the regulatory process is going to proceed until we actually have a piece of legislation, and even then because of the APA rules, Administrative Procedure Act rules, I don't believe I could comment on them.

Mr. SHIMKUS. Well, and I agree, but part of this process is a two-way process.

Mr. RANNAZZISI. Yes.

Mr. SHIMKUS. So hopefully people are listening to comments here to realize that we want to make sure that an unfunded mandate may not fall upon someone who is not expecting it.

Mr. RANNAZZISI. I could assure you that during rulemaking we go through notice and comment and we take all of those comments were very seriously.

Mr. SHIMKUS. Yes, I am not asking you to commit yourself. I am just using the bully pulpit to just make a point.

On these programs, who do you envision would run these programs? I mean, you have done some war gaming.

Mr. RANNAZZISI. Absolutely. The problem is that the programs are such a hodgepodge of different organizations and groups all surrounding law enforcement. At this point in time, you know, while we have not decided who would run the programs, we look to the States and the State regulatory boards to assist us with the program and kind of guide us along about what they would look at towards a program. So at this point in time, we always look to the States, you know, and take their recommendations to heart. So at this point in time we would probably look to the States.

Mr. SHIMKUS. Mr. Chairman, that is all I have and I yield back.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. Kerlikowske, PDMPs track prescriptions for drugs that might be subject to diversion or abuse. However, it is important to monitor the tracking programs to find out what is working and what is not. Is SAMHSA collecting information to help evaluate the NASPER program?

Mr. KERLIKOWSKE. Mr. Green, I actually don't know what information SAMHSA is collecting but I can tell you there are two things going on with evaluations of prescription PDMPs. One is, and it is a bit dated now, the 2006 study that was done that showed some benefits of the PDMPs. The second thing is that the CDC will be releasing, I believe by the end of summer, some research and evaluation on PDMPs. I would tell you that they are not perfect and that we need to make sure that more prescribers are using the PDMPs. That will be a key aspect and I think it is perhaps one of the weaknesses. But it is part of the responsibility for all of us, I believe, to get that word out to the prescribers that this is an effective, useful database, and if they do engage in it, it will help them a great deal.

Mr. GREEN. Are there any federal efforts to evaluate the State prescription-drug monitoring programs?

Mr. KERLIKOWSKE. There are. The CDC effort is an evaluation, and I don't know how many States, but it is an evaluation of different efforts in some of the different States.

Mr. GREEN. I have one more question, Mr. Chairman. Let me find it.

Mr. Rannazzisi, as we have heard, the Controlled Substances Act should not create a pathway for patients and others with leftover controlled substance to return them to pharmacies or take-back programs for proper disposal. To address the resulting problem, you stated the DEA has utilized existing regulations to assist law enforcement agencies to conduct community take-back programs. My question is, can you explain to us the logical issues and resource implications for the DEA in assisting these programs and can you describe how these programs ideally would operate if we amended the Controlled Substances Act so the DEA could issue regulations to enable drug take-back programs to accept these controlled substances?

Mr. RANNAZZISI. First of all, I noticed somebody on the panel mentioned that it was DEA regulations, a problem with DEA regulations. It is not a regulation problem, it is a statutory problem. The statute prohibits anyone, except for registrants, from transferring controlled substances. When an ultimate user obtains a con-

trolled substance, he is exempted from the registration requirement of the Controlled Substances Act. Because law enforcement has an exemption also, they could obtain or take in controlled substances. Currently, that is the only way we could do this, DEA or law enforcement working with communities, but the law enforcement office or the law enforcement agency has to be present, has to take that drug. It can't be done by any other person but the law enforcement agency.

I can't tell you exactly how the—since we don't have the bill yet, I can't tell you exactly how we would create an infrastructure. What I can tell you is law enforcement will still probably be involved, not so much on every take-back program but they will still have the exemption and they will still want to be involved. I know that our law enforcement partners on all of these initiatives have been very straightforward with us. They want to be involved because this is so important to them. As the director said, prescription-drug abuse is a nationwide problem and law enforcement is very aware of that problem and they will do everything in their power to remove those drugs from the illicit market.

Mr. GREEN. Well, it would seem like we need, particularly our committee and our jurisdiction, to provide assistance for folks so they can dispose of their prescription drugs including controlled substances in some way instead of just flushing them down into the water supply, and the studies we have seen and I think a lot of people have of the amount of prescription medication that is now in some of the water that ultimately we will be drinking is one way, if we can make it easier for people to legally and safely return unused prescriptions. So I appreciate what you are doing.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Green.

Next is the gentleman from Pennsylvania, Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. Rannazzisi, expand a little bit on how individuals currently dispose of their prescription drugs. With respect to controlled substances, how are individuals allowed to dispose of prescription drugs? I mean, do you allow pharmacies to accept those drugs?

Mr. RANNAZZISI. Pharmacies are not able currently to accept controlled substances back from their patients. That is just a requirement under the Act. The Act, again, allows for transfer of controlled substances from registrant to registrant. Since an ultimate user is not a registrant, a pharmacy cannot accept that back from them.

Mr. PITTS. So how do individuals currently dispose of prescription drugs?

Mr. RANNAZZISI. As the director said, there's three ways. Currently, ONDCP and HHS on their website, or ONDCP on its website has a model for drug destruction. It involves taking the drugs, deactivating them in something like wet coffee grounds, wrapping up and then throwing them in the trash. There's also on both ONDCP and HHS websites a list of narcotics and other controlled substances that may be flushed, or there are ongoing law enforcement take-back programs in certain communities where they could drop their medicines off.

Mr. PITTS. Mr. Kerlikowske, NASPER sets standards for protecting patient privacy in the controlled-substance monitoring program including restricting who may have access to prescribing information. Can you speak to this issue? Do you think it's important to have minimum criteria among these programs with regard to patient information?

Mr. KERLIKOWSKE. It is. It is one of the things that I think makes NASPER such an attractive law, and that is that it is driven by the States but clearly the States have taken on different issues regarding the blend between a law enforcement issue and a medical practice issue. There are State medical boards that work very hard to make sure that the physicians or all the prescribers are following those rules and regulations. There are certain protocols then for turning over the information at the particular appropriate time to law enforcement, and at the same time the States have made great strides forward under NASPER to make sure that patients and professionals in the medical practice, that the privacy issues are protected, and so I think that that is a wonderful part of the legislation.

Mr. PITTS. Now, NASPER requires that dispensers like pharmacies report each dispensing of a controlled substance no later than one week after the date the drug was dispensed. Do any States have real-time reporting in the controlled-substance monitoring programs and can you discuss the advantages or disadvantages of having a uniform real-time reporting requirement?

Mr. RANNAZZISI. I am not familiar with any of the real-time reporting requirements that the States have had. I think that one of the reasons for the one-week position is that quite often, particularly if it is—and this could apply more in rural areas—that the ability to have information stack up or pile up and not get entered into the database in a fairly timely manner could cause some difficulties both for a prescriber who wants to find out if in fact this patient was going to multiple other places in a short period of time and that would be helpful. I think many times the goal would be, if it was online and real time, would be helpful.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

Mr. Whitfield.

Mr. WHITFIELD. Thank you all very much for your time today and testifying on this legislation.

Mr. Rannazzisi, early on there was some policy discussions and really some disagreements about whether this program should be at HHS or Department of Justice. As someone involved in law enforcement, do you feel that there are adequate safeguards in this legislation that you can have access to fulfill your needs and objectives?

Mr. RANNAZZISI. And I am no expert on NASPER legislation, but from what I understand, currently there are adequate safeguards for us, for law enforcement.

Mr. WHITFIELD. Because we do think that that is important, and of course, I think the main thrust has been the safety of the use of prescription drugs, but we know it is a serious problem, drug abuse, and I had a lot of law enforcement people in my district, and I have actually been a little bit surprised that have actually formed

taskforces now to deal with the abuse of prescription drugs, and I really was not aware that it was such a major problem nationally, but from hearing your testimony, it is one of the most serious problems. Is that correct?

Mr. KERLIKOWSKE. Mr. Whitfield, you are absolutely correct. I don't think that the recognition has been there, and I think that spans across an awful lot of the populace about the dangers of prescription drugs and also about the problems that we are seeing from the abuse of prescription drugs. I think the most recent arrests in Kentucky, Tennessee and West Virginia from south Florida, almost 500 arrests, really helped to highlight that, but, you know, during the National Governors Conference, I had a chance to visit with Governor Manchin, and he said I cannot go anywhere in West Virginia to a public meeting in which someone is not telling me about a prescription-drug problem.

So I think all of the time and the attention that all of the federal agencies, ONDCP, DEA, EPA, et cetera have given to it, to work with this subcommittee and the subcommittee staff on this legislation, both in PDMPs and also in take-backs, is a good example of getting the information out there, and it is a good example of really government being so responsive and listening to essentially the cries of the public about this problem that will make us all safer, and I commend the subcommittee for their work.

Mr. WHITFIELD. Do either of your agencies or departments have any ongoing programs that are active in working with local law enforcement to give them suggestions on how to be more effective in this area of prescription-drug abuse?

Mr. RANNAZZISI. To start off, we reorganized the Office of Diversion Control and the field elements of the Office of Diversion Control and created tactical diversion squads, which are State and local taskforce. We have 34 in operation right now. We hope to have within the next year and a half 65 throughout the United States, and all they will concentrate on is prescription-drug diversion and chemical diversion. That's a State and local cooperative. And Kentucky State Policy is a perfect example. KSP has been on the leading edge of going after and tracking down people who are diverting controlled substances and we work very closely with Kentucky State Police and the State of Kentucky.

It is so important to address this problem as a State and local cooperative effort because of funding issues and because of fact that, you know, this is one issue that we are not going to be able to do it alone.

Mr. KERLIKOWSKE. And Congress has recognized the value of high-intensity drug trafficking areas, the 28 HIDTAs that are funded, and all of the HIDTAs which are comprised of State, local and federal law enforcement but also include some aspects of prevention and treatment. All of the HIDTAs are very much aware of the prescription-drug problem, and in many of these areas have shown real leadership and innovation in attempting to both work on take-backs to support PDMPs but also to do the necessary investigation and enforcement when we have either doctor shopping or physicians in fact, or prescribers, I should say, that may be abusing the law.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Whitfield.

Mr. Gingrey.

Mr. GINGREY. Mr. Chairman, thank you, and I am going to ask a series of questions of both Mr. R and Mr. K, and you can call me Mr. G.

First of all, the obvious, but what kind of prescription drugs are the most likely to be abused?

Mr. KERLIKOWSKE. The opioid painkillers.

Mr. RANNAZZISI. Yes, I have to agree with that.

Mr. GINGREY. And the reason I ask that, I expected that response, I have noticed that a lot of the even legitimate doctors who are involved in pain management, a lot of these physicians start out their professional career as anesthesiologists, but not always, and you see so many of these pain clinics that are popping up, as both of you know, and opioids, but recently it was brought to my attention that a lot of these doctors prescribe methadone now for pain, and as I said in my opening statement, I am a little bit dated. I haven't practiced for 10 years. But I was always thinking of methadone as what you gave people at these drug clinics where the hopeless addicts that could not ever get off opioids and you would give them a prescription for methadone. Tell me a little bit about that, what your knowledge of that is, and your concerns, if any.

Mr. KERLIKOWSKE. Methadone was originally created as a painkiller in the early 1900s. It became the gold standard for narcotic addiction treatment in the 1970s, and it is now reemerging as a very, very fine painkiller, especially in certain areas where the drug is used in combination with other drugs. The problem with methadone is the kinetics of the drug. The drug accumulates, and there are a lot of overdoses because of that.

Mr. GINGREY. It accumulates?

Mr. KERLIKOWSKE. Yes, it accumulates in the body. It stays in the body for a very long period of time. If a person is not following the doctor's instructions on how to take the drug, there could be overdoses. If the person is taking other substances with the drug, it affects the clearance of the drug, the patient could overdose. If it is an opioid-naive patient who has never taken an opioid before, the person could overdose. The drug is a very cheap, good painkiller, but it does have its issues if it is taken inappropriately without a doctor's supervision.

Mr. GINGREY. A two-edged sword, if you will.

Mr. KERLIKOWSKE. Yes.

Mr. GINGREY. Maybe Mr. Whitfield just asked this question about NASPER, and of course Chairman Pallone and Ranking Member Shimkus along with Mr. Whitfield have done the major work on NASPER and leading up this reauthorization, but do you feel that this will help in regard to all these concerns with abuse of prescription drugs, particularly the pain medication like methadone and other opioids?

Mr. KERLIKOWSKE. It is not the silver bullet but we have seen success in these programs. We think it has to be done in conjunction with a lot of the other things that were mentioned, the education of the public, both NASPER but also the take-back I think is a wonderful combination for Congress to take on and to move forward. I think we can actually—we took a hard look at the 10

months before I was in office, the 10 months after I came to office about the number of mentions in the press about prescription drugs, and it was a significant increase, so I think the more—and as Mr. Shimkus said, using the bully pulpit that you all have to bring this to the attention of the public and Dr. Gingrey, you in particular having the medical background, you serve as wonderful spokespersons to alert people to dangers that perhaps they just really have not recognized.

Mr. GINGREY. Well, I thank you for that, those kind words, and in fact, I have got a chemical background, a bachelor of science in chemistry, and a medical background. I had no idea that you could wrap up that medication with coffee grounds and throw it away. Can you tell me a little bit more about how that works, and if that information is on your website, how many people are going to go look and find that out and then all of a sudden rummaging through the trashcans looking for coffee grounds?

Mr. KERLIKOWSKE. Well, I think that is the real benefit of this hearing today and the real benefit of also the work that, as you said, Chairman Stupak did and Congressman has done on working on a clear, simpler, more easily understood take-back program. I think that is tremendously helpful. There are some drugs that are so potent and can be absorbed in the skin that EPA, FDA and ONDCP have recommended that they be disposed of by flushing down the toilet. There are others that need to be, as you said, made in combination with other things that are in the garbage that would make them particularly unattractive to be able to use. But having the take-back programs that are widely known and thought of I think will be a big help.

Mr. GINGREY. Well, I appreciate that.

I know my time is expired, Mr. Chairman, but I don't want to see people rooting through the trashcan or the toilet bowl, for that matter, so I like the take-back program. I yield back.

Mr. PALLONE. Thank you.

Let me ask unanimous consent to include in the record the annual report of the Operation Medicine Cabinet New Jersey. This is the Partnership for a Drug-Free New Jersey program that I mentioned before.

Without objection, so ordered.

[The information was unavailable at the time of printing.]

Mr. PALLONE. And now we have joining us with the subcommittee today Mr. Inslee, who is the prime sponsor of the Safe Drug Disposal Act legislation that we are considering. Mr. Inslee.

Mr. INSLEE. Thank you. Thank you for letting me join you. Before I ask a couple questions of a couple great witnesses, I just wanted to thank some people involved. This has been a great team effort, bipartisan. Particularly I want to note Bart Stupak, who has been working for a long time on this issue. Bart now at the end of his Congressional career will be known throughout history not only as making the greatest catch ever in Congressional history in the Republican dugout but also championing this issue, and I really want to thank Bart's leadership on this.

Also, Representatives Stupak, Waxman, Moran, Baldwin and Pallone, it has just been a great effort, and I think we have got a

good product here, and I appreciate the two witnesses, so I will ask a couple softball questions, if I can.

First, Mr. Kerlikowske, we are having a heck of a time filling your shoes back in Seattle. We are trying. It is really tough. We might have to hire three people actually to fill your shoes, and I appreciate your work on this. I just wonder if you might comment on the importance of making sure that the programs we do design are accessible and are easily accessed by communities and giving communities flexibility and how they are going to design these programs. I just wonder if you might want to comment on that.

Mr. KERLIKOWSKE. I do. Your work and initiative on this along with Congressman Stupak's work has been particularly helpful to us. I am really so impressed with the Safe Drug Disposal Act that is being considered because it really is kind of a whole-of-government approach, and we often sometimes hear that government doesn't listen or pay attention. This is a model bill. One of the things that I think will be particularly important is that we work very closely to make sure with the Department of Justice and the Attorney General's Office that the programs that are put into effect make sense, are easily understood, and more importantly, are evaluated and used, for helping to rid the medicine cabinets of some of these dangerous drugs and rid them in a way that, as you have remarked to me on a number of occasions, gotten rid of in a way that is very environmentally sensitive and make sure that we are protecting the environment. This is a wonderful opportunity for us to do a better job of protecting the public and to bringing to their recognition some of these dangers, and with the passage of this, as the process moves forward, we will be particularly attentive to the concerns that you have raised throughout the formulation of this legislation.

Mr. INSLEE. Thank you. I appreciate it.

Mr. Rannazzisi, I wonder if you would like to comment on the number of options that will be available, the number of locations where these take-back programs maybe appropriate. Do you just want to give us thoughts on that?

Mr. RANNAZZISI. Again, it would be premature without the legislation, the actual statute to comment on it. However, I could tell you that we have said all along what we would like to do is create a regulatory infrastructure that is not specific to one or two or three different programs but allows the States and entities within the State to create a program within those guidelines to fit the needs of their citizens, and I believe we could do that if given the opportunity by regulation, that flexibility to do that.

Mr. INSLEE. We will look forward to that. Again, thank you for your work. This is a big deal on a bipartisan basis. Actually, I think last week I saw a headline in Seattle that prescription-drug abuse became number one as far as abuse, I think in the State. So know this is happening nationwide, and we appreciate your work and thanks for all the bipartisan work, our teammates. Thank you.

Mr. PALLONE. Thank you, Mr. Inslee.

Mr. WHITFIELD. Chairman Pallone.

Mr. PALLONE. Sure. You want to——

Mr. WHITFIELD. No, I would just ask unanimous consent that each member have five legislative days to submit additional letters of support.

Mr. PALLONE. Absolutely, and also I would remind our witnesses that you may get additional questions from members. I asked the members to submit those additional written questions within 10 days or so, so you may get those additional questions from us.

Mr. SHIMKUS. Mr. Chairman.

Mr. PALLONE. Yes.

Mr. SHIMKUS. And I would ask just for a second, because Oregon was mentioned and it is prescribing pseudoephedrine, and that is an issue that we have talked before, and we will have debate, especially in the health care arena and access to family, cost of drugs, but I think it is also important to note that there has been an increase in Mexican drug meth cartel in Oregon at the same time. So there may be some benefits in home cooking. There may be an uptick in Mexican drug cartel, and it is important to keep that in the record.

Mr. PALLONE. Sure. Thank you.

So anyway, thank you very much for your input. We are actually going to go to markup pretty soon on the legislation. So this was very helpful to us. I appreciate it.

Let me mention to the members, we are supposed to have a vote, I don't know, any minute, I guess, within the next—two votes within the next few minutes on the Floor. So what I would ask is that we come back here about 15 minutes after the Floor votes and then we will begin the markup at that time, which is not only on these bills but some other bills as well that had previous hearings.

So without further ado, thank you all, and this subcommittee hearing is adjourned.

[Whereupon, at 11:12 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of Chairman Henry A. Waxman
Committee on Energy and Commerce
Subcommittee on Health
Legislative Hearing on H.R. 5710 and H.R. 5809
July 22, 2010

Thank you, Chairman Pallone, for holding this hearing and this afternoon's markup.

Prescription drug abuse is a serious and escalating public health problem. As we will hear today, a new study suggests that there has been a staggering 400% increase in hospital admissions for individuals needing treatment for prescription drug abuse.

A large portion of those who abuse prescription drugs access them in the home. This points to at least one obvious solution: we need to do everything we can to give people a way to get prescription drugs they are not using out of the home as soon as possible.

The Safe Drug Disposal Act introduced by Reps. Inslee, Smith, and Stupak will go a long way toward this goal. I applaud them for their leadership on this issue.

This legislation will promote the expansion of drug take-back programs that can safely dispose of unwanted drugs.

These programs will also have another important effect: they reduce the impact on the environment. When people do not have a safe place outside of the home where they can dispose of their unused drugs, they typically flush them down the toilet, causing them to ultimately end up in our waterways. We don't yet have a full picture of the human health and environmental impacts, but this raises serious concerns regarding drinking water and aquatic ecosystems.

This morning we are also looking at the role of state Prescription Drug Monitoring programs. These programs track prescriptions so that states can identify and address drug diversion or abuse. They help law enforcement, but they also help doctors and public health authorities prevent and respond to the potentially devastating effects of prescription drug abuse.

The NASPER program, first authorized in 2005, authorizes the Secretary to make grants to support these state programs. It also sets standards for privacy and interoperability. H.R. 5710 will reauthorize the program, enhance evaluation and reporting, and make other updates to the program.

These are much-needed pieces of legislation and I look forward to hearing the views of our witnesses here today.

STATEMENT OF THE HONORABLE JOE BARTON
RANKING MEMBER COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE HEARING:
July 22, 2010

I would like to thank Chairman Pallone for holding this hearing today to focus on two bills that address the rising levels of prescription drug abuse.

Prescription drugs provide valuable therapeutic benefits to hundreds of millions of Americans.. Unfortunately, some people chose to use some medications not for health but for entertainment. Limiting the abuse of prescription drugs has been a priority for this Committee and its Members for years. In fact, the first Health Subcommittee hearing held after I became Chairman of the Committee focused on strategies to deter prescription drug abuse.

In 2004, the National Center on Addiction and Substance Abuse at Columbia University reported that more Americans were abusing

controlled prescription drugs than were using cocaine, hallucinogens, inhalants and heroin combined. The center also said that the number of Americans who admit abusing prescription drugs nearly doubled to over 15 million between 1992 and 2003, and abuse among teens had tripled.

Just last week the Substance Abuse and Mental Health Services Administration reconfirmed that prescription drug abuse remains a serious public health threat. The report found the proportion of all substance abuse treatment admissions involving prescription pain relievers rose by over 400 percent from 2.2 percent in 1998 to 9.8 percent in 2008. This increase in the proportion of admissions associated with the abuse of these drugs occurred across the breadth of the U.S. population without regard to age, gender, education or employment.

In 2005, thanks to the leadership of Congressman Whitfield, Chairman Pallone, Chairman Stupak, and the late Charlie Norwood, this Committee passed the National All Schedules Prescription Electronic

Reporting Act, known to some as NASPER. NASPER was designed to reduce prescription drug abuse by providing physicians with the tools to stop this abuse before it starts. The law allows physicians to provide proper medication therapy to patients, while also cracking down on the interstate diversion of prescription medications.

It took until 2009 to get NASPER funded, so the program has yet to reach its full potential. I look forward to hearing from the witnesses today on the importance of prescription drug monitoring programs and to working with my colleagues to make this program successful.

The Committee also will hear testimony about legislation to improve drug take-back programs where pharmacies and others accept unused prescription drugs and dispose of them safely. Due to a technical reading of the Controlled Substances Act, these programs may not take back controlled substances. By passing this legislation, these programs could help further reduce the likelihood of prescription drugs being diverted to those to whom they were not prescribed. For obvious reasons, we don't want outdated, unused painkillers to sit in a million

home medicine cabinets, available for misuse. If these programs are already taking back prescription drugs for disposal, common sense should allow them to take back these controlled substances, as well.

Thank you again Mr. Chairman for holding this hearing. I yield back the balance of my time.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 28, 2010

The Honorable Henry Waxman
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Waxman and Ranking Member Barton:

The National Association of Chain Drug Stores (NACDS) applauds you and the Committee for advancing legislation to help address prescription medication abuse and diversion. Our members are committed to ensuring that prescription medications are used appropriately and we believe access to neighborhood pharmacies and pharmacist-provided care can improve medication adherence, thereby improving health outcomes, reducing costs and mitigating problems related to medication abuse, diversion and waste. We are pleased to add our strong support to legislation the Committee is considering.

NACDS represents 154 traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. NACDS members also include more than 900 pharmacy and front-end suppliers, and over 70 international members from 24 countries. Chains operate 37,000 pharmacies, and employ more than 2.5 million employees, including 118,000 full-time pharmacists. They fill more than 2.5 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

H.R.5809, the Safe Drug Disposal Act

NACDS supports efforts to find a safe and effective means for consumers to dispose of their unused medications, including controlled substances. We believe these programs must be structured to protect public health and safety and preserve the integrity of the drug distribution supply chain. We believe that "mail back" programs, such as one successfully tested in the state of Maine with the support of the Environmental Protection Agency, are an effective means of safely disposing of unused medications.

While some have suggested drug "take back" programs are a way to address disposal of unused medications, these programs can raise health and safety concerns. Having pharmacies accept previously-dispensed prescription drugs from the public is potentially hazardous since these drugs have left the secure drug distribution system. These products could be contaminated with infectious diseases or other hazardous substances. This would pose risks to the public and pharmacy personnel through exposure to contaminants and could possibly contaminate other products, including drugs or food. Moreover, drug take back programs can be impractical, since pharmacies are designed for the safe and efficient dispensing of medicines to consumers, not as collection sites.

We applaud the Committee's bipartisan leadership, and the bill's primary sponsors Representatives Inslee, Stupak and Smith, for working with us to address these concerns.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

We understand Congressman Stupak will offer an amendment to ensure that regulations by the Drug Enforcement Administration (DEA) will not require any entity to establish a drug disposal program, such as a take back program. This would leave pharmacies and other entities free to determine the best means for working with consumers and law enforcement to safely dispose of unused drugs. We strongly support the amendment.

H.R. 5710, the National All-Schedules Electronic Reporting Reauthorization Act
While most individuals take prescription medications responsibly, the potential exists for controlled substances to be diverted and abused. Numerous states utilize prescription drug monitoring programs as a tool to curb diversion and abuse of controlled substances. While these programs can be useful to law enforcement in combating diversion, it is important that they not be administratively burdensome or disruptive to patient care activities and the legitimate practices of pharmacy and medicine. Our industry works with all states that have prescription drug monitoring programs, which serve important national and state public health goals. H.R. 5710 will assist states with funding for state prescription drug monitoring programs and we are pleased to support this legislation.

H.R. 2923, the Combat Methamphetamine Enhancement Act
Our membership has long supported both local and national efforts to combat methamphetamine abuse and production. In fact, even before the introduction of state and federal legislation, the majority of the chain pharmacies took voluntary, proactive steps to reduce the theft and illegitimate use of products containing pseudoephedrine and ephedrine. Moreover, our members have worked closely with DEA and state and local law enforcement officials since 1995 to stem the tide of methamphetamine production in communities across the United States.

H.R. 2923 closes a loophole in the Combat Methamphetamine Epidemic Act of 2005 by requiring all entities that sell products containing pseudoephedrine to certify with DEA. We have endorsed this legislation and remain committed to working with federal policymakers to craft solutions to help combat methamphetamine abuse and production.

Thank you for your leadership on these important issues. We look forward to working with you as these bills move to the full House of Representatives for its consideration. If you have any questions, please feel free to contact Paul T. Kelly, Vice President, Federal Government Affairs, at (703) 549-3001.

Sincerely,



Steven C. Anderson, IOM, CAE
President and Chief Executive Officer

cc: The Honorable Frank Pallone, Chairman, Energy and Commerce, Subcommittee on Health

The Honorable John Shimkus, Ranking Member, Energy and Commerce, Subcommittee on Health

The Honorable Bart Stupak, Chairman, Energy and Commerce, Subcommittee on Oversight and Investigations

The Honorable Lamar Smith, Ranking Member, Judiciary Committee

The Honorable Jay Inslee

The Honorable Bart Gordon

The Honorable Ed Whitfield

