

**RESPONDING TO THE PRESCRIPTION DRUG  
EPIDEMIC: STRATEGIES FOR REDUCING ABUSE,  
MISUSE, DIVERSION, AND FRAUD**

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**HEARING**

BEFORE THE  
SUBCOMMITTEE ON CRIME AND TERRORISM  
OF THE  
COMMITTEE ON THE JUDICIARY  
UNITED STATES SENATE  
ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

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**TUESDAY, MAY 24, 2011**

U.S. SENATE,  
SUBCOMMITTEE ON CRIME AND TERRORISM,  
COMMITTEE ON THE JUDICIARY,  
*Washington, DC.*

The Committee met, pursuant to notice, at 9:04 a.m., in room SD-226, Dirksen Senate Office Building, Hon. Sheldon Whitehouse, Chairman of the Subcommittee, presiding.

Present: Senators Whitehouse, Klobuchar, and Blumenthal.

**OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, A U.S.  
SENATOR FROM THE STATE OF RHODE ISLAND**

Chairman WHITEHOUSE. The hearing will come to order. This morning's hearing considers a topic that is extremely important to the health and safety of our kids, of our families, and of our communities, and that is, "Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse, Diversion, and Fraud."

Used properly, under a physician's direction, pain relievers and other prescription drugs bring much-needed comfort to Americans. But their abuse poses a serious and growing threat to our communities and young people. In 2009, approximately 7 million Americans reported misuse of prescription drugs. The problem is particularly acute among teenagers. Prescription drugs are the second most abused category of drugs among our Nation's young people, and six of the top ten abused substances among high school seniors are prescription drugs.

Prescription drug abuse is extremely dangerous. Over the last 5 years, emergency room visits involving improper use of pharmaceuticals more than doubled. Too often, the consequences were deadly. According to the CDC, drug-related poisonings are now the leading cause of death due to unintentional injuries in my home State of Rhode Island and in 16 other States, greater even than motor vehicle accidents.

Diversion and abuse of prescription drugs can also impose significant financial costs on our health care system through emergency room visits and treatment of medical complications. We pay for that through higher private insurance premiums and higher Medicare and other public health costs.

The ever-growing epidemic of prescription drug abuse demands sustained attention from law enforcement, health care professionals, and Congress. It poses challenges similar to those faced from other illegal drugs. As with illegal drugs, for instance, large-scale criminal networks have developed for the diversion and distribution of prescription drugs.

However, there are unique challenges in the prescription drug context. These drugs can be readily available in our homes, giving teens easy and direct access. Approximately 70 percent of people aged 12 or older who used prescription pain relievers non-medically in 2009 got them from a friend or relative.

Furthermore, education about the threat of prescription drugs is more difficult because these legal drugs have an important medical purpose, are prescribed by physicians, and come from pharmacies. Teens are too often unaware of the dangers of misuse and abuse.

The special characteristics of prescription drugs demand a multi-pronged strategy for reducing wrongful use. This strategy should include educating prescribers and patients about responsible uses of these drugs, recognizing signs of abuse, providing appropriate treatments and interventions, and deploying appropriate law enforcement resources.

Electronic information-sharing systems, such as the prescription drug monitoring programs authorized in 43 States, are promising tools for identifying pill mills and doctor shoppers. I was pleased to get bipartisan legislation passed last year allowing the Government to perform sophisticated analyses of Medicare data in order to avoid paying fraudulent claims and to give law enforcement tools for investigating criminal fraud. There are analogous ways to strengthen prescription monitoring programs so that they have more complete prescription data, use advanced analysis to identify diversion or abuse, and better allow prescribers, law enforcement, and others to address these problems.

E-prescribing can also play a valuable role, limiting diversion, fraud, and medical mistakes by reducing opportunities for forgery and error. I am pleased that Rhode Island is a national leader in e-prescribing. We can combine the advantages of e-prescribing and of prescription monitoring programs to help physicians recognize early patterns of abuse.

Today's hearing seeks to advance these goals. I welcome our witnesses from the Office of National Drug Control Policy and the Drug Enforcement Agency, as well as from Brandeis University and my home State of Rhode Island.

I congratulate the Obama administration on the release of their proposals for responding to America's prescription drug abuse crisis. I look forward to working with the administration, Chairman Leahy, Ranking Member Kyl, and other Senators from both sides of the aisle on legislation to protect against prescription drug abuse.

I saw Senator Kyl this morning, and he indicated that he may not be able to attend the hearing today. His schedule has been, I guess, a little bit tumultuous, and if he can, of course, I will recognize him. But if he does not, I have been instructed to proceed.

We have Senator Sherrod Brown of Ohio here to kick off the hearing. Senator Brown has taken a keen interest in this issue, and we look forward to his statement. Thank you, Senator Brown.

**STATEMENT OF HON. SHERROD BROWN, A U.S. SENATOR  
FROM THE STATE OF OHIO**

Senator BROWN. Thank you, Chairman Whitehouse, for allowing me to testify today and for your leadership on this important Subcommittee on Crime and Terrorism.

Chairman Whitehouse and I served together on the Health, Education, Labor, and Pension Committee where we worked closely together on the Patient Protection and Affordable Care Act, and throughout our time in the Senate, I valued his expertise on the connections between our health care and our legal systems.

Today's hearing is an example of that connection, how the rampant abuse and trafficking of prescription drugs pose both a public health threat and a law enforcement threat. In recent years, more Ohioans have died from prescription drug overdoses than from car accidents. In 2008, statistics show that oxycodone and Percocet and other prescription drugs caused more overdoses in Ohio that year than heroin and cocaine combined. Prescription pain medications such as OxyContin are largely responsible for increasing overdoses and deaths in my State and across the country. Simply put, prescription drug abuse, as the Chairman said, is the fastest-growing drug problem in the Nation.

Almost every day in Ohio, there is a reported story of a child lost to prescription drug abuse or neighborhoods harboring its illicit trade. In southeast Ohio, the most rural part of the State, it is particularly tragic. Old factory towns and rural communities have become havens for prescription drug abuse. These stories, of course, are not limited to Ohio and Rhode Island. Across the country communities are struggling to find ways to respond and to develop strategies to reduce the diversion and abuse of prescription drugs.

Last year, I convened a first of its kind roundtable in southern Ohio with Federal and local law enforcement, community activists, elected officials, drug treatment leaders, and members from the medical community. They raised a concern with criminal manipulation of Ohio's Medicaid program, which spends upwards of \$820 million on prescription medicines. While most prescription pain medicines are used as prescribed, as the Chairman pointed out, and they are valuable, some criminals defraud the Medicaid system and fleece Ohio taxpayers by acquiring multiple prescriptions and filling them at multiple pharmacies.

A case of criminals defrauding taxpayers in the Medicaid system to sell and divert prescription drugs becomes a one-two punch in the stomach to the system. That is why last month I introduced the Stop Trafficking of Pills Act, which would establish a Medicaid lock-in program for Ohio and nationwide to crack down on the use of Medicaid cards to obtain and illegally resell prescription drugs. The bill would prevent prescription drug abusers from acquiring excess prescription drugs which they may abuse or illegally resell by barring them from visiting multiple doctors and pharmacies. Nearly 20 States already have something similar to the Medicaid lock-in program. South Carolina's Medicaid lock-in pilot program

targeted at high-use beneficiaries spurred a 43-percent decrease in the total number of prescribed prescription pain medications.

Consider Scioto County on the Ohio River in southern Ohio. In this Ohio River town, prescription drugs cause nine of every ten fatal drug overdoses. In nearly two-thirds of these cases, the individuals involved did not have prescriptions themselves, indicating, of course, they in all likelihood obtained the drugs illegally. An investigation by the GAO, which audited the Medicaid program of the five largest States, found 65,000 cases in which Medicaid beneficiaries visited six or more doctors and up to 46 different pharmacies to acquire these prescriptions. This same report found approximately 800 prescriptions written for dead patients and 1,200 prescriptions written by dead physicians.

Under a Medicaid lock-in program, States would identify high-risk prescription users, those who are receiving an excessive amount of prescription drugs or those who have been convicted of a drug-related offense. These high-risk prescription drug users would be placed in the program and assigned one physician and one pharmacy. It would mean no more doctor shopping, no more pharmacy hopping.

States would identify prescription drugs that are dispensed under Medicaid and that present a high risk of overutilization. The legislation requires the Federal Government to set up a similar lock-in program for Medicare, where the abuse is there but obviously not as high. Prescription drug abuse in Ohio and our Nation needs to be treated like the epidemic it is.

Chairman Whitehouse has been a leader on this issue, urging the DEA to implement electronic prescribing for controlled substances and calling for strong prescription drug monitoring systems.

Today's witnesses will describe the administration's comprehensive prescription drug strategy and ways FDA can crack down on the abuse, and community activists will describe the victims and families whom they represent, offering the stories behind the statistics and policies being discussed.

From the policies to the stories, it is clear prescription drug abuse knows no party lines. It is clear it is an issue of life or death in too many parts of our Nation, at least in my State especially in rural areas, which have experienced terrible job loss and economic hardship for hundreds of thousands of families.

I will stop there. I thank the Chairman for allowing me to testify.

Chairman WHITEHOUSE. Senator Brown, I appreciate very much your energy and your leadership on this issue, both here in Washington and in your home State of Ohio. It seems that Ohio and Rhode Island have a lot in common on this issue, and I look forward to continuing to work with you as you go forward. I particularly appreciate that, as busy as your schedule is, you took the time out this morning to come to this Committee, of which you are not a member, to make sure that your voice was heard here, and I am very grateful to you for that.

I know your schedule commands you to be elsewhere, so thank you very much for taking the trouble.

Chairman WHITEHOUSE. Now I will ask our first panel, Hon. Gil Kerlikowske and Hon. Michele Leonhart, to come forward. Let me ask you to stand and be sworn. Do you affirm that the testimony

you are about to give before the Committee will be the truth, the whole truth, and nothing but the truth?

Mr. KERLIKOWSKE. I do.

Ms. LEONHART. I do.

Chairman WHITEHOUSE. Thank you. Please be seated.

Thank you both for being here. It is an impressive turnout. And for those of you who do not know our witnesses, Gil Kerlikowske is the Director of the White House Office of National Drug Control Policy. Director Kerlikowske served as the chief of police for Seattle, Washington; was Deputy Director for the U.S. Department of Justice Office of Community-Oriented Policing Services; was police commissioner of Buffalo, New York; and served in the St. Petersburg, Florida, police department. He has been elected twice to be president of the Major Cities Chief, and he has received numerous awards and recognition for leadership, innovation, and community service.

He is joined by Michele Leonhart, who is Administrator of the Drug Enforcement Administration. Confirmed in December 2010, she had been the Acting Administrator since 2007 and Deputy Administrator since 2004. As a career DEA special agent, Ms. Leonhart held several key positions as she moved through the ranks of DEA, including as assistant special agent in charge of the Los Angeles Field Division. She has received numerous awards, including the Rank of Distinguished Executive in 2004, and the Presidential Rank Award for Meritorious Service in 2005 and 2000.

It is truly our privilege to have these two witnesses here, and why don't we go across the table. We will start with Mr. Kerlikowske. Please proceed with your statements.

**STATEMENT OF HON. R. GIL KERLIKOWSKE, DIRECTOR,  
WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY,  
WASHINGTON, DC**

Mr. KERLIKOWSKE. Chairman Whitehouse, thank you very much for this opportunity to address the important issue of prescription drug abuse in our country, and I am very grateful for the Committee's attention to this topic. Prescription drug abuse has been a major focus at ONDCP since my confirmation, and I have directed the National Drug Control Program agencies to address this epidemic in our country.

I have the responsibility to raise public awareness, coordinate Federal activities, and take action on drug issues that affect our Nation. The efforts that we have taken are balanced. They incorporate new research and evidence-based approaches to address drug use and its consequences.

Prescription drug abuse is the fastest-growing drug problem in the United States. It is categorized as a public health epidemic by the Centers for Disease Control and Prevention. The number of individuals who for the first time consumed prescription drugs for a non-medical purpose was similar to the number of first-time marijuana users. We have also seen a fourfold increase in addiction treatment admissions for individuals primarily abusing prescription painkillers from 1997 to 2007.

Even more alarming is the fact that about 28,000 Americans have died from unintentional drug overdoses in 2007, and prescrip-

tion drugs, particularly the opioid painkillers, are considered major contributors to the total number of drug deaths. And we believe there are two unique reasons for the growth in prescription drug abuse: easy accessibility to the drugs and the diminished perception of risk. A comprehensive approach is required to address this epidemic. It is important to balance prevention, education, and enforcement with the need for legitimate access to controlled substances.

The administration has created an inclusive Prescription Drug Abuse Prevention Plan that brings together Federal, State, local, and tribal groups to reduce prescription drug diversion and abuse. The plan expands upon the administration's National Drug Control Strategy and has four major areas.

The first is education. Mandatory prescriber education as well as patient and parent education is essential. Sixty-nine percent of narcotic analgesics are distributed in primary care offices and emergency departments. In addition, we want to make sure that patients and parents are fully aware of the dangers and the prevalence of prescription drug abuse and that they are educated about the safe use and proper storage and disposal of these medications. The FDA is implementing a Risk Evaluation and Mitigation Strategy plan that requires manufacturers of long-acting and extended-release opioids to ensure that training is provided to prescribers.

The second part of our plan includes that each State have a Prescription Drug Monitoring Program (PDMP), and Senator Brown mentioned the importance of those, and I know you have another witness that will be talking about those. But we are strongly supportive of those and that they have interoperability and that they be used by all of the prescribers.

We have also made significant investments in health information technology and continue to work with HHS particularly on health information exchanges. Opportunities include identifying ways to incorporate real-time PDMP data at the point of care and dispensing.

The third part of the plan calls for proper medication disposal. Unused medications that sit in our medicine cabinets are falling into the wrong hands, and by creating a method for proper disposal of expired or unused prescription drugs, we will benefit public health, public safety, and the environment. Passage of the Secure and Responsible Drug Disposal Act in 2010 was an important step forward in our efforts to make prescription drug disposal more accessible to individuals and to reduce the supply of drugs available. A drug disposal program has to be easily accessible to the public, environmentally friendly, cost-effective, and the cost burden should not be placed on consumers.

The last part of the plan is smart law enforcement. You have the expert sitting to my left to talk about that, but our main effort will be, as they have already done with the DEA's comprehensive work on pill mills, to address the issue of doctors who overprescribe, and of course, PDMPs help with doctor shopping. Our office, ONDCP, supports the HIDTAs, the High-Intensity Drug-Trafficking Areas, and we want to make sure that local law enforcement, with the cooperation of DEA, have the support that they need to understand

these complex investigations and do a better job of bringing drug dealers to justice.

In closing, I want to thank all of my colleagues in the executive branch, but particularly we could not be effective in any of these areas without the support of Congress.

[The prepared statement of Mr. Kerlikowske appears as a submission for the record.]

Chairman WHITEHOUSE. Thank you, Director Kerlikowske.  
Director Leonhart.

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

Ms. LEONHART. Chairman Whitehouse, Senator Klobuchar, thank you for the opportunity to discuss the growing epidemic of prescription drug abuse and the critical role of the Drug Enforcement Administration in the enforcement of our Nation's drug laws and regulations.

The diversion and abuse of pharmaceutical controlled substances is a significant and growing problem in the United States. Every leading indicator shows increases over relatively short periods of time in the use and abuse of these drugs. Pain clinics have emerged as a major source of controlled substances for non-legitimate medical purposes. DEA and other Federal, State, and local law enforcement agencies have developed great working relationships and continuously coordinate efforts to combat this emerging threat.

Federal administrative and criminal actions against a physician with controlled substance privileges is rare. However, such actions are warranted when a physician is issuing controlled substance prescriptions for an illegitimate purpose and operating outside the usual course of professional practice. And as Administrator, I have made prescription drug abuse a top priority.

I am especially alarmed that another contributing factor to the increase in prescription drug abuse is the availability of these drugs in the household. In many cases, prescription drugs 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 illegal distribution for profit. And the 2010 Partnership Attitude Tracking Study, which we call PATS, noted that 51 percent of those surveyed believe that most teens get prescription drugs from their own family's medicine cabinets.

DEA manages a robust regulatory program aimed at preventing and curbing diversion, all the way from the manufacturing level to the dispensing of these medications to patients. In working with Congress, DEA also obtained new authority last year to regulate the disposal of unused medications by ultimate users, thereby getting unused medications out of the household medicine cabinets in a lawful manner.

DEA is working diligently to promulgate disposal regulations. In the interim, DEA launched a nationwide take-back initiative in September of last year and again in April of this year, resulting in the combined collection of 309 tons of unwanted or expired medica-

tions. And DEA will continue to hold periodic take-back events until regulations are in place.

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. And 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 doctors. In this manner, DEA is committed to balancing the need for diversion control and enforcement with the need for legitimate access to these drugs.

DEA closely monitors the closed system through recordkeeping requirements and mandatory reporting at all levels of the supply chain. Due to enhancements to our regulatory resources, controlled substance manufacturers, distributors, importers, exporters, and narcotic treatment programs are receiving more inspections and audits than ever before. A key component to our enhanced investigative resources are tactical diversion squads. These unique groups combine the skills of special agents, diversion investigators, and task force officers. These TDS groups, as we call them, are dedicated solely toward investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes, and as of today, DEA has 37 operational TDS groups. DEA plans to add 27 more over the next few years.

One example of the effectiveness of these tactical diversion squads is Operation Pill Nation, which has targeted rogue pain clinics in South Florida since February of 2010 and culminated in a series of major takedowns this past February. This led to 32 arrests, including 12 doctors and 5 pain clinic owners, and DEA also immediately suspended 63 DEA registration numbers and issued orders to show cause on 6 DEA registrations, which resulted in the surrender of 29 DEA registration numbers. And this caused a ripple effect throughout South Florida and resulted in 54 more registration numbers being surrendered.

DEA recognizes that it cannot solve this problem alone, and DEA is working with our Federal, State and local, and private sector partners as a part of this administration's comprehensive approach to combating prescription drug abuse.

Many States also have adopted prescription drug monitoring programs, which are deemed to be a valuable tool in curbing diversion. The administration supports establishment of these programs in every State because 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.

In closing, prescription drug abuse is a dangerous threat, and DEA is determined to be a part of the solution. And with your support and that of our partners, I know we will continue to make a positive difference in the lives of millions of Americans and communities across the Nation. So I thank you for the opportunity to appear here today, and I look forward to answering your questions.

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



Chairman WHITEHOUSE. Thank you, Ms. Leonhart.

Chairman Leahy could not be here today, but he has offered a statement for the record reflecting, among other things, observations we got, Director Kerlikowske and I, with the Chairman at the hearing that he held up in Vermont last year with all of us together. And without objection, I will add that to the record of this hearing.

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

Chairman WHITEHOUSE. I have a couple of questions. I think I will probably pass on the drug disposal questions because we are joined by Senator Klobuchar, who was the author of the Secure and Responsible Drug Disposal Act of 2010 that was mentioned in the testimony. But I do want to mention on that that I was in Rhode Island the other day at the Narragansett Bay Commission's Bucklin Point Treatment Facility, and they are actually seeing effects from pharmaceuticals that are discarded down the drain out in the environment as they come through the treatment system and go out in that case into the river and then on down to the bay. So it is not a solution necessarily to have people dispose of this by throwing it down the drain. We really have to improve on that, and I suspect she will urge you to move those regulations with some degree of dispatch.

As you know, we have had a long battle over the e-prescribing regulations. I think that has been 3 years from when we had the first hearing, and your predecessors at DEA sat next to people from HHS and had completely different views of the world, and in the same administration. And I gather that that has all been worked through, but if you could bring me up to date on where we are under the interim final rule in terms of actual deployment and the ability to certify contractors and actually have e-prescribing take place in the field.

I am assuming that you view e-prescribing as an investigative and awareness asset in the drug diversion problem, and in that frame, I would like you to let me know where we stand.

Ms. LEONHART. Yes, Chairman. We do view e-prescribing as an important tool—a tool for law enforcement, actually. We have worked very hard, especially since last March when I signed the interim rule, which went into effect almost a year ago. June 1st will be a year. We have been in contact with the people that are putting together the systems. They are moving forward. And we understand the first ones may be ready this summer for audit and then come online and be available by the end of the year.

We have looked at a number of the comments that came in. The interim rule is in effect now. We believe the final rule will be ready to go early next year, and there should be no reason that people should not be moving forward to implement e-prescribing, which will help in many ways to include the diversion problem of prescription drugs, as well as help with fraud and enhance health for patients.

Chairman WHITEHOUSE. Is there actually e-prescribing of controlled pharmaceuticals under the interim final rule happening now? Or are people still waiting for the contractors to be certified so that it can actually happen? I mean, it is one thing to have the

rule be in operation. It is another thing to actually have something happen in the real world. And I am not sure that this has actually hit the real world yet. Could you let me know what the status is in terms of actual flow of data across e-prescribing networks of controlled pharmaceuticals?

Ms. LEONHART. Well, I can tell you it has not hit the real world yet, but the systems are being put in place. They first need to be audited. We understand one has announced called "Doctor First." It has announced that it is DEA compliant and is ready to move forward, and I believe it is in the auditing stages now and has identified over 150 different customers, and that will be the first one that we have heard of that will come online probably by the end of the year.

Chairman WHITEHOUSE. I am not going to remember the exact numbers that Senator Brown used, but he described individuals who had multiple prescriptions from multiple doctors and were using multiple pharmacies, and that is the type of thing that this sort of system can flag so that it does not happen, correct?

Ms. LEONHART. That is correct—that with the prescription drug monitoring programs, we will be able to identify people that are doctor shopping, as you just explained.

Chairman WHITEHOUSE. I will now recognize Senator Klobuchar, author of the Secure and Responsible Drug Disposal Act of 2010.

Senator KLOBUCHAR. Thank you. You remember that name better than I do. That is pretty good.

Thank you to both of our witnesses. Director Kerlikowske and I worked together back when he was police chief and I was county attorney. And then, of course, Ms. Leonhart, we have worked together as well, and you are from Minnesota so you can do no harm, as far as I am concerned.

[Laughter.]

Senator KLOBUCHAR. I wanted to go through—as Senator Whitehouse mentioned, we passed into law the Secure and Responsible Drug Disposal Act, something that Senator Cornyn and I authored, and got it through the House, and thank you for your help in doing that, Director Kerlikowske. And I wanted to find out the status of the rules. You know what this bill does, acknowledging that prescription drugs are the No. 2 way that kids can get addicted to drugs, the drugs sitting around in their parents' medicine cabinets. And this allows pharmacies to do take-back programs, more than just police departments; clarifies some of the details; also for long-term care facilities, which it turned out were flushing a lot of these pills down the toilet because they did not know what they could do legally. And I know that the regulations were included as part of the plan released by the White House.

Can you give us an update on the drafting of the regulations? And what are some of the key issues you will be looking at? And what do you think the timetable will be?

Mr. KERLIKOWSKE. Senator, since it is in the design of the rule-making, and the White House is not influencing the rulemaking, I would defer and ask that maybe Administrator Leonhart answer that question. Thank you.

Senator KLOBUCHAR. OK. Very good. Thank you.

Ms. LEONHART. Senator, I want to thank you for your support. I am not sure that bill would have passed without your fine support and the support of your colleagues. It is very important to us. I am pleased to say that we are on track and hope to have a final rule by the end of the year or early next year. In the meantime, we have held our second take-back just last month, which was even more successful than the first take-back in September.

We held a hearing, an open forum hearing, in January and had over 100 witnesses provide comments and submit comments that we are looking at very closely. And the good news is we are on track to have a final rule hopefully by the end of the year or January or February of next year.

Senator KLOBUCHAR. OK. Very good. And are you working with various stakeholders on the rules and getting input?

Ms. LEONHART. Absolutely. The public forum had stakeholders from all entities, and we have a wide range of recommendations and suggestions from them. And all options are on the table to come up with the best final rule we can get that allows for that safe and regular disposal.

Senator KLOBUCHAR. Very good, because I think that we know the take-back programs are great. They are becoming more and more popular. But to have something that would be just commonplace in pharmacies would be the best, and certainly helping all these long-term care facilities would be good as well.

I had a different kind of question, and it is about the use of synthetic drugs, including synthetic hallucinogens. And as you know, these drugs are not prescription medications, but I think it is clear that the abuse of these illegal drugs and prescription drugs are closely related. And I have a bill—Senators Grassley and Schumer have one, on certain types of synthetics, and I have one based on—it is called 2C-E, something that actually killed a young man in Minnesota and almost killed a number of others at a party. And I just wondered if you were aware of this problem, either of you, and if we have your support in moving forward on this legislation.

Ms. LEONHART. We are absolutely aware of the synthetics, and especially of the young man who lost his life in Minnesota with the use of the 2C-E compound. These are synthetics that are the drugs of the future. Whether it is synthetic cannabis or a synthetic stimulant or hallucinogen, young people are attracted to that, so it concerns us.

So we support any legislation, any tools that Congress can put forward that will help us combat that, and know that in Minnesota as well as the other States where these synthetics have shown up, we are working with State and local law enforcement. We are providing technical assistance, training, to do whatever we can to put a stop to that.

Senator KLOBUCHAR. OK. Director Kerlikowske.

Mr. KERLIKOWSKE. And, Senator, while the process is going on, the legislative process, we have used the bully pulpit of the White House to be able to bring to a lot of people's attention the problems of the things such as bath salts, synthetic drugs, et cetera. So that has been helpful in alerting people to the problem, and thank you.

Senator KLOBUCHAR. Very good. I just think the more we can list some of these as clearly illegal, that helps you with your education

process, makes parents aware of this new phenomenon with these drugs that I do not think anyone ever anticipated a decade ago.

My last question along the lines of the tools for all of you to use is that the administration's plan on prescription drugs makes reference to the role of Congress, and if you could touch further on the role of Congress. Can you talk about the potential need for further legislation in the area of illegal prescription drugs? Director Kerlikowske.

Mr. KERLIKOWSKE. Senator, we think one of the most important parts of the comprehensive prescription drug plan will be in mandatory prescriber education. When we developed President Obama's *National Drug Control Strategy*, his direction to me was to make sure that the voices of people across the country were heard, and we did that and included discussion around prescription drugs and information.

The actual prescription drug plan is more comprehensive, more specific, and we developed it very much in the same way—by listening to people all over the country, particularly a number of prescribing physicians, whether they were in emergency departments or whether they were in a number of other locations, for instance, pain management or primary care. And overwhelmingly the information that was provided to me by them was that additional information and education about addiction, about dependence, about prescribing pain medications was important and vitally needed. And overwhelmingly they had told me that it should be mandatory. Although voluntary education is certainly something that people appreciate, and I know that these are physicians who are very overworked, mandatory prescriber education is, in my opinion, very important.

Senator KLOBUCHAR. All right. Thank you very much.

Thank you, Mr. Chair.

Chairman WHITEHOUSE. And now we will turn to the distinguished Senator from Connecticut, whose many years of exemplary service as the Attorney General in Connecticut make him keenly aware of this issue. Senator Blumenthal.

Senator BLUMENTHAL. Thank you, Senator Whitehouse, and thank you for holding this hearing, and thank you especially for being attuned to this very, very difficult and profoundly important topic. And I thank you both for your great work on this issue.

I want to thank you also for the recommendation from the White House Office of National Drug Control Policy in its plan to combat prescription drug abuse to recommend that the Secretary of Veterans Affairs share patient information on controlled substance prescriptions with State prescription drug monitoring programs, which I think is very, very important. As you know, the VA also supports this request. And I will be introducing legislation within the coming days as part of a comprehensive program on veterans issues to support providing that tool in the toolbox, so to speak.

So I wonder if you or Director Leonhart could perhaps share with us and put on the record your views as to why this recommendation is important.

Mr. KERLIKOWSKE. Senator, thank you very much. I could not have a stronger partner than General Shinseki and the VA on this issue. I do not think there is anyone in this country that is not sup-

portive of our active-duty military and our returning veterans and how they can be helped. But we also know very correctly that self-medication, the use of prescription drugs in both the active-duty military—it has been well documented—and also returning veterans, is a significant problem. It is a problem for combat readiness and force readiness. It is a problem for local jurisdictions, particularly jurisdictions where National Guard returns and there may not be as large a military base or presence.

Prescription drug monitoring programs that are now in almost every State—and not all of them active, but we are working to help them to become more robust—are only as effective as how they are used. And if you can go into a VA hospital and obtain prescription drugs and then go down the street to a private physician, and the two systems do not talk to each other, that is dangerous for the patient. It puts the physicians in a difficult position because they do not know about what prescriptions are being offered to that patient by a different physician in a different facility. And so the support of the VA and the support of the Department of Defense on that issue, so that one system can clarify and talk to each other, is good for our veterans and our active-duty military. And it is clearly a patient safety issue, and I thank you for that support.

Senator BLUMENTHAL. Would you have anything to add, Ms. Leonhart?

Ms. LEONHART. I would add that it is a very serious problem: 5.3 million Americans are abusing painkillers, and among those 5.3 million are our veterans, especially returning veterans. And the leadership of Director Kerlikowske bringing the VA to the table has been significant and I think will in the end benefit all of our efforts, especially those that will most affect veterans. And thank you for your interest in that topic.

Senator BLUMENTHAL. It almost enables or encourages doctor shopping and abuse to have these two separate systems that are completely unlinked and simply do not communicate with each other.

How well—and I realize this is kind of an open-ended question, but how well are the State systems working? And do you note wide variation in their effectiveness? If you could give us a general assessment.

Mr. KERLIKOWSKA. There are a number of people that have looked at these. The CDC just recently released a report, although the data that they used was a bit dated. I have examined them and looked at them. There are some States—particularly what is called the KASPER system in Kentucky, which is very forward leaning in this area, but there are several problems, and we have addressed those in the prescription drug plan. One is that they should be interoperable and talk to each other.

During our 4-day trip to eastern Kentucky and also West Virginia, we learned that doctors would have to access multiple systems—those in Ohio, those in West Virginia, those in Kentucky—when it came to checking on patients and making sure that they were not overprescribing for patients who were seeing, in fact, other physicians. So the interoperability is key. The fact that it should be easy, that the information should be readily accessible

and should be in as close to real time as possible, are all important efforts.

So this is a great first step, all of the States, including the State of Florida, passing that legislation, moving forward, now making them more robust, making them used, and making them interoperable, are all key components of the prescription drug plan.

Ms. LEONHART. I would add that we have seen some promising information coming from the States that actually share that PDMP information with law enforcement. For instance, a recent study showed that there were lower death rates in States that were sharing with law enforcement, specifically in California, Texas, and New York. So it is a promising tool. Good to see that soon there are only two States that will be without PDMPs or without legislation pending.

Senator BLUMENTHAL. Thank you very much. Thank you both for your great work in this area.

Chairman WHITEHOUSE. Just to follow up on Senator Blumenthal's question, have you been alerted to any desire for Federal legislative changes to support the State initiatives in prescription drug monitoring? As I understand it, the Medicare and Medicaid billing information, for instance, access to that for purposes of identifying prescription drug abuse and diversion is being accomplished primarily at the State level. Are they running into common problems that we should attend to? Or is the State-based process, do you think, a successful one in terms of something that can go forward and continue to make progress on its own without further Federal legislation?

Mr. KERLIKOWSKE. Senator, we have widely discussed at the different hearings and the different visits that we have had around the country, the issue of a national PDMP. A couple things came into play.

One, the experts that have developed those systems say they would be very difficult to implement because of, for instance, just the difficulty of personal identification when it comes to common names across an entire Nation, an entire data base. That would be a problem.

Second, that the States design these and operate these themselves and, therefore, they can put into place the patient privacy, the confidentiality guidelines that they would like, and also who has access to it. I think there are a number of best practices, and I think as the evaluation continues on, I am pretty hopeful that the individual States by working together—and, of course, your next witness is certainly another subject matter expert in this—can be very helpful. But right now I am quite satisfied with what I am seeing at the State level.

Chairman WHITEHOUSE. Do you agree, Ms. Leonhart?

Ms. LEONHART. I do agree. I do believe that Congress could help, however, in the area of interoperability. And, of course, funding is an issue for the States moving forward with these systems.

Chairman WHITEHOUSE. Well, thank you both very much. This has been—do you have any further questions, Senator Blumenthal? Are you ready for the next panel? Should we go on? If you would like another round, I—

Senator BLUMENTHAL. I wanted to follow up on Senator Whitehouse's excellent question about encouraging the effectiveness of the drug monitoring programs, and I know that there is some reluctance to make it more national and impose kind of national requirements. But I wonder where you see the resistance to increasing the interoperability, which I think is really key. As it is in so many criminal justice information programs, the failure to link State systems is a major barrier. So I am wondering either now or if you want to think further about it and respond in writing or have a conversation about it, I would be very interested in following up on that issue.

Mr. KERLIKOWSKE. I know that the State of Ohio and the State of Kentucky have signed an interoperability agreement to begin sharing information. I think that shows some promise, and I would be happy to follow up to that question.

Senator BLUMENTHAL. Great. Thank you very much.

Thank you, Mr. Chairman.

Chairman WHITEHOUSE. Let me thank the witnesses. Let me reference back to a statement that Director Kerlikowske made about his role as the bully pulpit at the White House on some of these issues, which is a role we obviously encourage. But I would hope that you might also be a bit of a bully pulpit within the White House with our friends at the Office of Management and Budget as these relevant rulemakings proceed. It has been astounding to me as a newly elected Senator to see the pace at which Federal rulemaking slugs forward. And while I think the agencies themselves are not always absolved of responsibility, it does seem that there is a common thread that things do seem to bog down at OMB. And if there is anything you can do to move some of these along and get OMB to expedite to the extent that they can, I think that would be helpful.

I cannot tell you how long it took to get through the controlled pharmaceutical e-prescribing situation, and that was in theory with pretty much everybody on board as to the direction it should go. So I have become—I do not know what you would call it, but impatient, I guess, with the pace of Federal rulemaking. And you may be in a position to expedite it a bit, and if you can, I would urge you to do so. But I thank you for your dedicated efforts over many years in this area, and you, too, Ms. Leonhart. As Attorney General Blumenthal and I both know, you have people out in our streets and in the streets of foreign countries every day who are resourceful and brave, who take extraordinary risks to protect us. We have both had the pleasure and privilege of working with DEA agents who have been really among the finest Americans I have ever had the chance to work with. And so, I thank you for being here on their behalf.

The panel is excused, and we will take a 2-minute break while the next panel assembles itself. Thank you both for your testimony.

[Pause.]

Chairman WHITEHOUSE. All right. If the hearing room will come back to order, my first order of business is to add to the record of this proceeding a number of items:

First, a letter from our colleague, Senator Casey, and then statements from the Partnership at Drugfree.org; from the Community

Anti-Drug Coalitions of America; from the American Pain Foundation; from the American Academy of Pain Medicine; from the International Institute of Pharmaceutical Safety; from the Federation of State Medical Boards; and from the American Society of Interventional Pain Physicians. I appreciate all of their statements, and they will be, without objection, added to the record of these proceedings.

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

Chairman WHITEHOUSE. We now have our next panel. Our two witnesses are:

First, Laura Hosley. She is manager of community prevention for Rhode Island Student Assistance Services. She also serves as coordinator of the Jamestown, Rhode Island, Prevention Coalition and oversees the North Kingstown, Rhode Island, drug-free communities grant. She previously served as project manager at the University of Rhode Island's Cancer Prevention Research Center, worked as a student assistance counselor in Rhode Island middle and high schools, and directed a group home, serving individuals with mental illness and substance abuse problems. She has an undergraduate degree in education and psychology from the University of Rhode Island and a master's in management from Lesley University.

She is joined on our panel today by John Eadie, who is the director of the Prescription Monitoring Program Center of Excellence at Brandeis University. He previously served as director of the Division of Public Health Protection in the New York State Department of Health from 1985 to 1995, where he directed the State's pharmaceutical diversion program, including the prescription monitoring program. He was co-founder and president of both the Alliance of State with Prescription Monitoring Programs and the National Association of State Controlled Substances Authorities.

If I could ask you to stand while we administer the oath. Do you affirm that the testimony you are about to give before the Committee will be the truth, the whole truth, and nothing but the truth, so help you God?

Ms. HOSLEY. I do.

Mr. EADIE. I do.

Chairman WHITEHOUSE. Please be seated.

Ms. Hosley, welcome. Thank you for coming down from Rhode Island. Please present your statement.

**STATEMENT OF LAURA HOSLEY, MANAGER, COMMUNITY PREVENTION, RHODE ISLAND STUDENT ASSISTANCE SERVICES, WARWICK, RHODE ISLAND**

Ms. HOSLEY. Chairman Whitehouse, Senator Blumenthal, thank you for the opportunity to testify before you today on behalf of Rhode Island Student Assistance Services and the Jamestown and North Kingstown Substance Abuse Prevention Coalitions. I am pleased to provide you with our perspective on effective strategies for reducing the abuse, misuse diversion and fraud of prescription drugs.

Rhode Island is a small State, but we seem to show up in the top of the national statistics when it comes to substance abuse. In 2004, the last year the National Survey on Drug Use and Health



asked about the non-medical use of prescription drugs, Rhode Island was tied for fifth with two other States. In 2008, when the same survey asked about the use of pain relievers non-medically, Rhode Island came in seventh. It did not matter which of the five counties you looked at. They were all similar. The last Rhode Island SurveyWorks data showed that 1 percent of high school students have tried painkillers without a doctor's prescription.

I manage a drug-free communities grant in North Kingstown. Prior to this, I oversaw strategic prevention framework State incentive grants. In my 20 years of working in prevention, I had never seen such well-organized efforts as with these grants. After the first 3 years, we saw a drop in 30-day alcohol use of 14 percent and a 4-percent decrease in marijuana use among high school students. We had focused our efforts on underage drinking.

We have cooperative relationships with multiple key partners which make it relatively easy to work on media campaigns, policy changes, law enforcement efforts, and more. The national prescription drug take-back program was held on April 30th in conjunction with the DEA. In North Kingstown, the local police department and the State police filled five boxes. When I received the list of how many pounds of drugs were collected, I saw that the top eight communities were either drug-free communities grantees or had the strategic prevention framework grant, or both. Together they had collected over 75 percent of the 1,716 pounds of drugs. Cities and towns that have the funding can get citizens educated and involved. They get results.

I used to be a student assistance counselor. Student assistance counselors are on the front lines. Unfortunately, Federal and State funding no longer covers the cost to ensure that minimum programs are funded, especially since the safe and drug-free schools and communities funding was eliminated. The Rhode Island Student Assistance Program is a key element in the prevention infrastructure since the counselors are insiders. Along with providing early intervention, they can also assist with evaluation, policy, and enforcement efforts in the schools.

Last month, I heard the story of a student who barged into a student assistance counselor's office acting confused and incoherent. The counselor found out that she had taken prescription drugs that were not prescribed to her, along with LSD, and determined that she was in a drug-induced psychosis. The girl was taken to a hospital by ambulance where she stayed for 3 weeks. She is now back in school but needs to take lithium, which is usually prescribed for people with bipolar disorder, to remain stable enough to stay in school. She is still having crying bouts and difficulty handling stress. The boy who gave her the drugs has been released from prison and is allowed to attend school with an ankle monitor. Two lives connected by prescription drug abuse resulted in both having diminished chances for future success.

While Rhode Island is just beginning to address the complex issues related to prescription drug abuse among teens, I believe one of our more effective prevention mechanisms will be the student assistance program. These highly trained counselors are onsite where access for students is easy and confidential. Collectively, the student assistance program, working in tandem with community coali-

tions, has been successful in reducing the use and abuse of alcohol and tobacco. I have every reason to believe that continuing and expanding the student assistance program, along with coalitions through the drug-free communities program, will help communities handle the complexity of prescription drug abuse among teens.

I have provided more comprehensive recommendations in my written statement, but in the interest of time, I would like to focus on the one that is the most critical. I believe that with drug use on the rise and the elimination of the safe and drug-free schools and communities program, the Federal Government should focus more emphasis and funding on community and school-based substance abuse prevention and intervention strategies and programs by explicitly requiring that drug prevention and intervention programming be adequately included in the reauthorization of the Elementary and Secondary Education Act and by fully funding the drug-free communities program.

We have the potential to reduce the abuse of prescription drugs among youth in schools and communities throughout Rhode Island as well as nationwide.

Thank you for the opportunity to testify. I would be happy to answer any questions you may have.

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

Chairman WHITEHOUSE. Thank you, Ms. Hosley.

We will take Mr. Eadie's statement first, and then we can ask questions as a panel. But I wanted to thank you for the quality of your testimony. For those who have not read it but have just listened to you, you gave a summary today, but your full statement will be a part of the record, and it will be extremely helpful.

I wanted to also mention, specifically with respect to the recommendation that this be protected in the reauthorization of the ESEA, Senator Brown, who was here, has a very keen interest in all of this and has—I guess he has rotated off the HELP Committee now. I am not on the HELP Committee. We will be doing that bill in that Committee. And Senator Blumenthal is on that Committee as well. So Senators who have been here today—I guess Senator Klobuchar is not, but you have very good representation of that Committee here by, I guess, fortuity. So it was a good recommendation for you to make at this moment.

Mr. Eadie, please proceed.

**STATEMENT OF JOHN L. EADIE, DIRECTOR, PRESCRIPTION MONITORING PROGRAM CENTER OF EXCELLENCE, BRANDEIS UNIVERSITY, WALTHAM, MASSACHUSETTS**

Mr. EADIE. Good morning, Chairman Whitehouse and Senator Blumenthal. Thank you for the opportunity to appear before you on behalf of the Center of Excellence for Prescription Monitoring Programs at Brandeis University. We thank you for the honor of testifying on this critical matter.

The Center of Excellence seeks to help end the prescription drug abuse epidemic without compromising pain management or the legitimate prescribing of controlled substances. In collaboration with the Alliance of States with Prescription Monitoring Programs, the Center provides academically sound and practice-relevant informa-

tion, evaluation, and expertise to prescription monitoring programs and other stakeholders. The center is funded by a grant from the Department of Justice Bureau of Justice Assistance.

The urgency of our work is based upon our knowledge that: daily, 50 people in our Nation die from unintentional prescription opioid overdoses; and, daily, 20 times that number are admitted to hospital emergency departments for opioid overdoses.

At the Center of Excellence, we believe that we must improve our methods for identifying and interdicting prescription opioid abuse in order to slow down and reverse this epidemic's ever rising toll.

The rapid growth in States with prescription monitoring programs—and I am delighted to say that the number is now 48 States. Five have just passed legislation in the last few weeks, and it has been signed. And we just have the District of Columbia and two States left—is a very hopeful accomplishment. The majority of these States have been authorized since 2003, when the Harold Rogers Prescription Drug Monitoring Programs Grant funding began—a program administered by the Department of Justice's Bureau of Justice Assistance. Through that program, competitive grants have stimulated growth and enhancements among the PMPs. Important additional funding has been provided by the NASPER program until this new budget. That program, administered by the Substance Abuse and Mental Health Services Administration, is a formula grant program that has been important in assisting States' prescription monitoring programs by supporting their operations.

The continued operation of PMPs and the significant enhancements called for to address the prescription drug abuse epidemic appear to call for continuation and expansion of both unique programs.

In addition to Federal funding support, we need a rapid evolution of the prescription monitoring programs into a new generation of even more effective systems, a new generation whose hallmark must become proactivity. The new generation will take advantage of technological advances and integrate them into the fabric of PMP operations. Many characteristics of the new generation are highlighted in the White House Office of National Drug Control Policy's new Prescription Drug Abuse Prevention Plan, which you have discussed previously.

In addition, interstate PMP data sharing is essential. This must be completed in order to create a national network of State prescription monitoring programs that are interoperable through the Prescription Monitoring Information Exchange Hub, known as the PMIX Hub, which BJA, the IJSI Institute, and the Alliance of States with Prescription Monitoring Programs have been working to establish for 6 years with support from our center. The Hub is operational today, and several States are in process of interconnecting.

In addition, we need to work on the following issues:

We must increase the proactive reporting to prescribers across the Nation where PMPs analyze the data within their databases and send it out when they identify potential problems and let prescribers and, for that matter, pharmacists know what is going on.

We also have other changes to make within the systems. You have touched on some of them already.

Making data more timely. Oklahoma is pioneering such an effort today. Starting in April, they have got point-of-sale data going into their systems.

Making access seamless, using electronic health records as a way of doing that.

Combining prescription monitoring programs and e-prescribing, which you have discussed, is an important element and a new element.

Considering with public and private third-party payers the value of mandating prescribers to assess PMP data prior to issuing the first controlled substance prescription and periodically thereafter as a condition of payment.

In addition, we need to increase the requested reports and proactive use of the data for pharmacies. We need to also develop a verification system that PMPs would carry out to tie to dispensing, to make sure that the requirements—for example, if there is mandatory physician education, the prescription monitoring program should assure that that is being accomplished, that prescribers who are not trained are not going to prescribe, or if they do, report effectively.

We need to also—and I cannot emphasize this enough. We need to increase and improve the access that law enforcement agencies have to prescription monitoring program data, both in terms of solicited reports where they request reports and in terms of unsolicited reports where the PMPs proactively identify problems and send them out. The same thing is true for health professional licensing agencies.

There are other users of PMP data who need to be involved that are not currently involved. Just as an example, the Indian Health Services, Veterans Administration, and Department of Defense health care systems need to be integrated. And I know you have talked about that already, but this system has to be beyond that because it is not just the integration of VA and Department of Defense. It is the access to the other prescriptions issued for the same individuals in those systems who may be going outside to get cash paid prescriptions, which compounds and confounds what is going on within the VA system or the Department of Defense, and they are blind to it at the moment.

We need to develop an early warning system, and PMPs have the capability of doing just that.

We need to develop greater concern for youth. Our initial analysis identified significant concerns there.

And we need to talk about mandatory prescriber education. It is from my perspective exactly important, and I recommend it highly to you.

[The prepared statement of Mr. Eadie appears as a submission for the record.]

Chairman WHITEHOUSE. Thank you, Mr. Eadie. I appreciate it. And thank you, Ms. Hosley.

Your work in Rhode Island must have exposed you to some pretty well informed views about where it is that youngsters, in particular teenagers, are getting access to these prescription drugs.

And if you could comment a little bit about that and particularly how some of the earlier testimony about the need to improve on the regime of disposal could help this, because as I understand it, throwing them down the drain risks creating environmental problems, leaving them in the cabinet risks creating abuse or encouraging abuse, and there really is no clear third option that most Rhode Islanders are aware of.

Ms. HOSLEY. Well, as I wrote in my statement of record, students seem to know who are getting their wisdom teeth pulled and who might have access to painkillers especially. We hear that in schools kids have access to Adderall. So it seems to be something where the students may share the medications that they are prescribed, but also are getting it from medicine cabinets, from their parents and grandparents. I think just the fact that these prescriptions are overprescribed, they do tend to be sitting in people's homes.

So I think that increasing awareness is huge, and when we had the take-back program, we made sure that we publicized it in the papers and that we put it on the list serves to go to home to all the parents so that they were aware that there was a way for them to get the medications to a place to properly dispose of them.

I think the fact that they cannot just go at any time is a little difficult. I know I missed that date and still have some prescriptions sitting at home. But I heard that next year it might be twice in the next year. So at least if we had some type of mechanism in place for the disposal, that would help, but we really do need to increase the awareness.

You know, with funding such as the drug-free communities, we can put a multi-pronged strategy in place for whichever drug we are focusing on, and I do not think we have really done that yet as far as prescription drugs go. It is something we need to do, but I think that all the communities need to do it and not just certain ones who are able to get additional funding.

Chairman WHITEHOUSE. We have the good fortune in Rhode Island to have one of the largest pharmacy companies in the country headquartered right in Woonsocket—CVS—and perhaps you and I could work together with them once the regulations are finally through their Federal administrative rulemaking process, either at the end of the year or early next year, as DEA Director Leonhart suggested, and work with them on perhaps taking a leadership role in this area. So I look forward to working with you on that.

Mr. Eadie, the States tend to manage these prescription drug monitoring programs. There has been a relatively limited Federal role other than the grantmaking role. Interoperability has come up as an area where it might be suitable for the Federal Government to provide some support and some guidance to these State-based programs.

It appears that their State base actually is an asset in terms of awareness of local conditions, comfort about privacy and security issues, and things like that. Without taking those elements away, without making this something other than the State-based program that it is and has been, are there other ways than the interoperability where you think that the Federal Government could have a helpful role in supporting and guiding what would remain

under this model a State-driven prescription drug monitoring program?

Mr. EADIE. Chairman Whitehouse, I think there is a role. I think that things we—in mandatory education, for example, if that is required, then it should be a corollary that prescription monitoring programs should build into their system an ability to track that and make sure that the trained physicians are the ones who are—and dentists, for that matter, and other prescribers, are the ones who are actually prescribing. That is a simple thing.

Now, the larger question is how to involve the Federal Government without disrupting the value of the State-based systems, and the responsiveness that you have indicated is extremely important.

Innovation is also important. Without State-run programs, we would not have the electronic prescription systems available to doctors today. That was an innovation that started with the State of Nevada just a little over a dozen years ago, and it is now widespread across the Nation. I mentioned Oklahoma as an example. They are starting point of sale. They are pioneering that effort.

Massachusetts is pioneering efforts today for electronic health records integration. They also have an electronic-prescribing system testing in western Massachusetts, which you may or may not be aware of, but it was approved with a waiver by the Drug Enforcement Administration. It is funded by the Administration for Health Research and Quality. It is a small-scale project, but it has demonstrated that electronic prescribing by physicians can be operational and is effective, and that is ongoing today. It is actually operational at the moment. And we have been party to that and supporting that as it goes forward, and I think there is a major role for the future for that.

I think that electronic prescribing should be integrated with PMPs. At the moment that is not possible because it does not exist. But it should be integrated as quickly as possible, and I think that Federal funding support, which indicates support for that initiative, is important.

In short, I think that broad guidelines of criteria or of guidance are valuable. Being too specific at the Federal level, which is a tendency to anchor into Federal law or regulations specific things that States should do, will ossify the systems at a point today where the technology is rapidly evolving. We cannot afford to have anything that is rigid. But there can certainly be guidelines. There can certainly be statements of encouragement. There can be, in effect, minimal guidance such as States that are receiving Federal funding for PMPs should have built into them interoperability with them and other States. There should be or could be—the same thing as it relates to e-prescribing and other things—broad categories of requirements without specifics so that we can innovate, we can create, we can go forward.

Chairman WHITEHOUSE. OK. Well, we are certainly interested in that in Rhode Island because, as you know, we are one of the top e-prescribing States in the country.

Mr. EADIE. Yes.

Chairman WHITEHOUSE. We sort of go back and forth with Massachusetts as to who claims to be No. 1.

Mr. EADIE. Exactly.

Chairman WHITEHOUSE. And we are advanced enough in electronic health records that we are actually looking at a statutory health information exchange. And as we speak, data is actually flowing through something called Current Care in Rhode Island so that it is being populated automatically into electronic health records outside of a single corporation but across entities. So we look forward to working with you on those ideas, and I think if we can do that, then people who are at the front lines working with kids like Ms. Hosley will have an additional, as Senator Blumenthal said, tool in their toolbox.

And with that, Senator Blumenthal.

Senator BLUMENTHAL. Thank you, Mr. Chairman, and thank you both for being here from Massachusetts and Rhode Island, and thank you both for your work in this area. And I hope that folks in Rhode Island know how active and aggressive Senator Whitehouse has been with his background in law enforcement, but also his leadership in really moving the Judiciary Committee to take cognizance and take action in this area.

I want to ask you about some of the potential actions that drug companies themselves could take in the area of discouraging or stopping drug abuse, apart from improving the monitoring programs that exist in many States, particularly with respect to painkillers, whether there are actions that can be taken to provide for greater safeguards in these areas.

As you well know, OxyContin has been a continuing problem, oxycodone. There was an action by the Department of Justice and States, including Connecticut while I was Attorney General, relating to OxyContin. And the failure of the company that produces it to really follow perhaps more responsible measures in the marketing and selling of the pills that were subject to pain release mechanisms. And I do not want to single out, because it would be unfair to do so, any one company, but I wonder if you could give us your observations as folks who are dealing firsthand, on the ground, in the trenches, with this problem about actions that you see the pharmaceutical drug companies themselves potentially taking to reduce this problem.

Ms. HOSLEY. I am not sure whose responsibility it would be, but perhaps if a shorter timeframe was given when those prescriptions were prescribed so that they did not get a 30-day prescription for having their wisdom teeth removed and maybe had a 3-day with the option to renew. I think there is too much medication out there, and I think it is way beyond what needs to be out there, and that just invites the misuse and abuse of the drugs.

Mr. EADIE. I would recommend great care in the way in which funding from the manufacturers might be considered. Perhaps in the prevention area, the substance abuse prevention area, it would be helpful for having funding available. It certainly is an area where they have a need to share responsibility for what has happened with the use of their drugs.

When it comes to issues closer to regulatory activities and things like the prescription monitoring programs, I think that one has to be very careful about considering funding that is perhaps voluntary or so-called voluntary. I can give the example of our own situation at the Center of Excellence. We were approached by a major drug

manufacturer in our first month of existence and asked if we would be willing to collect data from prescription monitoring programs and provide it to them for their RIMS obligation as it related to a new product they were bringing on the market, a new controlled substance product. And we thought about it carefully and decided that we could not do that in good faith because, No. 1, there would be the appearance perhaps of conflict of interest on our part to do that; and second would be the potential reality of it—that is, there would be no way we could look at the data without knowing somewhere in the back of our minds that how we analyzed the data, the way we presented it, the kinds of charts we produced, the analysis we stated, all could be inadvertently influenced by our knowledge that future funding would rest on how happy that manufacturer would be with the reports we produced.

When we said no, thanked them, they came back with a counter proposal that we then serve in that capacity with 21 drug manufacturers, the ones working with the FDA on the RIMS project for the class-wide RIMS for the extended-release opioids. And we thought about that again. There was great value in collecting the data from the States. We still want to do that. It is very important to collect the data and analyze it. We know that from experience. But once again, the two caveats that I mentioned a moment ago came back to our cognitive function as we thought about it very carefully, and we thought about how easily a word change can be made in a document from a word that is choice of phrase, choice of how things are presented, there would be no way that we could protect ourselves against the thought in the back of our minds that next year's money would be dependent on how happy these manufacturers are with what we produce. And so we ultimately thanked them but said no.

Having said that, I think that applies generally across the board to any of the prescription monitoring program activities that States are involved with. I honor what the Florida State Legislature has just done in passing a law that refuses to allow their prescription monitoring program to accept funds from drug manufacturers, either directly or indirectly. I think that was a major step forward. As you probably know, there was \$1 million offered to them by a drug manufacturer. But let me give you examples.

We know that there are drug manufacturers that have been very active in supporting prescription monitoring programs for the last decade. But if you read their materials very carefully, there is no provision within that for the kind of proactive analysis of data and distribution of that data that is absolutely essential for prescription monitoring programs to go forward, particularly as it relates to law enforcement. And there is also—there has been in recent years a number of States that have enacted laws that have provided restrictions on law enforcement that extend to requiring court orders, requiring subpoenas, requiring a variety of what amount to, in our view, inappropriate restrictions on law enforcement's access to the data.

And so I think that there is room for manufacturers on the other hand to contribute to a fund that might be Congressionally mandated like the Food and Drug Administration establishes a fund that pays for its costs and which manufacturers are mandated to



contribute to that fund, and the fund is then used to cover the costs of the FDA in reviewing and approving their drugs.

Why couldn't, why shouldn't there be an equivalent fund established by mandate of the Federal Congress to drug manufacturers to contribute significantly to the funds necessary to operate these prescription monitoring programs? They benefit by it extraordinarily. There is no reason why they cannot and should not contribute to the solution to the problems created by their drugs.

Senator BLUMENTHAL. Well, I thank you for that answer. My time is up, but I look forward to working with both of you, and I want to say that the maker of OxyContin, by the way, has taken some very responsible steps. Purdue Pharma has taken some very important leadership steps in reason to these problems. And one area where I was thinking more could be done is in providing warnings, perhaps in restricting the length or amount of prescriptions as you have suggested, Ms. Hosley. But I look forward to working with you, and, again, thank you, Mr. Chairman, for your work in this area.

Chairman WHITEHOUSE. Thank you, Senator Blumenthal.

Let me thank my colleagues Senator Brown, Senator Klobuchar, and Senator Blumenthal all for participating in this hearing and, I guess, wrap up by saying how impressed I think we all have been by the information that we've heard today about the epidemic nature of the prescription drug problem and the rapid rate at which it is growing and affecting our emergency rooms, affecting our families, affecting our schools, affecting our communities. The areas that appear to need further attention and effort include public awareness, and I was glad that the Director of the Office of National Drug Control Policy, Director Kerlikowske, was here to talk about his efforts in that regard.

We appear to need to better coordinate our law enforcement resources, although it does appear that the prescription drug monitoring programs stand out as a growing and effective State-based vehicle for addressing this problem, but one that could be strengthened with further integration with electronic prescribing, further integration with electronic health records, some integration, beginning integration with the VA, Department of Defense, and Indian Affairs health systems, and improved interoperability State to State. So those seem to be worthy goals that come out of this hearing.

The last is that we do not seem to be in a very good place yet with respect to the disposal of unused controlled pharmaceuticals, that throwing them down the drain creates one set of problems, leaving them in the cabinet creates another set of problems. And we have not really developed a robust system for finding other ways to dispose of them, and we look forward to working particularly with the pharmacy and pharmaceutical industry to come up with solutions since it is their product that ultimately is at the heart of this problem.

So I appreciate Director Kerlikowske and Director Leonhart for taking their time and sharing with us their expertise this morning. I appreciate very much Ms. Hosley's testimony and her work in Rhode Island on the ground with the kids who are at the center of our attention really today, and Mr. Eadie for your many years

of service. I think that you are sort of the father or uncle, or whatever you would call it, of the PDMP movement, and clearly it is one of the success stories that we want to build on as we continue to move forward and address this epidemic.

We will keep the record of this hearing open for an additional 7 days, an additional week, if anybody wishes to add anything to the record. And other than that, the hearing will adjourn, and thank you very much for your testimony.

[Whereupon, at 10:31 a.m., the Subcommittee was adjourned.]  
[Questions and answers and submissions follow.]

## QUESTIONS AND ANSWERS

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

FOLLOWING MAY 24, 2011, HEARING ENTITLED,  
"RESPONDING TO THE PRESCRIPTION DRUG EPIDEMIC:  
STRATEGIES FOR REDUCING ABUSE, MISUSE, AND FRAUD"  
SUBCOMMITTEE ON CRIME AND TERRORISM  
COMMITTEE ON THE JUDICIARY  
UNITED STATES SENATE

Senator Charles Schumer

- I. In February of this year, several Senators and I sent a letter to Florida Governor Rick Scott citing our concern over his elimination of Florida's prescription drug monitoring program. As you know, previous congressional testimony from your office identifies an emerging trend of criminal organizations establishing a thriving business of transporting individuals to and from States lacking strong prescription drug monitoring programs and regulations. Similarly, the Drug Enforcement Administration (DEA) has identified Southern Florida as a major hub for prescription drug traffic, and local law enforcement have shared several anecdotal cases of this traffic invading New York's streets.
  - A. Has the Office of National Drug Control Policy (ONDCP) developed a more detailed understanding of prescription drug traffic patterns? If so, can you commit to updating my staff on the illegal movement of these substances?

**RESPONSE:** High Intensity Drug Trafficking Areas (HIDTAs) are actively engaged in discerning and monitoring the trafficking patterns for controlled prescription drugs in their respective regions. Several HIDTAs report that a major trafficking route involves unscrupulous pain clinic physicians in Florida dispensing or prescribing large quantities of prescription opioids to dealers and abusers. This illegal conduct constitutes a major source of supply for the opioids distributed in numerous states in Appalachia, the Great Lakes, and Northeast regions. The State of Florida did pass legislation to reduce the number of illicit pain clinics operating in the state earlier this year. In spite of this legislation, these criminal organizations are adapting. These groups are now either owning and/or operating adjoining pharmacies or partnering with a pharmacy that is complicit in the rogue operation. The Drug Enforcement Administration is taking steps to address this by reviewing and investigating new applications for DEA registrations involving a pharmacy. It is hoped that this legislative package, when combined with the implementation of the State's prescription drug monitoring program, and expanded regulatory action will reduce the supply of illicit prescription drugs that feeds the prescription drug abuse problem on the East Coast. Together with our colleagues at the Drug Enforcement Administration, we will facilitate briefings with interested staff on the issue.

It is important to note, however, that unlike other drug trafficking issues, the majority of the prescription drugs that are being abused are initially acquired from a DEA-registered practitioner. In many of these cases, the substances are prescribed by a medical professional after a proper diagnosis in order to treat an illness. However, in other instances the substances are acquired pursuant to an illegitimate prescription, i.e., a prescription issued outside the course of professional conduct and not for a legitimate medical purpose. When a practitioner issues a "prescription" under these circumstances, the prescription is invalid and the practitioner is in violation of the law. According to the National Surveys on Drug Use and Health for 2008, 2009, and 2010, 70 percent of individuals who report that they misused prescription pain relievers in the past year, obtained them the most recent time they were used from friends or family. In 80 percent of the instances where nonmedical users of prescription pain relievers aged 12 or older obtained the drugs from a friend or relative for free, the individuals indicated that their friend or relative had obtained the drugs from just one doctor; only 1.9 percent reported that the friend or relative had bought the drugs from a drug dealer or other stranger.

- B. Additionally, has the ONDCP identified prescription drugs moving across our borders for abuse? Are there signs of international drug trafficking organizations adopting these drugs in their traffic?

**RESPONSE:** ONDCP is developing a National Northern Border Counternarcotics Strategy (Strategy) that comprehensively addresses drug trafficking. Prescription drug trafficking is prominently addressed in the Strategy. The Strategy is the product of an extensive consultation process that began with hundreds of letters soliciting input from relevant Congressional delegations and Federal, state, local, and tribal law enforcement officials.

Through these consultations, ONDCP received information regarding prescription drug smuggling along the Northern border. According to U.S. Immigration and Customs Enforcement (ICE), pharmaceutical diversion is a serious problem along the border between New Brunswick, Canada, and the State of Maine, and as pill mills are shut down in the Southeastern United States, this threat could quickly spread across the rest of the Northern border.

Further, the DEA Plattsburgh Resident Office initiated multiple operations from 2009 to 2011 to combat the illegal distribution of crack cocaine, MDMA, and illegally diverted opiates. The opiates were smuggled across the Akwesasne Mohawk Reservation, while MDMA was smuggled through a Port of Entry in Jefferson County, New York. These operations have resulted in 38 Federal arrests to date.

Less-stringent Canadian law governing the control and dispensing of such drugs has made it easier for U.S. citizens traveling to Canada to obtain highly desired opiate and sedative compounds and return with them to the United States. ONDCP would be pleased to facilitate a briefing with DEA's Office of Diversion Control on this issue.

2. Director Kerlikowske, as you know, I have long supported ONDCP's High Intensity Drug Trafficking Area (HIDTA) program. Thanks in large part to our work together – and to the

diligent work of the NJ/NY HIDTA Director Chauncey Parker – the NJ/NY HIDTA is a major resource and drug intelligence hub for New York’s law enforcement.

- A. Has ONDCP been using this existing infrastructure to gather intelligence about the illegal movement and abuse of prescription drugs? Does/will ONDCP consider the movement and abuse of prescription drugs when evaluating requests for designations?

**RESPONSE: The 57 HIDTA Intelligence and Investigative Support Centers all gather information to identify regional drug threats. This information forms the basis for their annual Threat Assessments and is used to develop regional strategies to combat the threat. These documents are provided to ONDCP and provide valuable insight into national drug trafficking and production trends. ONDCP has used information on pharmaceutical threats received from the HIDTAs to help allocate HIDTA discretionary funds. The HIDTA Intelligence and Investigative Support Centers also prepare special products and assessments; for example, in 2010, the Houston HIDTA produced a specific assessment on regional prescription drug abuse and trafficking.**

**Information on the abuse and movement of prescription drugs is also used to evaluate petitions for designation as a HIDTA. ONDCP recently designated two counties in West Virginia (Mercer and Putnam) as part of the Appalachia HIDTA; each county demonstrated a significant problem with prescription drug abuse and diversion. We are currently working with law enforcement officials in Ohio who are preparing a petition requesting HIDTA designation, largely to gain assistance with regional prescription drug abuse and trafficking.**

3. While many parts of the nation struggle with the rampant abuse of prescription drugs, two supply-chain problems have emerged: first, robberies and burglaries of pharmacies are on the rise; second, the theft of cargo loads of medical products is a serious and dangerous problem that puts controlled substances in the hands of abusers and criminals, and endangers the public. More than 1800 pharmacy robberies have occurred across the country since 2007, according to a recent New York Times report. The crime wave has overwhelmed local law enforcement. Additionally, the theft of cargo loads of medical products is a documented and growing problem. Some of the frequently stolen goods are biologic and perishable, like insulin, that are then resold on the retail market, with their labels and expiration dates altered after they have been stored improperly. This has led to at least 40 instances of people becoming sick from using expired drugs. Some of these drugs are prescription pain pills that are then sold by drug dealers across the country. These drugs are stolen from warehouses, delivery trucks and pharmacies. Last year \$184 million worth of prescription drugs were stolen in the U.S., a 350% increase from 2007, according to the U.S. division of Freight Watch International, a supply-chain security consultant.

- A. Would you support greater tools to combat these growing criminal issues?

**RESPONSE: More tools to combat the growing issues involving the abuse and trafficking of prescription drugs would be, as a general matter, welcomed by law enforcement agencies participating in the HIDTA program. In fact, on July 28, ONDCP convened a meeting with the U.S. Department of Justice’s Office of Community Oriented Policing Services (COPS), Federal, state, and local law enforcement officials, and representatives from the pharmacy community to**

discuss the threat to public safety posed by pharmacy robberies and burglaries. The stakeholders discussed the importance of working with public safety officials to share best practices for preventing and reducing diversion of prescription drugs from pharmacies and improve data collection regarding the scope of the problem.

The ability to effectively and efficiently respond to the health and safety dangers inflicted by drug trafficking requires evolving approaches and equipment.

The Administration's prescription drug abuse prevention plan, released in April 2011 and included as an attachment to this transmittal, focuses on long-acting opioids, which are the primary cause of unintentional drug-induced overdoses. In 2007, the latest year for which we have data, 28,000 people died from unintentional drug overdoses. Therefore, while pharmaceutical trafficking is an issue for prescription medications generally, the main focus of our efforts has been on long-acting opioids, because these are the primary cause of mortality and emergency department visits. Our plan calls for education of prescribers, patients, parents, and youth; proper disposal of prescription drugs; increasing the number and effectiveness of state prescription drug monitoring programs; and enforcement.

- B. I and several of my colleagues have proposed legislation that would significantly increase the penalties for these types of offenses – is it your opinion that this could be a helpful tool for combating this burgeoning and tragic problem?

**RESPONSE: Equipping law enforcement and regulators with sufficient tools to carry out their legal and regulatory responsibilities is a critical element in addressing pharmaceutical drug diversion.**

4. I would like to take this opportunity to thank you for speaking out about the threat of the synthetic stimulants MDPV and mephedrone back in February. As you noted, “we know [these drugs] pose a serious threat to the health and well-being of young people and anyone who may use them. At a time when drug use in America is increasing, the marketing and sale of these poisons as “bath salts” is both unacceptable and dangerous.” You also stated that the drugs in so-called “bath salts” can cause chest pains, increased blood pressure, increased heart rate, agitation, hallucinations, extreme paranoia, and delusions.

- A. In light of these dangerous effects and the lack of any known industrial or medicinal use of these drugs, would you support emergency scheduling of these two compounds into Schedule I of the Controlled Substances Act by the DEA to immediately stop the legal sale of these drugs?

**RESPONSE: Yes. In fact, on September 8, 2011, the Drug Enforcement Administration published in the Federal Register their Notice of Intent to temporary schedule three synthetic stimulants, MDPV, mephedrone and methylene.**

- B. Would you support a permanent ban of these two compounds through legislation?

**RESPONSE:** We must examine the specifics of any legislation to provide necessary technical assistance. It is, however, important to note that when substances are controlled under the Controlled Substances Act they are not completely “banned”. Those entities or individuals who are appropriately registered with the DEA and have the appropriate protocols and state authorities can still conduct research with controlled substances for legitimate medical and scientific purposes.

**Senate Committee on the Judiciary**  
**Subcommittee on Crime and Terrorism**  
**Hearing entitled:**  
**“Responding to the Prescription Drug Epidemic:**  
**Strategies for Reducing Abuse, Misuse, Diversion, and Fraud”**  
**Questions for the Record to Administrator Leonhart**  
**From Senator Charles E. Schumer**  
**May 24, 2011**

1. In February of this year, several Senators and I sent a letter to Florida Governor Rick Scott citing our concern over his elimination of Florida’s prescription drug monitoring program. As you know, your agency has identified Southern Florida as a major hub of prescription drug abuse. Similarly, in previous congressional testimony, ONDCP identified an emerging trend of criminal organizations establishing a thriving business of transporting individuals to and from States lacking strong prescription drug monitoring programs and regulations, and local law enforcement have shared several anecdotal cases of this traffic invading New York’s streets.

A. Has the Drug Enforcement Administration (DEA) developed a more detailed understanding of prescription drug traffic patterns? If so, can you commit to updating my staff on the illegal movement of these substances?

**RESPONSE:** According to the 2010 National Survey on Drug Use and Health (the most current survey), there are more than 7 million Americans who abuse controlled substance prescriptions for nonmedical purposes. This is second only to the number of individuals who abuse marijuana. Consequently, there are numerous methods of diversion of these substances from the closed system of distribution to the illicit market.

The Drug Enforcement Administration (DEA) utilizes all of the tools available to determine prescription drug trafficking patterns, however, the methods employed by criminal entrepreneurs and drug seekers are quite diverse. These methods include, but are not limited to, doctor-shopping, burglaries/robberies of pharmacies, in-transit thefts, forged prescriptions, rogue Internet pharmacies, rogue pill mills, and thefts from family and friends’ medicine cabinets. Trends can also be affected by other dynamics. For example, a new trend may be the result of a newly developed drug or a new method of administration; a new marketing technique used by traffickers to peddle their drugs; or simply a new method of disseminating information about drugs.

Over the past few years trends have accelerated exponentially due to advances in technology, social networking, and the Internet. This was certainly evident between 2005 and 2009 when rogue Internet pharmacies were rampant. Florida was the epicenter for many of these illegal operations that dispensed millions of dosage units of hydrocodone and other controlled substances and legend drugs. What emerged after the passage of the Ryan Haight Act and the subsequent decline of domestic rogue pharmacies was a plethora of rogue pain



clinics. Dozens and dozens of these clinics sprang up in a relatively short period of time. And again, Florida was the epicenter for these illegal operations. DEA, working with their state and local counterparts, attacked these operations on all fronts. DEA deployed eleven Tactical Diversion Squads from across the country to marshal with agents, investigators and state and local law enforcement officials. Over the course of several months DEA targeted the pain clinics for investigation into the illegal distribution of controlled substances while also identifying and investigating the wholesale distributors supplying these clinics. While investigative efforts continue under Operation Pill Nation, as of October 25, 2011, this effort resulted in the closure of 40 clinics; the arrest of 47 individuals, including 27 doctors; the seizure of more than \$18.9 million in assets; the surrender or revocation of 92 DEA registrations; and a civil penalty of \$6 million against one of the wholesale distributors. DEA is continuing its investigations and, as a preventative measure, is expanding its efforts to scrutinize those individuals or organizations who are attempting to open new pharmacies in south Florida.

In addition to the above ongoing efforts, DEA is also conducting a parallel operation in the Greater Tampa, Florida area. Operation Pill Nation II is an attempt to cordon off efforts by criminal groups who seek to expand their activities northward or stop others from gaining a new foothold. As of November 8, 2011, this parallel operation has resulted in 57 arrests, the surrender of 6 DEA registrations, Immediate Suspension Orders issued against 4 DEA registrations, and the seizure of approximately \$300,297.00 in currency and assets.

Nationally, DEA also works regularly with state and local law enforcement on diversion investigations. These investigations involve the exchange of information on unilateral investigations as well as bilateral investigations. DEA utilizes its 48 Tactical Diversion Squads (TDS) across the United States to combine the skill sets of federal, state and local law enforcement officials who are co-located in a task force setting. TDS groups specifically work investigations involving the diversion of pharmaceutical controlled substances and listed chemicals. DEA has plans to expand the number of TDS groups to 63 over the next few years.

Finally, DEA maintains professional relationships with state medical and pharmacy boards in an effort to exchange information useful to meeting the agency's goals and objectives.

**B. Additionally, has the DEA identified prescription drugs moving across our borders for abuse? Are there signs of international drug trafficking organizations adopting these drugs in their traffic?**

**RESPONSE:** DEA and other agencies have identified or intercepted quantities of controlled substance pharmaceuticals or counterfeit controlled substance pharmaceuticals entering the United States. At the present time, however, these quantities have been limited and not linked to major, large-scale drug trafficking organizations. To combat these threats and to maintain the necessary vigilance, DEA maintains the largest foreign law enforcement presence in the world with 83 offices in 63 countries. This vast foreign footprint allows DEA

to work closely with foreign counterparts in developing a wide array of intelligence. DEA is also a participating member of the Permanent Forum of International Pharmaceutical Crimes (PFIPC). This organization consists of representatives from fifteen different countries. The purpose of the organization is to exchange information and foster mutual cooperation regarding international pharmaceutical crimes.

2. **While many parts of the nation struggle with the rampant abuse of prescription drugs, two supply-chain problems have emerged: first, robberies and burglaries of pharmacies are on the rise; second, the theft of cargo loads of medical products is a serious and dangerous problem that puts controlled substances in the hands of abusers and criminals, and endangers the public. More than 1800 pharmacy robberies have occurred across the country since 2007, according to a recent New York Times report. The crime wave has overwhelmed local law enforcement. Additionally, the theft of cargo loads of medical products is a documented and growing problem. Some of the frequently stolen goods are biologic and perishable, like insulin, that are then resold on the retail market, with their labels and expiration dates altered after they have been stored improperly. This has led to at least 40 instances of people becoming sick from using expired drugs. Some of these drugs are prescription pain pills that are then sold by drug dealers across the country. These drugs are stolen from warehouses, delivery trucks and pharmacies. Last year \$184 million worth of prescription drugs were stolen in the U.S., a 350% increase from 2007, according to the U.S. division of Freight Watch International, a supply-chain security consultant.**

**A. Would you support greater tools to combat these growing criminal issues?**

**RESPONSE:** Some of the drugs cited above are not controlled substances and consequently are not within the jurisdiction of the Drug Enforcement Administration. For those substances that do fall under the jurisdiction of the DEA, we regularly work with state and local law enforcement on diversion investigations. These investigations involve the exchange of information on unilateral investigations as well as bilateral investigations. DEA also has 48 Tactical Diversion Squads (TDS) operational across the United States. These TDS groups combine federal, state and local law enforcement officials who are co-located in a task force setting. The TDS groups specifically work investigations involving the diversion of pharmaceutical controlled substances. DEA has plans to expand the number of TDS groups to 63 over the next few years.

**B. I and several of my colleagues have proposed legislation that would significantly increase the penalties for these types of offenses – is it your opinion that this could be a helpful tool for combating this burgeoning and tragic problem?**

**RESPONSE:** DEA does not have a position on your proposal. We would welcome the opportunity to work with you and your staff.

3. **As you know, I have introduced legislation to ban the synthetic stimulants MDPV and mephedrone – the two harmful chemicals being sold legally as “bath salts” or “plant food” throughout the country. I am very concerned about the effects of these drugs and I am pleased to know that your office has been working diligently on gathering information on these drugs that mimic the effects of cocaine and methamphetamine.**

**Last month, I sent a letter to you and Attorney General Holder, urging you to use emergency scheduling authority to ban MDPV and mephedrone. Your office has since indicated that you are moving in the direction of banning these two substances.**

- A. Can you give us a timeframe for when you could place MDPV and mephedrone on the list of controlled substances using emergency authority and stop the legal sale of these harmful compounds?**

**RESPONSE:** With respect to any temporary scheduling action, DEA published a Notice of Intent in the Federal Register (76 FR 55616) on September 8, 2011, to temporarily place MDPV, mephedrone and methylone in Schedule I. As required by statute, DEA could not publish a Final Order temporarily scheduling these substances any sooner than thirty days from the date the Notice of Intent was published. On October 21, 2011, DEA published that Final Order in the Federal Register (76 FR 65371) placing these substances in schedule I on a temporary basis. The effective date for the final order was October 21, 2011.

Activities that occurred prior to the effective scheduling date are subject to prosecution under the Controlled Substances Act’s analogue provisions (21 U.S.C. 813). DEA has determined that MDPV is an analogue of MDEA and mephedrone is an analogue of methcathinone, both schedule I controlled substances. At trial, however, the government would have to establish analogue status, in accordance with the statutory definition, to the finder of fact beyond a reasonable doubt.

## SUBMISSIONS FOR THE RECORD



4700 West Lake Avenue  
 Glenview, IL 60025 - 1485  
 847-375-4731 Phone  
 847-375-6429 Fax  
 info@painmed.org

www.painmed.org

May 20, 2011

The Honorable Sheldon Whitehouse  
 United States Senate  
 Hart Senate Office Building, Room 717  
 Washington, D.C. 20510

Dear Senator Whitehouse:

I had the privilege of meeting with your counsel, Justin Florence, on Tuesday afternoon, May 17, 2011, to discuss the American Academy of Pain Medicine's perspectives on remediation of the two large-scale, high-impact public health problems of inadequate treatment of chronic pain and prescription opioid-related morbidity and mortality due to misuse, abuse, and diversion. AAPM has been working with the U.S. Food and Drug Administration, the White House Office of National Drug Control Policy, and the Federation of State Medical Boards, recognizing that there are no simple solutions to these problems and that a coordinated public-health approach will be required. We are gratified that this is the direction being taken by the President, through the interagency approach enumerated by Director Kerlikowske, wherein he has stated:

*"The toll our Nation's prescription drug abuse epidemic has taken in communities nationwide is devastating. We share a responsibility to protect our communities from the damage done by prescription drug abuse. This plan will build upon our already unprecedented efforts to coordinate a national response to this public health crisis by addressing the threat at the Federal, state, and local level."*

In concert with AAPM's mission and responsibility to the profession and our physician members specifically, the Academy sees the healthcare provider provisions—particularly those having to do with **healthcare provider education**—as especially pertinent areas where we can be supportive:

- Work with Congress to amend Federal law to require practitioners (such as physicians, dentists, and others authorized to prescribe) who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration. This training would include assessing and addressing signs of abuse and/or dependence. (ONDCP/FDA/DEA/SAMHSA)
- Support efforts that will require drug manufacturers, through the Opioid Risk Evaluation and Mitigation Strategy (REMS), to develop effective educational materials and initiatives to train practitioners on the appropriate use of opioid pain relievers. (FDA/ONDCP/SAMHSA)

- In concert with Federal agencies that support their own healthcare systems, serve as an educational resource for their practitioners and other healthcare providers on proper prescribing and disposal of prescription drugs. (VA/HHS/IHS/DOD/BOP)
- Work with appropriate medical and healthcare boards to encourage them to require education curricula in health professional schools (medical, nursing, pharmacy, and dental) and continuing education programs to include instruction on the safe and appropriate use of opioids to treat pain while minimizing the risk of addiction and substance abuse. Additionally, work with relevant medical, nursing, dental, and pharmacy student groups to help disseminate educational materials, and establish student programs that can give community educational presentations on prescription drug abuse and substance abuse. (HHS/SAMHSA/ONDCP/FDA/HRSA/NIDA/DOD/VA)
- In consultation with medical specialty organizations, develop methods of assessing the adequacy and effectiveness of pain treatment in patients and in patient populations, to better inform the appropriate use of opioid pain medications. (HHS/CDC/SAMHSA/FDA)
- Work with the American College of Emergency Physicians to develop evidence-based clinical guidelines that establish best practices for opioid prescribing in the Emergency Department. (CDC/FDA/ONDCP/NIDA/SAMHSA/CMS)
- Work with all stakeholders to develop tools to facilitate appropriate opioid prescribing, including development of Patient-Provider Agreements and guidelines. (HHS/FDA/SAMHSA/NIDA)

It may also be helpful to reiterate the testimony provided to the FDA in its deliberations on class-wide REMS for long-acting opioids. The stated goal of these REMS is to “ensure that the benefits of these drugs continue to outweigh certain risks.”

AAPM recognizes that it has a responsibility to offer actionable solutions that can be rapidly and widely implemented while at the same time proving operationally and budgetarily sound. With these principles in mind, AAPM offers the following recommendations, believing that a thoughtful and reasoned application of REMS will positively impact two major health crises in America today—the crisis of undertreated pain and the crisis of prescription drug abuse:

- **Implement a national (or coordinated state) Prescription Monitoring Program (PMP) with real-time data available to physicians and pharmacists.** The value of PMPs is clearly outlined in the National All Schedules Prescription Electronic Reporting (NASPER) Act, which was signed by President Bush on August 12, 2005. Yet, funding for the implementation of PMPs has been lacking. Additionally, prescribers must be able to access PMP data from a confidential site, so that this information can be used as a prophylactic, rather than reactive, tool.

NOTE: Auditing for use of this system can be readily automated, providing a ready means of attributing REMS effectiveness.

- **The REMS should cover the entire class of opioid medications.** Any attempt to regulate only a portion of the opioid class of medications will drive prescribers, users, and misusers of these medications to the other, less stringently regulated, but often abused members of the class of medications. This will not diminish abuse or misuse and will very likely result in decreased access to appropriate therapy for some legitimate patients.
- **Develop REMS education programs with extensive expert input.** The REMS should provide a comprehensive core curriculum that builds on proven approaches to training and spans the continuum of medical education from medical school through CME. The curriculum should be offered through a variety of means and media—including electronic, print, and in-person offerings—to ensure the broadest reach and accessibility. Individuals completing **this curriculum should be entitled to Continuing Education credits** from respective sources (medical, nursing, pharmacy). Content should include core principles of prescribing and practice, with key elements from the Controlled Substances Act (and respective State statutes/code for state-based tailoring of curriculum), the Federation of State Medical Board Model Policy, the American Academy of Pain Medicine/American Pain Society Guideline for Chronic Opioid Therapy and other authoritative sources. An active link could be maintained on the FDA website, with reminder notices sent to all pharmacists and potential prescribers (physicians, nurse practitioners) in advance of state license renewal and DEA registration renewal.

NOTE: Auditing for use of this system can be readily automated, providing a ready means of attributing REMS effectiveness.

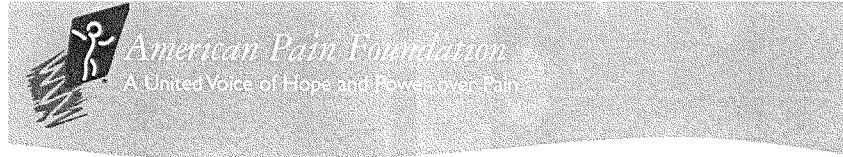
I hope this summary of our perspectives—and means by which well-crafted, public-health oriented policies may lead to the desired goals of improving the health of the millions of individuals living with chronic pain while greatly reducing prescription opioid abuse—will be helpful in your legislative work.

The Academy would be pleased to be of any further service to the Senator or the Sub-Committee chairs.

Sincerely,



Perry G. Fine, MD  
President



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May 23, 2011

The Honorable Sheldon Whitehouse  
United States Senate  
Hart Senate Office Building, Room 717  
Washington, D.C. 20510

Dear Senator Whitehouse:

Last week Malene Davis, PhD and Perry Fine, MD met with Justin Florence from your staff to discuss the challenges and possible remedies for addressing the dual public health problems of the undertreatment and mistreatment of pain in America and the misuse, abuse and diversion of prescription opioid medications. Dr. Fine represented the American Academy of Pain Medicine, the principal professional organization devoted to improving the treatment of pain. Ms. Davis represented the American Pain Foundation (APF).

The American Pain Foundation is the largest consumer advocacy and education organization in the country dedicated to improving the quality of life of people affected by pain. The CDC reports that there are over 76 million Americans affected by pain. In that number are millions dealing with the kind of pain that, if untreated or inappropriately treated, results in serious curtailment of quality of life and function. According to a recent statement by FDA Commissioner Margaret A. Hamburg, M.D., *"Long-acting and extended-release opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients, but we know that they pose serious risks when used improperly, with serious negative consequences for individuals, families, and communities"*

The rate of misuse and abuse of prescription medicines is a serious concern that requires a coordinated national focus. The recent announcement of the President's action plan to address the national prescription drug abuse epidemic is a promising effort that offers a coordinated, multi-pronged approach to diminishing misuse and abuse of prescription medications. As in the recent announcement of this policy, it is well recognized that for many persons with chronic pain, opioids are a legitimate, effective treatment option to relieve suffering and improve function and quality of life. Sadly, for some, they pose substantial safety risks and toxicity.

APF applauds efforts by the President, ONDCP, FDA, and DEA to educate America's prescribers about safe prescribing of all controlled substances. We hope that such education will help prescribers improve competency and confidence in using these useful drugs when they are safe and in the patients' best interest and avoiding all inappropriate and harmful prescribing. We commend the administrations public health approach to

201 N. Charles Street, Suite 710 • Baltimore, MD 21201-411 • Toll-free: (888) 615-7246 • Email: [info@painfoundation.org](mailto:info@painfoundation.org)  
[www.painfoundation.org](http://www.painfoundation.org)

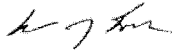
addressing the difficult problems of prescription drug abuse and under-treated pain in the United States. We trust that congress will continue to support such public health strategies.

The American Pain Foundation recognizes that opioids represent an important option for pain relief that also have increasingly recognized risks. Consumers deserve safety and effectiveness as equally important pillars of access to legitimate treatment. We look forward to working with Congress on efforts to ensure that prescriber education is as pervasive and effective as possible and to promote policy that addresses the problem of medication abuse as well as appropriate access to essential drugs.

Sincerely,



Scott M. Fishman, M.D.  
President and Chair



Will Rowe  
CEO

201 N. Charles Street, Suite 710 • Baltimore, MD 21201-4111 Phone: (410) 783-7292 Fax: (410) 385-1832  
[www.painfoundation.org](http://www.painfoundation.org)



**TESTIMONY TO THE SENATE JUDICIARY COMMITTEE, SUBCOMMITTEE ON  
CRIME AND TERRORISM**

*RESPONDING TO THE PRESCRIPTION DRUG EPIDEMIC: STRATEGIES FOR REDUCING  
ABUSE, MISUSE, DIVERSION, AND FRAUD*

May 24, 2011

Senator Whitehouse, and members and staff of the Committee on Judiciary Subcommittee on Crime and Terrorism:

Thank you for inviting the American Society of Interventional Pain Physicians (ASIPP) to provide a written testimony on behalf of the Executive Committee.

ASIPP was founded in 1998 for the promotion, development and use of safe and appropriate pain treatments, including the appropriate use of medication. ASIPP is a not-for-profit professional organization comprised of over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 7,000 trained and qualified physicians practicing interventional pain management in the United States. We have been active in preventing prescription drug use, overuse, and abuse. The National All Schedules Prescription Electronic Reporting Act (NASPER) was created by ASIPP and signed into law by President George W. Bush in 2005. This law requires states to collect prescription information for Schedule II, III, and IV medications. It also requires states to have the capability to share this information with each other. This can decrease cross-border narcotic trafficking.

After the liberalization of laws governing opioid prescribing for the treatment of chronic non-cancer pain by state medical boards in the late 1990s (1), and with the introduction of new pain management standards for inpatient and outpatient medical care implemented by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 2000 (2), many physicians and organizations began advocating for increased usage of opioids in the treatment of chronic pain (3-14). Opioids, in general, and the most potent forms of opioids including Schedule II drugs, in particular, have dramatically increased (15-17). This dramatic increase has been due to a shift in the regulations largely driven by published, albeit weak, evidence suggesting that opioids could be used safely in selected persons with chronic non-cancer pain (18, 19), by the advocacy of physicians and others who felt constrained by the near absolute prohibition of such before that time (6) and by consensus of professional societies of pain specialists who believe that chronic pain had been previously undertreated (13). Despite the escalating use and abuse of therapeutic opioids (4), nearly 15 to 20 years later the scientific evidence for the effectiveness of opioids for chronic non-cancer pain remains unclear. Concerns continue regarding efficacy (3-5, 19, 20); problematic physiologic effects such as hyperalgesia (21), hypogonadism and sexual dysfunction (22); and adverse side effects – especially the potential for misuse and abuse (23, 24) – and the increase in opioid-related deaths (25-40). Meanwhile, numerous efforts by organizations for appropriate use and exercise of constraints have been misrepresented, with these opinions used to a minimum extent (3, 4, 10, 41-47).

The treatment of chronic pain, therapeutic opioid use and abuse, and the nonmedical use of prescription drugs have been topics of intense focus and debate (3-5, 47-99). Due in some measure to the campaign of alleged undertreatment of pain (100-122), Americans, constituting only 4.6% of the world's population, have been consuming 80% of the global opioid supply, and

99% of the global hydrocodone supply, as well as two-thirds of the world's illegal drugs (4,10-12,122,123). Retail sales of commonly used opioid medications (including methadone, oxycodone, fentanyl base, hydromorphone, hydrocodone, morphine, meperidine, and codeine) have increased from a total of 50.7 million grams in 1997 to 126.5 million grams in 2007. This is an overall increase of 149% with increases ranging from 222% for morphine, 280% for hydrocodone, 319% for hydromorphone, 525% for fentanyl base, 866% for oxycodone, to 1293% for methadone (14). In 2005 and 2006, over 120 million prescriptions for hydrocodone were issued and hydrocodone continues to be the number one prescribed drug in the United States (10,14,123-125). Average sales of opioids per person have increased from 74 milligrams in 1997 to 369 milligrams in 2007, a 402% increase. It is no surprise then that surveys of nonprescription drug abuse (4,126-131), emergency department visits for prescription controlled drugs (132-138), unintentional deaths due to prescription controlled substances (28-40,139-145), therapeutic use of opioids, and opioid abuse (15-17,48-103,140,146-174) have been steadily rising.

Chronic pain has been defined by the ASIPP (175,176) as, "pain that persists 6 months after an injury and beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years that may continue in the presence or absence of demonstrable pathology; may not be amenable to routine pain control methods; and healing may never occur."

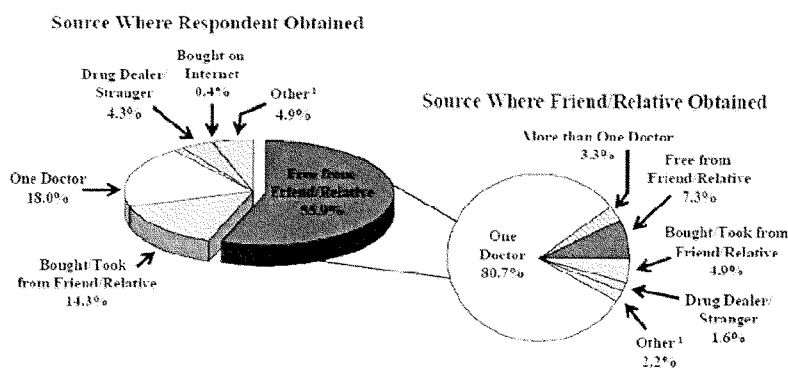
Chronic persistent pain can cause significant impairment of physical and psychological health, and performance of social responsibilities, including work and family life (175-182). While modern medicine has shown significant improvements in the understanding of pain

(including diagnosis and treatment) (175,176,183-227), chronic pain continues to be an epidemic resulting in vocational, social and family discord, which may make the difference between life and death, and is accompanied by claims of inadequate treatment (100-121,175,176,228-231).

Prevalence and associated disability continue to increase. Harkness et al (179), in a 2000 publication, showed that there was a large difference in the prevalence of musculoskeletal pain over a 40-year period of investigation. The results showed that overall, the prevalence of low back pain increased from 8.1 to 17.8% in males, and it increased from 9.1 to 18.2% in females. Similarly, Freburger et al (180) reported the rising prevalence of chronic low back pain following an evaluation of North Carolina (USA) households conducted in 1992 and repeated in 2006. The results showed an increasing prevalence of chronic impairing low back pain over the 14-year interval from 3.9% in 1992 to 10.2% in 2006, with an overall increase of 162% in low back pain and an annual increase of 11.6% associated with care-seeking and disability.

### 1.0 SOURCE OF PRESCRIPTION DRUGS

Of importance to the medical profession is the source of prescription-type pain relievers used non-medically. Among persons aged 12 or older who used pain relievers non-medically in the past 12 months, 55.9% reported that they received the drug for free from a friend or relative (126). Another 8.9% bought the drug from a friend or relative, and 5.4% took them from a friend or relative without asking. An additional 18% reported that they got the drug from just one doctor. In contrast, only 4.3% got the pain relievers from a drug dealer or other stranger, and only 0.4% reported buying the drug on the internet (Fig. 1).



Note: Totals may not sum to 100% because of rounding or because suppressed estimates are not shown.  
<sup>1</sup> The Other category includes the sources: "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

**Fig. 1.** Source where pain relievers were obtained for most recent nonmedical use among past year users aged 12 or older: 2007-2008.

In 81.7% of the cases where nonmedical users of prescription pain relievers obtained their drugs for free from a friend or relative, the individuals indicated that their friend or relative had obtained the drugs from just one doctor (126). Only 1.6% reported that a friend or relative had

bought the drug from a drug dealer or other stranger. Even more striking is the fact that in 2007-2008, 42.8% of past year methamphetamine users reported that they obtained the methamphetamine they used most recently for free from a friend or relative, with an additional 30.1% buying it from a friend or relative. Only one in 5 users of methamphetamine (21.17%) bought it from a drug dealer or other stranger (126).

## 2.0 PRESCRIPTION OPIOID ABUSE

Prescription opioids are abused among the populations with or without pain, and in patients receiving or not receiving opioids. The abuse is associated with substantial risks to the patients and the nation as a whole with increasing emergency department visits, deaths, and federal drug spending.

Along with the increase of prescriptions for controlled drugs from 1992 to 2003 of 154% (151), there was also a 90% increase in the number of people who admitted abusing controlled prescription drugs. Mahowald et al (158) and White et al (232) evaluated opioid abuse in the insured population of the United States. Opioid abuse was determined to be present in 6.7 to 8 per 10,000 persons insured. However, opioid abusers also presented with multiple comorbidities and expenses 8 times higher than for non-abusers (\$15,884 vs. \$1,830).

The cost of opioid abuse is enormous. The White House Budget Office estimated drug abuse costs to the US Government to be approximately \$300 billion a year (10,123). The White House Office of National Drug Control Policy (ONDCP), a component of the Executive Office of the President, established by the Anti-Drug Abuse Act of 1998, has been spending \$12-13 billion each year.

The central question when prescribing opioids for chronic noncancer pain is how best to balance the risk of opioid abuse with the pain relief provided by these medications (4,10,19,25,36,37,45,46,49,51-55,60,61,63-66,144,164,233-242). While proponents claim extremely low levels of opioid abuse (243), opioids are by far the most abused drugs, especially in chronic pain management settings (4,12,19,25,36,37,46,144,233-235). Numerous investigations have illustrated drug abuse in 18-41% of patients receiving opioids for chronic pain (10,48,49,51-55,60,61,63-66,241,242,244).

Martell et al (48), in a systematic review of opioid treatment for chronic back pain, estimated the prevalence of lifetime substance use disorders to range from 36 to 56%, with a 43% current substance use disorder rate. Furthermore, aberrant medication-taking behaviors ranged from 5 to 24%.

Multiple investigators have also studied the issue of illicit drug use in chronic pain patients receiving controlled substances (51,61,63-66,241,242). The results showed that illicit drug use in patients without controlled substance abuse was found in 14–16% of patients and illicit drug use in patients with controlled substance abuse was present in 34% of the patients (51,53,54). Illicit drug use was significant in chronic pain patients in general, but illicit drug use was similar in patients using either long-acting or short-acting opioids (64). In a study on effective monitoring of opiates in chronic pain patients evaluating 111,872 specimens collected over a 1-year time period from pain treatment facilities throughout the USA (241), and in another study evaluating 938,586 specimens, a significant proportion were shown to have abnormal drug testing with non-prescribed medications, illicit drugs and inappropriate intake of drugs (242). In other evaluations, it was shown that adherence monitoring will in fact decrease controlled substance abuse and illicit drug use (61,66).

Along with an increase of prescriptions for controlled drugs from 1992 to 2002 of 154%, there was also a 90% increase in the number of people who admitted abusing controlled prescription drugs. Studies also evaluated opioid abuse in the insured population of the USA (232). Opioid abuse was determined to be present in 6.7–8 per 10,000 persons insured; however, opioid abusers presented with multiple comorbidities and expenses 8-times higher than for non-abusers (US \$15,884 vs. \$1830).



### 3.0 DRUG POISONING AND DEATHS

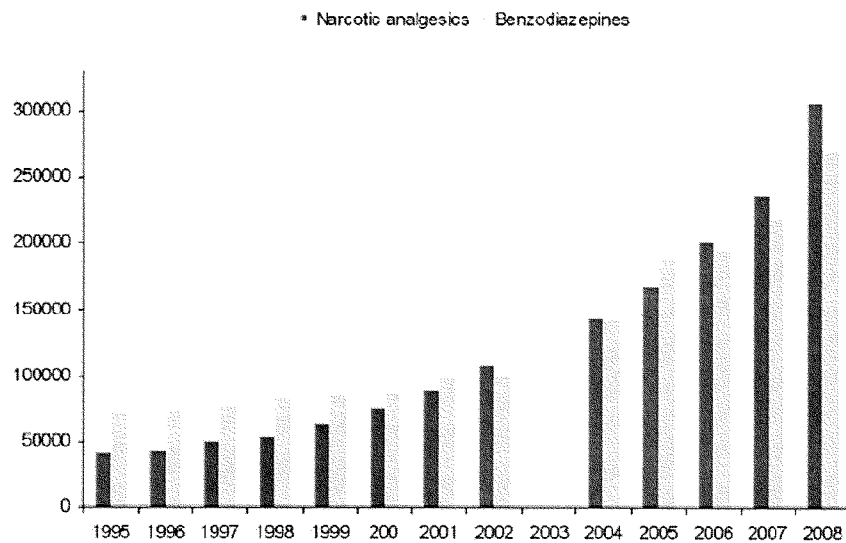
Unintentional drug poisonings in the United States are common. Unintentional, or accidental, with no harm intended, includes drug overdoses resulting from drug misuse, drug abuse, and taking too much of a drug for medical reasons (245).

#### 3.1 *Emergency Department Visits*

The Drug Abuse Warning Network (DAWN) publishes results of emergency department visits with drug misuse and abuse. In 2008, DAWN (132) published results with over one million emergency department visits involving an illicit drug.

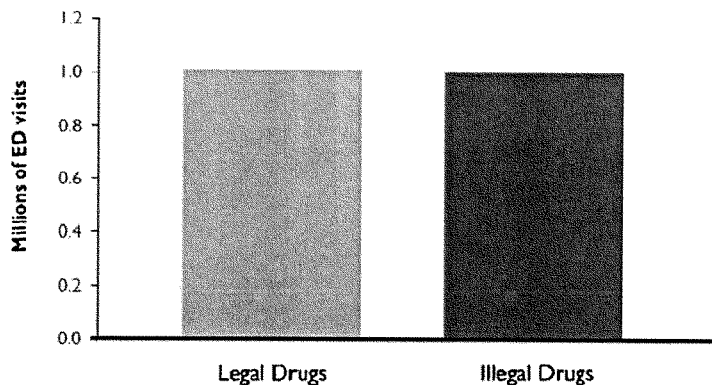
1. Hydrocodone/combinations in 89,047 emergency department visits,
2. Oxycodone/combinations in 105,208 emergency department visits, and;
3. Methadone in 63,629 emergency department visits.

Emergency department visits for narcotics were 305,885 in 2008 compared to 42,857 in 1995, a 614% increase over a period of 13 years (Fig. 2). Among the psychotherapeutic agents, the anxiolytics (anti-anxiety agents, sedatives, and hypnotics) were the most frequent, occurring in 30% of the visits associated with nonmedical use of pharmaceuticals (132). DAWN estimated that 271,700 emergency department visits were associated with nonmedical use of pharmaceuticals involving benzodiazepines in 2008, compared to 71,609 in 1995, a 279% increase over a period of 13 years (71,132-134).



**Fig. 2.** *Drug abuse related emergency department visits.*

In 2008, DAWN estimates show that prescription or over-the-counter drugs used non-medically were involved in 1.0 million emergency department visits, and illicit drugs were involved in 1.0 millions visits (Fig. 3).

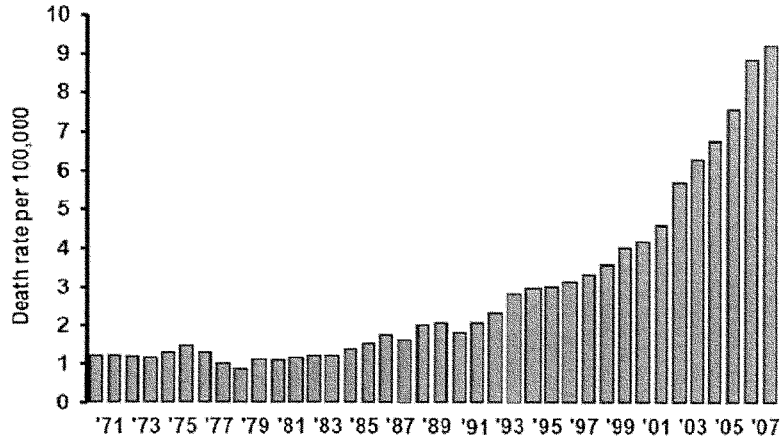


Source: Drug Abuse Warning Network.

**Fig. 3.** *Estimated numbers of emergency department visits involving legal drugs used non-medically and illegal drugs, United States, 2008.*

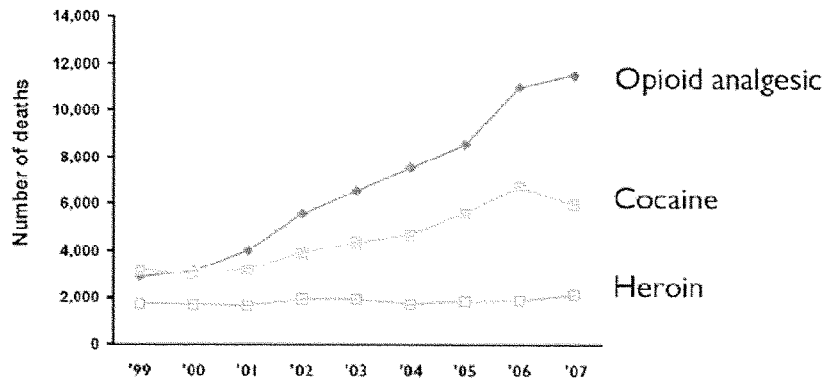
### 3.2 Deaths Due to Opioids

Drug overdose death rates have risen steadily in the United States since 1970 as illustrated in Fig 4. In 2007, 27,658 unintentional drug overdose deaths occurred in the United States. Drug overdose deaths were second only to motor vehicle crash deaths among leading causes of unintentional injury death in 2007 in the United States. Consequently, rates have increased roughly 5-fold since 1990. Age-adjusted rates of drug overdose deaths for whites have exceeded those among African-Americans since 2003. It has been stated that increasing drug overdose death rates is largely because of prescription opioid painkillers. In 2007, the number of deaths involving opioid analgesics was 9.3 times the number involving cocaine and 5.38 times the number involving heroin. Figure 5 illustrates unintentional drug overdose deaths by major type of drug in the United States from 1999 to 2007. It has been reported that these deaths are secondary to an unusual increase of prescription opioids during the last 20 years which has been over 10-fold because of a movement toward more aggressive management of pain.



Source: National Vital Statistics System

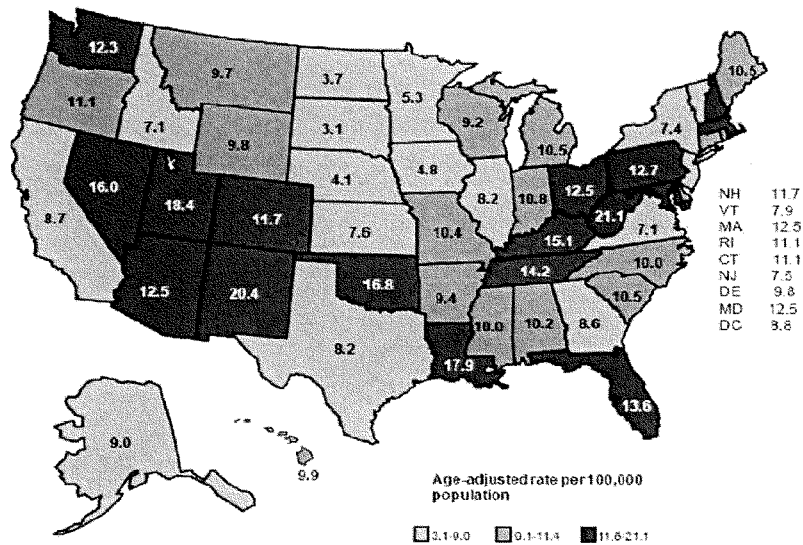
Fig. 4. Rate of unintentional drug overdose deaths in the United States, 1970-2007.



Source: National Vital Statistics System

Fig. 5. Unintentional drug overdose deaths by major type of drug, United States, 1999-2007.

Significant regional variations also have been reported in relations to overall drug overdose death rates. It has been shown that states in the Appalachian region and the Southwest have the highest death rates (Fig. 6). The highest drug overdose death rates was found in West Virginia, which was nearly 7 times that of state with the lowest drug overdose death rate, South Dakota. In 2007, states such as California and New York had some of the lowest overall death rates among all states because of low opioid overdose rates. In contrast, in the early 1990's these states had some of the highest overall rates, largely because of high heroin and cocaine overdose rates.

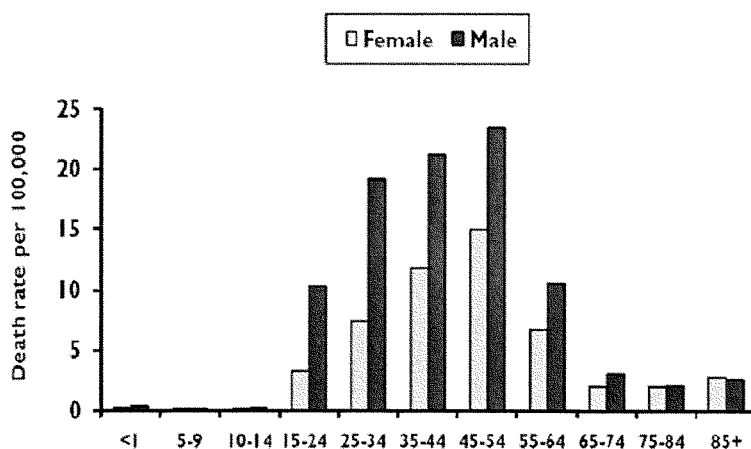


Source: National Vital Statistics System

**Fig. 6.** Drug overdose death rates by states, 2007.

It also has been demonstrated that men and middle aged people are more likely to die from drug overdosage. In 2007, 18,029 drug overdose deaths occurred among males and 9,626

among females (Fig. 7). Essentially, male rates have doubled and female rates have tripled since 1999. In general, it has been stated that men have historically had higher rates of substance abuse than women.



Source: National Vital Statistics System

Fig. 7. Unintentional drug overdose death rates by sex and age group, United States, 2007.

Further, for both sexes, the highest rates were in the 45 to 54 years old age group with rates declining dramatically after the age of 54. Finally, after age 64, the male and female rates become comparable, probably as a result of the reduction of the rates of substance abuse with age.

#### 4.0 DRUG DIVERSION

Prescription drug 'diversion,' defined as the unlawful channeling of regulated pharmaceuticals from legal sources to the illicit market place, has been a topic of widespread commentary, and is of interest to regulators and providers (246). The abuse of many different prescription drugs has been escalating since the early to mid-1990s (246,247). Diversion can occur in many ways, including the illegal sale of prescriptions by physicians, patients and pharmacists, doctor shopping, forgery, robbery and theft. However, it has been shown that the majority of the drugs come from a single physician's prescription and that family members share it (4). Inciardi et al (246) described diversion as a disorganized for-profit industry. They described it as 'disorganized' because there are so many different players involved in the phenomenon, including physicians, pharmacists and other healthcare professionals; drug abusers, patients, students, street dealers and white collar criminals; tourists, saloon keepers and all types of service personnel, to name but a few. Federal agencies maintain that the diverted drugs enter the illegal market primarily through 'doctor shoppers,' inappropriate prescribing practices by physicians and improper dispensing by pharmacists (246). Inciardi et al (246) in a study of the mechanisms of prescription drug diversion among drug-involved club- and street-based populations, concluded that while doctor shoppers and the internet receive much of the attention regarding diversion, the data showed there are numerous active street markets involving patients, Medicaid recipients and pharmacists as well. They also suggested that the contributions of residential burglaries, pharmacy robberies and thefts and 'sneak thefts' to the diversion problem may have been understated.

In an updated manuscript, Inciardi et al (247) described the results of an ultra-rapid assessment of prescription opioid abuse and diversion in an urban community. They reported that the primary sources of prescription drugs on the street were the elderly, patients with pain and doctor shoppers, as well as pill brokers and dealers who work with all of the former. They also described that the popularity of prescription drugs in the street market was rooted in the abusers' perceptions of these drugs as less stigmatizing, less dangerous and less subject to legal consequences than illicit drugs. Furthermore, they showed that the abuse of prescription opioids also appears to serve as a gateway to heroin use.

In multiple European countries where methadone is not available for prescription use, its abuse is minimal. Further, the oxycodone abuse is also much less than other drugs. Surprisingly buprenorphine was more commonly abused than methadone and oxycodone in multiple other countries.



## 5.0 MONITORING OF ABUSE

Misuse, abuse, and diversion should be addressed on 3 fronts.

1. Prescription drug monitoring programs (supply)
2. Screening tools to monitor opioid adherence (demand)
3. Development of Abuse Deterrent Formulations (ADF) of opioids (drugs).

### 5.1 *Prescription Monitoring Programs*

PMPs collect state-wide data about prescription drugs and track their flow (122,248). There are 3 components of these programs. First is data collection for prescriptions that shows the physicians who wrote them and the pharmacies that dispensed them. Pharmacies are required to report the data by law. Physicians are encouraged to report but are not mandated to do so. Second, there should be a central repository for this data, and lastly there should be a protocol in place describing how this data from the central repository can be made available to appropriate authorities and agencies. To date, 38 states have PMPs, but there is a significant difference in the manner and frequency with which the data is collected.

President George W. Bush signed into law the NASPER in 2005 which was created by ASIPP and enacted by Congress (249). This law requires states to collect prescription information for Schedule II, III, and IV medications. It also requires states to have the capability to share this information with each other. This can decrease cross-border narcotic trafficking. It is heartening to know that this program is now funded by the federal government.

At one point, only 3 states allowed physician's access with physician-friendly programs to monitor drug utilization. These included Kentucky, Utah, and Idaho. Now, with enactment of NASPER and/or other funding from the Harold Rogers Prescription Monitoring Program,

multiple states are operating physician-friendly programs where pain physicians can identify the risk of overuse and abuse (122,248-251).

### ***5.2 Development of Abuse Deterrent Formulations of Opioids***

The pharmaceutical industry is under growing pressure to develop ADFs of opioids (252). This potentially can curtail abuse but still have opioids readily available for pain management for those who need them. It is imperative that ADFs be developed because opioids are attractive for abuse. The potential for abuse depends on the formulation, route of administration, and rapid rise of plasma concentration resulting in drug liking and reinforcement. Various types of ADFs are being developed, but these do not necessarily decrease abuse in those who will consume the drug intact. Some ADFs employ physical barriers that resist common methods of tampering like crushing the pill and subjecting the pill to various chemical manipulations to extract active ingredients so that they can be snorted or chewed. A combination of opioid agonists and opioid antagonists have been tried. One such example is Talwin, but it also decreases its efficacy to treat moderate pain. Another ADF is a prodrug that needs to be metabolized to an active form after ingestion to produce an analgesic action. It incorporates aversive stimulants like niacin or capsaicin. If the drug is tampered with before ingestion, the aversive stimulants are released, producing an uncomfortable physical sensation. Manufacture of ADFs also can increase the manufacturing cost of the opioids. In the long run though, it might be economical if the ADFs can change the pattern of behavior associated with abuse of prescription opioids, thereby decreasing the consequences and associated medical costs as well as death. ADFs can also make the active ingredient less accessible and less attractive for those who would like to use the drug by an alternate route.

### 5.3 *Urine Drug Testing*

There are a variety of biological specimens used in performing laboratory drug testing (e.g., urine, blood, sweat, saliva, hair, and nails). Each provides differing levels of specificity, sensitivity, and accuracy. No single instrument or assessment method has universal predictive utility because there could be multiple reasons and factors involved in drug abuse and/or misuse. However, urine drug testing (UDT) is regarded as the gold standard. This is primarily because urinary tests allow for the presence or absence of certain drugs to be evaluated with good specificity, sensitivity, ease of administration, and cost (253). Urine drug concentrations and metabolites also tend to be high in urine, allowing longer detection times than serum concentrations (254). However, debate continues regarding the clinical value of UDT, partly because most current methods are designed for, or adapted from, forensic or occupational deterrent-based testing for illicit drug use and are not entirely optimal for applications in the chronic pain management setting (253). Yet, with appropriate consideration of the caveats against misinterpretation (arising from limits of specificity, and/or false-positive or false-negative screens), UDT can be a useful tool to aid in both the ability to evaluate patients' compliance with prescribed regimens of controlled substances, and to diagnose the misuse or abuse of prescribed drugs or use of illicit agents. However, UDT has been used, misused, and abused due to financial incentives, and the influence of medical licensure boards, the Drug Enforcement Agency (DEA), and other governmental agencies (242,253,255-259). UDT is most commonly used for 2 purposes: ensuring compliance by patients who are using the prescribed opioid(s), and monitoring the use of non-prescribed or illicit substances in the population receiving opioid therapy for chronic pain (260).

In the therapeutic phase of chronic pain management, either during the initiation, titration, or maintenance of opioid treatment, UDT can be useful in detecting non-compliance, unauthorized drug use, doctor shopping, and diversion. Multiple investigators have studied the importance of UDT and adherence monitoring. They found positive evidence for reducing prescription drug abuse, as well as illicit drug use (66).

There is no evidence to guide physicians on identifying chronic pain patients who should have UDT and how often. Multiple descriptions have been provided. Some recommendations include patients' risks for opioid misuse and addiction and aberrant drug-related behaviors.

A practical approach would include baseline drug testing, if appropriate; initiation of opioid therapy and compliance monitoring within one to 3 months after baseline monitoring; and routine, random monitoring approximately every 6-12 months or so, with provision for monitoring for unexpected results, complaints, or behavior patterns.

Thus, the majority of patients will receive a baseline test, initiation of the compliance test, and one year monitoring within the first 15 months or so. After that, if the patient is continuing with a pain management program, testing will only be required once a year. However, patients with abnormal results will require more frequent testing based on the results and the philosophy of the prescribing physician.

An algorithmic steps in UDT in chronic pain are described in Figure 8.

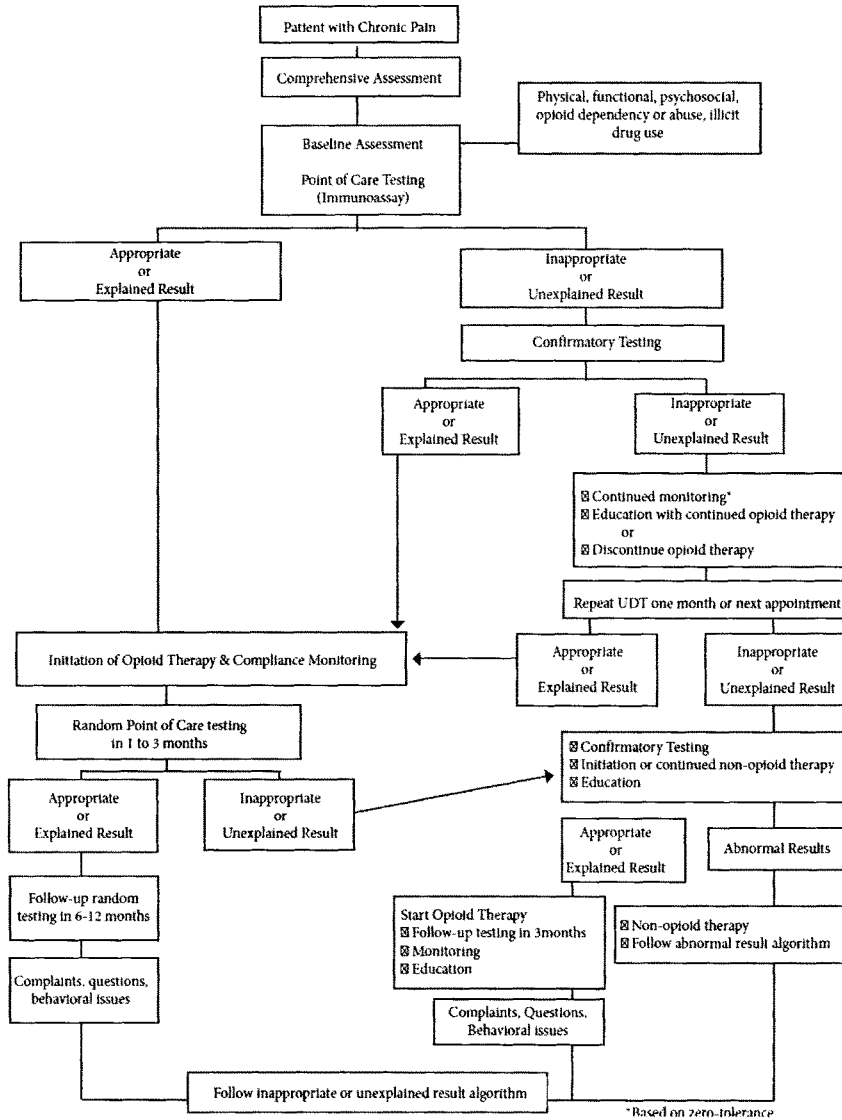


Fig. 8. Algorithmic steps in urine drug testing in chronic pain.

**6.0 STEPS IN PRESCRIBING OPIOIDS**

Table 1 Illustrates an algorithmic approach for long-term opioid therapy in chronic pain with a ten-step process that includes initial evaluation, establishment of the diagnosis, establishing medical necessity for opioids, assessing the risk–benefit ratio, establishing treatment goals, informed consent and agreement, initial dose adjustment, maintenance in the stable phase, adherence monitoring and assessment of outcomes.

**Table 1.** *Ten-step process: An algorithmic approach for long-term opioid therapy in chronic pain.*

<b>STEP I</b>	Comprehensive initial evaluation
<b>STEP II</b>	Establish diagnosis <ul style="list-style-type: none"> <li>◆ X-rays, MRI, CT, neuro-physiologic studies</li> <li>◆ Psychological evaluation</li> <li>◆ Precision diagnostic interventions</li> </ul>
<b>STEP III</b>	Establish medical necessity (lack of progress or as supplemental therapy) <ul style="list-style-type: none"> <li>◆ Physical diagnosis</li> <li>◆ Therapeutic interventional pain management</li> <li>◆ Physical modalities</li> <li>◆ Behavior therapy</li> </ul>
<b>STEP IV</b>	Assess risk-benefit ratio <ul style="list-style-type: none"> <li>◆ Treatment is beneficial</li> </ul>
<b>STEP V</b>	Establish treatment goals
<b>STEP VI</b>	Obtain informed consent and agreement
<b>STEP VII</b>	Initial dose adjustment phase (up to 8-12 weeks) <ul style="list-style-type: none"> <li>◆ Start low dose</li> <li>◆ Utilize opioids, NSAIDs and adjuvants</li> <li>◆ Discontinue <ul style="list-style-type: none"> <li>• Lack of analgesia</li> <li>• Side effects</li> <li>• Lack of functional improvement</li> </ul> </li> </ul>
<b>STEP VIII</b>	Stable phase (stable – moderate doses) <ul style="list-style-type: none"> <li>◆ Monthly refills</li> <li>◆ Assess for four A's <ul style="list-style-type: none"> <li>• Analgesia</li> <li>• Activity</li> <li>• Aberrant behavior</li> <li>• Adverse effect</li> </ul> </li> <li>◆ Manage side effects</li> </ul>
<b>STEP IX</b>	Adherence monitoring <ul style="list-style-type: none"> <li>◆ Prescription monitoring programs</li> <li>◆ Random drug screens</li> <li>◆ Pill counts</li> </ul>
<b>STEP X</b>	Outcomes <ul style="list-style-type: none"> <li>◆ Successful – continue <ul style="list-style-type: none"> <li>• Stable doses</li> <li>• Analgesia, activity</li> <li>• No abuse, side effects</li> </ul> </li> <li>◆ Failed – discontinue <ul style="list-style-type: none"> <li>• Dose escalation</li> <li>• No analgesia</li> </ul> </li> </ul>

	<ul style="list-style-type: none"><li>• No activity</li><li>• Abuse</li><li>• Side effects</li><li>• Non-compliance</li></ul>
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Theoretically, opioids have no maximum or ceiling dose, but there is little evidence to guide safe and effective prescribing at higher doses and there is no standardized definition of what constitutes a 'high' or 'low' dose. Chou *et al.*, by panel consensus in the American Pain Society (APS) guidelines, defined high-dose opioid therapy as greater than 200 mg daily of oral morphine or equivalent, based on maximum opioid doses studied in randomized trials and average opioid doses observed in observational studies (261).

Furthermore, multiple arguments may be made with regard to the definition of mild, moderate and high disease. These definitions vary from practitioner to practitioner and guideline to guideline. A conservative approach for a low dose is up to 60 mg of morphine equivalence; a moderate dose is 61–120 mg of morphine equivalence; and a high dose is 121–200 mg of morphine equivalence (212-215,220-222). However, these recommendations vary widely.

Recognizing that many of our patients are already on long-term opioid therapy, steps I, II and III may have already passed. In those cases, if appropriate, acceptable and trustworthy evaluations are available, one may pass steps I–III and go to step IV. However, if reliable information is not available, the patients have to be assessed or re-assessed starting all over again. Finally, the ten-step process provides an exit strategy in step X, rather than maintaining the loop forever.

#### **6.1 Documentation & Medical Records**

The physician should keep accurate and complete medical records, which include all aspects of interventional pain management and medical care. These comprise of, but are not limited to:

- ◆ Medical history and physical examination
- ◆ Diagnostic, therapeutic and laboratory results

- ◆ Evaluations and consultations
- ◆ Treatment objectives;
- ◆ Discussion of the risks, benefits and limitations of treatments
- ◆ Details of different treatments and medications, including date, type, dosage and quantity prescribed
- ◆ Instructions to the patient
- ◆ Periodic reviews of outcomes, including documentation of functional status, preferably using validated tools.

Records should remain current and be maintained in an accessible manner and readily available for review, not only for the physician and other members of the practice, but also for authorities.

To be in compliance with controlled substance laws and regulations required to prescribe, dispense or administer controlled substances, the physician must have an active license to practice medicine and comply with applicable regulations. Physicians should not prescribe scheduled drugs for themselves or immediate family, except in emergency situations.

The following criteria should be considered carefully in providing controlled substances:

- ◆ Complete initial evaluation, including history and physical examination;
- ◆ Psychological evaluation;
- ◆ Physiological and functional assessment, as necessary and feasible;
- ◆ Definition of indications and medical necessity:
  - Pain of moderate-to-severe degree
  - Suspected organic problem

- Documentation of failure to respond to noncontrolled substances, adjuvant agents, physical therapy and interventional techniques
- For patients with interventional techniques as the primary modality, controlled substance drugs may be used as a second-line treatment
- For nonopioid controlled substances, appropriate documentation of psychological disorders should be maintained
- Continued opioid prescription requires monitoring of the '4 As':
  - Analgesia
  - Activity
  - Aberrant behavior
  - Adverse effect
- ◆ The use of the lowest possible dose to provide adequate analgesia with minimum side effects should be the goal of opioid therapy;
- ◆ In general, do not combine opioids with sedative-hypnotics, benzodiazepines or barbiturates for chronic noncancer pain unless there is a specific medical indication for the combination;
- ◆ Adherence to the controlled substance agreement, with patients understanding the risks and benefits of controlled substances and the policy and regulations of the practitioner, including controlled substances being prescribed by only one practitioner and being obtained from only one pharmacy;
- ◆ Monitoring for drug abuse or diversion should be routine and, if confirmed, referral to rehabilitation centers may be made, with termination of prescriptions of controlled substances;

- ◆ Use caution when prescribing acetaminophen-containing opioids, especially given the ubiquitousness of acetaminophen in over-the-counter medications. Short-term use (<10 days) should be less than 4000 mg/day, while chronic use should probably be limited to 2500 mg/day.

While there are no universally accepted tools to assess opioid responsiveness, it is important to use a tool that monitors both function and pain relief.

Although opioids may be useful for the treatment of chronic pain, aberrant behavior and/or no improvement in function and pain after an adequate trial of opioids should trigger a consideration to discontinue the opioids, tapered over several weeks to avoid withdrawal symptoms. Evidence of diversion or illegal use warrants an immediate discontinuation of the medication. Clonidine 0.1 mg *per os* or transdermal can be offered to counteract the majority of withdrawal symptoms (3).

## 7.0 EDUCATION

Education is lacking at all levels primarily for physicians, pharmacists, and the public at large (262,263) and compounded by misinformation. Of 979 physicians surveyed regarding the diversion and abuse of controlled prescription drugs showed the following (262):

### *Physicians:*

- ◆ Physicians perceive the 3 main mechanisms of diversion to be:
  - Doctor shopping (when patients obtain controlled drugs from multiple doctors) (96%)
  - Patient deception or manipulation of doctors (88%)
  - Forged or altered prescriptions (69%).
- ◆ 59% believe that patients account for the bulk of the diversion problem.
- ◆ 47% said that patients often try to pressure them into prescribing a controlled drug.
- ◆ Only 19% of surveyed physicians received any medical school training in identifying prescription drug diversion.
- ◆ Only 40% of surveyed physicians received any training in medical school in identifying prescription drug abuse and addiction.
- ◆ 43% of physicians do not ask about prescription drug abuse when taking a patient's health history.
- ◆ One-third of physicians do not regularly call or obtain records from the patient's previous (or other treating) physician before prescribing controlled drugs on a long-term basis. Health Insurance Portability and Accountability Act (HIPAA) regulations have made this step much more difficult.

- ◆ 74% have refrained from prescribing controlled drugs during the past 12 months because of concern that a patient might become addicted to them.

In a recent study (263) based on questionnaire responses from 248 primary care physicians, published results showed that the most common concerns about prescribing opioids for chronic pain were prescription drug abuse and addiction. Other concerns included: adverse effects, tolerance, interaction with other medications, not knowing enough about which narcotic to prescribe, not knowing enough about dosage requirements, and having partners who prefer not to use opioids for treating chronic pain. The majority of the physicians were comfortable in prescribing narcotics to someone with terminal cancer but less confident in prescribing for patients with back pain. They were even less comfortable with prescribing narcotics to patients with a past history of drug or alcohol abuse. The survey also noted that only a small percentage of physicians are conducting urine toxicology screens on their patients either before or during opioid therapy, and that this was dependent on whether or not they had a system to track patients on opioids.

In two prospective evaluations of 500 patients in each study (52,61) with enhanced monitoring, it was shown that overall prescription controlled drug abuse reduced from 18% to 9%; whereas illicit drug use reduced from 22% to 16%. Significant decreases were observed in Medicaid patients.

Van Rooyan (264) described physician education as follows:

- ◆ The majority of physicians do not know that the long-term safety and effectiveness of opioids for management of non-malignant pain have *not* been substantiated.

- ◆ The majority of physicians do not know that patients seeking pain relief for chronic, non-malignant pain often have underlying psycho-social problems and need psychological or rehabilitation services or would respond well to other non-drug interventions.
- ◆ In busy medical practices, particularly primary care and family practice office settings, often, pain therapy is based not on science, but on intuition or hearsay, and ends up aggravating rather than ameliorating prescription pain medication abuse and addiction.
- ◆ Expansion of opioid therapy for patients who might benefit more from non-drug interventions or alternate drugs, without consideration of the accompanying risks of opioids, is based on pharmaceutical promotion.

Pharmacists fear of being labeled opiophobic by opioid and advocacy lobby.

The National Center of Addiction and Substance Abuse (CASA) survey (262) of 1,303 pharmacists regarding diversion and abuse of controlled prescription drugs showed the following:

- ◆ When a patient presents a prescription for a controlled drug:
  - 78% of pharmacists become “somewhat or very” concerned about diversion or abuse when a patient asks for a controlled drug by its brand name;
  - 27% “somewhat or very often” think it is for purposes of diversion or abuse.
- ◆ 52% believe that patients account for the bulk of the diversion problem.

- ◆ Only about half of the pharmacists surveyed received any training in identifying prescription drug diversion (48%) or abuse or addiction (50%) since pharmacy school.
- ◆ 61% do not regularly ask if the patient is taking any other controlled drugs when dispensing a controlled medication; 25.8% rarely or never do so.
- ◆ 29% have experienced a theft or robbery of controlled drugs at their pharmacy within the last 5 years; 20.9% do not stock certain controlled drugs in order to prevent diversion.
- ◆ 25% do not regularly validate the prescribing physician's DEA number when dispensing controlled drugs; 1 in 10 (10.5%) rarely or never do so.
- ◆ 83% have refused to dispense a controlled drug in the past year because of suspicions of diversion or abuse.

Pharmacists may be involved in prescription drug diversion, first by selling the controlled substances and then, using their database of physicians and patients to write and forge prescriptions to cover their illegal sale.

#### ***Patients***

Patients also have many concerns about the lack of education. The problem list is long and extensive. A non-inclusive list is as follows:

- ◆ Undertreatment of pain.
- ◆ All patients are under suspicion.
- ◆ The interest in receiving opioids for chronic pain, fueled by advertising by pharmaceutical companies.



- ◆ Unproven, misunderstood regulations of JCAHO and other organizations mandating monitoring and appropriate treatment of pain.
- ◆ Media coverage of undertreatment of pain.
- ◆ Numerous organizations providing advocacy guidelines and standards.
- ◆ Patient advocacy groups advising them to demand more opioids.
- ◆ Very little or no effort on educating the public about non-opioid management.
- ◆ Access to Internet and a daily bombardment of the easy availability of drugs.
- ◆ Patient beliefs that they have the right to total pain relief.
- ◆ The lack of interest on behalf of the patients to understand deleterious effects of opioids and benefits of non-opioid techniques.

As described in the recent document on responding to America's Prescription Drug Abuse Crisis from the White House a crucial first step in taking the problem of prescription drug abuse is to raise awareness through the education of parents, youth, patients, and health care providers.

A crucial first step in tackling the problem of prescription drug abuse is to raise awareness through the education of parents, youth, patients, and healthcare providers. Although there have been great strides in raising awareness about the dangers of using illegal drugs, many people are still not aware that the misuse or abuse of prescription drugs can be as dangerous as the use of illegal drugs, leading to addiction and even death.

In addition, prescribers and dispensers, including physicians, physicians assistants, nurse practitioners, pharmacists, nurses, prescribing psychologists, and dentists, all have a role to play in reducing prescription drug misuse and abuse. Most receive little training on the importance of appropriate prescribing and dispensing of opioids to prevent adverse effects, diversion, and

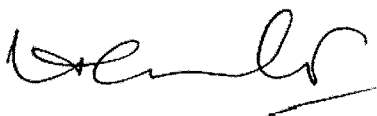
addiction. Outside of specialty addiction treatment programs, most healthcare providers have received minimal training in how to recognize substance abuse in their patients. Most medical, dental, pharmacy, and other health professional schools do not provide in-depth training on substance abuse; often, substance abuse education is limited to classroom or clinical electives. Moreover, students in these schools may only receive limited training on treating pain.

A national survey of medical residency programs in 2000 found that, of the programs studied, only 56 percent required substance use disorder training, and the number of curricular hours in the required programs varied between 3 to 12 hours (265). A 2008 follow-up survey found that some progress has been made to improve medical school, residency, and post-residency substance abuse education; however, these efforts have not been uniformly applied in all residency programs or medical schools (266).

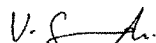
#### **7.1 Health Care Provider Education**

Comprehensiveness must be provided starting with medical school, residency programs, and with assessment of knowledge in practice as condition for DEA license for prescription of Schedule II and III drugs. This training also should include assessing and addressing the assessment of symptoms and signs of abuse and/or dependence.

Thank you for providing us with this opportunity. If you have any further questions, please feel free to contact us.



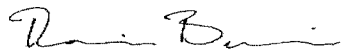
**Laxmaiah Manchikanti, MD**  
Chairman of the Board and Chief Executive Officer, ASIPP and SIPMS  
Medical Director, Pain Management Center of Paducah  
Associate Clinical Professor, Anesthesiology and Perioperative Medicine  
University of Louisville, Kentucky  
2831 Lone Oak Road  
Paducah, KY 42003  
270-554-8373 ext. 101  
[drm@asipp.org](mailto:drm@asipp.org)



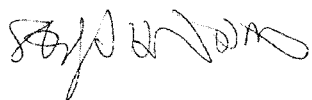
**Vijay Singh, MD**  
Executive Committee Chairman, Lifetime Director, ASIPP  
Medical Director, Pain Diagnostic Associates  
1601 Roosevelt Road  
Niagara, WI 54151  
715-251-1780  
[vj@wmpnet.net](mailto:vj@wmpnet.net)



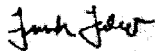
**Allan Parr, MD**  
President, ASIPP  
Medical Director, Premier Pain Center  
7015 Highway 190 East Service Road, Suite 101  
Covington, LA 70433  
985-809-1997  
[alparr@alparr.com](mailto:alparr@alparr.com)



**Ramsin Benyamin, MD**  
 Immediate Past President, ASIPP  
 Medical Director, Millennium Pain Center  
 Clinical Assistant Professor of Surgery, College of Medicine, University of Illinois  
 1015 S. Mercer Ave  
 Bloomington, IL 61701  
 309-662-4321  
[ramsinbenyamin@yahoo.com](mailto:ramsinbenyamin@yahoo.com)



**Standiford Helm, MD**  
 President Elect, ASIPP  
 Medical Director, Pacific Coast Pain Management Center  
 24902 Moulton Parkway, Suite 200  
 Laguna Hills, CA 92637  
 949-462-0560  
[drhelm@pcpmc.com](mailto:drhelm@pcpmc.com)



**Frank Falco, MD**  
 Executive Vice President, ASIPP  
 Medical Director, Midatlantic Spine  
 Clinical Assistant Professor, Temple University Medical School  
 139 East Chestnut Hill Road  
 Newark, DE 19713  
 302-369-1700  
[cssm01@aol.com](mailto:cssm01@aol.com)



**Joshua Hirsch, MD**

Board of Directors, ASIPP

Chief of Minimally Invasive Spine Surgery, Depts. of Radiology and Neurosurgery  
Massachusetts General Hospital

Associate Professor of Radiology, Harvard Medical School

55 Blossom St., Gray 289

Boston, MA 02114

617-726-1767

[jahirsch@partners.org](mailto:jahirsch@partners.org)



**David Caraway, MD, PhD**

Vice President – Strategic Planning, ASIPP

St. Mary's Pain Relief Center

510 Bell Farms Lane

Palmyra, VA 22963

434-882-1790

[carawaymd@aol.com](mailto:carawaymd@aol.com)

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ROBERT P. CASEY, JR.  
PENNSYLVANIA

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## United States Senate

WASHINGTON, DC 20510

Statement for the Record  
Senate Subcommittee on Crime and Terrorism  
"Responding to the Prescription Drug Epidemic:  
Strategies for Reducing Abuse, Misuse, Diversion, and Fraud"  
May 24, 2011

Chairman Whitehouse and Ranking Member Kyl, I commend you for holding this important and timely hearing on prescription drug abuse. Despite the best efforts of law enforcement and substance abuse professionals, drug abuse remains a vexing problem facing urban, rural, and suburban communities alike. Drug addiction and abuse have impacted nearly every region of my home state of Pennsylvania, and police report that drug-related crime is on the rise. I urge you to act quickly to write and pass legislation to stem the cycle of addiction where it often begins: the abuse of prescription drugs.

Over the past decade, doctors have increasingly prescribed powerful painkillers like OxyContin, a drug with characteristics similar to heroin, to help patients with severe pain. Because these opioid drugs are very powerful, those who use them both for legitimate and illegitimate purposes often become addicted. Prescription painkillers are easily obtained through friends, family, so-called "doctor shopping", and over the Internet. These drugs are very expensive, however, and users are increasingly making a dangerous transition from prescription painkillers to heroin.

According to the National Drug Intelligence Center's Eastern Pennsylvania Drug and Gang Threat Assessment 2011, heroin trafficking and abuse have increased sharply in recent years, with many youth in particular transitioning from abuse of prescription opiates to heroin. Two recent heroin-related incidents in Western Pennsylvania are of particular concern to me. In early May, a 20-year old college student was killed in McKees Rocks when he tried to trade an iPad for \$200 worth of heroin. Last week, a seven-year-old kindergarten student brought heroin to his elementary school and distributed it to three classmates. He told police he'd found the drug in his parents' bedroom.

I understand you are developing legislation in partnership with the Office of National Drug Control Policy to address prescription drug abuse, and I commend this effort. In writing this legislation, I urge you to consider the link between prescription drug abuse and heroin addiction. While not every heroin user becomes an addict through prescription drugs, we cannot effectively address one problem without addressing the other. I look forward to working with you on this issue and would like to offer my staff as a resource as you write this important legislation. Please feel free to contact Christina Baumgardner in my office at (202) 224-6324. Thank you for your consideration.



Robert P. Casey, Jr.  
United States Senator

PRINTED ON RECYCLED PAPER





STATEMENT  
OF  
HUMAYUN J. CHAUDHRY, DO, FACP  
PRESIDENT AND CHIEF EXECUTIVE OFFICER  
FEDERATION OF STATE MEDICAL BOARDS

BEFORE THE  
SUBCOMMITTEE ON CRIME AND TERRORISM  
COMMITTEE ON THE JUDICIARY  
UNITED STATES SENATE

“RESPONDING TO THE PRESCRIPTION DRUG  
EPIDEMIC: STRATEGIES FOR REDUCING ABUSE,  
MISUSE, DIVERSION, AND FRAUD”

MAY 24, 2011

**NATIONAL OFFICE**

400 FULLER WISER ROAD | SUITE 300 | EULESS, TX 76039  
(817)868-4000 | FAX (817)868-4098 | WWW.FSMB.ORG

**ADVOCACY OFFICE**

1110 VERMONT AVE. NW | SUITE 1000 | WASHINGTON, DC 20  
(202)530-4872 | FAX (202)530-4800

**U.S. Senate Judiciary Committee, Subcommittee on Crime and Terrorism****Hearing on Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse, Diversion, and Fraud****May 24, 2011****INTRODUCTION**

Chairman Whitehouse, Ranking Member Kyl, and Members of the Subcommittee, thank you for the invitation to submit testimony in response to the nation's prescription drug abuse epidemic, and the efforts of the Federation of State Medical Boards (FSMB) and the medical regulatory community in developing strategies to reduce the risk of addiction, abuse, and diversion of opioids and other controlled substances.

**FSMB BACKGROUND**

The Federation of State Medical Boards (FSMB) is a national non-profit organization representing the 70 state medical and osteopathic boards of the United States and its territories. With offices in Texas and Washington, D.C., the FSMB leads by promoting excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of state medical and osteopathic boards in their protection of the public.

The FSMB was founded in 1912, as the result of a merger between the National Confederation of State Medical Examining and Licensing Boards (established in 1891) and the American Confederation of Reciprocating Examining and Licensing Boards (established in 1902). The FSMB looks forward to celebrating our 100<sup>th</sup> Anniversary in April 2012.

**AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS**

A report recently released by the White House Office of National Drug Control Policy (ONDCP) accurately depicts the dramatic rise in recent years of individuals, particularly teens, misusing and abusing prescription drugs. As cited in *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, the U.S. witnessed a 48% increase in opioid prescription dispensing from 2000 to 2009, rising from 174 million prescriptions to 257 million, respectively. Moreover, opiate overdoses are now most commonly attributed to prescription drug abuse.

Though prescription drug abuse has garnered significant attention in recent years on Capitol Hill and in the media, for more than a decade state medical and osteopathic boards have sought to address this issue and provide guidance to physicians and other health care professionals on the appropriate prescribing of controlled substances, including opioid analgesics.

**FSMB POLICY INITIATIVES TO COMBAT PRESCRIPTION DRUG ABUSE**

Prior to the mid-1990s, few states had adopted pain management policies that would simultaneously educate physicians and patients on appropriate and up-to-date pain treatment techniques, as well as ways in which to identify and communicate the dangers associated with prescription drug abuse.

According to the Centers for Disease Control and Prevention (CDC), 76.5 million Americans suffer from pain. Therefore, state medical and osteopathic boards recognize the danger of limiting access to pain medications for patients with legitimate needs, as unmanaged pain can have detrimental effects on a patient's quality of life. Many of the individuals who suffer from chronic pain require prescription drugs, in conjunction with other treatment modalities, to resume normal living activities, and have no intention of abusing the medication. Opioids can be necessary components of proper pain management treatment. As such, state boards have sought to develop a balance between minimizing the potential for prescription drug misuse, abuse, and diversion while also assuring patients have access to appropriate pain treatments.

Recognizing the importance of establishing a pain policy framework that would support good medical practice while incorporating safeguards to minimize the potential for abuse and diversion, the FSMB launched its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, with input from state medical and osteopathic boards, leading pain and addiction specialists, and law enforcement, including the Drug Enforcement Administration (DEA). These consensus guidelines were revised and expanded in 2004 in the *Model Policy*, which sets forth core principles for safe opioid prescribing. To date, 45 state boards have adopted policies similar to the FSMB's *Model Policy*, while 28 of those have explicitly adopted the FSMB's *Model Policy*.

The *Model Policy* has had a significant impact in achieving more consistency in the promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice. To expand the educational outreach on behalf of state medical and osteopathic boards, the FSMB and its Research and Education Foundation supported a project in 2007 to translate the core principles into practical, clear steps that can be implemented into clinical practice. The resulting book, *Responsible Opioid Prescribing: A Physician's Guide*, authored by pain expert Scott Fishman, M.D., has been distributed by 22 state medical and osteopathic boards to more than 160,000 physicians and other prescribers and is an accredited CME activity.

However, with the alarming increase in prescription drug abuse, the FSMB and state medical and osteopathic boards have recognized the need to increase regulatory efforts to safeguard the public through increased education and enforcement to curtail the unlawful prescribing of controlled substances. Accordingly, the FSMB is working with Dr. Fishman and other content experts to revise and expand *Responsible Opioid Prescribing* to reflect the aims of the ONDCP, Food and Drug Administration (FDA), and Substance Abuse and Mental Health Services Administration (SAMHSA). The FSMB is also supporting state efforts to implement prescription drug monitoring programs and working with a broad spectrum of stakeholders to seek inter-

disciplinary regulatory and enforcement approaches to achieve the mutually shared goals of combating prescription drug abuse, misuse, and diversion while protecting patients' access to quality pain care.

#### **ONDCP PLAN AND FSMB POLICY RECOMMENDATIONS**

While enhanced patient and provider education is fundamental, additional strategies are necessary to reduce prescription drug abuse. As such, the FSMB applauds the intent and four key solutions put forth in ONDCP's *2011 Prescription Drug Abuse Prevention Plan*.

The FSMB strongly affirms the value of prescription drug monitoring programs (PDMPs), and calls for the establishment and adequate funding of PDMPs in every state. Though nearly all states have authorized PDMPs, only 35 states have functional PDMPs in operation. In particular, state medical and osteopathic boards play a key role in training prescribers on the use and value of PDMPs.

In this regard, the FSMB calls on Congress to reauthorize the National All Schedules Prescription Electronic Reporting (NASPER) Act. This grant program, administered by SAMHSA, will continue to aid states in establishing PDMPs, thereby providing prescribers with accurate and up-to-date prescription history information in order to better care for their patients as well as to identify those individuals that may be "doctor shopping."

In these efforts, we also recognize that without the availability of convenient and proper medication disposal procedures, far too many drugs are available to America's youth simply by opening the family medicine cabinet. Therefore, efforts must be taken to educate the public on ways to properly and safely dispose of unused, unneeded, and/or expired medication. The FSMB is a proud sponsor of the DEA's National Prescription Drug Take-Back Day, and looks forward to continuing to support mechanisms for the safe disposal of pain medications.

The FSMB also supports enhanced law enforcement techniques to identify and crackdown on unlawful prescribers and pharmacies. Moreover, state medical and osteopathic boards will continue in their efforts to combat sham pain clinics and "pill mills" that are in clear violation of accepted standards of medical practice.

#### **CONCLUSION**

In conclusion, the Federation of State Medical Boards is in strong support of the efforts put forth by the Obama Administration and the U.S. Congress to dramatically reduce prescription drug abuse in the United States. Given the demonstrated bi-partisanship, we applaud the Administration, Members of Congress, and federal and state agencies who are working together to address this issue. Cooperation and coordination between federal and state agencies is, and will continue to be, essential.

The FSMB will continue to work with its Member Boards to promote physician and patient education related to responsible opioid prescribing and the risks associated with prescription drug abuse. We also look forward to our ongoing work with ONDCP, FDA, DEA, and other federal and state agencies as we partner together to reduce prescription drug abuse.

The FSMB praises the Subcommittee for taking the initiative in holding this hearing and raising public awareness about prescription drug abuse, and we stand ready to assist you in any way that we can.

Thank you again for the opportunity to submit testimony on behalf of the Federation of State Medical Boards.

Written Statement For the Record of General Arthur T. Dean  
 Major General, U.S. Army, Retired  
 Chairman and CEO  
 Community Anti-Drug Coalitions of America  
 625 Slaters Lane, Suite 300  
 Alexandria, VA 22314  
 "Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse,  
 Diversion and Fraud"  
 Committee on the Judiciary  
 Subcommittee on Crime and Terrorism

Prescription drug abuse is a major national problem that affects communities throughout the country. The 2009 National Survey on Drug Use and Health found that the percentage of Americans reporting nonmedical pain reliever use in the past year, as well as in the past month, has increased among every age group during the last year: 12 to 17; 18 to 25; and 26 and older.<sup>1</sup> According to the most recent (2010) national Monitoring the Future (MTF) Survey, prescription drugs account for 8 of the top 14 most frequently abused drugs by our nation's youth.<sup>2</sup> Also according to MTF, 59.1 percent of 12<sup>th</sup> graders abusing prescription drugs receive them from a friend or relative. This is followed by 37.8 percent who bought them from a friend or relative; 32.5 percent who obtained them from a prescription; 19.5 percent who bought them from a dealer/stranger; 18.8 percent who took from a friend or relative; 11 percent who obtained them from some other source; and 1.1 percent from the internet.

The fact that so many youth are obtaining these prescription drugs from friends and relatives indicates that the general public needs to be better educated about: 1) the

<sup>1</sup> Substance Abuse and Mental Health Services Administration. (2010). *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings* (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4586Findings). Rockville, MD. Available: <http://oas.samhsa.gov/nsduhLatest.htm>

<sup>2</sup> Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (December 14, 2010). "Marijuana use is rising; ecstasy use is beginning to rise; and alcohol use is declining among U.S. teens." University of Michigan News Service: Ann Arbor, MI. Available: <http://www.monitoringthefuture.org>

dangers of prescription drug abuse; 2) the need to safely store prescription drugs (to keep them away from youth or others who do not have a prescription); and 3) the proper way to dispose of unused/expired prescription drugs. There is also a need to ensure that doctors, dentists and other legal prescribers are better educated, both in terms of proper prescribing protocols and signs and symptoms of abuse among their patients.

**CADCA's Involvement in Prescription Drug Abuse Prevention**

CADCA has been on the front lines addressing prescription drug abuse for nearly 10 years. It has undertaken a number of initiatives at the national level, ranging from hosting town hall meetings across the country to raise awareness of the problem, to developing tools to help coalitions prevent and reduce prescription drug abuse in their communities.

Since 2001, CADCA has engaged in ongoing educational and communications efforts around prescription drug abuse. It has developed a number of publications, including but not limited to: Strategizer 38: *Prescription Drug Abuse Prevention – Where Do We Go From Here?*; Strategizer 52: *Teen Prescription Drug Abuse: An Emerging Threat*; several *Prescription Drug Abuse Prevention Toolkits*; and a newspaper supplement to educate parents and youth about the dangers of drug use. The goal of these publications is to provide community anti-drug coalitions and others at the community level, with the relevant science and research on prescription drug abuse in a format and manner that enhances their ability to understand and implement effective prevention strategies. CADCA also has hosted five CADCA TV shows on prescription and over the counter medicine abuse to raise awareness at the national level.

In addition to these efforts, CADCA has provided testimony in support of SMART Rx, an effort led by the U.S. Fish and Wildlife Service, to educate the public on the proper disposal for prescription medications; supported Dispose My Meds, a program of the National Community Pharmacists Association; and raised public awareness through a series of presentations – both at CADCA Forums and in other venues, such as the Maine Pharmaceutical Symposium. CADCA has encouraged the United States Congress to make substance abuse prevention, and particularly the misuse and abuse of prescription drugs a major priority. In fact, in 2009 the theme of CADCA’s Capitol Hill Day at its National Leadership Forum was Prescription for Prevention and coalition leaders from across the country attended a rally on Capitol Hill to raise awareness about this issue.

#### **Comprehensive Community Based Prevention**

CADCA recognizes that the misuse and abuse of prescription drugs is a multi-dimensional problem that demands comprehensive, coordinated solutions.<sup>3</sup> We know from research and practice that effective prevention is not a “one size fits all” proposition and that there are no silver bullets to address these issues - “As the field of prevention has matured, it has been recognized that any single strategy is unlikely to succeed and a reinforcing set of strategies has the greatest potential to reduce use”.<sup>4</sup> Successful prevention hinges on the extent to which schools, parents, law enforcement, business, the

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<sup>3</sup> Bronfenbrenner, U. (1979). *The ecology of human development: Experiments by nature and design*. Cambridge, MA: Harvard University Press. Fawcett, S. B., Francisco, V. T. & Schultz, J. A. (2004). Understanding and improving the work of community health and development. In J. Burgos & E. Ribes (Eds.), *Theory, basic and applied research, and technical applications in behavior science*. (pp. 209-242). Guadalajara, Mexico: Universidad de Guadalajara.

<sup>4</sup> Johnson, K., Holder, H., Ogilvie, K., Collins, D., Ogilvie, D., Saylor, B, Saltz, B. (2007). A community prevention intervention to reduce youth from inhaling and ingesting harmful legal products. *Journal of Drug Education*, 37(3), 229.



faith community, and other community groups work comprehensively and collaboratively through data-driven, community-wide efforts to implement a full array of education, prevention, enforcement and treatment initiatives. A comprehensive, data driven approach that appropriately mobilizes each of the key sectors and actors who have a role in reducing access to and availability of prescription drugs as well as changing social norms about the harm that misuse and abuse of these substances can cause is critical. In the case of prescription drug abuse this would include parents, caregivers, grandparents, doctors, pharmacists, dentists, school personnel, law enforcement, the media, the faith community and others.

Population level changes in substance use, including prescription drug abuse, cannot be achieved absent an infrastructure to effectively assess, prevent, treat and provide recovery support to the affected individuals and communities. In instances where this infrastructure has been in place, communities have successfully prevented and pushed back against entrenched and emerging drug issues, such as marijuana, methamphetamine, K2 and the misuse and abuse of prescription drugs.

This infrastructure both defines and supports the roles, responsibilities, community sectors/partners and capacity needed to bolster community based prevention efforts. It focuses on building and strengthening the infrastructure and capacity for data-driven decision making and identifying, implementing and evaluating effective substance abuse prevention strategies, programs, policies and activities.

The strength of this comprehensive community wide approach is that it not only identifies a community's issues, problems and gaps, but also its assets and resources. This allows a community to plan, implement and evaluate its efforts across all community

sectors in all relevant settings for individuals, families, schools, workplaces and the community at large.

### **Seven Strategies to Affect Community Change**

CADCA trains community anti-drug coalitions throughout the country in effective community problem-solving strategies so that they are able to use local data to assess their specific substance use and abuse-related issues and problems and develop comprehensive, data driven, multi-sector strategies to address them. CADCA trains community anti-drug coalitions on how to collect and analyze local data. Specifically, we teach coalitions to systematically engage in the following evidence-based processes: 1) assess their prevention needs based on epidemiological data<sup>5</sup>; 2) build their prevention capacity<sup>6</sup>; 3) develop a strategic plan<sup>7</sup>; 4) implement effective community prevention programs, policies and practices<sup>8</sup>; and 5) evaluate their efforts for outcomes.<sup>9</sup>

When coalitions get to the implementation phase of the process, CADCA trains them on how to execute seven strategies to affect community change for drug use, generally, and for prescription drug abuse specifically. These seven strategies have been developed

<sup>5</sup> Butterfoss, F.D. (2007). *Coalitions and partnerships for community health*. San Francisco, CA: Jossey-Bass.

<sup>6</sup> Ibid.

<sup>7</sup> Collie-Akers VL, Fawcett SB, Schultz JA, Carson V, Cyprus J, Pierle JE. (July 2007). Analyzing a community-based coalition's efforts to reduce health disparities and the risk for chronic disease in Kansas City, Missouri. *Preventing Chronic Disease* [serial online]. 2007 Jul. Available from [http://www.cdc.gov/pcd/issues/2007/jul/06\\_0101.htm](http://www.cdc.gov/pcd/issues/2007/jul/06_0101.htm). Hays, C.E., Hays, S.P., DeVille, J.O., & Mulhall, P.F. (2000). Capacity for effectiveness: The relationship between coalition structure and community impact. *Evaluation and Program Planning*, 23, 373-379.

<sup>8</sup> Foster-Fishman, P.G., Berkowitz, S.L., Lounsbury, D.W., Jacobson, S., & Allen, N.A. (2001). Building collaborative capacity in community coalitions: A review and integrative framework. *American Journal of Community Psychology*, 29(2), 241-261.

<sup>9</sup> KU Work Group for Community Health and Development. (2007). *Use Promising Approaches: Implementing Best Processes for Community Change and Improvement*. Lawrence, KS: University of Kansas. Retrieved November 12, 2008, from the World Wide Web: <http://ctb.ku.edu/en/promisingapproach/>. Roussos, S.T. & Fawcett, S.B. (2000). A review of collaborative partnerships as a strategy for improving community health. *Annual Review of Public Health*, 21, 369-402.

by researchers to categorize interventions.<sup>10</sup> Based on what their local data and conditions and indicate, coalitions implement mutually reinforcing combinations of these seven strategies, which include:

- Providing information - this strategy involves raising awareness within the community-at-large - to include youth, parents, police officers, healthcare providers and educators to name a few – with educational presentations, workshops or seminars and data or media presentations. The goal is to increase the knowledge base of the community and raise general awareness around prescription drug abuse. Many coalitions execute this strategy by implementing local media campaigns. For example, in Rhode Island, the Woonsocket Prevention Coalition implemented the “Free and Easy to Find.....Drugs Are Not Only Available on the Streets” and “Kids Don’t Need a Drug Dealer to Get High...Safeguard Your Prescriptions, Safeguard Your Teen” media campaigns to raise widespread awareness about the dangers of prescription drug abuse in their communities. Similarly, the Carter County Drug Task Force in Ashland, Kentucky distributed 35, 000 Push Cards on “*Preventing Abuse of Prescription and Over-the-Counter Medications*” and 35,000 Push cards distributed on “*Guidelines for Proper Disposal of Prescription Drugs*”. Coalitions often launch these types of campaigns during National Medicine Abuse Awareness Month, held every October.
- Enhancing skills – this strategy provides workshops, seminars or other activities that are designed to increase the skills of those who can prevent, identify and treat

<sup>10</sup> Paine-Andrews, A., Fisher, J., Berkely-Patton, J., Fawcett, S.B., Williams, E., Lewis, R., Harris, K. (2002). Analyzing the Contribution of Community Change to Population Health Outcomes in an Adolescent Pregnancy Prevention Initiative. *Health Education & Behavior*, 29(2). 183-193.

prescription drug abuse – including healthcare and dental providers, pharmacists, parents and adult care givers, educators, law enforcement, businesses and youth. In order to implement this strategy, the Saratoga Partnership for Prevention in Saratoga Springs, New York held a Youth Summit to educate their local youth about prescription drug abuse, while NCADD of Middlesex County has delivered several community education presentations to enhance the skills of community members who can prevent and identify prescription drug abuse, such as law enforcement, youth, parents and the medical community.

- Providing Support – this strategy provides reinforcement and encouragement for participation in activities that prevent prescription drug abuse and is designed to stop prescription drug abuse before it ever starts. The Shelby County Drug Free Coalition in Saginaw, Alabama implemented this strategy by partnering with local pharmacies to distribute prescription drug warnings to raise awareness about the dangers of abuse.
- Enhancing or reducing access and barriers – this strategy utilizes the systems and services that reduce illegal access to prescription medications while protecting access for those who legitimately need medications to relieve pain. It targets healthcare providers, pharmacists, law enforcement officials, educators and public health officials and encourages entire communities to take action. The Delaware Coordinating Council to Prevent Alcohol and Other Drug Abuse in Muncie, Indiana reduced barriers to proper medicine disposal by partnering with the Delaware County TRIAD program, a community based organization sponsored

by the Delaware County Sheriff's office, which provides proper disposal of unused and expired medication.

- Changing consequences – this strategy focuses on increasing or decreasing the probability of a specific behavior by changing the consequences (e.g., increasing public recognition for deserved behavior, individual and business rewards, taxes, citations, fines, revocations and loss of privileges). The Sylvania Community Action Team (S.C.A.T.) in Pennsylvania partnered with its local schools to implement clear and strict policies related to the possession of illegal and prescription drugs on school grounds to help decrease the misuse and abuse of prescription drugs among youth.
- Changing physical design – this strategy focuses on safeguarding prescription medicines to ensure that they will not be misused and abused, and targets everyone in the community. It involves changing the physical design or structure of the environment to reduce access and availability. The Cherokee Nation in Oklahoma implemented this strategy by installing a permanent medicine drop off box in the lobby of their police station and by working with local homebuilders to ensure that the installation of one locking medicine cabinet is standard in every new home they build. The installation of these locking cabinets is free of charge to the homeowner as the coalition partnered with Muskogee CAN to purchase the locks.
- Modifying and changing policies – this strategy is aimed at changing policies, laws and procedures to prevent current and future prescription drug abuse. The target audience includes lawmakers, state and local public officials, employers

and others involved in setting rules and regulations. In carrying out this strategy, coalitions often support the passage and utilization of prescription drug monitoring programs, drug take-back and disposal legislation, statutes that support increased penalties against doctors who practice unscrupulous prescribing procedures, those who participate in doctor shopping, etc. For example, the Metropolitan Drug Commission in Knoxville, Tennessee submitted an application through the State of Tennessee for a planning grant to develop a statewide prescription drug task force to assist in the early detection, intervention and prevention of prescription drug abuse and addiction, the education of both the health care community and the public, and to assist law enforcement with access to the developing state Prescription Drug Program created through the Controlled Substance Monitoring Act of 2002.

**Relevant Local Data Is Critical**

Prescription drug abuse can manifest itself differently depending on the community. Access and availability are two local conditions that can vary from locality to locality. For example, in one community, youth may primarily obtain prescription drugs from family members without their knowledge; in another community, the source may be peers; and in yet another, it could be access to “black market” distribution channels. It is for this reason that the collection and availability of local data is a critical component of effective local prevention efforts.<sup>11</sup> Sound data collection systems (such as student surveys) that allow communities to collect local data about the nature and extent of the prescription drug problem are a necessary component of comprehensive

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<sup>11</sup> Shortell, S.M., Zukoski, A.P., Alexander, J.A., Bazzoli, G.J., Conrad, J.A., Husnain-Wynia, R., Sofaer, S., Chan, B.Y., Casey, E., & Margolin, F.S. (2002). Evaluating partnerships for community health improvement: Tracking the footprints. *Journal of Health Politics, Policy and Law*, 27(1), p. 49-92.

community level approaches to preventing substance abuse. It is the availability and analysis of local data that allows communities to specifically tailor their efforts and local resources to documented, actionable local conditions.

Another important source of prescription drug related data is available from statewide Prescription Drug Monitoring Programs (PDMPs). Currently, 35 states have PDMPs, and an additional nine states are working to implement recently enacted PDMP laws.<sup>12</sup> De-identified, aggregate data from these PDMPs could be a valuable data source for community coalitions to get timely information to help determine where prescription drug problems exist, what the trends and patterns of abuse are, and where to best target resources to address these problems.

Local data is also a critical tool for identifying the specific factors that influence the decision of youth to misuse and abuse prescription drugs. Among the strongest indicators of whether or not youth will use/abuse a particular drug is their perceptions of its danger or harmfulness. Research demonstrates that illegal drug use among youth declines as the perception of risk increases<sup>13</sup> (see Attachment 1). According to the National Institute on Drug Abuse (NIDA), because prescription drugs are prescribed by a doctor, youth often have the misperception that these drugs are safer to abuse than “street drugs”.

Access and availability are also factors youth take into consideration when deciding whether or not to misuse or abuse drugs and alcohol – the more available and

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<sup>12</sup> National Alliance for Model State Drug Laws. (2011) Status of State Prescription Drug Monitoring Programs. Available: <http://www.namsdl.org/documents/StatusofStates3-28-11.pdf>

<sup>13</sup> Johnston, L.D. (1991). Toward a theory of drug epidemics. In R.L. Donohew, H. Syper, & W. Bukoski (Eds.). *Persuasive communication and drug abuse prevention* (pp. 93-132). Hillsdale, NJ: Lawrence Erlbaum. Johnston, L.D. (October 14, 1999). Testimony Submitted to the Subcommittee on Criminal Justice, Drug Policy and Human Resources of the Government Reform Committee, United States Government, For Hearings on the National Youth Anti-Drug Media Campaign.

accessible a substance is the easier it is to abuse.<sup>14</sup> Between 1991 and 2009, prescriptions for stimulants increased from 5 million to nearly 40 million, and prescriptions for opioid analgesics increased from 45 million to 180 million. Additionally, according to a study published in last week's Journal of American Medicine<sup>15</sup>, "56% of painkiller prescriptions were given to patients who had filled another prescription for pain from the same or different providers within the past month." According to the study, "nearly 12% of the opioids prescribed were to young people aged 10-29" and "dentists were the main prescribers for youth aged 10 – 19 years old." Data such as this clearly shows that access and availability play a critical role in the misuse and abuse of prescription drugs. As a result of the increase in prescriptions for pain medicines and stimulant medications, these prescription drugs are available in more and more American households. Currently, the public at large does not have an adequate understanding of how to safely store and dispose of these prescription drugs, making it easy for motivated individuals to access and abuse or sell them. The exponential increase in the number of prescriptions for stimulants and opioid analgesics, as well as the fact that patients were easily able to fill multiple prescriptions within a short period of time, clearly indicates the need to better educate medical and dental professionals about prescription drug abuse and appropriate prescribing practices to reduce the misuse and abuse of these drugs, without jeopardizing legitimate pain management.

#### **The Drug Free Communities Program**

<sup>14</sup> Birckmayer, J.D., Boothroyd, R.I., Fisher, D.A., Grube, J.W., & Holder, H.D. (2008). *Prevention of underage drinking: logic model documentation*. Unpublished manuscript, Pacific Institute for Research and Evaluation, Calverton, Maryland. Retrieved from <http://www.pirc.org/documents/UnderageDrinking.doc>

<sup>15</sup> Volkow, N., McClellan, T. (2011). Curtailing diversion and abuse of opioid analgesics without jeopardizing treatment. *Journal of American Medicine*. 305(13), p. 1346-1347. National Institute of Health, U.S. Department of Health and Human Services, National Institute on Drug Abuse. (2011). Analysis of opioid prescription practices finds areas of concern. NIDA In the News. Available: <http://nida.nih.gov/pdf/news/NR040511.pdf>



Community anti-drug coalitions, and specifically Drug Free Communities (DFC) program grantees, are ideally poised to implement effective, comprehensive data driven prevention strategies. The DFC program has been a central, bipartisan component of our nation's demand reduction strategy since its passage in 1998 because it recognizes that the drug issue must be dealt with in every home town in America. As a condition of their grant, DFC grantees are required to carry out ongoing surveillance and monitoring activities, and, as a result, can address the major and emerging substance abuse issues in their communities. The DFC program recognizes that in order to be sustainable over time it must have community buy-in and participation, and therefore requires all grantees to provide a dollar for dollar match in non-federal funds. The evaluation of the DFC program conducted by ICF International, found that youth drug, alcohol and tobacco 30 day use rates are lower, by statistically significant margins, in DFC funded communities than in those communities that do not have DFC coalitions.

Due to the preexisting infrastructure that DFC grantees have in place, these coalitions are already properly organized and armed with the right data to effectively address prescription drug abuse in their communities. They are uniquely suited to address and implement comprehensive prescription drug prevention strategies because they are data driven, know their community epidemiology and are capable of understanding the multi-sector interventions required to reduce the availability and use of prescription drugs.

DFC coalitions have implemented a number of effective programs and strategies to reduce prescription drug abuse and have achieved measureable results. For example, in Caribou, Maine, the Aroostook Substance Abuse Prevention (ASAP) Coalition utilized a

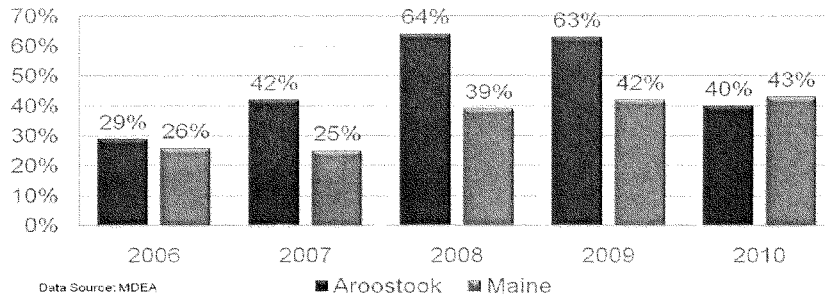
data-driven approach to identify prescription drug abuse as a major issue in their community. The coalition identified: who was using; how they were obtaining; and what issues this caused for particular sub populations of youth. After obtaining this information, the coalition worked with various community sectors to implement a strategic plan to prevent and reduce the misuse and abuse of prescription drugs. In doing so, the coalition:

- implemented a comprehensive social marketing campaign to educate the public about the dangers concerning the misuse and abuse of prescription drugs in a variety of venues, including television, school mailings and pharmacy stuffers;
- provided training to healthcare providers in hospitals throughout the county on prescription drug abuse and pain management related issues;
- created and disseminated to healthcare providers throughout the county, the Diversion Alert Program, which is a monthly mailer of individuals charged with prescription/illegal drug related crimes; and
- promoted and funded a prescription drug take back program.

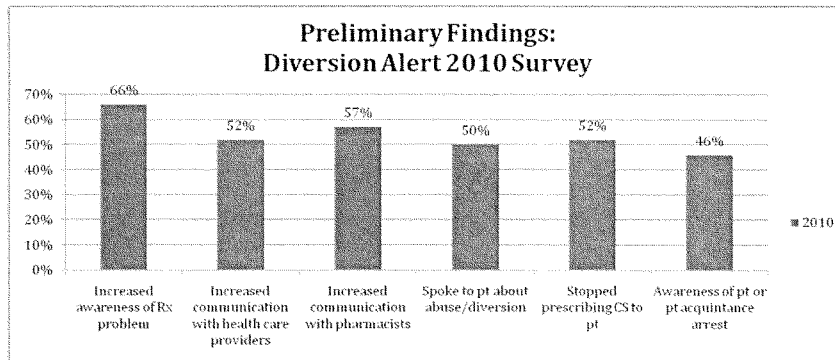
As a result of this data-driven, multi-sector approach, the ASAP Coalition has pushed back against the misuse and abuse of prescription drugs in its community.

For instance, although the number of pharmaceutical related arrests in Aroostook County started out much higher than the statewide average in 2008 (64 percent in Aroostook County compared to 39 percent for the State), through its efforts, the coalition helped reduce this number to 40 percent in Aroostook County while the statewide percentage actually increased to 43 percent.

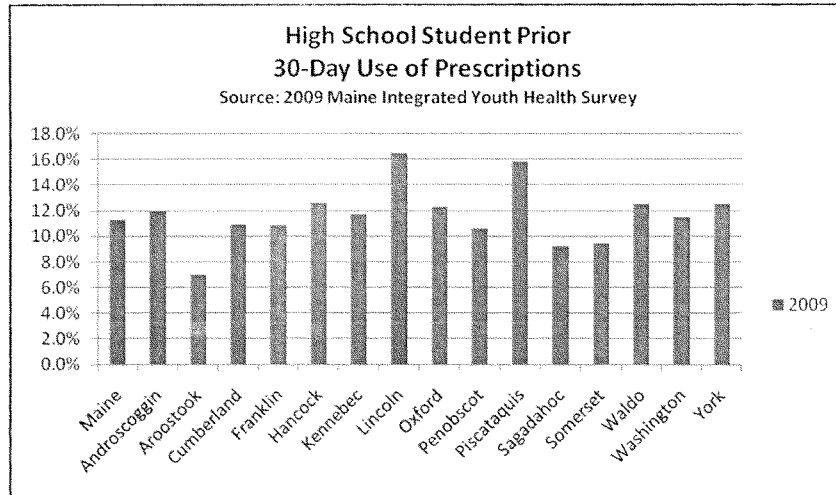
**MDEA Pharmaceutical Related Arrests:  
Aroostook County & Maine  
2006-2010**



The ASAP Coalition also increased physician engagement and response to the prescription drug abuse/diversion problem as a result of their participation in the Diversion Alert Program:



Finally, because of its prevention efforts, Aroostook County has the lowest rate of past 30 day prescription drug use among high school students in the State of Maine, at just under 7 percent.



The results that the ASAP Coalition has achieved are not an anomaly. Many DFC coalitions and other anti-drug coalitions throughout the country are achieving significant outcomes in reducing the misuse and abuse of prescription drugs (see Attachment 2).

**Conclusion**

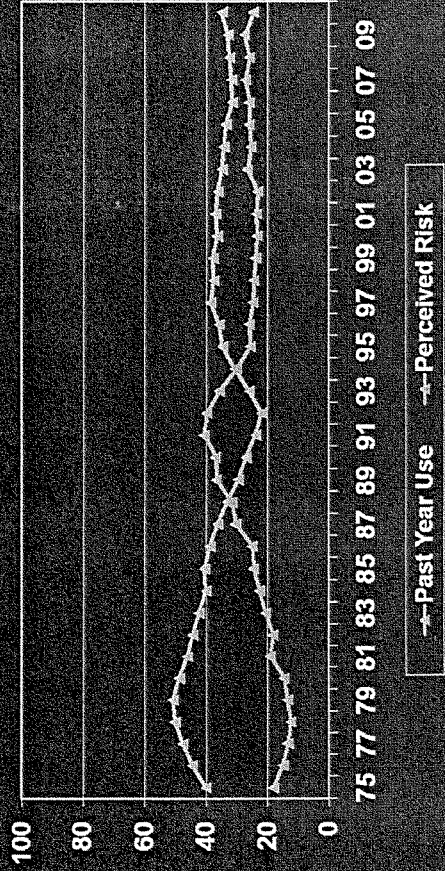
The misuse and abuse of prescription drugs is a major problem that impacts individuals, families, schools and communities throughout the country. It is a problem that demands a comprehensive multi-faceted approach at all levels, federal, state and community. Community anti-drug coalitions and DFC grantees should be an essential component of any prescription drug abuse diversion strategy because they are data driven, know their community epidemiology and are capable of understanding the multi-sector interventions required to reduce the availability and use of prescription drugs at the local level. The Office of National Drug Control Policy considers the DFC program critical in driving down prescription drug use rates. Community coalitions can quickly

identify and combat drug issues such as the misuse and abuse of prescription drugs before they attain crisis proportions because they implement effective, data driven strategies at the local level. Community coalitions can and should be used as a major component of any strategy that is developed to address prescription drug abuse and diversion.

In addition, there is a great need for: (1) expansion of effective PDMP programs to ensure adequate coverage in every state, with both the enhanced abilities to begin to function with interoperability among states, as well as be a source of de-identified, aggregate data for use in identifying hot spots and areas that need enhanced prevention, treatment and enforcement emphasis and resources; (2) enhanced education and training of medical and dental professionals in proper prescribing protocols for prescription drugs with the potential for abuse and diversion; (3) enhanced opportunities to raise the general public's awareness about the dangers of prescription drug abuse as well as the proper ways to store and dispose of them; (4) enhanced opportunities for prescription take back and other large scale disposal programs to be more routinely available in states and communities; (5) enhanced law enforcement and legal remedies to close down "pill mills" and other venues that allow for the easy, and questionable access and availability of prescription drugs with a great potential for abuse and diversion; and (6) expansion of the number of DFC funded communities, as well as enhanced training opportunities for more communities across the country to be organized to identify their local drug issues and implement comprehensive, data driven strategies to effectively address their local prescription and other drug abuse problems.

# Attachment 1

## 12<sup>th</sup> Graders' Past Year Marijuana Use vs. Perceived Risk of Occasional Marijuana Use



SOURCE: University of Michigan, 2010, Monitoring the Future Study

## Attachment 2

### *Drug Free Communities Grantees Work to Prevent and Reduce Prescription Drug Abuse*

Due to the preexisting infrastructure that Drug Free Communities (DFC) grantees have in place, they are uniquely suited to address and implement a comprehensive prescription drug strategy because they are data driven, know their community epidemiology and are capable of understanding the multi-sector interventions required to reduce the availability and use of prescription drugs. Below are select examples of DFC coalitions that have reduced the misuse and abuse of prescription drugs in their communities.

**Colorado** - Between 2006 and 2008 the Southwest Denver Coalition contributed to a decrease of 55.6 percent in past 30 day use of prescription drugs among 10<sup>th</sup> graders. In 2006, 27 percent of respondents reported using prescription drugs in the past 30 days, while in 2008 only 12 percent of respondents had used prescription drugs in the same time frame

**Florida** - Between 2006 and 2010 the StandUp Polk Coalition contributed to a decrease of 34.5 percent in past 30 day use of prescription drugs among middle schoolers. In 2006, 2.9 percent of respondents reported using prescription drugs in the past 30 days, while in 2010 only 1.9 percent of respondents had used prescription drugs in the same time frame.

**Kansas** – Between 2007 and 2008 the Regional Prevention Center contributed to a decrease of 10.3 percent in lifetime use of prescription drugs among 10<sup>th</sup> graders. In 2007, 20.3 percent of respondents reported using prescription drugs, while in 2008 only 18.2 percent of respondents had used prescription drugs in their lifetime.

**Kentucky** - Between 2004 and 2008 the Carter County Drug Task Force contributed to a decrease of 62.5 percent in past 30 day use of prescription drugs among 8<sup>th</sup> graders. In 2004, 8 percent of respondents reported using prescription drugs in the past 30 days, while in 2008 only 3 percent of respondents had used prescription drugs in the same time frame.

**Michigan** - Between 2005 and 2009 the Ottawa Substance Abuse Prevention Coalition contributed to a decrease of 23.9 percent in past 30 day use of prescription drugs among 12<sup>th</sup> graders. In 2005, 15.9 percent of respondents reported using prescription drugs in the past 30 days, while in 2009 only 12.1 percent of respondents had used prescription drugs in the same time frame.

**Nebraska** - Between 2003 and 2007 the South Central Substance Abuse Prevention Coalition contributed to a decrease of 79.3 percent in past 30 day of prescription drugs among 12<sup>th</sup> graders. In 2003, 9.1 percent of respondents reported using prescription drugs in the past 30 days, while in 2007 only 2.5 percent of respondents had used prescription drugs in the same time frame.

**Pennsylvania** - Between 2008 and 2010 the Upper Bucks Healthy Youth Coalition contributed to a decrease of 42.9 percent in past 30 day use of prescription drugs among 8<sup>th</sup> graders. In 2008, 7 percent of respondents reported using prescription drugs in the past 30 days, while in 2010 only 4 percent of respondents had used prescription drugs in the same time frame.



**Congressional Testimony by the Prescription Monitoring Program Center of Excellence at Brandeis University**

**Committee on the Judiciary, Subcommittee on Crime and Terrorism, United States Senate**

**Enhancing Prescription Monitoring Programs' Ability to Impede the Prescription Drug Abuse Epidemic**

**May 24, 2011**

**Statement of:**

John L. Eadie, MPA  
Director  
Prescription Monitoring Program Center of Excellence  
Heller School for Social Policy and Management  
Brandeis University  
Waltham, MA

Good morning Chairman Whitehouse and distinguished members of the Subcommittee. My name is John Eadie. I am the Director of the Prescription Monitoring Program Center of Excellence at Brandeis University. Thank you for the opportunity to appear before you on behalf of the Center to discuss our work on enhancing Prescription Monitoring Programs' ability to impede the prescription drug abuse epidemic. We thank you for the honor of testifying on this critical matter.

The PMP Center of Excellence seeks to help end the prescription drug abuse epidemic in the United States without compromising accepted standards of pain management or the legitimate prescribing of controlled substances. In collaboration with the Alliance of States with Prescription Monitoring Programs, the Center provides academically sound and practice-relevant information, evaluation, and expertise to PMPs and their stakeholders. The Center is funded by a grant from the Department of Justice Bureau of Justice Assistance.

Our work is focused on helping PMPs identify and implement the most effective means possible for them to intervene in the prescription drug abuse epidemic. Our work includes:

- Identifying PMP Best Practices, including innovative, cutting edge developments that will increase PMP effectiveness.
- Encouraging innovative uses of PMP data.
- Assisting in the deployment and evaluation of interstate PMP data sharing.

- Advancing the methodology for assessing PMP effectiveness to identify, improve and extend the applications of PMPs.
- Analyzing PMP performance measures and identifying improvements in measurement.
- Analyzing and disseminating relevant information through a clearinghouse.
- Providing support to states and federal agencies.

The urgency of our work is based upon our knowledge that:

- Daily, 50 people in our nation die from unintentional prescription opioid overdoses and
- Daily, twenty times that number are admitted to hospital emergency departments for opioid overdoses.

At the PMP Center of Excellence, we believe that we must improve our methods for identifying and interdicting prescription opioid abuse in order to slow down and reverse this epidemic's ever rising toll.

Prescription Monitoring Programs collect from pharmacies information regarding prescriber, pharmacy, patient, and drug information regarding each controlled substance prescription dispensed within their states and, in some cases, prescriptions sent by mail order into their states. The data is compiled in each PMP's database and then made available to prescribers, pharmacies, law enforcement, health professional licensing agencies, and, depending on the state, to Medicaid Programs, medical examiners, drug courts, drug treatment programs and others. De-identified data is generally made available to researchers and evaluators and patients may see their own data in some states.

The rapid growth in states with prescription monitoring programs, with 48 states now having statutorily authorized PMPs, is a very hopeful accomplishment. The majority of these programs have been authorized since 2003, when the Harold Rogers Prescription Drug Monitoring Programs Grant program began. Administered by the Department of Justice's Bureau of Justice Assistance, the Harold Rogers' competitive grant program has stimulated growth and enhancements among the PMPs.

Funding provided by the NASPER program, as administered by the Substance Abuse and Mental Health Administration, is a formula grant program that has been important in assisting states' PMPs by supporting their operations.

The continued operation of PMPs and the significant enhancements called for to address the prescription drug abuse epidemic appear to call for continuation and expansion of both unique programs.

In addition to federal funding support, we need a rapid evolution of the PMPs into a new generation of even more effective systems, a new generation whose hallmark must be proactivity. The new generation will take advantage of technological advances and integrate them into the fabric of PMP operations. Many of the characteristics of the new generation are highlighted in the White House Office of National Drug Control Policy's new Prescription Drug Abuse Prevention Plan.

**Interstate PMP Data Sharing** --The first thing that must be completed is a new National Network of State PMPs that are interoperable through the Prescription Monitoring Information Exchange (PMIX) Hub which BJA, the IJSI Institute, and the Alliance of States with Prescription Monitoring Programs have been working to establish for six years. The Hub is operational and several states are in process of interconnecting, with support from the PMP Training and Technical Assistance Program and our Center at Brandeis University.

**PMP Model Act provisions** -- The foundation for much of the new generation of PMPs rests in the Alliance of States with Prescription Monitoring Programs' *PRESCRIPTION MONITORING PROGRAM MODEL ACT 2010 Revision* at ([www.pmpalliance.org](http://www.pmpalliance.org)).

*Section 7, Providing Prescription Monitoring Information*

- (a) The [designated state agency or entity] should review the prescription information. Such reviews should include but not be limited to:
  - (i) A review to identify information that appears to indicate if a person may be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances. When such information is identified, the [designated state agency] should notify the practitioners and dispensers who prescribed or dispensed the prescriptions.
  - (ii) A review to identify information that appears to indicate if a violation of law or breach of professional standards may have occurred. Whenever such information is identified, the [designated state agency] should notify the appropriate law enforcement and/or professional licensing, certification or regulatory agency or entity, and provide prescription information necessary for an investigation.
- (b) The [designated state agency] is authorized to provide information in the prescription monitoring program upon request only to the following persons.

- (I) Persons authorized to prescribe or dispense controlled substances or other drug required to be submitted under Section 5 of this Act, for the purpose of providing medical or pharmaceutical care for their patients or for reviewing information regarding prescriptions that are recorded as having been issued or dispensed by the requester.
- (II) A patient who requests the patient's own prescription monitoring information, or of the parent or legal guardian of a minor child, in accordance with procedures established under [insert state statute granting individuals access to state held information concerning themselves].
- (III) [Insert name or type of state boards and regulatory agencies that supervise or regulate a profession that is authorized for controlled substances or other drug required to be submitted under Section 5 of this Act activity] if the request is pursuant to an investigation or is pursuant to the agency's official duties and responsibilities.
- (IV) Local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing controlled substances or other drug required to be submitted under Section 5 of this Act pursuant to the agency's official duties and responsibilities.
- (V) [Insert state Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services] regarding Medicaid program recipients or Medicaid program providers.
- (VI) [Insert titles of medical examiners, coroners or others authorized under law to investigate causes of deaths] for cases under investigation pursuant to their official duties and responsibilities.
- (VII) Personnel of the [designated state agency] for purposes of administration and enforcement of this Act, or [insert state controlled substances act], [if any other state statute is applicable, insert "or" and reference the other statutes].

*[Note: A state may determine to authorize additional agencies to request and receive prescription information including substance abuse treatment providers, worker's compensation board reviewers who are health care professionals, drug court judges, department of corrections' health care professional staff, and probation departments, if they cannot receive information under other provisions already authorized in (I) through (VII)]*

- (c) The [designated state agency] may provide information to public or private entities for statistical, research, or educational purposes after encrypting or removing the patient name, street name and number, patient ID number, and month and day of birth that could be used to identify individual patients and/or persons who received prescriptions from dispensers.

*[Note: A state may choose to further restrict information released to researchers by encrypting or removing information that could be used to identify a prescriber, a pharmacy, or any other person.]*

**With this Model Act as the foundation, the following changes are indicated:**

1. **Prescribers: proactive (unsolicited) reports** -- Some PMPs proactively analyze their databases and, when they identify probable doctor shoppers, they send an unsolicited report to the prescribers. Experience indicates such reports result not only in reducing the subsequent prescriptions obtained by the doctor shoppers but also in a significant increase in prescribers requesting solicited PMP data and in a general reduction in prescriptions to doctor shoppers, even those for whom no report is sent out. We need to increase PMP use of unsolicited reports by:
  - a. Automating PMP analysis by developing algorithms that can be computer applied and validated.
  - b. Automating unsolicited reports by sending out alerts by email or by computer generated letters that advise prescribers that they have been prescribing to a person who may be a doctor shopper and informing the prescriber how they can access the information regarding this person. Several PMPs are working to develop this capability.
  - c. Automating follow-up, including tracking of prescriptions received by the probable doctor shopper subsequent to the unsolicited reports.
2. **Prescribers: requested (solicited) reports** - Upon request, PMPs provide prescription histories to prescribers so they can make clinically sound decisions prior to issuing prescriptions for controlled substances and can avoid being duped by doctor shoppers. This is generally done by PMPs providing web-portals through which prescribers may request data. We need to increase prescriber use of PMPs through:
  - a. Making data more timely – in April, the Oklahoma PMP began collecting data from pharmacies at point of sale; we need to expand this to all PMPs.
  - b. Making access seamless – Massachusetts PMP is moving to make its PMP interoperable with Electronic Health Records so prescribers can access the PMP from a single EHR sign-on; we need to expand this to all PMPs.
  - c. Combing PMPs and e-Prescribing of Controlled Substances – PMPs should become interoperable with e-Prescribing systems so:
    - i. Obtaining of an e-prescribing certification for controlled substances should be accepted by PMPs as authentication for access to PMP data.
    - ii. As prescribers enter the name of a controlled substance drug for e-prescription, the patient's controlled substances history from the PMP pops up on their electronic device.

- iii. As each e-prescription is sent to a pharmacy, a copy should be routed to the PMP database.
  - iv. As each e-prescription is dispensed, the PMP should match the pharmacy's dispensing record to the corresponding e-prescription from the physician to identify any alterations and, if any, report to the appropriate agency.
- d. Considering with public and private third party payers the value of mandating prescribers to access PMP data prior to issuing the first controlled substance prescription and periodically thereafter, as a condition of payment.
- i. Reimbursement to prescribers for any additional time will need to be considered.
  - ii. If such is required, third party payers will need automated assurance from the PMP that the prescriber accessed the PMP.
  - iii. As provided in the Office of National Drug Control Policy's new Prescription Drug Abuse Prevention Plan, the PMP Center of Excellence is planning a meeting with third party payers and PMPs for 2011; this subject will be explored at the meeting.
3. **Pharmacies: requested (solicited) reports and proactive (unsolicited) reports** -- It is imperative for pharmacists to request and review PMP data prior to dispensing prescriptions for controlled substances.
- a. The interoperability of PMPs with Electronic Health Records should include providing data to pharmacies in the manner described above for prescribers.
  - b. The e-Prescribing of Controlled Substances should include the PMP interoperability described above.
  - c. PMPs should forward proactive (unsolicited) reports to pharmacists, just as to prescribers.
4. **Pharmacies: verifications prior to dispensing** – In addition to the above, automated systems need to be designed to assure that controlled substances prescriptions are only dispensed after appropriate verification that requirements have been met. For example, should mandatory prescriber education be established (which the Center strongly supports), the list of trained prescribers should be automatically checked before a prescription is dispensed. The factors identified in the 2009 GAO report should be reviewed prior to dispensing, including verification that the prescriber is currently licensed and registered with DEA, has no licensure or registration restrictions that would affect controlled substances prescribing, and is not deceased. Likewise, patients known

to be deceased should not be allowed to have prescriptions dispensed in their names. Pharmacies will need to be properly compensated for this new work.

5. **Law Enforcement Agencies** – Local, state and federal Law Enforcement agencies and investigators are essential users of PMP data. This can be seen in the relatively lower death rates of unintentional opioid deaths in California, New York and Texas, i.e. these states have a long history of providing PMP solicited reports and unsolicited reports to investigators with law enforcement authority. Increased use of PMP data by law enforcement is essential if we are going to impede the prescription drug abuse epidemic. We need to increase PMP use by law enforcement by:
  - a. Encouraging states to adopt policies that permit and encourage use of PMP data by law enforcement investigators.
  - b. Updating state PMP systems to automate law enforcements' approved access to the PMP data.
6. **Health Professional Licensing Agencies** – Agencies such as State Medical Boards and State Pharmacy Boards need ready access to PMP data to investigate potential misconduct and inappropriate use of controlled substances, e.g. self-abuse, over prescribing, and offering drugs to solicit sexual favors. Likewise, PMPs need to analyze their data and forward unsolicited reports to licensing boards when patterns of possible misconduct are found. This process needs to be automated to the extent feasible.
7. **Other users of PMP data** – If the expansion of the prescription drug abuse epidemic is to be slowed and reduced, then other parties need to have access to PMP data. Some states permit some of the parties below to have access, but this needs to be regularized and expanded across the nation:
  - a. State's Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services regarding Medicaid program recipients or Medicaid program providers.
  - b. Appropriate Medicare personnel.
  - c. Medical examiners, coroners or others authorized under law to investigate causes of deaths for cases under investigation pursuant to their official duties and responsibilities.
  - d. Substance abuse treatment providers.
  - e. Worker's compensation board reviewers who are health care professionals.
  - f. Drug court judges.

- g. Department of corrections' health care professional staff, and probation departments, (if they cannot receive information under law enforcement provisions).
  - h. The Indian Health Services, Veterans Administration, and Department of Defense health care system (not just their prescribers but also the health care clinical supervisors who oversee prescribing and dispensing within those systems).
  - i. Health care systems' peer review organizations in order to identify and intervene in prescriber and pharmacist over-prescribing and miss-prescribing as early as possible, i.e. before the practices rise to the level that licensure or law enforcement action are required.
  - j. Other third party payers' health professional care reviewers - this is not currently being done and will require careful design to protect all data, but given the nature and extent of the epidemic, it appears unwise not to develop means by which PMPs and other third party payers can meaningfully exchange information.
8. **Early Warning System** – Pioneering work by the Massachusetts Department of Public Health's PMP and the principal investigator at the Center has identified an important new function for PMP data. Using spatial analysis methodology to examine Massachusetts PMP data when the drug OxyContin was introduced and subsequent years, a rapid expansion of doctor shopping can be seen, beginning in the first year, 1996. Review of data for 2005, shows that doctor shopping for all opioids had become widespread across the state and was concentrated most heavily in five geographic areas. A geospatial comparison to hospital data on opioid overdoses and opioid related deaths shows the same five areas had the highest rates of overdoses and deaths. Had this analysis been possible in prior years, the MA PMP could have issued warnings before the overdoses and deaths became epidemic. Warnings could be sent to all community, state and national stakeholders including health care practitioners, law enforcement, education, substance abuse prevention and treatment organizations, schools, parent teacher organizations, religious organizations and other groups. We must learn from this and assure that this does not happen again. We need to:
- a. Fully develop the early warning methodology at the Center by obtaining data from other states that have already agreed to participate in a pilot development.
  - b. After development, provide the methodology to those states that are equipped to do the analyses.



- c. Provide a service for those states not equipped to do their own analysis, i.e. the states can forward de-identified/encrypted PMP data to the Center so we can apply the methodology and return analyzed reports to them.
  - d. Compile analyzed information at the Center in order to produce regional and national warning information as changes emerge.
9. **Concerns for youth** – In response to Surgeon General Regina Benjamin's initiative to examine prescription drug abuse among youth, the Center has worked with the Maine, South Carolina and Wyoming PMPs to examine prescribing and doctor shopper patterns. The data indicates an increase in youth who are obtaining opioid prescriptions, during and after high school. Most surprisingly, the Wyoming data on doctor shoppers shows that peak of doctor shopping is among those aged 30 to 39, with a very large number 29 and younger. This represents a drop in age of almost two decades for those most actively involved in doctor shopping, compared with earlier research. This serves as a call for us to analyze PMP data from many states as rapidly as possible and, if the pattern holds up in other states, to get the word out widely. The nation's efforts to curtail youthful abuse of prescription drugs may need to add a new focus on stemming doctor shopping and other forms of prescription diversion among younger persons.
10. **Mandatory Prescriber Education** – A majority of prescribers have insufficient training in the use of opioids and other prescription controlled substances to safely prescribe these drugs. Such education needs to include training in not only the proper use of the drugs but also the misuse of, abuse of, and addiction to these drugs by bona fide patients; the nature and extent of doctor shopping; the extent of theft, counterfeiting and forgery of a prescribers' prescription pads; and how to access and use PMP data. As noted above, such training should not only be required but technologically monitored by pharmacies prior to dispensing. In addition, PMPs should periodically review their databases to assure that prescribers were trained at the time their prescriptions were dispensed; non-compliance should be proactively reported by the PMP to DEA and the state professional licensing agency.

Written Statement of

**Stevan Gressitt, M.D.**

**Founding Director, International Institute for Pharmaceutical Safety**

Faculty Associate, University of Maine Center on Aging

Academic Member, Athens Institute for Education and Research, Athens, Greece

University of New England, College of Pharmacy

Department of Pharmaceutical Sciences

**Associate Professor of Clinical Psychiatry**

University of New England, College of Osteopathic Medicine

Co-Principal Investigator of U.S. E.P.A. Grant # CH-83336001-0

(Safe Medicine Disposal for ME)

For:

"Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse,  
Diversion and Fraud

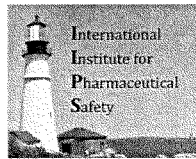
Committee on the Judiciary

Subcommittee on Crime and Terrorism

May 24, 2011

9:00 AM

Dirksen-226



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NEW ENGLAND

**Stevan Gressitt, M.D.**  
**Founding Director,**  
**International Institute on**  
**Pharmaceutical Safety**  
University of New England,  
College of Pharmacy  
Department of Pharmaceutical  
Sciences  
Faculty Associate, University  
of Maine Center on Aging  
Academic Member, Athens  
Institute for Education and  
Research, Greece  
Associate Professor of  
Clinical Psychiatry  
University of New England,  
College of Osteopathic  
Medicine  
716 Stevens Avenue  
Portland, Maine 04103  
[gressitt@gmail.com](mailto:gressitt@gmail.com)  
Cell: 207-441-0291  
[www.henzos.une.edu](http://www.henzos.une.edu)



**DRUG**  
**DISPOSAL**

May 23, 2011

There is a perspective on the Prescription Drug Abuse epidemic that has not been widely noted. The final estimated number of deaths for the United States Revolution was 25,000; less than now dies annually from prescription drug overdose. A former US Attorney in Maine noted that the problem is such that we can neither arrest our way nor prosecute our way out of the situation. From a broader perspective, it is more adequately described as a situation where neither arresting, prosecuting, imprisoning, educational efforts, nor treatment resources will in and alone any one of them address the faintest edge of a problem that is now diffused throughout society. All are necessary as well as regulatory reform that is underway most notably at the US DEA in implementing S 3397.

Traditional efforts at each of the approaches listed above have not kept the problem from spreading in part as there is a tendency for each of the approaches to be isolated from each of the others. Efforts to address diversion in the distribution chain for instance can be extended through the entire lifecycle of pharmaceuticals through to destruction. Track and tracing is increasingly important through to the end user not just for diversion avoidance but for product recall. Identifying what is wasted can help with methods to reduce the waste in the first place and subsequently reduce the potential for diversion, misuse, or abuse.

From the outset of individual researchers working on attempting to address disposal of consumer unused

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medication, there was little initial awareness between various Federal agencies on what other agencies were doing. As that has improved, the lack of funding for research, pilot projects, education, prevention measures, has not improved. Many programs addressing the unused drug return problem have no resources for education and vice versa. The conflict between 50 separate state regulations and Federal regulations has not improved as various jurisdictions either wait for someone else to move first or take action that may well conflict with other jurisdictional regulations that may even clash.

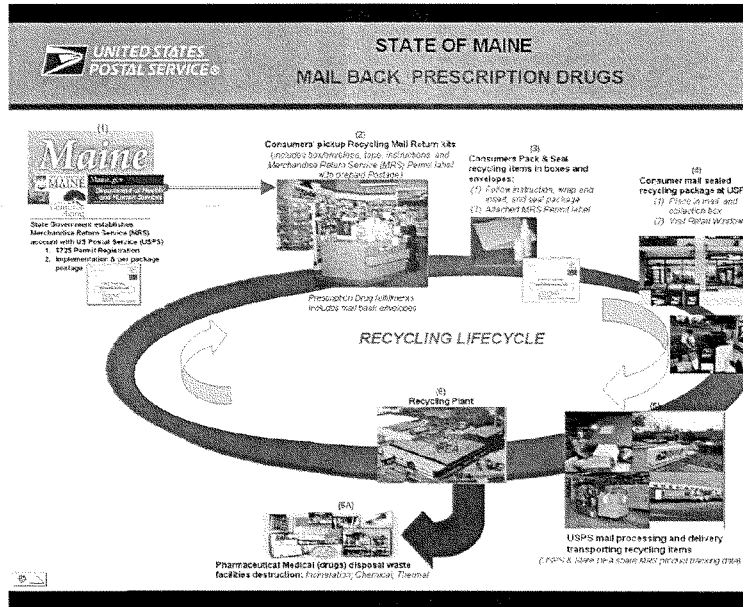
Most of the following will address the area we are most familiar with but the overall message must be that to address the current problem funds must be refocused and coordination must be the primary approach along with cooperation.

### **Introduction**

Today, in nearly every home across America, there is a medicine cabinet containing unused prescription and over the counter medications. These can include controlled medications such as morphine, oxycodone, valium, and Tylenol with codeine as well as non-controlled antibiotics and cardiovascular medications. While all were originally prescribed for legitimate purposes they are now sitting in the unlocked medicine cabinet unused. They represent a serious hazard to children. They have become an attraction to initiate burglaries. They are now one of the most significant sources of teen drug use. They are also an emerging source of identified pollution in our waterways.

Our United States Environmental Protection Agency funded pilot has shown definitively that residents across the State of Maine are eager to rid their homes of these unused medicines and thus these potential hazards in a safe and environmentally friendly way. What was required to achieve this goal was the development of an effective and easy way to enable citizens to dispose

of unused medications. I will provide an overview of the process we developed, tested and now can report on its overwhelming success. The diagram below succinctly outlines the process we developed.



Before developing our current program, we reviewed a number of antidrug programs and noted that some were quite expensive to join, or to purchase quite professionally produced materials. Many programs focused on public awareness campaigns, exhortations to just say “no,” or were extensive displays with impressive visual effects, or handouts, or “take aways,” or even trinkets. However none of these programs actually addressed the critical safety goal of removing drugs from harm’s way. We knew that this element needed to be included or even an explicit goal and put together an approach that has now been tested and successful.

Why did the State of Maine need this program? Diverted, abused, and misused prescription drugs are a major cause of accidental poisonings and arrests in the State. The State is ranked by the 2009 National Drug Intelligence Center Drug Threat Assessment as first in the country in terms of the perceived relationship of pharmaceuticals to violent crime and property crime, and second in terms of the availability of pharmaceuticals for abuse. Forty percent of Maine law enforcement agencies perceive prescription drug misuse as the State’s most serious drug threat.

The Safe Medicine Disposal for ME (SMDME <http://www.safemeddisposal.com/> ) program is a statewide model for the disposal of unused household medications using a mail-back return envelope system. Established through State legislation in 2005<sup>1</sup> (Public Law 2003 Chapter 679) and implemented in 2007 with a grant from the U.S. Environmental Protection Program's Aging Initiative, the program is authorized to handle both controlled and non-controlled medications. The significance of the law is that it defined assistance with consumer unused medication as an explicit part of the Maine Drug Enforcement Agency responsibilities. This significance cannot be underestimated as this was the single fundamental legal approach we developed to open doors to the federal DEA and to the USPS. We are unaware of any other states taking this step explicitly while attempting on the other hand to bypass that step. All drugs collected undergo high-heat incineration, according to the procedure already established for Maine's law enforcement drug seizures.

In 2007 the State of Maine legislature further funded this initiative by enacting LD 411, "An Act to Establish a Pilot Program for the Return of Unused Prescription Drugs by Mail." Additional resources were then provided to extend the original United States Environmental Protection Agency ( U.S. E.P.A.) funded pilot more broadly across the state and which allowed the program to continue for an additional two years beyond the initial U.S. E.P.A. grant. The U.S. E.P.A. grant has expired and the funds allocated through LD 411 are ending. There are only 2,500 mailers left and efforts are being made now for redistribution of some from lower to higher demand sites within the state.

The highly rural nature of Maine and its distinction as being the "oldest state in the nation" (based on median age of residents) presented distribution, collection, and financial challenges for mounting a state-wide expired and unwanted prescription drug return program.

Six reasons for citizens to tackle unused drug disposal have been identified<sup>2,3,4,5</sup>:

- (1) To curtail childhood overdoses
- (2) To restrict household drug theft
- (3) To limit accumulation of drugs by the elderly
- (4) To protect our physical environment
- (5) To restrain improper international drug donations, and
- (6) To eliminate waste in the international health care systems of all countries.

The U.S. Postal Service system was chosen as the method for addressing these challenges due to the fact virtually all of Maine's citizens have regular access to the mail, and the US Mail has a special protection under law.

### **Program Development and Operation**

The goals for the prescription drug return program in Maine included:

- 1) to devise, implement and evaluate a mail-back plan to remove unused and unwanted medications, both prescription and over-the-counter, from residences;
- 2) to dispose of them in compliance with applicable State and federal laws and sound environmental practices, and
- 3) To test the effectiveness of an educational campaign about the hazards to life, health, and the environment posed by improper storage and disposal of unwanted medications.

A cost-effective model for the disposal of unwanted medication would be created and implemented, and an educational campaign would be instituted in each of Maine's 16 counties. Further, the project was scheduled to address potential barriers to participation due to age, infirmity, rural locale, and other challenges.

Program objectives included:

- 1) Calculating the weight, type and hazardous characteristics of returned medications by actual pill count and drug classification;
- 2) Calculating the cost of the mail-back program as a model for future use nationally, by other organizations and states; and
- 3) Offering a statewide education campaign targeted toward the proper use and disposal of prescription drugs with an initial focus on citizens 65 and older. With State support this was expanded to the entire population of the State of Maine.

Many project partners throughout the state and nation contributed significantly to program success including: the Maine Drug Enforcement Agency, the Maine Department of Health and Human Services, its Office of Adult Mental Health Services, and Office of Substance Abuse, the Maine Benzodiazepine Study Group, the Maine Department of Environmental Protection, the U.S. Postal Service, the Maine Department of Health, the Maine Office of the Attorney General, the U.S. District Attorney for Maine, and the University of Maine Center on Aging. A technical expert advisory task force was formed that included members from each of these and a cadre of partnering organizations. A Community advisory group provided a critical consumer perspective, including the perspectives of individuals involved "on the front line:" the older adult project volunteers handling community education and marketing.

A number of national specialists and associations also committed to the project including the Community Medical Foundation for Patient Safety and the National Council on Patient Information and Education. Rite Aid Corporation, the nation's third largest drugstore chain and

the largest on the east coast, formally committed to participation in the pilot project with their pharmacies serving as distribution site locations. Researchers from the University of Maine Margaret Chase Smith Policy Center contributed to project evaluation and a manual for replication development.

An “operational test agreement” was formed between the U.S. Postal Service and the Maine Drug Enforcement Agency – the first of its kind. Operational test agreements are traditionally crafted so the postal service can test out novel options. A letter of authorization under 21 CFR 1307.21 was issued to the Maine Drug Enforcement Agency by the U.S.D.E.A.<sup>6</sup>

The pilot program began with 11 participating pharmacies in four counties serving as envelope distribution sites, and over a period of two years expanded to include approximately 150 pharmacies and health and human services agencies in all 16 counties of Maine. The program currently maintains a waiting list of interested community-based envelope distribution sites.

Using a double verification process, MDEA law enforcement personnel counted and collected returned mailers from the Post Office on a regularly scheduled basis and took them directly to a secure consolidation facility. The audit process involved a repeat count of the number of packages received and verification of accounting logs conducted by the U. Maine Center on Aging. Throughout the process the MDEA maintained continuous, unbroken custody of the returned medicine.

Cataloging of returned drugs was done under law enforcement supervision by volunteer project pharmacists and pharmacy students from Husson University and the University of New England Colleges of Pharmacy over a total of eight counting events. As participation has increased over time, the program moved from cataloging 100% of returns to a 25% random sample to a 20% random sampling procedure and then to 10% due to volume. Using a sampling method was found to be both cost effective and yielded a data sample that was statistically representative of the full inventory data set. For the envelopes that did not receive a full inventory, all non-controlled drugs were sorted for disposal, and all controlled drugs were fully inventoried.

During the cataloging, drugs were sorted according to whether they were controlled drugs or not and further into controlled hazardous or controlled non-hazardous categories. This sorting method facilitated appropriate disposal and therefore helped control disposal costs.

Public education and outreach was limited as indicators of success from early on left the problem of how to avoid building unrealistic expectations given the time limited nature of the pilot. The fear was that if there was a buildup of expectation that could not be met there would be dissatisfaction at least till the program could be sustainable and a period of confusion and discontinuity of service.

#### **Program Results and Findings**



The mail-back program, during its first two phases of EPA-funded operation, has disposed of more than 2,300 lbs of drugs, representing 3,926 envelopes. A total of 9,400 envelopes were distributed during this period representing a 42% envelope utilization and return rate. Additionally, over 380,000 pills were cataloged via the drug inventory process, 2,777 telephone calls were answered via the program helpline, 250 pounds of controlled drugs have been destroyed, the average weight of a returned envelope was 7 ounces, and the estimated Average Wholesale Price (AWP) of medicine collected was \$572,772.35.

Approximately 17% of the drugs were schedules II, III, and IV –“controlled drugs.” These include narcotic pain relievers, tranquilizers and sedatives, as well as stimulants.

Most returns were in tablet/capsule form. Fourteen percent of returns represented liquids, gels, ointments and patches. A negligible amount of medical supplies and devices were returned including unused morphine pumps.

Full, unused bottles were sometimes returned, including prescriptions from mail-order pharmacies or VA pharmacy services, as well as anti-retroviral drugs for HIV/AIDS treatment. It was not uncommon to find a mix of local and mail order pharmacies represented in mailers where a patient was receiving the same drug from both sources.

Based on surveys and analysis of returned drugs, it is estimated that the percentage of individuals indicating using trash or toilet to dispose of drugs prior to the program = 83% x 2,373 lbs of drugs = 1,970 lbs of drugs prevented from entering the water supply and landfills.

Findings from program participant surveys confirm multiple reasons for drug accumulation in their homes, including:

- Medicine belonged to a deceased family member (19.6%)
- A physician told the patient to stop taking the medication or gave the patient a new prescription (27.3%)
- The person had a negative reaction or allergy to the medicine (11.9%)
- The person felt better or no longer needed the medicine (18%)

Participants had multiple reasons for removing the drugs from their homes, including concerns for the environment, drug compliance, drug safety, as well as for preventing drug diversion. Some noted they did not want anyone else to use the medicine. Some were concerned about the potential poisoning dangers to children, or the risks of drug abuse diversion. Often the medicine was expired or outdated and no longer useful. Nearly half (46%) of those surveyed reported that, in the absence of a take back program, they would have flushed drugs down the toilet. Another one third (37%) would have dumped left over prescriptions into their trash. Overwhelmingly, 77% of program survey respondents cited participation because, “it’s best for the environment.”

The per-envelope cost in the initial years of the program is greatest given the staff time and effort needed to design and implement the program. Donated time and effort by pharmacists and pharmacy tech staff and Community Educator volunteers reduced operational costs. Phases I and II actual and in-kind contributions calculate to \$18.79 per unit mailer. Subsequent mailer costs (Phase III) are calculated at \$7.50 per unit mailer<sup>7,8</sup>. These costs were based on full commercial prices with no bulk discounts and should be clearly viewed as subject to further reduction with expansion of volume.

An unexpected benefit of this program is that the information gathered is proving to be a unique and rich source of useful drug utilization and patient compliance/adherence data. In addition there has been some initial work begun by the University of New England College of Pharmacy in identifying whether or not our sampling could provide the basis for post-market surveillance of counterfeit product.

#### **Policy Implications**

The mail back method returned a large quantity of drugs that would have otherwise been disposed of directly into the water system through flushing or into landfills through the trash. A short survey inserted in the envelope allowed us to track the reasons for participation, the sources of the drugs, and the demographic profile of the participants. This is information that is useful not only for project planning and education, but also policy development. Data gathered during this project has already begun to shape policy both statewide and nationally. For example, a recent MaineCare (Maine's Medicaid program) policy change has led to the enactment of limits for some drugs on how much of a supply can be filled in an initial prescription. Further data collection on compliance data can refine policy further and with more measured impacts and outcomes based on the evidence.

#### **Program Accomplishments and Conclusions**

The Safe Medicine Disposal for ME program has allowed drugs to be returned directly to one agency within the State, which reduced coordination costs and provides for secure collection and consolidation of returns. In Maine, the Maine Drug Enforcement Agency (MDEA) has statewide jurisdiction and was involved from the outset in concept development. This program partnership with Maine Drug Enforcement Agency has facilitated a review and subsequent approval of the program by the federal Drug Enforcement Agency. The statewide mail-back model offers a centralized coordination component, adds an element of confidentiality and anonymity not found with in-person take back programs and is the least burdensome of all models in terms of consumer participation.

Maine's citizen mail back program has demonstrated that this approach is not only feasible, but effective, and highly popular. The program utilized a phased implementation plan, beginning by targeting elders and focusing on pharmacies as distribution sites for the mail back envelopes. A

broader target population was then phased in, adults of all ages, as well as a broader range of distribution sites (other providers of health services).

The mail back program provides a rich opportunity to educate a broad public citizenry about prescription drugs and the environment via community outreach and information distributed with the mailer. It involves citizens in an easy, "DIY" (do it yourself) problem-solving program that prevents environmental harm, prevents drug diversion, and prevents poisoning. Community education by older adults was found to be both effective and engaging while encouraging new users of the program to spread the word in their local communities. It is for this reason the consumer involvement should be a key component in any drug return program model.

We think that one possible extension of the program would be to offer an amnesty or anonymity for returns of illegal drugs as long as proper controls are exercised with proper authorization given the US DEA for the issuance of such regulations to control the very real specter of diversion. This potential for diversion also cannot be underestimated both of controlled drugs and the potential of non-controlled drugs returning through the gray market for repeat sales. Prosecution for just this has occurred already.

Though predominantly distribution was through pharmacies, there have been meetings where attendees received mailers. There have been individual requests called in. A number of potential distribution systems have been identified. Starting with elementary school and setting an example in school health classes where distributing mailers along with messages regarding medication safety can impact the child's household storage of medicine. Long term care facilities could use a process to facilitate their disposal in larger envelopes or boxes. In a preliminary conversation with a hospital organization great interest was shown in distributing mailers to discharged patients with the message to put what they may no longer be taking in a mailer and get rid of it and put their new medicine in their medicine cabinet. As the majority of drug-drug interactions or adverse events occur shortly after hospital discharge this is the ideal time to offer this sort of readmission prevention program. In addition, drug-drug interactions or adverse events are one of the more significant causes of readmission. Neither payers nor hospitals can afford to continue to have the readmission rates that now exist and have sought for ways to reduce it. This is one promising option. Even one saved readmission is worth a great many mailers. Law enforcement has expressed desire that they have a larger share of the mailers for their community based drug abuse prevention efforts. Hospice pharmacies have expressed interest in adding mailers to their shipments so that family members can deal with departed family members left over medications. There are a wide variety of possible uses and methods of distribution that serve a number of different purposes, all for the benefit of the public health. Continuation and expansion of the Maine program could continue to provide useful information for more evidence-based policy and regulatory decision making. Indeed in addition to the hearing at which we are presenting today in Washington, in the next legislative session across the country there are a patchwork of potentially further complicating bills that address unused drug disposal.

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The prospect of these various jurisdictions, including municipalities, coming up with similar or compatible legislation is not likely given the varied and broad range of perspectives and interests in the problem of what to do with unused medications.

A major challenge for this and other disposal programs across the United States continues to be sustainable funding for such efforts. All disposal programming, whether mail back or event-based take back programs, require a considerable amount of time and effort to plan, execute, and educate the public. The first two phases have shown us that the interest and the community need exist and in fact, clearly outweigh the resources available to address the issue of drug disposal. However, it is imperative to continue as many programming and outreach efforts as possible to provide drug disposal options directly to the consumer at the same time that information is disseminated so as to avoid the confusion and misinformation the surrounds the issue of drug disposal.

Our experience has identified national need for such a program to be brought to the public as soon as possible. In 2005<sup>9</sup>, the United States Pharmacopeia passed a resolution to address unused medicine and reiterated this position at the 2010 Convention<sup>10</sup>. Within the past month the American Medical Association House of Delegates passed Substitute Resolution 515 which states:

*RESOLVED, that our AMA support initiatives designed to promote and facilitate the safe and appropriate disposal of unused medications. (New House Of Delegates Policy)<sup>11</sup>*

### **Conclusion**

The removal of the unused medication from risk for misuse has an inestimable value if only one life is saved from overdose or accidental poisoning.

We believe that this project could serve as a model for replication both at a state level and nationally. There are implications for health care policy, as exemplified by the State of Maine adopting pharmacy regulations to reduce waste, and CMS issuing a request for comment for a similar Medicare Part D approach. There are implications for environmental policy in looking at relative risks, and for law enforcement in looking at how to reduce both supply of, and demand for, illicit drugs. We believe that other benefits exist, but a proposal resulting from this project is the recommendation and invitation we make that the program be continued and expanded, and plans developed for replication in the immediate future. We hope we have made a significant contribution to the environmental as well as public health of the country.

There are several additional contributions that Congress can make besides funding that would facilitate this process.

1. The first is enabling funding legislation for the United States Drug Enforcement Administration to promulgate regulations and provide grants to ensure that diversion is minimized and that best practices are followed. The Executive Office of the White House Office of National Drug Control Policy has likewise the need for adequate funding to be able to seed and foster innovative and proven helpful that do not fall in to the current general mainline. Likewise the budget must reflect the need for education, public as well as professional, and public awareness.
2. The other is to review enabling legislation for the United States Postal Service to more readily expand availability of their services to the consumers of the country.
3. There is also the need for a better coordination between the various Federal agencies and the various and individual state agencies. DEA has a need for new avenues of communication outside the law enforcement community to hazardous waste and disposal and reverse distributors, while EPA could use new forums for communication with law enforcement across the country and within the multiplicity of jurisdictions that have an interest in solving this problem. This brings increasing time urgency for Federal action and facilitation of best practices nationwide.
4. There currently is no national resource or research center on drug disposal. Instituting one is sorely needed for dissemination of best practices and evaluation of evidence and policy. This has been proposed in several settings for the last two years.
5. Initiate the review of what pharmaceuticals are wasted and are being returned so that policy can be reviewed for better practices as occurred in Maine and as CMS is now considering. Adherence and compliance are issues that impact significantly the health of the entire country and efforts to improve will likewise reduce waste and potential for diversion.

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**Contact:**

***Lenard Kaye, Principal Investigator***

***Jennifer Crittenden, Program Manager***

University of Maine Center on Aging

Bangor, ME

<http://www.safemeddisposal.com/>

***Stevan Gressitt, M.D., Co-Principal Investigator***

Faculty Associate, University of Maine Center on Aging

Founding Director, Maine Institute for Safe Medicine

University of New England, College of Pharmacy

Department of Pharmaceutical Sciences

716 Stevens Avenue

Portland, Maine 04103

[gressitt@gmail.com](mailto:gressitt@gmail.com)

<http://www.benzos.une.edu/>

Cell: 207-441-0291

Written Testimony of Laura Hosley  
Manager of Community Prevention  
Working Together for Wellness, North Kingstown's Prevention Coalition  
Rhode Island Student Assistance Services  
300 Centerville Road, Suite 301S, Warwick, RI 02886  
"Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse,  
Diversion and Fraud"  
Committee on the Judiciary  
Subcommittee on Crime and Terrorism

**Background Information**

Chairman Whitehouse, Ranking Member Kyl and other distinguished members of the Subcommittee on Crime and Terrorism, thank you for the opportunity to testify before you today on behalf of the Working Together for Wellness, North Kingstown's Prevention Coalition and Rhode Island Student Assistance Services (RISAS). I am pleased to provide you with our perspective on effective strategies for reducing the abuse, misuse diversion and fraud of prescription drugs.

RISAS has been developing, establishing and implementing the Student Assistance Program (SAP) in Rhode Island public school settings since 1987. This program is based on the Substance Abuse and Mental Health Services Administration (SAMHSA) evidenced-based model, Project Success. This school-based alcohol, tobacco and other drug abuse prevention/early intervention program is currently being implemented in 44-50 Rhode Island secondary schools. I was a Student Assistance Counselor in middle and high schools for ten years, and then became a project manager for my agency. I am currently the Grant Manager for a Drug Free Communities (DFC) grant in North Kingstown, RI, as well as the Coalition Coordinator for Jamestown, an island community which sends its high school students to North Kingstown.

The coalition is designed to bring together representatives from multiple sectors to work together to address the local substance abuse issues. The members and staff look at data and information collected through focus groups, interviews and surveys, assess the strengths and weaknesses of the community, devise a plan based on evidence-based strategies, gain support from partners, implement the activities, programs and policies, and evaluate the outcomes. This process helps to educate and mobilize the community in its efforts to reduce youth substance youth rates.

Prior to the DFC grant, the Town of North Kingstown had received a Strategic Prevention Framework State Incentive Grant (SPF SIG), focused on underage drinking.

The 2010 results from the Health and Wellness Surveys given to the North Kingstown High School students (n=1,274) showed a 14% decrease in 30 day alcohol use and a 4% decrease in 30 day marijuana use. These outcomes can be attributed to the comprehensive strategies that were

implemented, consisting of a high school social norms marketing campaign and chemical health policy, linked with the school's established SAP. The 2010 results for the three Warwick high schools (n=2,326) showed an 8% decrease in alcohol use and a 10% decrease in marijuana use over the past year. RISAS also managed the City of Warwick's SPF SIG initiative.

The independent program evaluator concluded that a positive impact on the perceptions and behavior of the students in the high schools was a direct result of the combination of an SAP linked with other evidence-based strategies, including community and social norms marketing media campaigns, school and city policy changes, enforcement and education provided through the SPF SIG grant, and RISAS in partnership with the prevention task forces and school districts.

The Strategic Prevention Framework model prepared the Town of North Kingstown to successfully compete for the Drug Free Communities grant. The DFC program and approach works and when applied to prescription drug abuse will work as well in reducing use through similar approaches and strategies.

#### **Prescription Drug Abuse in Nationally and in Rhode Island**

Our agency recently held an all day workshop specifically on prescription drug abuse. Counselors confirmed that, for at least the past six years, they have been seeing students who are misusing and abusing these substances. Through a youth focus group, I learned that the students who had their wisdom teeth removed were suddenly very popular because others knew that they had been prescribed pain medication.

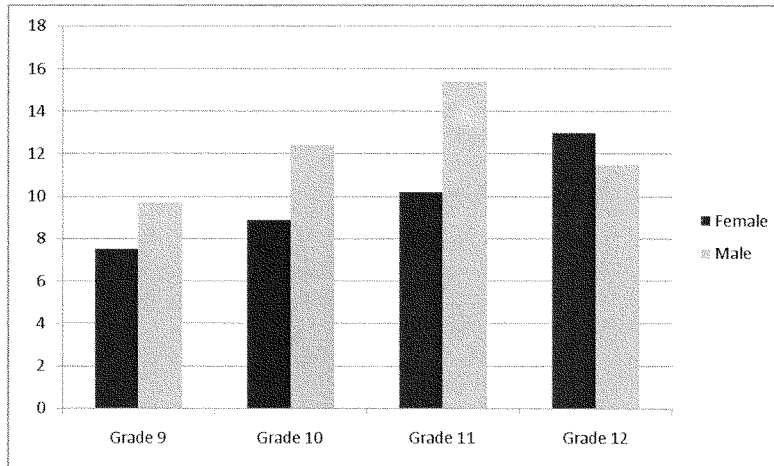
The pervasive nature of prescription drug abuse in Rhode Island is evident both anecdotally and statistically. According to the National Survey on Drug Use and Health (NSDUH), from 2002, 2003 and 2004, which is the latest year that state estimates specifically on the non-medical use of prescription therapeutics is available, for the nation as a whole, an annual average of 6.2 percent of persons aged 12 or older had used a prescription psychotherapeutic drug non-medically in the twelve months leading up to the survey. Rhode Island was tied with two other states for the 5<sup>th</sup> highest ranked state for misuse of any prescription psychotherapeutic drug, with 7.7 percent of those aged 12 and older reporting the non-medical use of prescription therapeutics in the past year.

According to the National Survey on Drug Use and Health's 2007-2008 State Estimates of Substance Use, throughout the country, an annual average of 4.9 percent of persons aged 12 or older used pain relievers non-medically in the 12 months leading up to the survey. Rhode Island is ranked 7<sup>th</sup> highest in terms of states with highest rates of abuse, with 6.28% of those aged 12 and older reporting the non-medical use of prescription pain relievers in the past year.

The Rhode Island SurveyWorks 2010-2011 survey shows that 11 percent of high school students report having tried painkillers, such as Vicoden and Percocet, without a doctor's permission. In



grade 9 alone, 9.1 percent had already used them. The prior instrument, called SALT, did not measure this concerning issue.



RI SurveyWorks 2010-2011 – Percentage of students who report having tried painkillers without a prescription

This past year, the North Kingstown Prevention Coalition added questions to the Health & Wellness Survey that we are using to collect data on substance abuse in the high school to enable us to identify the actual prevalence of local prescription drug abuse to help with strategic planning and implementation.

Unfortunately, the Youth Risk Behavior Surveillance System (YRBSS), which monitors health-risk behaviors such as tobacco use, alcohol and drug use, and sexual behaviors, as well as the prevalence of obesity and asthma among youth and young adults, does not include a question on prescription drug abuse. The Center for Disease Control (CDC), which conducts the YRBS should be encouraged to add questions to that instrument to help states and communities get the data they need related to youth prescription drug misuse and abuse.

Nationwide, an estimated 0.4 percent of persons aged 12 or older misused sedatives in the past year. Three of the nine highest-ranking States for sedative misuse were in New England: Massachusetts (1.0 percent), **Rhode Island** (0.7 percent), and Connecticut (0.6 percent).

Rhode Island is a small state, with approximately one million residents on one thousand square miles of land. Despite our small geography, our substance abuse statistics are often higher than the nationwide average. All of the RI counties reported approximately the same numbers for this measure.

Rhode Island	5.80
Bristol and Newport	5.90
Kent	5.76
Providence	5.79
Washington	5.78

**Nonmedical Use of Pain Relievers in the Past Year among Persons Aged 12 or Older, by Substate Region\*: Percentages, Annual Averages Based on the National Survey on Drug Use and Health's 2007-2008 State Estimates of Substance Use**

State/Substate Region	Estimate
Total United States	4.89
Northeast	4.13
Midwest	4.93
South	4.88
West	5.48

#### **Prescription Drug Abuse**

Prescription drug abuse is a disturbing trend that has been increasing for a variety of reasons. Over prescribing of medications has become commonplace, including to young people. Teenagers, who are most likely to be risk-takers and impulsive due to their immature stage of brain development, have access to pills due to a lack of easy disposal methods for adults. The advent of social media gives students instant communication methods formerly not available to them, which leads to problems such as misperceptions about safety, the extent of use, and can also glamorize and trivialize abuse. The high prevalence of prescription drug abuse is being driven by two key factors. First, there are major misperceptions about the dangers of prescription drugs which are widely viewed as safer than street drugs such as cocaine or methamphetamines.

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Because these medications can be legally obtained from a doctor, there is this distorted perception that they are not as dangerous as other illicit substances.

Second, prescription drugs are more widely available than they were in the 1990's. Over 20 years, the number of prescriptions for opioid analgesics in the U.S. has gone from 45 million to 180 million, more than a four-fold increase, and prescriptions for stimulants increased from 5 million to nearly 40 million, an eight-fold increase, according to Nora Volkow, Director of the National Institute on Drug Abuse. Research has shown that the majority of abusers obtain pain and stimulant medications from friends or family members, although they also buy them from dealers and on the Internet, or get prescriptions from one or more doctors.

Mainly due to these factors: doctors need to be better educated on the proper treatment of pain and prescribing of narcotics and the general public would greatly benefit from education on the correct use of these medications and the dangers that come with their misuse. In addition, training in drug recognition for school administrators, nurses and other staff is an important strategy to help diagnose students who have begun to misuse prescription drugs early rather than waiting for a crisis to occur.

#### **Prescription Drug Monitoring Programs**

A centralized system for monitoring the distribution of controlled substances needs to be in place in every state, with the ability to be interoperable among states. This will help curtail "doctor-shopping" and allow physicians and pharmacists to better coordinate with each other to recognize patients who are obtaining multiple prescriptions.

Often prescription drug use does not occur in isolation. Alcohol use is prevalent, with statistics showing about half of students in the high schools in Rhode Island having consumed alcohol in the past 30 days. The percentage increases each year that the student stays in school. In many cases, prescription drug abuse may occur in conjunction with drinking or other drug use, magnifying the effects of each substance. The use of alcohol in combination with illicit and other drugs is of particular concern given the potentially dangerous additive or interactive effects that may result. Research shows that the use of alcohol in combination with other drugs is associated with a variety of negative outcomes such as overdose, suicide, risky sexual behavior, alcohol dependence, depression, and social consequences such as legal, work, and health problems.

SAMSHA data estimated that 188,981 alcohol-related emergency department (ED) visits were made by patients aged 12 to 20 in 2008. 70 percent involved alcohol only, and 30 percent involved alcohol in combination with other drugs. Illicit drug use was indicated in more than two thirds (68.4 percent), and pharmaceutical drugs were involved in more than one half (55.1 percent) of ED visits involving alcohol in combination with other drugs among patients aged 12 to 20. Examination of selected pharmaceutical drugs reveals that 17.8 percent of alcohol-related ED visits involved drugs that treat anxiety or insomnia (e.g., benzodiazepines and barbiturates),

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15.3 percent involved narcotic pain relievers (e.g., codeine and hydrocodone), 7.2 percent involved antidepressants or antipsychotics, and 5.3 percent involved acetaminophen products.

These statistics point to the importance of monitoring drug-related ED visits among underage drinkers. Using surveillance and reporting of ED data can be a helpful strategy in raising awareness—particularly among parents and youth—about the dangers and physical harm that may result from mixing alcohol and drugs together. ED health providers are well-placed to identify youth who may be in need of further substance abuse assessment or treatment and to provide subsequent referrals.

### **Rhode Island's Substance Abuse Prevention Efforts**

#### **Community Coalitions**

A comprehensive, multi-sector, community-wide approach is the best way to address an issue such as prescription drug abuse. One strategy alone will not work; therefore, implementing changes on multiple levels increases the chances that more people will be reached.

Strong communities with knowledgeable leaders can institute changes through cooperation and partnerships. Community coalitions such as those funded through the DFC program, of which we are a recipient, mobilize schools, law enforcement, churches, businesses, government and citizens, including youth, to work together on a full array of substance use and abuse, including prescription drugs. Schools are a critical partner in these coalitions and help to deliver necessary and effective programs and services. Community coalitions help to ensure that programs and policies are in place in schools and other community sectors to protect youth and promote healthy behavior, so that students can reach their fullest potential.

Rhode Island has a system of community coalitions that have been in existence for over twenty years. We have observed that the communities that are most successful in addressing substance abuse problems within their community are the ones that were awarded DFC grants. Of the 39 cities and towns in Rhode Island, ten have DFC grants. The two goals inherent in this grant are building the capacity of the coalition and community and reducing substance abuse among youth. Having the resources in terms of staff time and funding makes a huge difference in capability and results. These DFC coalitions are data-driven, know their community epidemiology and because they are multi sector can begin to address new and emerging drug trends such as prescription drug abuse, quickly, comprehensively and effectively. Three intensive weeks of mandatory training in the strategic planning framework model through the National Community Anti-Drug Coalition Institute provides expertise to the group working on these important issues. Competence increases credibility and the likelihood that partners will want to get involved and support the projects. Working to make population level changes in drug use requires the application of environmental strategies in the area of policy-making. Examples of what a coalition can accomplish are changes in school policies, town ordinances and police

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procedures, all of which can have the scale and scope, when implemented and enforced to change attitudes and behavior. In the DFC communities, successful implementation of media campaigns, law enforcement efforts, social norms marketing campaigns, educational efforts and policy changes give the coalitions the confidence and competence needed to successfully address their substance use/abuse problems. Although prescription drug abuse is not new, Rhode Island has not comprehensively addressed the issue. Comprehensive tobacco prevention efforts paid off with lower smoking rates and underage drinking efforts have decreased alcohol consumption.

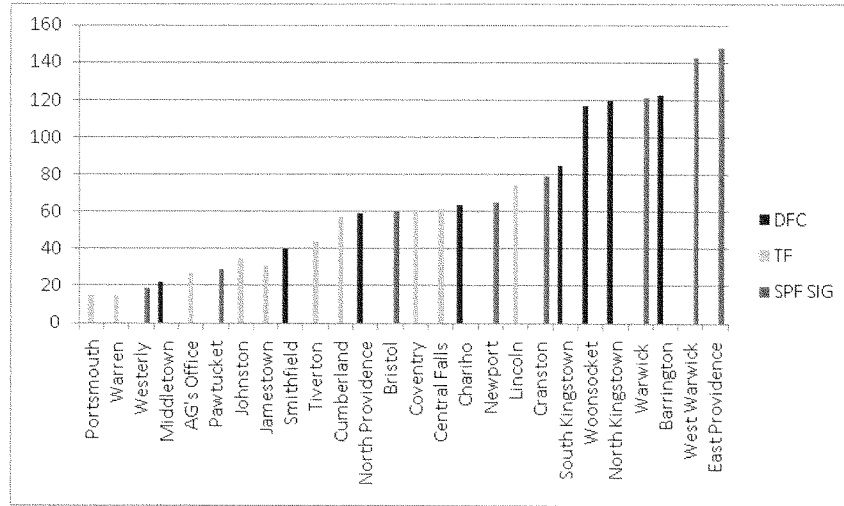
The DFC community in which I currently work ensures open discussions among all of the community sectors and stakeholders and works to implement the community's strategic priorities. Major changes in school policies were ready to fall apart until they were revitalized through the coalition's leadership. Funding for the Student Assistance Program was in jeopardy until community coalition advocates pointed out the statistics related to this issue and the likely consequences of removing an effective program. New programs that have been successful in similar communities are being proposed and supported by the DFC coalitions. Research shows a marked difference between towns and cities that receive this funding and ones that do not; the DFC program clearly improves performance and affects population change.

Coalitions can help prevent access to prescription drugs by involving the entire community. The National Prescription Drug Take-Back Day provided our coalition with an excellent way to get information out to parents and the community about the misuse of prescription drugs among youth. Because the date was set ahead of time, it gave our coalition the lead time to get to media outlets involved. Posters were sent to police stations and distributed, in many cases, by volunteers, to local business and public buildings. Since, by Rhode Island law, these drugs are not able to be disposed of through pharmacies, the DEA, working in conjunction with the local and state police departments, presented the opportunity and had positive results. As part of the Take-Back campaign promotion, information was presented surrounding the dangers of prescription drug abuse and the risk of teenagers gaining access to drugs and taking them. The community coalitions helped to seize the opportunity to participate in the conversations so that there was ownership of the problem and collectively the community could be a part of the solution. Coalitions facilitate the ability for a community to be organized and have the relationships with those who need to be involved, ensuring that the projects can be carried out effectively.

In North Kingstown, five full boxes were collected by the local state police barracks and town police department. Overall, in Rhode Island, 1,716 pounds of drugs were collected. The DFC Prevention Coalitions in each community worked with their partners to reduce access to and availability of prescription drugs in their communities through participating in the take-back program. Many took advantage, because they already had the relationships with their police department and local businesses. At least ten RI communities did not participate at all. The eight communities that took in the most prescription drugs by weight were all current DFC and/or

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former SPF SIG grant recipients. The cities and towns that received DFC funding as well as the coalitions that had received SPF SIG funding had the state's eight highest prescription drug collection rates, amounting to more than 75% of the total weight of drugs taken back.



4/30/11 Prescription Drug Take-Back Day – Graph represents pounds of drugs taken back by each community

**Student Assistance Programs**

The SAP is located in schools where adolescents have easy access to highly trained counselors and where alcohol and other drug use-related risk factors, such as drinking at an early age, poor academic performance, deviant school behavior and poor parent-child relationships are more likely to be detected than at home. On-site Master's-level Student Assistance Counselors (SACs) are utilized to provide a wide range of prevention and early intervention services. Parents, school administrators, teachers and others in the community find the SAP a highly effective model for addressing alcohol, drug and other problems, which negatively impacts academic performance and attendance.

SAPs in Rhode Island are highly valued by schools and communities and in some municipalities, represent the only prevention "program" available to youth. The current challenge is that the state general revenue funding does not provide sufficient coverage to ensure that at least minimum programs are funded statewide. Furthermore, the programs were dependent upon the Safe and Drug Free Schools and Communities (SDFSC) funding to not only successfully implement the program, but also to use the funding to leverage other sources of funding for

program support. Unfortunately, the SDFSC program has been zeroed out and is no longer available. This has created a major funding issue for substance abuse prevention and intervention programming, not only in RI, but throughout the nation. The RI SAP is a key element in the prevention infrastructure at the municipal level and it is critically important as youth served by the intervention are those who are at-risk in multiple areas, such as substance use/abuse, academic failure, truancy, delinquency, and early/unwanted pregnancy.

The SAP provides services to over 6,500 teens every year, including the neediest populations in the core cities. This model has proven effective in reducing and eliminating substance use. The young people who visit the Student Assistance Counselors' offices suffer from pain and distress, and have a safe haven to find healthy solutions to their problems. Teenagers feel comfortable with an accepting and non-judgmental adult in a location where there is easy access: their school.

SAPs implement school-wide activities and promotional materials to increase the perception of the harm of substance use, positively change social norms about substance use, and increase enforcement and compliance with school policies and community laws. These resources are extremely valuable, but services will be reduced and in some cases eliminated without increased funding.

Recently, a young person in Rhode Island took prescription drugs that were not prescribed to her, along with LSD. She abruptly barged into the Student Assistance Counselor's office, exhibiting very confused verbal behavior. Teachers and friends expressed their concern about her. She was taken to the school nurse, who was going to send her home, but the counselor, realizing that the girl was in a drug-induced psychosis, recommended that she be transported by ambulance to the hospital. The girl was hospitalized for three weeks and may have permanent brain damage. She is back in school, but is on Lithium, a medication typically prescribed for patients with bipolar disorder. Because she had disrupted the neurotransmitters in her young brain through her drug use, she now needs medication to keep her stabilized enough to be able to function in school. She is still experiencing crying bouts and having difficulty handling daily stress.

The Student Assistance Counselor is also working with the young man who gave her the drugs. He was placed in the Adult Corrections Institute, then given home confinement, but is allowed to attend school. When he returned to school, with an ankle bracelet, he expressed anger over his restricted freedom. Two lives connected by prescription drug abuse resulted in both having diminished chances for future success.

We all know that the use of drugs and alcohol by grade school students impairs their ability to learn. The value of prevention is in its ability to improve student performance and improve social conditions. Most parents are not prepared to take on substance abuse intervention without professional support and help. Most students will not confide at that level with their parents. The

Student Assistance Program is designed to provide services that are grounded in evidence-based modern science, and to provide access to those students who need them the most.

We see three types of students in schools: the student who will try whatever type of drug is offered to them, saying "why not?"; the student who refuses potentially harmful substances, saying "why would I do that?"; and the student who is on the fence, may not be sure, may not be confident, and could go either way. What has been discussed and role-modeled in the family, as well as the strength of the schools' and community's policies, programs and practices, will impact which direction the students will take when faced with drug use choices. Initiation is the first step in the continuum, so preventing the first use is the key. Education and support helps to raise awareness and increase competencies so that families can be more confident that the children will not become drug-involved.

### **Conclusion**

While Rhode Island is just beginning to address the complex issues related to prescription drug abuse among teens, I believe one of the more effective prevention mechanisms will be the Student Assistance Program. These highly-trained counselors are on-site where access for students is easy and confidential. Collectively, the SAP, working in tandem with community coalitions, has been successful in reducing the use and abuse of alcohol and tobacco. I have every reason to believe that continuing and expanding the SAP program, along with community coalitions through the DFC program, will help communities handle the complexity of prescription drug abuse among teens. In addition, I believe it is critical that: 1) prescription drug monitoring programs be fully operational in every state and have the ability to be interoperable; 2) questions related to youth prescription drug misuse and abuse be added to CDC's YRBS survey; 3) doctors be better educated on the proper treatment of pain and prescribing protocols; 4) the general public be better educated about the correct use of prescription medications, the harms associated with their misuse and abuse, and their proper disposal; 5) school administrators, nurses and other staff be trained in drug recognition so that they can intervene with students who have begun to misuse prescription drugs early rather than waiting for a crisis to occur; 6) data on drug-related emergency department visits be collected, and emergency department doctors be better trained to identify, assess and provide referrals to treatment when necessary; and 7) with drug use on the rise and the elimination of the SDFSC program, the federal government should focus more emphasis and funding on community and school based substance abuse prevention and intervention strategies and programs, through reauthorization of the Elementary and Secondary Education Act and the Drug Free Communities program. Taken together, each of these recommendations has the potential to reduce the abuse of prescription drugs among youth in schools and communities throughout Rhode Island, as well as nationwide.

Thank you for the opportunity to testify. I would be happy to answer any questions you may have.

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

**“Responding to the Prescription Drug  
Epidemic: Strategies for Reducing  
Abuse, Misuse, Diversion, and Fraud”**

Senate Committee on the Judiciary  
Subcommittee on Crime and Terrorism

Tuesday, May 24, 2011  
9:00 a.m.  
226 Dirksen Senate Office Building

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

**Statement of R. Gil Kerlikowske**  
**Director, Office of National Drug Control Policy**  
**Executive Office of the President**  
**before the Subcommittee on Crime and Terrorism**  
**Committee on the Judiciary**  
**United States Senate**  
**entitled, "Responding to the Prescription Drug Epidemic:**  
**Strategies for Reducing Abuse, Misuse, Diversion, and Fraud"**  
**May 24, 2011**

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

As Director of the White House Drug Control Policy office and chief advisor to the President on anti-drug efforts, I am charged with producing the *National Drug Control Strategy*, which directs the Nation's anti-drug efforts and establishes programs, a budget, and guidelines for cooperation among Federal, state, and local entities. My position allows me to raise public awareness and take action on drug issues affecting our Nation. As we have gained a better understanding of addiction, it has become increasingly clear that a comprehensive approach is required to address the complexity of our Nation's drug problem. The Obama Administration recognizes that addiction is a disease, and that prevention, treatment, and law enforcement must all be included as part of a strategy to stop drug use, get help to those who need it, and ensure public safety.

The 2010 *National Drug Control Strategy*, released by President Obama in May 2010, commits to reducing drug use and its consequences through a science-based public health approach to policy. This *Strategy* was the result of a nine-month consultative effort with Congress, Federal agencies, state and local partners, and hundreds of concerned citizens. 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 youth – safe, healthy, and protected from the enormous costs of substance abuse, while ensuring that our seniors, as well as our vulnerable and sick, have access to the prescription drugs they need to reduce pain, mitigate disease, and preserve life.

The *Strategy* establishes specific goals by which to measure our success. We have worked and are continuing to work with dozens of agencies, departments, Members of Congress, state and local organizations, and the American people to make significant reductions in illicit drug use and the consequences it bears. Our efforts are balanced and incorporate new research and smarter strategies to better align policy with the realities of drug use 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 2009, nearly 24 million Americans ages 12 or older needed treatment for an illicit drug or alcohol use problem. However, less than 11 percent received the necessary treatment for their disorders.<sup>1</sup>

The Administration's *Strategy* includes action items that comprehensively address all areas of drug control. Since its release, ONDCP and our Federal partners have made significant progress on these items. In addition, we have highlighted three signature initiatives; prescription drug abuse, prevention, and drugged driving.

We are currently finalizing the 2011 *Strategy*, which builds upon the *Strategy* released in 2010. The 2011 *Strategy* addresses issues of concern to specific populations, including active duty service members, Veterans and their families, college students, women and children, and those in the criminal justice system. The 2011 *Strategy* continues our efforts to coordinate an unprecedented government-wide public health approach to reducing drug use and its negative consequences in the United States, while maintaining strong support for law enforcement. As with the 2010 *Strategy*, the 2011 *Strategy* continues to emphasize drug prevention, early intervention programs in health settings, aligning criminal justice policies and public health systems to divert non-violent drug offenders into treatment instead of jail, funding more scientific research on drug use, and expanding access to substance abuse treatment.

Today, I am here to testify specifically on prescription drug abuse. Prescription drug abuse is the fastest-growing drug problem in the United States and is characterized as a public health epidemic by the Centers for Disease Control and Prevention. In recent years, the number of individuals who, for the first time, consumed prescription drugs for a non-medical purpose was similar to the number of first-time marijuana users.<sup>2</sup> The 2010 Monitoring the Future study – a national survey on youth drug use – found that six of the top ten substances used by 12<sup>th</sup> graders in the past year were pharmaceuticals.<sup>3</sup> In addition, there has been a four-fold increase in addiction treatment admissions for individuals primarily abusing prescription painkillers from 1998 to 2008.<sup>4</sup>

The increase in the percentage of treatment admissions for abuse of pain relievers spans every age, gender, race, ethnicity, education, employment level, and region. The estimated number of emergency department visits linked to non-medical use of prescription drugs doubled between 2004 and 2009, and this dramatic rise occurred among men and women of all age groups.<sup>5</sup> Even more alarming is the fact that nearly 28,000 Americans died from unintentional drug overdoses in 2007, and prescription drugs—particularly opioid painkillers—are considered major contributors to the total number of drug deaths; in 2007, they represented 42 percent of

<sup>1</sup> Substance Abuse and Mental Health Services Administration 2010. *Results from the 2009 National Survey on Drug Use and Health: National Findings*.

<sup>2</sup> *Ibid.*

<sup>3</sup> University of Michigan 2010 Monitoring the Future: A Synopsis of the 2010 Results of Trends in Teen Use of Illicit Drugs and Alcohol.

<sup>4</sup> Substance Abuse and Mental Health Services Administration 2010. The Treatment Episode Data Set (TEDS) Report.

<sup>5</sup> Substance Abuse and Mental Health Services Administration. The DAWN Report: Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. 2010. <http://www.oas.samhsa.gov/2k10/DAWN034/EDHighlightsHTML.pdf>

unintentional drug overdoses.<sup>6</sup> In 17 states and the District of Columbia, drug-induced deaths now outnumber motor vehicle crash deaths.<sup>7</sup>

Substance use has also affected our military, Veterans, and their families. According to a 2008 Department of Defense survey, 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%).<sup>8</sup> Equally concerning is the fact that substance abuse affects many of the estimated 75,600 homeless Veterans.<sup>9</sup> The Department of Veterans Affairs (VA) does not currently participate in state Prescription Drug Monitoring Programs; however, the VA is very supportive of reducing barriers to its participation in state PDMPs.

The ease of accessibility to prescription drugs, combined with a low perception of risk, make reducing prescription drug abuse particularly difficult. For instance, of persons aged 12 or older who used pain relievers non-medically between 2008 and 2009, 70 percent obtained the drug they abused from a friend or relative.<sup>10</sup> Research also shows that because prescription drugs are manufactured by reputable pharmaceutical companies, prescribed by licensed clinicians, and dispensed by pharmacists, they are perceived as safer to abuse than illegal drugs. Recent studies found teens perceived prescription drug abuse as safer, less addictive, and less risky than use of illegal drugs, and believed that drugs obtained from a medicine cabinet or pharmacy – such as narcotic pain relievers (e.g., Vicodin or Oxycontin) or stimulants (e.g., Ritalin or Adderal) – are not as dangerous as drugs obtained from a drug dealer.<sup>11</sup>

As these statistics demonstrate, the abuse of prescription drugs is a problem of ever-increasing concern. Although beneficial when used as prescribed by a healthcare professional for legitimate medical purposes in the usual course of professional conduct, prescription drugs can be just as dangerous and deadly as illicit drugs when misused or abused. We must ensure that prescription drugs are only used as prescribed and by the person to whom they were prescribed. 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, multifaceted public health and public safety approach to address this epidemic. It is important to balance prevention, education, and enforcement with the need for legitimate access to controlled substances.

The realities of prescription drug abuse demand action, and any policy response must be approached thoughtfully and strike a balance between our need to prevent diversion and abuse of pharmaceuticals with the need to ensure legitimate access. As science has successfully developed valuable medications to alleviate suffering, such as opioids for cancer pain and benzodiazepines for anxiety disorders, more individuals have been able to access the medicines

<sup>6</sup> Centers for Disease Control and Prevention. Unintentional Drug Poisoning in the United States. July 2010.

<sup>7</sup> Centers for Disease Control and Prevention. National Center for Health Statistics, "National Vital Statistics Report", 2009.

<sup>8</sup> 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.

<sup>9</sup> U.S. Department of Veterans Affairs Budget Request for Fiscal Year 2012. Statement of Secretary Eric Shenseki. <http://veterans.house.gov/hearings/Testimony.aspx?TID=3785&Newsid=2279&Name=%20Hon.%20Eric%20K.%20Shinseki%20>

<sup>10</sup> Substance Abuse and Mental Health Services Administration. 2010. *Results from the 2009 National Survey on Drug Use and Health: National Findings*.

<sup>11</sup> [http://www.rwjf.org/files/research/Full\\_Teen\\_Report%205-16-06.pdf](http://www.rwjf.org/files/research/Full_Teen_Report%205-16-06.pdf)

they need. Unfortunately, the increased availability of opioid and benzodiazepine medicines has also led to the unintended consequence of increased medication abuse. The Administration developed an inclusive plan which brings together a variety of Federal, state, local, and tribal groups to reduce prescription drug diversion and abuse. The recently released 2011 Prescription Drug Abuse Prevention Plan, "Epidemic: Responding to America's Prescription Drug Abuse Crisis", expands upon the Obama Administration's *National Drug Control Strategy* and includes action in four major areas to reduce prescription drug abuse:

The first pillar of our response plan is education. Sixty-nine percent of narcotic analgesics are distributed in primary care offices and emergency departments,<sup>12</sup> and surveys of healthcare professionals and professional schools have shown there are significant gaps in educational training on pain management, substance abuse, and appropriate prescribing. Mandatory prescriber education is therefore essential. In addition, we should make sure parents and patients are fully aware of the dangers and prevalence of prescription drug abuse and are educated about the safe use and proper storage and disposal of these medications.

The Food and Drug Administration has developed a Risk Evaluation and Mitigation Strategy (REMS) for long-acting and extended-release opioids. This REMS requires all manufacturers of long-acting and extended-release opioids to ensure training is provided to prescribers of these medications. The manufacturers must also develop information that prescribers can use when counseling patients about the risks and benefits of opioid use.

The second pillar of our plan encourages each state to have a prescription drug monitoring program (PDMP). PDMPs are state-wide databases that contain information on dispensed controlled substances prescribed by healthcare providers. 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, and insurance fraud investigative tool. Information contained in the PDMP can be used by prescribers and pharmacists to detect drug-drug interactions, and to identify patients who may be doctor shopping for prescriptions to sustain a prescription drug addiction; and under specific circumstances, regulatory and law enforcement officials can also use the information to pursue cases involving rogue prescribers or pharmacists, or "pill mills" and other forms of diversions.

Historically, no single provider or entity had complete visibility of all prescriptions being obtained by a patient. PDMPs provide clinicians with quick access to their patients' complete history of controlled substances use. Despite the benefits of PDMPs, many states lack a program, and many states that do operate PDMPs lack interoperability. All states should have operational PDMPs with mechanisms in place for sharing between states. Additionally, there must be a high utilization among healthcare providers, and checking a PDMP should be a regular part of an office visit just like checking for insurance coverage. We are very pleased to report that several States, including Maryland, Georgia, Nebraska, and Arkansas have recently passed

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<sup>12</sup> Raofi S, Schappert SM. Medication therapy in ambulatory medical care: United States, 2003–04. National Center for Health Statistics. Vital Health Stat 13(163). 2006

legislation to implement prescription drug monitoring programs, leaving just two states and the District of Columbia, without legislation authorizing a PDMP.

The Federal government has also made significant investments in health information technology and continues to work with state Health Information Exchanges to create an electronic health network within states. ONDCP is currently engaged with the Office of Science and Technology Policy and the Office of the National Coordinator for Health Information Technology at the Department of Health and Human Services to explore connecting PDMPs with state Health Information Exchanges. We are also exploring ways to incorporate real-time PDMP data at the point of care and dispensing. These advances will maximize the public health and public safety benefits of PDMPs.

The third pillar of our plan calls for proper medication disposal. Nearly 70 percent of people report getting their painkillers from a friend or relative. Unused medications sitting in our medicine cabinets are falling into the wrong hands. There is a need for proper medication disposal programs, so unused or expired medications are disposed of in a timely, safe, and environmentally responsible manner. We must change public perception to one where properly disposing of unused prescription medication is second nature. By creating a method for disposal of expired or unused prescription drugs, we will benefit public health, public safety, and the environment.

On April 30, 2011, the Drug Enforcement Administration (DEA) held the second National Prescription Drug Take-Back Day, where they collected 188 tons of unwanted or expired medications for safe and proper disposal. This represents a 55 percent increase over last year. There were 5,361 take-back sites available across all 50 States.

The passage of the Secure and Responsible Drug Disposal Act in 2010 was an important step forward in our efforts to make prescription drug disposal more accessible to individuals and to reduce the supply of drugs available for diversion and abuse. DEA is in the process of rule-making to permit disposal of prescription drugs more convenient and accessible. If we want to ensure a reduction in the amount of prescription drugs available for diversion and abuse, a drug disposal program needs to be easily accessible to the public, environmentally friendly, and cost-effective, and the cost burden must not be placed on consumers.

The fourth and final pillar of the plan is enforcement. Smart law enforcement is an essential component of our plan. Our main focus is assisting states in addressing "pill mills" and doctor shopping, because they contribute significantly to the prescription drug abuse epidemic. More specifically, we plan to ensure that technical assistance on model regulations and laws for pain clinics are available to states. ONDCP also will continue to support High Intensity Drug Trafficking Areas as they address diversion and trafficking of pharmaceuticals and listed chemicals. Lastly, the National Methamphetamine and Pharmaceutical Initiative, which is funded by ONDCP, will work to provide training to law enforcement for pharmaceutical crime investigations.

In closing, I recognize that none of the things ONDCP and my Executive Branch colleagues want to accomplish for the Nation are possible without the active support of Congress. Thank you for the opportunity to testify here today on this public health epidemic.

**Statement Of Senator Patrick Leahy (D-Vt.),  
Chairman, Senate Judiciary Committee,  
Hearing Before the Subcommittee on Crime And Terrorism on  
"Responding to the Prescription Drug Epidemic:  
Strategies for Reducing Abuse, Misuse, Diversion, and Fraud"  
May 24, 2011**

Today, the Subcommittee on Crime and Terrorism holds a very important hearing on the prescription drug epidemic. I commend Senator Whitehouse for holding this timely hearing, and for his leadership on this issue. This administration's strong commitment to curbing prescription drug crime and abuse is exemplified today by the participation of the Director of the Office of National Drug Control Policy (ONDCP), Gil Kerlikowske and Drug Enforcement Agency Administrator Michele Leonhart. I look forward to their testimony, as well as that of the other witnesses.

Earlier this year, the Office of National Drug Control Policy released its plan to combat prescription drug abuse. The plan reflects significant efforts by ONDCP, the U.S. Department of Health and Human Services, the Food and Drug Administration, and the Drug Enforcement Administration to deal with this serious problem, and it will help advance a serious discussion about what solutions work best. A comprehensive response like that reflected in the national plan, which includes education and prevention, is an important step toward breaking the cycle of drug abuse and crime.

At a Judiciary Committee field hearing in Barre, Vermont, last year, Senator Whitehouse, Director Kerlikowske and I heard directly from people on the front lines in Vermont about the state's efforts to combat drug-related crime, and particularly the growing problem of prescription drug abuse. It is disturbing that more and more people are becoming addicted to prescription painkillers like Oxycontin. Perhaps most disturbing is the fact that more and more of our children than ever before are turning to these drugs at an early age.

Cities and towns like Barre are finding that the best solutions to the prescription drug epidemic involve all segments of the community coming together with law enforcement to find meaningful, community-based solutions that address the underlying causes of these problems. Vermont's civic-minded, all-hands-on-deck approach to the prescription drug problem emphasizes prevention and treatment efforts, which are crucial to the success of any anti-drug strategy. It is also important that the Federal Government continue to support community prevention-based programs like the Drug Free Communities grant program and the Boys and Girls Clubs to bring communities together to tackle these intractable problems.

Prescription drug addiction and related crime continues to hurt the people of small towns and small cities in Vermont and across America, and I am committed to working with Senator Whitehouse and others to find bipartisan, commonsense solutions to the prescription drug epidemic. Today's hearing is an important step forward. I welcome a productive discussion.

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# Department of Justice

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STATEMENT FOR THE RECORD OF  
MICHELE M. LEONHART  
ADMINISTRATOR  
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE  
SUBCOMMITTEE ON CRIME AND TERRORISM  
COMMITTEE ON THE JUDICIARY  
UNITED STATES SENATE

ENTITLED  
"RESPONDING TO THE PRESCRIPTION DRUG EPIDEMIC: STRATEGIES FOR  
REDUCING ABUSE, MISUSE, DIVERSION, AND FRAUD"

PRESENTED ON  
MAY 24, 2011

**Statement for the Record of  
Michele M. Leonhart  
Administrator  
Drug Enforcement Administration  
United States Department of Justice**

**Subcommittee on Crime and Terrorism  
Committee on the Judiciary  
United States Senate**

**“Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse,  
Diversion, and Fraud”  
May 24, 2011**

Chairman Whitehouse, Ranking Member Kyl, and distinguished Members of the Subcommittee, on behalf of the 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 dangers of prescription drug abuse.

*Overview*

The diversion and abuse of pharmaceutical controlled substances is a significant and growing problem in the United States. Leading indicators show substantially high levels in the abuse and misuse (non-medical use) of these drugs and the consequences associated with such actions. These indicators include, but are not limited to: the National Survey on Drug Use and Health, Monitoring the Future Study, Partnership Attitude Tracking Study (PATS), Drug Abuse Warning Network (DAWN) data, Treatment Episode Data Set, American Poison Control Centers data, and the National Forensic Laboratory Information System (NFLIS).

- According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2009 National Survey on Drug Use and Health (NSDUH), 7 million Americans were current non-medical users of psychotherapeutic drugs, significantly higher by 12 percent compared to 2008. Over three-quarters of that number, 5.3 million Americans, abused pain relievers.
- The NSDUH survey also indicated that the non-medical use of prescription drugs was second only to marijuana abuse.
- On average, more than 7,000 people 12 years and older initiate use of a controlled substance pharmaceutical drug for non-medical purposes every day.

- The Centers for Disease Control and Prevention (CDC) reported that the number of poisoning deaths involving any opioid analgesics increased from 4,041 in 1999 to 14,459 in 2007, more than tripling in 8 years.<sup>1</sup>
- SAMHSA's Treatment Episode Data Set shows that between 1998 and 2008 the number of persons admitted for treatment that reported any pain reliever abuse increased more than fourfold.
- According to DAWN data, the number of emergency department visits involving the misuse or abuse of pharmaceuticals increased by 98.4 percent between 2004 and 2009. The prescription drugs most implicated were opiate/opioid pain relievers, oxycodone products increased 242 percent, and hydrocodone products increased 124 percent.
- The approximate number of cases submitted by state and local law enforcement to forensic labs between 2001 and 2009 increased significantly (330 percent for oxycodone, 314 percent for hydrocodone, and 281 percent for methadone).

Statistics concerning the abuse of pharmaceutical controlled substances and prescription medication also reveal disturbing trends. Persons aged 12 years and older who used prescription drugs non-medically in the past month exceeded the number of current users of cocaine, heroin, hallucinogens, and methamphetamine combined.<sup>2</sup> In this age range, prescription drug abuse is second only to marijuana use.<sup>3</sup>

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 illegal drugs.<sup>4</sup> Because prescription medications are manufactured by pharmaceutical companies, prescribed by physicians and other medical professionals, and dispensed by pharmacists, teens and young adults often have a false sense of security regarding these potent and sometimes dangerous medications. This false sense of security can end in tragedy. In 2010, about 1 in 4 teens admitted to using a prescription drug not prescribed to them by a doctor at some point in their lives.<sup>5</sup> Teens continue to report that their parents do not talk to them about the risks of prescription drugs in the same manner as they discuss other substances of abuse.<sup>6</sup>

The 2010 Monitoring the Future study reported that Vicodin, a brand name pain reliever containing the narcotic hydrocodone, is one of the most commonly abused drugs among 12<sup>th</sup>

<sup>1</sup> Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, August 20, 2010.

<sup>2</sup> Substance Abuse and Mental Health Services Administration. Results from the 2009 National Survey on Drug Use and Health.

<sup>3</sup> Ibid, p. 14.

<sup>4</sup> Partnership for a Drug-Free America, 2008 Partnership Attitude Tracking Study, Key Findings.

<sup>5</sup> Partnership for a Drug-Free America, 2010 Partnership Attitude Tracking Study.

<sup>6</sup> 2010 Partnership Attitude Tracking Study, p.18.

graders: in 2010, about 1 in 13 (8%) reported non-medical use in the previous year.<sup>7</sup> On average, every day 2,100 12-17 year olds abuse a prescription pain reliever for the first time.<sup>8</sup>

The economic impact on the United States from the non-medical use of prescription opioids in 2006 was estimated at \$53.4 billion, (\$42 billion in lost productivity, \$8.2 billion in criminal justice costs, \$2.2 billion in treatment costs, and \$944 million in medical complications).<sup>9</sup>

*Drug Enforcement Administration & the Diversion Control Program*

Under the Controlled Substances Act (CSA), Congress established a “closed system” of distribution designed to prevent the diversion of controlled substances. 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. To maintain the closed system, every entity that manufactures or distributes controlled substances, or proposes to engage in the manufacture or distribution of any controlled substance, must obtain a DEA registration authorizing such activity. In addition to the requirement that DEA registrants maintain copious records of all transactions involving controlled substances, the closed system is monitored by the Automation of Reports and Consolidated Orders System (ARCOS).

**The Automation of Reports and Consolidated Orders System (ARCOS)**

The Automation of Reports and Consolidated Orders System (ARCOS) is DEA’s database that captures controlled substance activity from the point of manufacture and/or distribution to the point of sale to the retail level registrant (e.g., pharmacies, hospitals, practitioners, teaching institutions, researchers, analytical labs, importers/exporters, and Narcotic Treatment Programs). Approximately 1,100 manufacturers and distributors report data to ARCOS. Just under 70.9 million transactions were reported to ARCOS in 2010. Manufacturers of bulk and/or dosage form controlled substances must report inventories, acquisitions, and dispositions of all substances in schedules I and II, schedule III narcotics, and Gamma-Hydroxybutyric Acid (GHB) in Schedule III. Additionally, manufacturers must report synthesizing activities involving all substances in schedules I and II, schedule III narcotics, Gamma-Hydroxybutyric Acid (GHB) substances in schedule III, and selected psychotropic controlled substances in schedules III and IV.

Distributors of bulk and/or dosage form controlled substances must report inventories, acquisitions, and dispositions of all substances in schedules I and II, schedule III narcotics, and Gamma-Hydroxybutyric Acid (GHB) substances in schedule III. Once the substance has been sold to the retail level registrant, ARCOS does not capture further transaction information (i.e., from practitioner to end user, from pharmacy to end user, etc.).

<sup>7</sup> 2010 Monitoring the Future Study. University of Michigan, Ann Arbor.

<sup>8</sup> Substance Abuse and Mental Health Services Administration, 2009 National Survey on Drug Use and Health.

<sup>9</sup> Hansen, RN et al. 2011. “Economic costs of non-medical use of prescription opioids. *Clinical Journal of Pain*, Mar-April; 27(3):194-2-2.

### The Quota System

DEA establishes manufacturing and procurement quotas each year for schedule I and II controlled substances in order to avoid the overproduction of these substances, for the purpose of reducing the risk of diversion to illicit traffic. Accordingly, the quota system serves the vital purpose of reducing the risk of diversion. Pursuant to 21 U.S.C. § 826(a), the Attorney General is required to determine "the total quantity and establish production quotas for each basic class of controlled substance in schedule I and II . . . to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks." These determinations, which are known as aggregate production quotas, "represent those quantities of controlled substances that may be produced in the United States in" the relevant calendar year. The aggregate production quota is then allocated among those registered manufacturers who apply for, and demonstrate a need for, a manufacturing quota.

Pursuant to DEA regulation, a registrant seeking a manufacturing quota is required to submit an application form justifying the quantity it seeks to manufacture. The completed form must provide, for the particular basic class, the data for the current and preceding 2 calendar years to include: 1) its authorized individual manufacturing quota; 2) the actual or estimated quantity manufactured; 3) the actual or estimated or net disposal; 4) the actual or estimated inventory allowance; and 5) the actual or estimated inventory as of December 31. In addition to the desired individual manufacturing quota which is being sought, the applicant is required to state any additional factors which the applicant finds relevant to the fixing of his individual manufacturing quota, including the trend of (and recent changes in) his and the national rate of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

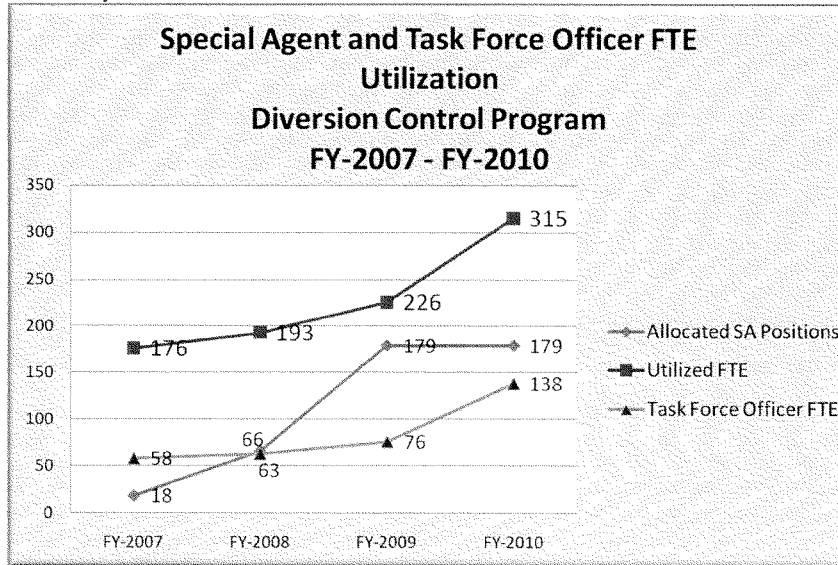
### Restructuring

The substantial increase in the abuse of prescription drugs is fueled by many factors, including the development and marketing of new controlled substances, and ever-changing methods of diversion such as rogue Internet pharmacy schemes or rogue pain clinics. Attempts to prevent, detect, and reduce the diversion and abuse of controlled substance pharmaceuticals continue to evolve. The DEA has taken action on several fronts over the past few years to help reduce this growing problem.

In October 2008, the then Acting Administrator authorized a two-pronged reorganization of the Diversion Control Program. The first prong involved a substantial expansion in the number of Tactical Diversion Squads (TDS) and their deployment throughout the United States. This approach would provide a significant increase in the number of Special Agents and Task Force Officers who possess the requisite law enforcement authorities needed when conducting criminal investigations, i.e. the ability to conduct surveillance, make arrests and execute search warrants. The second prong of the reorganization plan called for a renewed focus on DEA's regulatory oversight of more than 1.3 million DEA registrants.

**Expansion of Tactical Diversion Squads**

Tactical Diversion Squads (TDS) investigate suspected violations of the Controlled Substances Act and other appropriate Federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and Task Force Officers (who come from a variety of state and local law enforcement agencies). TDS groups are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shopping," prescription forgery rings, and doctors or pharmacists who illegally divert controlled substance pharmaceuticals and listed chemicals). Tactical Diversion Squads develop sources of information and disseminate intelligence to appropriate elements for the development of leads and targets. As of May 13, 2011, DEA has 37 operational TDS groups. DEA plans to add 26 more TDS groups over the next few years. With the expansion of Tactical Diversion Squads across the U.S., the number of diversion-related criminal cases has increased. These Tactical Diversion Squads have also been able to increase the number of diversion-related Priority Target Organization (PTO) investigations. PTO investigations focus on those criminal organizations or groups that significantly impact local, regional or national areas of the country. In addition, the Special Agent (SA) and Task Force Officer (TFO) work hours dedicated to diversion-related criminal cases has also increased dramatically.



### Changes in Regulatory Investigations

As stated above, the second prong to the reorganization plan was to provide for enhanced regulatory oversight of more than 1.3 million registrants, a number which grows at an annual rate of approximately 2.5 percent. These registrants conduct a variety of business activities and vary in size and complexity. This portion of the plan required DEA to hire additional Diversion Investigators (DI) and create a new training curriculum. In FY 2009, the Office of Diversion Control developed and instituted this new training curriculum, which was designed to retrain and retool all Diversion Investigators in regulatory investigations. As of December 2010, all Diversion Investigators completed this training.

With more Diversion Investigators focused on the regulatory aspects of the Diversion Control Program, DEA increased the frequency of scheduled inspections to improve its regulatory oversight. As a result, the President's FY 2011 budget request of 60 more DI positions was authorized, and the FY 2012 budget requests an additional 50 DI positions. This renewed focus on regulatory control has enabled DEA to take a more proactive approach on multiple fronts to ensure that DEA registrants are complying with the Controlled Substances Act and implementing regulations. For example, DEA has revised its timetable regarding the frequency with which it will inspect/audit specific registrant categories such as controlled substance manufacturers (which includes bulk manufacturers); distributors; importers; exporters; narcotic treatment programs; DATA-waived practitioners; researchers; and chemical handlers.

DEA's efforts are also aimed at ensuring that DEA registrants maintain effective controls against diversion by designing and operating systems that disclose to the registrant suspicious orders for controlled substances. In 2005, DEA established the Distributor Initiative Program to remind distributors of their responsibilities under the CSA and its implementing regulations concerning suspicious orders. Since its inception in August 2005 through May 13, 2011, DEA has briefed 75 DEA-registered corporations/companies comprising 215 distribution centers concerning illegal Internet pharmacy operations and rogue pain clinics. As a result, some distributors have voluntarily stopped selling or voluntarily restricted sales of controlled substances to certain domestic pharmacies and practitioners. Some distributors have also cut off the supply of controlled substance pharmaceuticals to certain customers as a result of their own intensified efforts spurred by the Distributor Initiative Program. From June 2006 through May 13, 2011, distributors have refused to sell controlled substances to approximately 1,517 customers that the distributors believed were placing suspicious orders for controlled substances.

DEA's enhanced regulatory oversight and investigative efforts have resulted in the identification of various distributors who failed to adhere to their regulatory responsibilities. Consequently, DEA took administrative action against these distributors, and also referred them for civil penalty action which resulted in record-breaking civil penalties negotiated with the registrant, e.g., \$13.25 million civil penalty paid by McKesson Drug Corporation in April 2008; \$34 million civil penalty paid by Cardinal Health in October 2008; and \$75 million civil penalty in addition to \$2.6 million in civil forfeitures against CVS Corporation in October 2010. And in April 2011, the Harvard Drug Group agreed to pay a civil penalty of \$8 million.

**Addition of Intelligence Research Specialist Positions**

Due to the ever-increasing complexities of diversion investigations, another much-needed enhancement to the Diversion Control Program was the addition of Intelligence Research Specialists dedicated to working these types of investigations. Before FY 2006, the Diversion Control Program had no authorized Intelligence Research Specialist (IRS) positions allocated to the Program. In FY 2006, 40 IRS positions were allocated to the DCP with another 33 allocated in FY 2007. Even with this increase in positions, more IRS work hours are attributed to the Diversion Control Program than are allocated. As a result, DEA requested and was authorized to increase by 14 IRS positions in the Diversion Control Program in FY 2011. In addition, another increase of 9 IRS positions is requested in FY 2012. The inclusion of this job series into the Diversion Control Program will help DEA conduct its investigations more efficiently and effectively.

**Level of Effort by Drug Type**

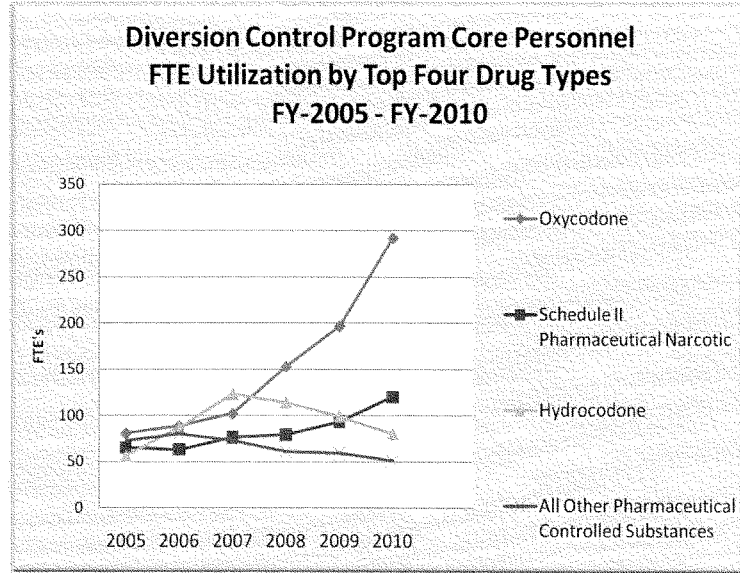
The restructuring of the Diversion Control Program has allowed investigative efforts to focus on specific problem areas, as shown in the charts below. For example, cases focused on oxycodone increased by 210 percent between FY 2005 and FY 2010, but have decreased for those involving hydrocodone, due to a significant decrease in domestic rogue internet pharmacies.

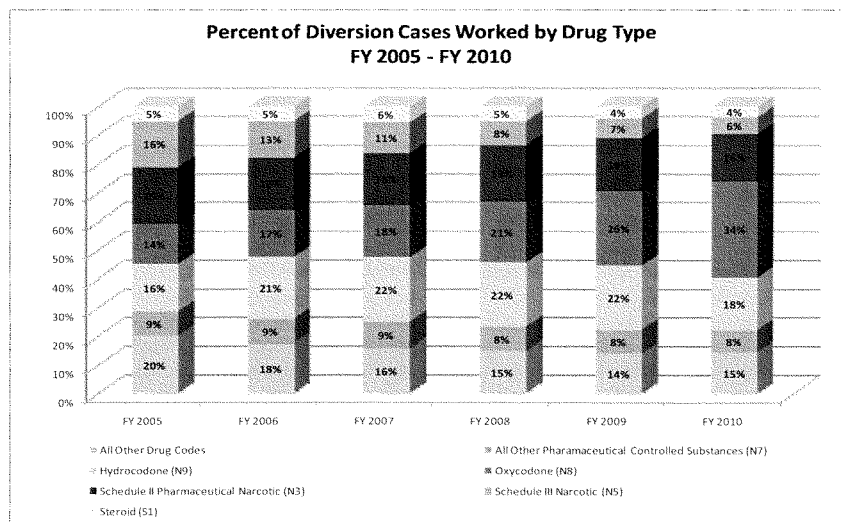
Between fiscal years 2006 and 2009, rogue Internet pharmacies were a major source of diversion. The rogue Internet pharmacies were responsible for the diversion of tens of millions of dosage units of hydrocodone. DEA responded to these rogue operations with investigations such as *Operation Baywatch*, *Operation CyberRx*, *Operation Lightning Strike*, *Operation TexRx*, and *Operation Control/Alt/Delete*. Although many domestic rogue Internet pharmacies that distributed controlled substances were eliminated after the Ryan Haight Act was implemented in April 2009, the problem has not been resolved with regard to foreign-based Internet pharmacies, and we continue to take steps to address it. In addition, rogue domestic Internet pharmacies selling mostly non-controlled substance and exempted<sup>10</sup> prescription drugs, including Carisoprodol, Tramadol, and what are commonly known as "lifestyle drugs," continue to pose a significant challenge.

What followed in the wake of these rogue Internet pharmacies was an almost immediate shift in the method of diversion and the type of pharmaceutical drugs being diverted. Today, a plethora of rogue pain clinics line the streets of south Florida. They supply drug seekers and pill distributors from up and down the entire East Coast with dangerous and powerful pharmaceuticals. Within these pill mills, the legitimate practice of medicine has given way to unadulterated greed. However, unlike the rogue Internet pharmacies, the practitioners at these rogue clinics are not dispensing hydrocodone, a schedule III controlled substance. They are dispensing and prescribing oxycodone, a schedule II controlled substance.

<sup>10</sup> "Exempted prescription products" are prescription drugs that contain certain nonnarcotic controlled substances yet are exempt from some provisions of the Controlled Substances Act. 21 C.F.R. § 1308.32. One example of an exempted prescription product is butalbital (brand name Fioricet), which would otherwise be a schedule III controlled substance because it contains a derivative of barbituric acid.







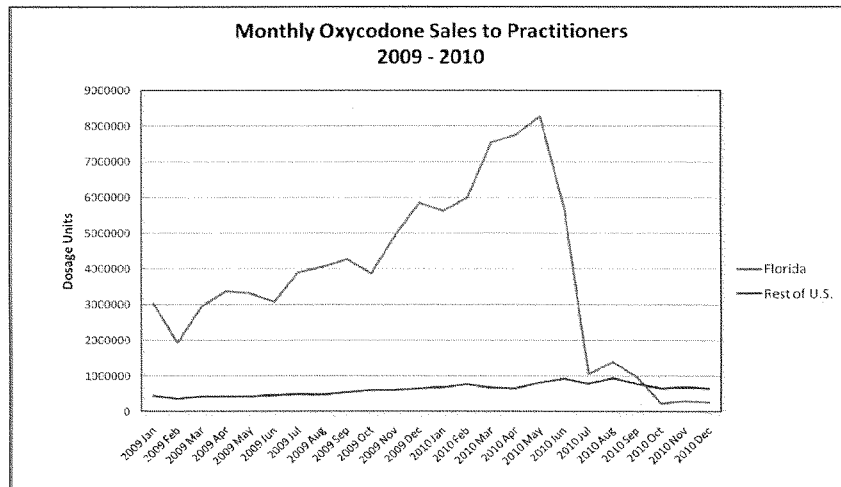
DEA, working with its state and local partners, has put forth a substantial investigative effort towards these rogue clinics which has been dubbed *Operation Pill Nation*. This operation involved the mobilization of eleven Tactical Diversion Squads from across the United States to marshal with the Miami TDS and other state and local agencies in a concerted effort to attack and dismantle the hundreds of rogue pain clinics that continue to plague south Florida. On February 23, 2011, as part of *Operation Pill Nation* DEA conducted a coordinated effort with more than 500 state and local law enforcement officers in a massive takedown which included:

- o 21 search warrants executed at clinics, residences, and other locations in south Florida;
- o 25 arrested on various federal and state drug and money laundering charges, of which 5 were medical doctors and 5 were pain clinic owners;
- o Seizure of approximately \$7 million in assets (\$3 million dollars in US currency and a variety of other real property, jewelry, and assets including 62 vehicles, some of which were exotic cars); and
- o Immediate Suspension Orders issued against 14 DEA registrations, 1 Order to Show Cause issued against 3 DEA registrations, and the surrender of 7 DEA registrations.

As of April 12, 2011, *Operation Pill Nation* has resulted in the surrender of 83 DEA registrations (71 physicians, 8 pharmacies and 4 wholesale distributors); Immediate Suspension Orders issued against 63 DEA registrations (held by 37 physicians, 1 distributor); Orders to Show Cause issued against 6 DEA registrations; 38 clinics closed; and 32 arrests (12 physicians, 5 clinic owners and 15 clinic employees). Additionally, more than \$16.4 million in assets have been seized thus far as a result of this operation (\$11.9 million in US currency and approximately

\$4.5 million in vehicles, jewelry, real property, and other assets). One of the wholesale distributors has agreed to pay a civil fine of \$8 million.

One component of the strategy for *Operation Pill Nation* is to identify the wholesale distributors that are supplying the controlled substances to these rogue pain clinics. In June 2010, DEA took administrative action against four wholesale distributors that were supplying rogue pain clinics in south Florida. Subsequent to that action, sales of oxycodone to dispensing practitioners in Florida plummeted. Florida also implemented legislation (effective October 2010) that limits a practitioner's ability to dispense controlled substance medications to what a patient would need in a 72-hour period.



In addition to *Operation Pill Nation*, Tactical Diversion Squads and Diversion Groups across the United States continue to investigate large-scale diversion schemes. These investigations often result in the immediate suspension, revocation, or surrender of a registrant's DEA registration and in many cases in parallel civil and criminal proceedings.

*The Family Medicine Cabinet & Proper Disposal*

Another factor that contributes to the increase of prescription drug abuse is the availability of these drugs in the household. 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 illegal distribution 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 NSDUH

indicates that 70 percent of Americans 12 and older who used pain relievers non-medically in the past year obtained the drugs from a friend or relative.<sup>11</sup> The Administration recognizes the issue of prescription drug abuse as described in the *National Drug Control Strategy*. One of the action items set forth in the Strategy is to increase prescription return/take-back and disposal programs.<sup>12</sup>

On September 25, 2010, DEA coordinated the first-ever National Take-Back Initiative. Working with more than 3,000 state and local law enforcement partners, take-back sites were established at more than 4,000 locations across the United States. This massive undertaking resulted in the collection of 121 tons of unwanted or expired medications that were summarily disposed of.

In October 2010, Congress passed and the President signed into law the Secure and Responsible Drug Disposal Act of 2010. DEA has been working diligently to promulgate the regulations pertinent to this Act. On January 19 and 20, 2011, DEA conducted a public meeting to discuss the development of procedures for the surrender of unwanted controlled substances by ultimate users and long term care facilities. Specifically, this meeting allowed all interested persons—the general public including ultimate users, pharmacies, law enforcement personnel, reverse distributors, and other third parties—to express their views regarding safe and effective methods of disposal of controlled substances. The Act and implementing regulations will provide the basic framework that will allow Americans to dispose of their unwanted or expired controlled substance medications in a secure and responsible manner.

DEA is working diligently to promulgate disposal regulations. In the interim, DEA launched a second National Take-Back Initiative on April 30, 2011. Americans participating in the DEA's second nationwide event turned in more than 376,593 pounds (188 tons) of unwanted or expired medications for safe and proper disposal at the 5,361 take-back sites that were available in all 50 states, plus Guam, Puerto Rico, and in the U.S. Virgin Islands. This is 55 percent more than the 242,000 pounds (121 tons) the public brought in during last September's event.

The DEA's Take-Back events are a significant piece of the White House's prescription drug abuse prevention strategy released last month by the White House Office of National Drug Control Policy (ONDCP). Purging America's home medicine cabinets of neglected drugs is one of four action areas, or pillars, for reducing prescription drug abuse and diversion laid out in *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. The other pillars include education of health care providers, patients, parents and youth; establishing prescription drug monitoring programs in all the states; and increased enforcement to address doctor shopping and pill mills.

Numerous national organizations joined the DEA and its state and local partners in putting on last April's Take Back Day, including ONDCP; the American Association of Poison Control Centers; the Community Anti-Drug Coalitions of America; D.A.R.E. America; the

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<sup>11</sup> Substance Abuse and Mental Health Services Administration. Results from the 2009 National Survey on Drug Use and Health.

<sup>12</sup> 2010 National Drug Control Strategy, p. 32

Federation of State Medical Boards; various agencies of the U. S. Department of Health and Human Services; the International Association of Chiefs of Police; the National Association of Attorneys General; the National Family Partnership; the National Organization of Black Law Enforcement Executives; the National Association of Boards of Pharmacy; the National District Attorneys Association; the National Sheriffs' Association; and The Partnership at Drugfree.org.

*Conclusion*

Prescription drug abuse is a serious problem. DEA has the statutory responsibility of enforcing the Controlled Substances Act and its implementing regulations. Efforts towards this end help to minimize the availability of pharmaceutical controlled substances to non-medical users and preserve the integrity of the closed-system of distribution. Reducing prescription drug abuse is vital to the health and welfare of the American people and is a priority for this Administration.

Chairman Whitehouse, Ranking Member Kyl, and distinguished Members of the Subcommittee, thank you for the opportunity to appear today to discuss this important issue.



WWW.NCPA.NET.ORG

**Statement of the  
National Community Pharmacists Association**

**Responding to the Prescription  
Drug Epidemic:**

*Strategies for Reducing Abuse, Misuse, Diversion, and Fraud*

**U.S. Senate Committee on the Judiciary  
Subcommittee on Crime and Terrorism**

May 24, 2011

Chairman Whitehouse, Ranking Member Kyl and Members of the Subcommittee, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share the community pharmacy perspective regarding issues relating to the dangers of prescription drug diversion. NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises, and chains. Independent pharmacies are often located in rural and underserved areas.

**Importance of Access to Effective Pain Treatments for Appropriate Patients**

Community pharmacists recognize the importance of addressing the serious problem of prescription drug diversion and abuse. NCPA encourages community pharmacists to commit themselves to supporting national and local efforts to prevent the abuse of both prescription and non-prescription drugs, while at the same time recognizing that Congress should not diminish access to effective pain treatments for people who need them.

According to statistics from the Centers for Disease Control and Prevention, pain is a serious and costly public health issue, impacting 76.5 million Americans.<sup>1</sup>

<sup>1</sup> National Center for Health Statistics Report: Health, United States, 2006, Special Feature on Pain

100 Daingerfield Road  
Alexandria, VA 22314-2888  
(703) 683-8200 PHONE  
(703) 683-3619 FAX

THE VOICE OF THE COMMUNITY PHARMACIST

Community pharmacists play an integral role in assuring that these patients have timely access to opioids and in the process provide vital counseling to ensure that these medications are not misused, abused or diverted. The fact that nearly 70 percent of prescription drug abusers obtain prescription drugs from the family medicine cabinet or friends should serve as a vital reminder that efforts to curb abuse and diversion must be focused on proper disposal of these products.<sup>2</sup>

#### **From Dispensing to Disposal – Pharmacists & Pharmacies Are Valuable Resources**

NCPA has long supported efforts to properly dispose of unused, unwanted or expired medication through safe, secure and environmentally responsible take-back programs. In 2009, NCPA joined the national effort to find sensible solutions by creating a prescription drug disposal program for our members. Consumers want ongoing, convenient and clear disposal options. Consumer surveys demonstrate that local pharmacies are the most convenient locations to which consumers seek to return unused or expired medicines.<sup>3</sup>

The NCPA Prescription Disposal Program, Dispose My Meds, highlights the pharmacist's role as a respected and knowledgeable resource on medications. Pharmacies participating in the Dispose My Meds program are not allowed to take back controlled substances. In the past year alone, the Dispose My Meds program has collected well over 25,000 lbs. of unused/expired *non-controlled* medications.

The intent of the *Secure and Responsible Drug Disposal Act of 2010* is to encourage the Attorney General to establish regulations which prevent the diversion of controlled substances, but still "allow public and private entities to develop a variety of methods of collection and disposal of controlled substances."

NCPA has clearly stated our position to DEA that community pharmacies, as both state and DEA licensed entities, provide a safe and viable outlet for consumers to dispose of unwanted controlled substances, and that those pharmacies who volunteer to participate in take-back programs should be considered by the DEA as appropriate locations to receive unused controlled substances. NCPA is currently surveying the extent and type of medication waste in households, in relation to our disposal program.

Last year's survey results showed that a disproportionate percentage of returned medications come from mail order pharmacies, which could be contributing to the problem. Also, programs that automatically ship medications to patient homes which are utilized in some prescription benefit programs may result in intentional or unintentional stockpiling.

Community pharmacists stand ready to assist in efforts to better understand the issues surrounding unused medications and look forward to gathering more robust data if our members' pharmacies become legal outlets to receive unused controlled substances.

<sup>2</sup> The Treatment Episode Data Set; The TEDS Report. July 15, 2010.

<http://oas.samhsa.gov/2k10/230/230PainRelvr2k10.htm>

<sup>3</sup> January 2006 Washington Citizens for Resource Conservation (WCRC) SoundStats® Report

**Illegal Internet Pharmacies Continue to Contribute Significantly to Drug Diversion**

Purchasing prescription drugs without a prescription remains a viable option as illegitimate drug distributors continue to host Web sites that will ship drugs to anyone regardless of their need for the drug. Many of these Web sites dispense medications without a valid prescription, as required by the Federal Food, Drug, and Cosmetic Act. Rogue, illegitimate drug trafficking operations are anathemas to legitimate independent community pharmacies. They are hazardous to patient safety, and create among both the general public and policymakers undeserved negative impressions of pharmacists and the valuable practice of pharmacy.

While not infallible, additional checks and balances are in place when a licensed pharmacist directly provides the patient's medication to the patient. NCPA supports efforts to control illegal distribution of controlled substances outside of the community pharmacy setting and strongly recommends that increased emphasis and meaningful oversight be placed on these illicit entities.

**Role of the Community Pharmacist in Efforts to Prevent Drug Diversion**

NCPA supports and plays a primary role in several efforts that serve to decrease prescription drug misuse, abuse and diversion. These efforts include appropriately structured FDA Risk Evaluation and Mitigation Strategies (REMS), prescription drug monitoring programs, and educational programs for our members focused on appropriate pain management. In addition, NCPA members are actively engaged in electronic prescribing, which can help to alleviate some of the problems with drug diversion once systems comply with DEA requirements.

**Conclusion**

NCPA is committed to working with Members of Congress—and state and local law enforcement officials—to combat the inappropriate use and diversion of prescription drugs and is committed to working towards sensible solutions. Thank you for your time and for the opportunity for us to share the viewpoints of independent community pharmacy.



**PAIN CARE COALITION**

*A National Coalition for Responsible Pain Care*

American Academy of Pain Medicine • American Headache Society • American Pain Society  
American Society of Anesthesiologists

**BY HAND DELIVERY**

May 20, 2011

The Honorable Sheldon Whitehouse  
Chair, Subcommittee on Crime and Terrorism  
Committee on the Judiciary  
United States Senate  
717 Hart Senate Office building  
Washington, DC 20510

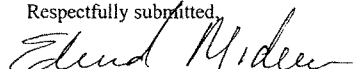
**Re: June 24, 2011 Hearing on Responding to the Prescription Drug  
Epidemic: Strategies for Reducing Abuse, Misuse, Diversion, and  
Fraud**

Dear Senator Whitehouse:

The Pain Care Coalition applauds the Subcommittee for holding an important hearing on recently announced Administration initiatives to combat the growing public health problem of prescription drug abuse. The pain care professionals we represent believe firmly that a comprehensive approach to the problem is necessary if effective solutions are to be found. We offer the enclosed Statement and Recommendations for the Subcommittee's consideration. We ask that both be included in the record.

The Coalition stands ready to work with you and others on the Subcommittee to advance policies that responsibly balance the need to deter the abuse and diversion of powerful pain drugs, while maintaining access to essential pain medications and other therapies for patients in need. If we can be of assistance to you and your staff in any way, please contact us at any time.

Respectfully submitted,

  
Edward Michna, MD, JD, BS Pharm.  
Chair

Attachments

## PAIN CARE COALITION

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*A National Coalition for Responsible Pain Care*

American Academy of Pain Medicine • American Headache Society • American Pain Society  
American Society of Anesthesiologists

### PCC STATEMENT ON ABUSE AND DIVERSION

OF

### CONTROLLED SUBSTANCES

The Pain Care Coalition applauds efforts by Federal policy makers to address the misuse of prescription painkillers, particularly opioids regulated under the Controlled Substances Act. Abuse and diversion of these powerful drugs are serious public health problems with potentially tragic consequences for individuals, their families and their communities. The problem has escalated rapidly in recent years, particularly among young people, and has now reached epidemic proportions in some parts of the country. Aggressive action is required, and required now. Cooperation between and among stakeholders in the public and private sectors, and at the Federal, state and local level, will be essential to turn the tide. The health care professionals represented in the Pain Care Coalition are committed to playing a leadership role in the search for and implementation of responsible solutions.

At the same time, the fight against abuse and diversion must preserve access by clinicians and patients to these drugs for those who need them. Opioids are just one therapeutic option for individuals afflicted with acute or chronic pain. They are not appropriate for all patients or all pain disorders, and thus require careful and experienced clinical judgment on a patient-by-patient basis. But for millions of Americans, they are an appropriate option, when appropriately used under clinical supervision, to restore function and quality of life. Indeed, for many, they are the only currently effective therapeutic option. Thus, it is vitally important that the fight against opioid abuse be balanced with the continuing fight for effective pain management.

Pain is a huge public health problem in the United States. The Centers for Disease Control estimates that 76 million people are afflicted every year--more Americans than are affected by diabetes, heart disease and cancer combined. Given the prevalence of pain, and the terrible suffering of patients when pain is not effectively treated, it is simply not responsible public policy to take effective therapies "off the table."

The causes of prescription drug misuse are complex, and finding solutions will demand multidimensional approaches. The Pain Care Coalition believes that the following elements must

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be included in a comprehensive response if that response is to have a reasonable prospect for success:

- A concerted campaign of **public education** emphasizing both responsible pain management and the dangers of abusing painkillers for non-medical purposes;
- Improved understanding and enhanced prescribing practices for **prescribers, dispensers, and other caregivers**;
- An effective national system of **prescription monitoring** for controlled substances;
- Increased **biomedical research** for alternative non-opioid therapies and **behavioral research** on substance abuse and addiction;
- **Payment and coverage** policies that facilitate access, without biasing clinical decision-making towards particular therapeutic options based solely on cost rather than long term benefit;
- New approaches to **safe drug disposal**; and
- **Aggressive enforcement** of existing laws.

The Pain Care Coalition's detailed recommendations in each of these areas are attached. The Coalition pledges its support for policy initiatives consistent with these recommendations, and stands ready to work actively for their enactment and implementation.

Attachment

## PAIN CARE COALITION

*A National Coalition for Responsible Pain Care*

American Academy of Pain Medicine • American Headache Society • American Pain Society  
American Society of Anesthesiologists

### ATTACKING ABUSE AND DIVERSION OF PRESCRIPTION DRUGS

#### RECOMMENDATIONS OF THE PAIN CARE COALITION

The Pain Care Coalition believes that the following elements are essential components of an effective public policy response to the growing problem of non-medical use of prescription painkillers.

#### 1. PUBLIC EDUCATION

Recommendation: DHHS should undertake a national public education campaign on pain management which includes information on (1) the role prescription opioids play as one therapeutic option for some patients with some conditions, (2) the safe use and disposal of such drugs, and (3) the risks to patients and society when such drugs are used for non-medical purposes or without appropriate clinical oversight.

Note: Legislation authorizing such a program has already passed the House of Representatives twice on a bi-partisan, non-controversial basis as part of the National Pain Care Policy Act. (See for example H.R. 756, 111<sup>th</sup> Cong.) Whether expressly authorized by Congress or undertaken administratively by the Executive Branch, a visible public awareness campaign could be initiated quickly, and would serve to reinforce other aspects of a comprehensive approach to the problem.

#### 2. PROFESSIONAL EDUCATION

Recommendation: (a) fund in FY 2012 and beyond section 759 of the Public Health Service Act.

Note: Congress has already authorized, through section 4305 (c) of Pub. L. 111-148, a modest education and training program to improve the academic infrastructure for multi-disciplinary pain care training, including the responsible use of opioids in clinical practice. This program could be implemented immediately by the Health Resources and Services Administration at DHHS if funds were appropriated for it.

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Recommendation: (b) require demonstrated competence to support safe and effective clinical practice with respect to prescribing opioids and other controlled substances as part of pain management diagnosis and treatment.

Note: Most medical students and other health professionals receive insufficient training in both pain management and addiction medicine, including responsible prescribing practices, during their undergraduate and graduate training programs. There is a need for many to supplement core curricula through CME, particularly for primary care physicians. Since pain is a subjective complaint, practitioners need tools enabling them to effectively discern between the vast majority of patients that are truly experiencing pain, and the much smaller minority that seek pain drugs for illegitimate purposes. Ideally, demonstration of an adequate knowledge base in pain management should be linked to state medical licensure and enforced through state Boards of Medicine, and this is already happening in some states. In states where this is not required, the PCC would support a link to the prescriber's Drug Enforcement Agency registration status, via amendment to the Controlled Substances Act, **if**:

- Any linkage of competency testing or education to DEA registration is done on an all schedules basis. Permitting practitioners to "opt out" of new requirements by simply avoiding particular drugs or classes of drugs could reduce patient access to necessary pain management and increase overall public health risks;
- The core competencies and knowledge base requisite to safe and effective prescribing are developed by the professions with expertise in pain medicine and addiction medicine, free of industry bias. Instruments to demonstrate competence and knowledge, as well as CME offerings to achieve this level of understanding, are also developed by these professions;
- Program content is tailored specifically to the needs of different specialties and pain conditions and disorders. For example, primary care physicians seeing a wide range of pain conditions need training that differs somewhat from that appropriate to neurologists sub-specializing in migraine or neuropathic pain, or spine surgeons specializing in low-back pain;
- Competency testing or CME is delivered through professional societies or similar entities, alone or in collaboration with one another; and
- There is a level playing field permitting those appropriately credentialed in pain or addiction medicine to develop and deliver competency testing or CME within their areas of expertise, and without arbitrary distinctions based on historical anomalies in Board certification.

### 3. EXPANDED PRESCRIPTION MONITORING

Recommendation: The Federal NASPER program should be legislatively re-authorized, with improvements, and consistently funded.

Note: Effective prescription monitoring programs (“PMPs”) can be important tools for clinicians confronted with patients exhibiting addictive behaviors or otherwise seeking prescriptions of controlled drugs for non-medical purposes. They also further quality care by giving clinicians a more complete view of the patient’s prior or current drug use. Currently, PMPs are state-based programs operating under a Federal framework and with some Federal funding. They are, however, still just a patchwork of programs that are sometimes only as strong as the weakest link. For example, if one state has a mature program but a neighboring state has none, abusing patients will seek multiple prescriptions across state lines. Recent evidence suggests that problem “patients” will travel considerable distances to obtain supplies for illicit purposes, so that even PMP “interoperability” among neighboring states is not sufficient.

The PCC believes that NASPER provides the appropriate framework for state-based PMPs, but that it needs to be strengthened in several respects:

- It needs to be permanently authorized and funded;
- It needs stronger incentives for states not yet participating to “get on board;” and
- It should include a Federally-funded and managed, with appropriate privacy and security protections, national data base of controlled substance prescriptions that individual state PMPs can access in a “real time” electronic environment. The data base should be integrated with e-prescribing systems and protocols to the fullest extent possible.

#### 4. RESEARCH

Recommendation: (a) NIH, with Congressional support, should increase both basic and translational research funding directed at developing new pain management therapies

Note: Opioids are heavily prescribed for pain patients because (1) they are available and (2) at least for many patients and conditions, they work. They are also relatively inexpensive. (See 5 Below) Even practitioners knowledgeable about the adverse side-effects experienced by some patients, or concerned by the potential for abuse and diversion, are highly motivated to reduce patient suffering. Particularly in primary care environments, without specialized and sub-specialized pain management expertise, opioids are the obvious “tool in the toolkit.” Practitioners in all settings need more alternative tools, and finding them will require a significant increase in research efforts.

Despite the prevalence of pain as a public health problem, NIH spends less than 2 % of its research dollars in this field. Without a single NIH Institute or Center devoted to pain research, efforts are fragmented in many different research “silos” across the NIH. Recent efforts to better coordinate effort through the NIH Pain Consortium, and to encourage breakthrough research projects through the NIH “Common Fund,” are encouraging. They must be continued and amplified.

Just as research is critical to finding non-opioid medications and other therapeutic options, further bio-medical, behavior and population based research on drug dependence and addiction is required. The pending combination of two long standing institutes—NIDA and NIAAA—into one new entity must be implemented so as to increase, not dilute, existing efforts focused on prescription drug abuse. Similarly, SAMHSA funding must be maintained if its programs are going to realize their potential in this area.

## 5. PAYMENT AND COVERAGE POLICIES

Recommendation: The Centers for Medicare and Medicaid Services (“CMS”), with outreach to private payors, should do a comprehensive review of payment and coverage policies that may serve to promote opioid prescribing to the detriment of other therapies.

Note: As noted above, opioids are heavily prescribed because they are available, they work for many patients, and they are generally inexpensive relative to other therapeutic options. Their relatively low short term cost makes them attractive to payors. For this reason, other therapeutic options that may be superior for some patients and some conditions, that have fewer downside risks than opioids, and that may well be less expensive in the long run, face payment and coverage barriers. Ensuring appropriate payment for the most clinically appropriate therapeutic option should be part of any comprehensive approach to ensuring good pain management. Otherwise, a coverage or payment bias towards opioids may well substitute cheaper care for better care.

When opioid therapy is indicated, coverage and payment policies must support the other elements of comprehensive pain care that ensure **safe use**, including counseling services, aggressive monitoring through follow-up office visits, drug testing, and similar patient compliance-related services, and **effective use**, including behavioral, psychological and rehabilitative therapies, as well as other indicated medical and interventional approaches.

## 6. SAFE DRUG DISPOSAL

Recommendation: Congress should authorize a reverse drug distribution system, modeled on medical waste disposal laws, with pharmacies and/or hospitals as the repositories of choice for unused prescription medications.

Note: Both survey and anecdotal evidence suggest that many abusers and diverters of prescription opioids obtain their drugs from people they know, often family members, for whom the drugs have been legitimately prescribed. Fear of side effects from or potential addiction to opioids make patients reluctant to complete the full dose prescribed, just as patient convenience and fear of untreated pain make practitioners reluctant to prescribe what may turn out to be an insufficient course of drug therapy. The consequence of both is a large quantity of unused medication that lingers in family medicine cabinets when it should be promptly disposed.

Periodic drug “take back” events provide powerful opportunities for patient education, but they do not provide an ongoing mechanism for safe and convenient disposal of unused medication. Warnings labels that simply encourage the flushing of excess pills are environmentally questionable. Consumers need a simple and convenient “drop-off” point where drugs can be disposed of when they are ready to be disposed of, and not just once or twice a year when the next “take back” event is scheduled. Hospitals already are charged with dealing with dangerous medical and biological wastes under proven regulatory requirements. At least one state already uses this infrastructure for dealing with unused pharmaceuticals. Pharmacies are also a logical “drop off” point if similar regulatory requirements were developed. These models should be explored, with the ultimate objective being a uniform national solution.

## 7. ENFORCEMENT

Recommendation: Existing laws governing controlled substances, pharmacies, and medical practice must be vigorously enforced, and in a coordinated fashion, along with other prosecutorial tools frequently used against organized criminal activity.

Note: Recent “strike force” activities in South Florida and elsewhere demonstrate the effectiveness of existing law enforcement authorities, and call into question the need for expanded regulation of medical practices specializing in pain medicine. The PCC believes that recent experience with legislation directed at “pill mills” in Florida is instructive. By imposing financial and administrative burdens on legitimate pain programs that do write large numbers of opioid prescriptions due to the patient conditions being treated, and by producing certain unintended consequences for others that use very few opioids because of the different conditions they treat, these well-intended legislative responses have missed the mark.

The Federal Controlled Substances Act defines the legitimate medical use of opioids to include the treatment of pain and, with special waiver or licensing, the treatment of addiction. State Medical Boards have the regulatory authority to determine what constitutes appropriate medical practice within the standard of care in the treatment of pain and of addiction. The PCC doubts that operations accurately characterized as “pill mills” are legitimate medical practices in need of heightened supervision in order to bring them within the standard of care. Rather, they appear to be rogue physicians and pharmacists fronting for what may be much larger criminal enterprises. They should be treated by law enforcement just as any other drug distribution “ring” would be treated. Clinics or physicians whose legitimate intention is to treat pain or addiction, but whose practices fall outside the standards of care, should be addressed by existing quality improvement mechanisms, and ultimately by intervention of the State Medical Boards.



THE PARTNERSHIP  
AT DRUGFREE.ORG

Testimony of Steve Pasierb, President and CEO

The Partnership at Drugfree.org

*“Responding to the Prescription Drug Epidemic:  
Strategies for Reducing Abuse, Misuse, Diversion and Fraud”*

Subcommittee on Crime and Terrorism

United States Senate

May24, 2011

Chairman Whitehouse, Ranking Member Kyl, Members of the Subcommittee, thank you for inviting me to submit testimony about the problem about prescription drug abuse.

#### **Overview**

The Partnership at Drugfree.org is a nonprofit organization that helps parents prevent, intervene in and find treatment for drug and alcohol abuse by their children. My testimony today will be focused on teens and young adults since that population is the focus of the Partnership's work.

When the Partnership addresses prescription drug abuse, we also consider over-the-counter cough and cold remedies which some teens use to get high. The abuse of prescription medications and over-the-counter remedies are both examples of beneficial medications being used in risky, unhealthy ways. Because today's hearing is focused on the diversion of prescription drugs, I will restrict my remarks to the non-medical use of Rx medications.

The abuse of prescription medications – legal substances of tremendous benefit if used appropriately – is the single most troubling phenomenon on today's drug landscape. The misuse and intentional abuse of a diverse range of prescription medications has become a significant health threat and entrenched consumer behavior in American society.

According to the 2010 Partnership Attitude Tracking Study – or "PATS" study -- sponsored by the MetLife Foundation, teen abuse of Rx medicines continues to be an area of major concern, with abuse rates holding steady at levels that should be worrisome to parents. The data found one in four teens (25 percent) reported taking a prescription drug not prescribed for them by a doctor at least once in their lives, and more than one in five teens (23 percent) used a prescription pain reliever not prescribed for them by a doctor.

#### **Contributing Factors to Teen Prescription Drug Abuse**

Why have we as a nation not been able to reduce this risky behavior? There are several reasons:

1. **Access.** These substances are readily available to teens -- in their own medicine cabinets and the medicine cabinets of friends -- and very often they are available for free. The Partnership's data are similar to the findings of the National Survey on Drug Use and Health (NSDUH) which shows that over 70% of prescription drug abusers say that they got those drugs from family or friends. In addition, nearly half (47%) of teens in our PATS survey say that it is easy to get these drugs from parents medicine cabinets and more than a third (38%) say it is available everywhere..

That is why the Partnership worked with Abbott to create "Not In My House," a website to educate parents of teens about the need to monitor their medications, safeguard them and dispose of them properly when no longer needed.

It is also why we strongly supported both of the Drug Enforcement Administration's prescription drug "Take Back" days -- where they collected a total of more than 300 tons of pills from thousands of locations in all 50 states. If we are able to get people to properly dispose of unneeded medications, we can make a significant dent in the supply of prescription medications that are being abused.

The proliferation of "pill mills" in certain areas of the country -- where, for a price, individuals are able to obtain prescriptions for controlled substances without legitimate medical need -- is a growing concern. Closing pill mills, having interoperable prescription monitoring programs to curtail doctor shopping, and educating prescribers about both addiction and pain management would likely go a long way towards reducing the supply of these medications in America's medicine cabinets.

2. **Perception of Risk.** Teens' perception of the risks associated with abusing prescription drugs is relatively low. Partnership research shows that less than half of teens see "great risk" in trying prescription pain relievers such as Vicodin or Oxycontin that a doctor did not prescribe for them. The University of Michigan's "Monitoring the Future" survey data going back over thirty years demonstrates that teens' perception of the risk associated with any substance of abuse, along with perceptions of "social disapproval," correlates significantly with actual teen abuse of that substance. Low perception of risk, coupled with easy availability, is a recipe for an ongoing problem.
3. **Motivations.** Research conducted by the Partnership in 2007, with support from Abbott, cast new light on the motivations of teens to abuse prescription drugs. We have traditionally thought of teens abusing illegal drugs and alcohol either to "party", or to "self-medicate" for some serious problem or disorder: adolescent depression, for example.

But our 2007 research, like the research done among college students by Carol Boyd and Sean McCabe at the University of Michigan, suggests a wider range of motivations for young people's abuse of prescription drugs, including an emerging set of "life management" or "regulation" objectives. Teens appear to be abusing these drugs in a utilitarian way, using stimulants to help them cram for a test or lose weight, pain relievers to escape some of the pressure they feel to perform academically and socially, tranquilizers to wind down at the end of a stressful day. Once these substances have been integrated into teens' lives and abused as study or relaxation aids, it may become increasingly difficult to persuade teens that these drugs are unnecessary or unsafe when taken without a prescription.

This research also showed that prescription drug abuse is not a "substitute" behavior. That is to say, teens generally do not use prescription medication to get high *instead of* taking another substance. What we have found is that prescription drugs may act as a kind of "bridge" between the use of alcohol and marijuana, which many teens see as relatively benign substances, and harder "scarier" drugs such as cocaine.

4. **Parents.** Parents – who are usually our most valuable ally in preventing teen drug use – are generally ill equipped to deal with teens' abuse of prescription drug use, a behavior that was probably not on their radar when they were teenagers. They find it hard to understand the scale and purposefulness with which today's teens are abusing medications, and it's not immediately clear to them that the prime source of supply for abusable prescription drugs is likely to be their own medicine cabinet. Further, many parents themselves are misusing, or perhaps abusing, prescription drugs without having a prescription. In our study with Abbott, 28% of parents said they had used a prescription drug without having a prescription for it, and 8% of parents said they had given their teenaged child an Rx drug that was not prescribed for the teen. Our recent PATS study revealed that 22% of parents said there were situations where it would be OK for a parent to give a teen a prescription drug not prescribed for him or her.

Our 2010 PATS study also showed that teens continue to report that their parents do not talk to them about the risks of prescription drugs at the same levels of other substances of abuse. Fewer than one in four teens reported that a parent had discussed the risks of taking a prescription pain reliever (23%) or any prescription drug (22%) without a doctor's prescription. Contrast that to the relatively high number of teens who say their parents have discussed the risks of alcohol (81%) and marijuana (77%).

Much more work needs to be done to motivate parents to discuss the risks of prescription drug abuse with their teens. Partnership research through the years has demonstrated that kids who learn a lot at home about the risks of abusing drugs are half as likely to use. Encouraging these conversations and ongoing parental monitoring is key to reducing teen Rx abuse.

5. **Need to Do More.** Finally, the reason why we have not yet been able to reduce teen abuse of prescription medications is that our efforts as a nation have been inadequate, at least to date. There has simply not been sufficient public attention or resources devoted to this threat.

The backdrop to all of this is that the national drug prevention infrastructure has been eroding for the past few years as the budget for the National Youth Anti-Drug Media Campaign has shrunk significantly, the Safe and Drug Free Schools and Communities State Grant program has been eliminated, and changes have been proposed to the state prevention and treatment block grant that could put prevention funding in jeopardy. With dwindling resources, it is impossible for government alone to mount the kind of effort that is needed to turn the tide on this problem.

Director Kerlikowske, Administrator Leonhart, Commissioner Hamburg, Director Volkow and others have done an excellent job of calling attention to this problem, both within government and among the public. Director Kerlikowske identified Rx abuse as one of his top three priorities and his recently released Rx strategy is a road map to aggressively addressing the problem; the DEA prescription drug "Take Back" days have

begun the essential task of educating the public that old unneeded medication must not remain in the medicine cabinet; the FDA is putting the spotlight on this issue as part of the Safe Use Initiative; and NIDA is engaged in targeted research, education and outreach that will be critical to curbing this behavior. The Community Anti-Drug Coalitions of America and the Treatment Research Institute are also doing important work in this area and should be commended for their efforts.

We know that when there is a well-funded effort to educate parents about the dangers of Rx abuse, we can increase awareness. In the first half of 2008 ONDCP's National Youth Anti-Drug Media Campaign devoted \$14 million (a \$28 million value with the media match) to a parent-targeted campaign aimed at raising awareness about the risks of Rx abuse and motivating parents to take action. The campaign, which ran from February to July 2008, yielded significant and impressive results: parent perceptions about the prevalence of teen Rx abuse increased 10 percent and belief that it is a serious problem among teens jumped 17 percent. The likelihood that parents would take action also changed significantly: the number of parents who said that they would safeguard drugs at home increased 13%; monitor prescription medications and control access increased 12%; properly dispose of medications went up by 9%; and set clear rules about all drugs, including not sharing medications was up by 6%.

This shows that a major public education campaign can help to turn the tide on this entrenched behavior. The ONDCP Media Campaign's funding is in jeopardy and may even be eliminated in the coming year so we cannot assume that it will be able to help deliver this message. The private sector – pharmaceutical companies, generic drug manufacturers, wholesalers, distributors, retailers, etc – will need to help finance a campaign of the magnitude necessary to change the attitudes that underlie the behavior of nonmedical use of prescription medicine.

A number of individual pharmaceutical companies have stepped forward to work with the Partnership and other national organizations. Purdue Pharma funded some of our initial research to get our arms around this problem in 2004. They have also helped to fund a number of the parent intervention and treatment resources at drugfree.org as well as some of our community education efforts. Abbott underwrote the in-depth consumer research conducted in 2007 to assess the attitudes and beliefs underlying the behavior of prescription drug abuse. We also worked with them to create "Not In My House," a website designed to educate parents of teens to monitor their medications, secure them properly and properly dispose of them when no longer needed.

While we are grateful for the efforts of our partner companies, if our nation is going to reduce teen abuse of prescription medication we need to step up efforts dramatically. *We need a sustained, multi-year effort funded by the pharmaceutical industry, the generic drug manufacturers, pharmaceutical distributors, chain drug stores, healthcare providers and other key stakeholders to:*

- (1) support a major, independent paid media campaign alerting consumers to the risks of abusing medicine and the importance of safeguarding and safely disposing of medicine.

This effort might include tagging the pharmaceutical industry's large inventory of direct-to-consumer advertising and pointing viewers towards an objective and comprehensive online prevention resource;

- (2) educate and enlist prescribers, pharmacists and other healthcare professionals about addiction and pain management;
- (3) coordinate outreach by employees of all the relevant stakeholder companies and other interested parties to increase awareness about Rx abuse and disposal at the local level;
- (4) educate policymakers at the local, state and federal level about this problem so that we can promote policies that will help reduce both the supply of and demand for prescription drugs to abuse; and
- (5) implement an evaluation tool that will measure and hold the program accountable.

### **Conclusion**

We believe that the abuse of prescription medications – legal substances of great benefit when used properly – is the single most troubling phenomenon on today's drug abuse landscape. We remain committed to a long-term effort to educate the public on the risks of intentional medicine abuse and to reducing the level of abuse in society. We have laid important groundwork in this area but feel that there needs to be a major paid media and public relations campaign over the next five years in order to change the relevant attitudes and behavior of not only teens but also parents, policy makers, and prescribers. This effort must be focused not only on raising awareness about the risks of taking medications without a doctor's prescription but it must also be a call to action to all adults to take responsibility for what is in their medicine cabinets and dispose of unneeded prescriptions in a timely manner.

This education campaign needs to be accompanied by coordinated community education efforts and public policy changes. And, of course, it should be rigorously evaluated.

The misuse and intentional abuse of a diverse range of prescription medications has become a significant health threat and entrenched consumer behavior in American society.

We appreciate the time and attention that the Subcommittee is giving to raising awareness and looking for ways to reduce the abuse, misuse and diversion of prescription drugs in our country. The Partnership at Drugfree.org stands ready to work with the Subcommittee on this and other substance abuse matters.

**About The Partnership at Drugfree.org**

The Partnership at Drugfree.org is a nonprofit organization that helps parents prevent, intervene in and find treatment for drug and alcohol use by their children.

By bringing together renowned scientists, parent experts and communications professionals, we not only translate current research on teen behavior, addiction and treatment into easy to understand, actionable resources at drugfree.org, but we offer hope and help to the parents of the 11 million teens and young adults who need help with drugs and alcohol.

Our website allows parents to connect with each other, tap into expert advice and find support in their role as hero to their kids.

And, across the nation via our community education programs, we have trained more than 1,500 professionals who are working daily with local leaders, concerned citizens, parents and teens — in neighborhoods, schools, civic organizations, community centers and churches — to deliver research-based programs designed to help communities prevent teen drug and alcohol abuse.

**Senator Jay Rockefeller**  
**Statement for the Record**  
**Senate Judiciary Subcommittee on Crime and Terrorism**  
**Hearing on “Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse, Diversion, and Fraud”**  
**May 24, 2011**

Chairman Whitehouse, Ranking Member Kyl, and Members of the Subcommittee:

Thank you for holding this hearing and for your commitment to addressing the fastest growing drug problem in America: the rapid increase in deaths and overdoses from prescription drug abuse. A comprehensive and collaborative approach – encompassing prevention, treatment, and law enforcement – is critical to solving this devastating problem.

Prescription drug abuse has rapidly become one of America’s most pressing public health concerns. Prescription drug abuse poses a unique and multifaceted challenge that spans clinical research, medical practice, public health, law enforcement, and social services, including child welfare. My home state of West Virginia has been hit particularly hard with the highest drug overdose death rate in the nation. Nine out of ten of those deaths were due to prescription drugs. But I know that every state is struggling with this serious problem.

More than 27,000 people died from drug overdoses in the United States, a number that has risen five-fold since 1990 and has never been higher. That equates to one death every 19 minutes. Recent reports from the Centers for Disease Control and Prevention (CDC) show that prescription drugs are the second most commonly abused category of drugs, behind marijuana and ahead of cocaine, heroin, methamphetamine, and other drugs.

The primary cause for this increase in prescription drug overdose deaths is from a class of prescription painkillers called opioids. Deaths from opioids have skyrocketed in the last decade. Opioid overdoses have caused more than 11,000 deaths in 2007 alone –more than heroin and cocaine combined -- and visits to emergency departments for opioid abuse more than doubled between 2004 and 2008. Moreover, these deaths may be underreported because there is no comprehensive reporting system for opioid-related deaths in the United States.

In the last twenty years, there has been at least a ten-fold increase in the medical use of opioid painkillers. Let there be no doubt: there is a clear and pressing need for effective clinical pain management, whether for acute pain or for chronic pain caused by illness, injury, or a lifetime of work in labor-intensive jobs. However, the legitimate need for pain management must be accompanied by effective measures to reduce misuse, overdose, and diversion of these powerful prescription drugs. Physicians and other health care professionals are not routinely trained in evidence-based pain management; indeed, fewer than half of physicians have received any training in medical school in identifying prescription drug abuse or drug diversion. Many physicians who obtain a license from the Drug Enforcement Agency to prescribe narcotics have probably never been trained in the pharmacology of the medications and the addictive powers of these medications, because there is no training requirement for obtaining a license to prescribe these prescription drugs.



Unlike other types of prescription drugs, pain killers pose a significant challenge to health care practitioners trying to distinguish between people in real pain and people seeking painkillers illegitimately. State prescription drug monitoring programs, such as the National All Schedules Prescription Electronic Reporting Program (NASPER), are a critically important tool to help physicians identify patients who are “doctor-shopping” for prescription painkillers. However, these programs have been woefully underfunded at the federal level and are not always fully utilized by prescribers. Additionally, patients who receive prescriptions for legitimate injuries and serious pain may not be fully aware of the addictive nature of these drugs, and may not have the means to seek professional treatment for their addictions. Nationwide, access to substance abuse treatment is severely lacking, especially in special situations like families needing residential treatment, teens, or in cases where the person addicted to painkillers is also a victim of domestic violence.

Law enforcement agencies also face significant challenges, as barriers to appropriate prevention and treatment are complicated by the rampant and lucrative market for illegitimately obtained prescriptions – both within and across state lines. In a telling, but tragic, sign of the times, the routes to Florida are now referred to the “OxyContin Express” because they are well-travelled by drug traffickers and people seeking pain medication in Florida, who then bring them back to sell or use in Appalachia.

While I am saddened to see the staggering statistics associated with prescription drug abuse, I am encouraged that there is genuine interest and a renewed commitment to addressing this problem, and I applaud this Subcommittee for exploring solutions to curbing this epidemic.

In February 2011, I met with Director Kerlikowske and a diverse group of stakeholders in West Virginia to talk about the impact of prescription drug abuse on our children and youth. On March 8, 2011, I introduced legislation in the Senate that would help curb the abuse and misuse of painkillers. The Prescription Drug Abuse and Prevention Act of 2011 (S. 507) offers a comprehensive approach that will address prescription drug abuse on a number of fronts. This legislation calls for new training requirements for health care professionals before they can be licensed to prescribe these powerful drugs; consumer education on the safe use of painkillers and how to prevent diversion and abuse; basic clinical guidelines for safe use and dosage of pain medications; increased federal support for state prescription drug monitoring programs; and comprehensive reporting of opioid-related deaths that would help guide more effective solutions.

I am also encouraged by the Administration’s National Action Plan, “Epidemic: Responding to America’s Prescription Drug Abuse Crisis.” This plan calls for a comprehensive approach to prescription drug abuse, including mandatory provider education, better tracking and monitoring prescriptions through state-based electronic databases, and proper and convenient disposal of unused medication. Additionally, the plan highlights the importance of partnerships with law enforcement to successfully crack down on pill-mill operators, illegal interstate trafficking, and other criminal violations.

In closing, we must find a balance: ensuring appropriate access to prescription medications while keeping them out of the wrong hands. I thank the Subcommittee for calling attention to this critical issue and look forward to our continued attention to finding real solutions.



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Earl Ray Tomblin  
Governor

Bureau for Behavioral Health and Health Facilities  
350 Capitol Street, Room 350  
Charleston, WV 25301  
Phone: 304-558-0627 Fax: 304-558-1008

Michael J. Lewis, M.D., Ph.D.  
Cabinet Secretary

May 24, 2011

Dear Chairman Whitehouse and Members of the Subcommittee:

Greetings from West Virginia, the 35<sup>th</sup> state, a state fully embedded in Appalachia and filled with men, women and children whose culture is synonymous with caring, kindness, a hard day's work and simplicity. In recent years our state, like many others in our country, has been confronted by the complexities and devastating impact of prescription drug misuse and abuse. For many of us, one of our worst nightmares is losing a loved one in an automobile accident. For West Virginians, our fears are taking a new shape as we are losing more mothers, fathers, sons and daughters to drug overdoses than automobile accidents. Drug overdose is the leading cause of accidental deaths in the State. Furthermore, West Virginia has the nation's highest rate of drug related deaths.

- ✦ *Drug overdoses now kill more West Virginians each year than car accidents do.*
- ✦ *The greatest increases of deaths from drug overdoses are not in urban but rural areas.*
- ✦ *In a five year span from 1999-2004 deaths resulting from drug overdose in West Virginia rose 550 percent. This was the largest increase for any state in the country and is the leading cause of accidental death in the state.*

Over the past couple of years, I along with my staff have travelled throughout West Virginia to speak directly with what I consider my "extended family" about this epidemic. During our travels and through participation in multiple community focus groups, community forums and summits held around our great state we have heard first-hand about prescription misuse and abuse and the trail of devastation being left behind. Families are being torn apart with some never to be mended again as a direct result of this pervasive issue. Most West Virginians thought they knew the evils to watch for – "big city" drugs like, heroine and cocaine, but our killers are much closer to home.... our medicine cabinets. Nine out of 10 of the overdose deaths in the state are due to prescription drugs. Unfortunately for our state that means we are in a battle with a foe

whose resources are abundant. According to the Kaiser Foundation, per capita, West Virginians fill more prescriptions than any other state.

In February of this year Senator Rockefeller and Director Kerlikowske visited West Virginia and participated in a prescription drug roundtable and summit in Huntington and Charleston, WV respectively. At both events the impact that prescription drug use is having on our children was a topic of discussion. We heard from community professionals and caregivers who are committed to our youth and to insuring that they have opportunities to flourish. Senator Rockefeller's commitment to preserving the promise and future of our youth is echoed in the sentiments from those joining this day's events as well as others across our state who work daily to impact positively the lives of those served. Director Kerlikowske's visit offered support to our work and we heard first hand from both he and Senator Rockefeller that many in Washington are equally as driven to address this crisis.

Just last week I participated in a Prescription Drug Summit sponsored by Congressman Rahall in the Southern region of West Virginia. During this Summit we heard from community members who are scared, tired, and quite frankly "fed-up" with this rampant issue. One grandmother fighting tears as she muttered each word, shared with me her son's battle with substance abuse which ultimately led to his death, and her family's struggle to raise her deceased son's three children as the mother of those three children also suffers from drug addiction (and used substances throughout each pregnancy). Stories like this are frequent and are perpetuating a culture of children without parents figuratively and literally and is annihilating our culture and the safety and security that has historically complimented it.

Experts speculate that the reason for the upswing in WV rates is embedded in our Appalachian culture. We *trust* our physicians and if a doctor prescribes it, then it must be safe. There is a perception that prescription drugs are safer than illegal drugs. We are at a disadvantage, because we do not recognize the face of our enemy. As you may be aware, addiction to prescription drugs often begins with seemingly good intentions of "sharing" what we have with friends and family members. We are people who care deeply for our friends and family and that often means sharing our prescriptions with people who "we believe" need them. According to the National Survey on Drug Use and Health (NSDUH), most prescription drug abusers obtain their drugs from family and friends. Research has shown that close to two-thirds of the people who abuse prescriptions drugs get them from friends and neighbors for free.

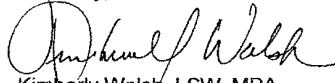
- ✦ *In WV, 64% of non-medical users of pain relievers reported getting the most recently used drug from a friend or relative for free, and another 7.6% reported buying them from a friend or relative.*
- ✦ *In recent data from the WV Prescription Drug Abuse Quit Line, callers identified **emotional pain** not just physical pain as precursors to prescription drug abuse.*

As we continue to hear these staggering statistics and listen to testimony from the community, it is quite evident that a comprehensive battle must be waged that includes substance abuse and mental health prevention/promotion, treatment and enforcement. Our Bureau commits federal and state dollars directly into community based prevention education strategies that include: Drug Take Back Days and Safe Prescription Use and Storage for consumers. In the coming year additional funding will target best practice guidance for Pharmacists and Physicians, maintenance of a prescription drug abuse quit line and support of existing successful law enforcement efforts such as drug market intervention strategies.

Health Care Reform will assist many in becoming eligible to receive services but further increases the problem that we face in West Virginia of not having enough residential treatment services available to support those in need. As WV partners with other states like Ohio and Kentucky to improve inter-state relationships and share proven strategies, we will learn innovative methods of adding services and utilizing a voucher system to help anyone willing to seek treatment for their prescription drug abuse addiction. In addition we will address clinical standards and development of protocols essential to the governance of medication assisted treatment programming and promotion of consistent enforcement and reporting practices.

While these efforts will help support those already using substances, we must continue to tirelessly promote prevention and education of all substances of abuse in the state universally. In West Virginia we are committed to continuing to pursue behavioral health integration and partnerships among our state and local substance abuse and mental health service support systems. It is through these partnerships that we have realized our collective strength, some pockets of success and it is through these partnerships and collaboration with our statewide family that we will fight to positively impact the misuse and abuse of prescription drugs in West Virginia.

Sincerely,



Kimberly Walsh, LSW, MPA  
Deputy Commissioner

cc: Senator John D. Rockefeller