

**WARNING: THE GROWING DANGER OF
PRESCRIPTION DRUG DIVERSION**

HEARING
BEFORE THE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING,
AND TRADE
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

APRIL 14, 2011

Serial No. 112-39



Printed for the use of the Committee on Energy and Commerce
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THURSDAY, APRIL 14, 2011

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

The subcommittee met, pursuant to call, at 8:05 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bono Mack (chairman of the subcommittee) presiding.

Members present: Representatives Bono Mack, Blackburn, Stearns, Harper, Lance, Cassidy, Guthrie, Olson, McKinley, Pompeo, Kinzinger, Butterfield, Gonzalez, Towns and Inslee.

Staff present: Paul Cancienne, Policy Coordinator, Commerce, Manufacturing, and Trade; Brian McCullough, Senior Professional Staff Member, Commerce, Manufacturing, and Trade; Gib Mullan, Chief Counsel, Commerce, Manufacturing, and Trade; Anita Bradley, Senior Policy Advisor, Chairman Emeritus; Shannon Weinberg, Counsel, Commerce, Manufacturing, and Trade; Alex Yergin, Legislative Clerk; Michelle Ash, Democratic Chief Counsel; and William Wallace, Democratic Policy Analyst.

Mrs. BONO MACK. Good morning. The subcommittee can now please come to order.

Someone once said, I would like mornings better if they started later, and amen to that, especially as a Californian. But I truly appreciate the effort that everyone has made to be here for a somewhat unprecedented 8:00 in the morning hearing, although as I said, as a Californian, my clock still says it is 5:00 in the morning.

But seriously, when it comes to the topic at hand, there is no better time than right now to discuss it. Today, prescription drug abuse is a deadly serious and rapidly escalating problem all across America. We have an obligation to tackle it head on. The chair now recognizes herself for an opening statement.

OPENING STATEMENT OF HON. MARY BONO BACK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Since 2003, more than 5,000 U.S. service men and women have died in Iraq and Afghanistan. As Americans, we celebrate their lives and we mourn their deaths. They will always be remembered by a grateful nation.

Yet today, there is a mostly forgotten war also being fought right here at home in both small towns and large cities all across the

United States. This costly and rapidly escalating struggle against prescription drug abuse and addiction is expected to claim the lives of some 30,000 Americans this year alone.

For the most part, this battle is being waged in remote outposts of the human mind, where scientists now tell us that childhood trauma, genetics, mental disorders, stress, thrill seeking, social pressures, severe pain from injuries and illnesses, and, yes, the horrors of combat, all contribute to devastating addictions, which in turn, all too often lead to tragic and avoidable deaths. But what is even more insidious is the way these powerfully addictive drugs quickly turn people without any real emotional or physical problems into desperate people suddenly facing life-or-death problems. Few things are more destructive.

According to the Centers for Disease Control, drug overdose is the second leading cause of accidental death in the United States, in large part due to prescription drug abuse, and the problem is growing every single day. According to a recent national survey, some 7 million people age 12 or older regularly abuse prescription drugs, and there are approximately 7,000 new abusers every single day, many of them teenagers and young adults. That alarming trend is taking a huge toll on society.

Today, the abuse of prescription drugs, especially painkillers, stimulants and depressants, is the fastest-growing drug problem in America. As someone who has been deeply and personally affected by this issue, I hope today's hearing will lead to a better understanding of the enormous scope of this problem, the staggering costs, both emotionally and financially, that it imposes on families and communities, and the need for a greater sense of urgency as a Nation in addressing it.

I believe one critically important first step is to do a better job of monitoring and limiting access to prescription drugs containing controlled-released oxycodone hydrochloride, including the popular painkiller OxyContin. Originally, OxyContin was intended to be prescribed only for severe pain as a way to help patients dealing with late-stage cancer and other severe illnesses. Today, however, more and more people across America are being prescribed OxyContin, as well as other generic oxycodone drugs, for less severe reasons, clinically known as moderate pain, greatly expanding the availability and potential for abuse of these powerfully addictive narcotics.

For people all across America, prescription drug abuse is a day-to-day struggle. Over time, it destroys families and wreaks havoc on communities all across the Nation. Someone with a toothache or a sore back should not be prescribed a potentially addictive painkiller. I agree that expanded public education plays a role in addressing the problem, but we are not going to make any real progress until we limit access to these powerful narcotic drugs and ensure that only patients in severe pain can obtain them.

The pervasiveness of prescription drug abuse made national headlines recently when Federal, State, and local law enforcement agencies, led by the Drug Enforcement Agency, cracked down on so-called "pill mills" in Florida, resulting in dozens of arrests, including five doctors.

Congress needs to make it much more difficult for these rogue pain clinics to operate, and we should treat offenders like any other street drug dealer. By better coordinating the efforts of local, State and national agencies and by reducing the supply of highly addictive opioid painkillers, I am convinced that we can eventually save thousands of lives and spare millions of families from the headache and heartache of addiction.

A recent Denver Post article highlighted why these powerful drugs are so attractive to thieves, drug dealers and unscrupulous doctors. According to the Post, OxyContin costs \$1 per milligram on the street and comes in doses ranging from 15 to 80 milligrams. So a dealer selling 1,000 tablets can make up to \$80,000.

What does that mean in human terms? Well, a recent report by the National Institute on Drug Abuse has found that nearly one in 20 high school seniors have reported abuse of OxyContin. And yet another disturbing report by the Substance Abuse and Mental Health Services Administration shows a staggering 400 percent increase in admissions of people aged 12 years and older for treatment of prescription drug abuse between 1998 and 2008. Clearly, we have a daunting challenge in front of us.

I would like to thank all of our distinguished panelists, especially DEA Administrator Leonhart, ONDCP Director Kerlikowske, Governor Scott and Governor Beshear for their personal commitment to this important issue. If we are going to win the war against prescription drug abuse, we must all serve as soldiers.

[The prepared statement of Mrs. Bono Mack follows:]

PREPARED STATEMENT OF HON. MARY BONO MACK

Since 2003, more than 5,000 U.S. service men and women have died in Iraq and Afghanistan. As Americans, we celebrated their lives and mourned their deaths. They will always be remembered by a grateful nation.

Yet today, there is a mostly forgotten war also being fought—right here at home—in both small towns and large cities all across the United States. This costly and rapidly escalating struggle against prescription drug abuse and addiction is expected to claim the lives of some 30,000 Americans this year alone.

For the most part, this battle is being waged in remote outposts of the human mind, where scientists now tell us that childhood trauma, genetics, mental disorders, stress, thrill seeking, social pressures, severe pain from injuries and illnesses, and, yes, the horrors of combat—all contribute to devastating addictions, which in turn all too often lead to tragic and avoidable deaths.

But what's even more insidious is the way these powerfully addictive drugs quickly turn people without any real emotional or physical problems into desperate people suddenly facing life-or-death problems. Few things are more destructive.

According to the Centers for Disease Control, drug overdose is the second leading cause of accidental death in the United States—in large part due to prescription drug abuse. And the problem is growing every single day.

According to a recent national survey, some 7 million people age 12 or older regularly abuse prescription drugs, and there are approximately 7,000 new abusers every day—many of them teenagers and young adults. That alarming trend is taking a huge toll on society.

Today, the abuse of prescription drugs—especially painkillers, stimulants, and depressants—is the fastest-growing drug problem in America. As someone who has been deeply and personally effected by this issue, I hope today's hearing will lead to a better understanding of the enormous scope of this problem, the staggering costs—both emotionally and financially—that it imposes on families and communities, and the need for a greater “sense of urgency” as a nation in addressing it.

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Originally, OxyContin was intended to be prescribed only for severe pain as a way to help patients dealing with late-stage cancer and other severe illnesses. Today, however, more and more people across America are being prescribed OxyContin, as well as other generic oxycodone drugs, for less severe reasons—clinically known as moderate pain—greatly expanding the availability and potential for abuse of these powerfully addictive narcotics.

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Clearly, we have a daunting challenge in front of us. I would like to thank all of our distinguished panelists—especially DEA Administrator Leonhart, ONDCP Director Kerlikowske, Governor Scott, and Governor Beshear—for your personal commitments to this important issue.

If we are going to win the war against prescription drug abuse, we must all serve as soldiers.

Mrs. BONO MACK. The gentleman from Texas is now recognized for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. CHARLES A. GONZALEZ, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GONZALEZ. Madam Chair, thank you very much, and thank you for calling this most important hearing and for inviting so many experts that will create our four distinguished panels of witnesses.

I need to apologize because I will be absent for part of the hearing and hopefully will be returning, but at around 8:30 I will have to go to another presentation and hopefully come back, but we should have some members on our side of the aisle.

I also wish to extend the apologies of ranking members Butterfield and Waxman, who are disappointed that they cannot be here at this time, obviously due to a conflict in commitments.

According to the 2010 National Drug Control Strategy, the fastest growing form of substance abuse in the United States is the non-medical use of prescription drugs including opiates, pain relievers, tranquilizers, sedatives and stimulants. Under the careful supervision of a doctor, these medications can alleviate severe pain

or help those suffering from mental disorders like psychosis, depression, anxiety, insomnia or attention deficit hyperactivity disorder.

Teens and young adults are increasingly susceptible to prescription drug abuse. Seven out of the top 10 substances most abused by young people are prescription medications. Like their older counterparts, teens most frequently obtain non-medical pain relievers, tranquilizers and stimulants from a friend or a family member. Despite popular misconceptions to the contrary, research indicates that even teens and young adults misuse prescription drugs not just to get high but for a variety of reasons. The Partnership for a Drug-Free America answers that teens do so to party, to get high in some cases but also to manage or regulate their lives. They are abusing some prescription stimulants to give them additional energy and ability to focus when they are studying or taking tests. They are abusing prescription pain relievers and tranquilizers to cope with academic, social or emotional stress.

Many teenagers draw key distinctions between these drugs and illicit street drugs, characterizing their use of prescription drugs as responsible, controlled or even safe. Researchers have concluded that the growing popularity of prescription drugs also reflects the perception that these drugs are safer than street drugs. There are several programs at the Federal, State, and local level that seek to curb prescription drug abuse and diversion.

I look forward to the testimony of our witnesses so that we may determine what is working and what more can be done to stop the growing problems. And Madam Chair, unlike many of the hearings we have, and we have such contentious differences of opinion, I don't think we are going to have that today. I think we are just going to try to identify what works and that we move forward and lend the assistance at the Federal level to everyone out there in attempting to curb a very serious problem, and I yield back at this time.

Mrs. BONO MACK. I thank the gentleman for his words and for the spirit with which he said them, and now the chair recognizes Mr. Pompeo for 1 minute.

OPENING STATEMENT OF HON. MIKE POMPEO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. POMPEO. Thank you, Madam Chair.

I just briefly want to say thank you for holding this hearing. Thanks for bringing attention to this incredibly important issue. I am the father of a 20-year-old son. I know the kinds of things he is seeing at Kansas University. I know the kinds of challenges that young people have, and I look forward to your testimony this morning so that we can get the facts, learn a little bit about what works so that we can develop good Federal policy that will minimize the risk from this very real concern that I think lots of parents have all across the country.

So thank you all for coming this morning. Thank you, Madam Chairwoman. I yield back the balance of my time.

Mrs. BONO MACK. I thank the gentleman, and the chair recognizes Mr. Guthrie for 1-1/2 minutes.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. GUTHRIE. Thank you, Madam Chairman. I won't take too much time because I will speak a little later when our governor is here in the next panel. But I just want to thank you for bringing attention to this issue. It is important. It is important in my State, like all States, but we particularly have a problem and we are looking forward to the next panel, but I just wanted to say thank you so much for having this hearing today.

Mrs. BONO MACK. I thank the gentleman, and recognize the gentleman from Texas, Mr. Olson, for 1-1/2 minutes.

OPENING STATEMENT OF HON. PETE OLSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. OLSON. I am pleased to be here early this morning, and I thank the chair for her leadership in holding this hearing to shed light on a problem of prescription drug diversion and abuse. I know this issue is greatly important to the chair, and I commend her on assembling an impressive group of witnesses.

Prescription drug abuse in America is not an issue we should take lightly. As a parent of two children, it is very concerning to me to see statistics showing that on a daily basis 2,500 American teenagers are trying prescription drugs for the first time, 2,500 per day. The vast majority of these teens are getting drugs from their own house, taking them from their parents' medicine cabinet and using them or giving them to friends. Given this, it is so important that parents are educated about the risks of prescription drug abuse in addition to knowing about and utilizing drug disposal and take-back programs.

I thank the chair for her commitment to America's youth and I look forward to hearing from our witnesses. I yield back.

Mrs. BONO MACK. I thank the gentleman, and the chair recognizes Mr. Harper for 30 seconds.

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

Mr. HARPER. Thank you, Madam Chair, and I certainly welcome the witnesses. It is quite an impressive lineup. We look forward to hearing what each has to say today.

This is an important issue, and it has devastated families that I know back home. Spending years as a prosecutor, you see what it does to many unintended victims in this, and I just look forward to looking for solutions and ways that we can solve this and help these families, and I want to thank you, Madam Chair, for holding this very important hearing.

Mrs. BONO MACK. I thank the gentleman. Everybody is so happy this morning. The chair recognizes Mr. McKinley for 30 seconds.

OPENING STATEMENT OF HON. DAVID B. MCKINLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WEST VIRGINIA

Mr. MCKINLEY. Thank you, Madam Chairman, and I join that. I thank you for holding this hearing this morning on this topic. As a father of four and a grandfather of six, I see what they are going to be facing. I saw what happened in our society back in the 1960s. It wasn't pretty, and what these kids are facing today is shocking.

My wife is a critical care nurse and works in the emergency room of a hospital, and she tells me time and time again of the horrors, so many people come in that have abused the drugs and what it is doing to our Nation.

So I welcome you and thank you very much for holding this hearing so we can learn more how we can address this and save our next generation. Thank you very much.

Mrs. BONO MACK. I thank the gentleman, and the chair is pleased to recognize the vice chair of the committee, Ms. Blackburn, for 30 seconds.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. And thank you, Madam Chairman.

Welcome to our witnesses, and thank you all for being here with us today.

There are three points that I think that as we work through what is an emotional debate that we need to be thinking about. First, to what extent should duly licensed prescription drug manufacturers be required to spend time, money and resources on trying to envision every new way that their product might be abused? Secondly, if we begin to restrict the approval of new prescription drugs, what impact will it have on patients who desperately rely on them to cope with debilitating pain and are just trying to make it through another day? And perhaps the most important question is, How do we deal with personal and parental responsibility? And I yield back.

Mrs. BONO MACK. I thank the gentlelady, and the chair recognizes the gentleman from New York, Mr. Towns, for 5 minutes.

OPENING STATEMENT OF HON. EDOLPHUS TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TOWNS. Thank you very much, Madam Chair. Let me thank you and Congressman Butterfield for having this hearing and also I want to thank Congressman Gonzalez for filling in on his behalf.

This is a very serious issue, and I am very pleased, however, that a number of provisions in the recently enacted Patient Protection and Affordable Care Act could yield some very positive results in our efforts to curb this growing problem.

We must educate families about the dangers of loose prescription drugs in their households. We must also utilize other relevant Federal laws and procedures in order to safeguard against prescription drug diversion. Some of these safeguards include a recently proposed risk evaluation and mitigation strategy. If implemented by

the FDA, this strategy could train prescribers, catalog patient information and administer periodic effectiveness assessment tests. Other safeguards would involve improving the communication abilities of our law enforcement officials, doctors, pharmaceutical dispensers so that frequent abusers can be brought to justice.

Tackling the growing danger of prescription drug abuse will require bipartisan support, and that is the reason I was happy to hear the comment made by Congressman Gonzalez, that we are all on the same team when it comes to these kinds of things and when it comes to protecting our young people, and I am really happy about that.

This public health issue requires the input and resources of all relevant stakeholders to ensure this problem is fully addressed. This is not one that we should get involved in the blame game. I think there is enough blame here for everybody to share. I think it is time to come together to see in terms of what we can do on both sides of the aisle, of course, every stakeholder that is involved in this issue, because this is an issue that if blame would solve it, then it would not even be here because of all the years we have been complaining about it.

But I think the time now has come when we must roll up our sleeves and together work to see what we can do to be able to curtail the fact that especially with our young people who the numbers seem to keep going up and up.

I look forward to hearing from our witnesses today and working with my colleagues to ensure Congress plays a vital role in protecting families from the growing danger of prescription drugs. And let me say to the chairperson that I really, really appreciate her involvement here and hope that we will continue to work together to see in terms of what we might be able to do to protect the lives of many of our young people who have gotten involved in this and of course I think that we can do a lot better.

Thank you very much. I yield back.

Mrs. BONO MACK. I thank the gentleman, and now to move to the panel. We have the first panel, one of four that will be before us today. Each of the witnesses has prepared an opening statement that will be placed in the record. Each of you will have 5 minutes to summarize that statement in your remarks.

On our first panel, I am honored that we would have these two distinguished witnesses, the Hon. Gil Kerlikowske. When I first met him, I couldn't say the name and so I have come a long way. Hon. Gil Kerlikowske, Director of the Office of National Drug Control Policy, and the Hon. Michele Leonhart, Administrator of the Drug Enforcement Agency.

Good morning to both of you, and thank you for your hard work, and you will each be recognized for 5 minutes. You probably know the drill. There are lights over there, and as they are green, you are well on your way. When you see the yellow lights, you are down to the wrap-up time, and when you hit red on the light, if you could then sum up your comments and we will then move on to the next witness.

So Director Kerlikowske, you may begin with your first 5 minutes. Thank you.

**STATEMENTS OF R. GIL KERLIKOWSKE, DIRECTOR, OFFICE OF
NATIONAL DRUG CONTROL POLICY; AND MICHELE M.
LEONHART, ADMINISTRATOR, DRUG ENFORCEMENT ADMIN-
ISTRATION**

STATEMENT OF GIL KERLIKOWSKE

Mr. KERLIKOWSKE. Well, thank you, Ms. Chairman Bono Mack, and thank you, Ranking Member Gonzalez and the distinguished members of the committee for the opportunity to address prescription drug issues.

I really applaud the committee's focus on this topic. Prescription drug abuse has been a major focus since my confirmation, and I have directed that the national drug control program agencies address this epidemic in our country.

Let me pause for a minute. As a long-time police chief in Seattle for 9 years, I paid attention to what caused harm in my community. Quite frankly, the abuse of prescription drugs wasn't on my radar screen, and quite frankly, I believe that around the country this has not received the attention that it needs.

As the President's chief advisor on drug policy, this position demands that I raise public awareness and take action on drug issues affecting the Nation. The efforts in the President's drug control strategy are balanced. They incorporate new research, evidence-based approaches to address drug use and its consequences.

In 2008, over 23 million Americans ages 12 or older needed treatment for an illicit drug or alcohol use problem. However, only 11 percent received that necessary treatment for that substance use disorder.

Well, today I am here to talk about prescription drug abuse. Prescription drug abuse, as was mentioned, is the fastest growing drug problem in the United States and it is categorized as a public health epidemic by the Centers for Disease Control and Prevention, and in recent years the number of individuals who for the first time consumed prescription drugs for non-medical purposes was similar to the number of first-time marijuana users. The 2010 Monitoring the Future, a national survey on youth drug use, found that six of the top 10 substances used by 12th graders were pharmaceuticals. We have also seen a fourfold increase in addiction treatment admissions for individuals, primarily abusing prescription painkillers. That was from 1997 to 2007. And even more alarming is the fact that over the last 5 years, emergency visits linked to misuse or abuse of pharmaceuticals has nearly doubled, and at the same time emergency room visits for illegal drugs like heroin and cocaine remained relatively flat.

Furthermore, deaths from prescription drugs are increasing at a staggering rate, and State data show that seven people in Florida, four people in Ohio, three people in Kentucky die every day from an unintentional overdose. The latest national data found that more than 27,000 Americans died from unintentional drug overdoses in 2007. Prescription drugs, particularly the opioid painkillers that were mentioned, are considered major contributors to the total number of drug deaths. And in 17 States and the District of Columbia, drug-induced deaths are now the leading cause of injury death.

And there are two unique reasons for the growth of the prescription drug abuse: easy accessibility to these drugs and the perception of risk. For instance, persons age 12 or older who use pain relievers non-medically in the past year between 2008 and 2009, nearly 70 percent obtained the drug they abused from a friend or a relative. And research shows that because prescription drugs are manufactured by reputable pharmaceutical companies, they are prescribed by licensed clinicians, they are dispensed by pharmacists, they are perceived as safer to abuse than illegal drugs, and we know that is not true and we know that young people aren't buying them in a piece of tinfoil from behind a gas station.

In addition, recent studies found perceived prescription drug abuse as safer, less addictive and less risky than using illegal drugs, and the drugs obtained from the medicine cabinet or the pharmacy were in their perception not as dangerous as those drugs that were obtained in other ways.

A comprehensive approach is required to address the epidemic because prescription drug abuse problems pose unique challenges. It is important to balance prevention, education and something close to my heart, enforcement, with the need for legitimate access to the controlled substances was mentioned. Therefore, the Administration has created an inclusive plan which brings together a variety of Federal, State, local, and tribal groups to reduce prescription drug diversion and abuse, and while we have outlined our approach to this issue in the 2010 Drug Control Strategy, the Administration developed a separate plan focused specifically on prescription drugs and next week Director Leonhart and I along with our Federal partners will release the Administration's plan. Our prescription drug abuse prevention plan has four parts: education, prescription drug monitoring programs, proper medication disposal and enforcement, and the first part of our response plan is education. Mandatory prescriber education as well as patient and parental education is essential.

Second, each State should have a prescription drug monitoring program. These known as PDMPs are statewide databases that contain information on dispensed and controlled substances prescribed by health care providers. PDMPs should be interoperable and have the ability to share prescriber information.

The third part of our plan calls for proper medication disposal. Seventy percent of the people, as I said, reported getting their painkillers from a friend or relative, and we need to ensure that proper medication disposal programs are available, and in September, DEA held their National Take Back Day and collected over 120 tons.

Let me just close and say that I thank you for your attention, and I really appreciate the witnesses that will be coming after me, and my heart as a police chief goes out to those that have suffered.

[The prepared statement of Mr. Kerlikowske follows:]



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

**“Warning: The Growing Danger of
Prescription Drug Diversion”**

House Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and
Trade

Thursday, April 14, 2011
8:00 a.m.
2123 Rayburn House Office Building

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

**HOUSE COMMITTEE ON ENERGY AND COMMERCE:
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE
OPENING STATEMENT OF R. GIL KERLIKOWSKIE
DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

April 14, 2011

Chairman Bono Mack, Ranking Member Butterfield, and distinguished members of the Committee, thank you for this opportunity to address prescription drug abuse in our country. The Office of National Drug Control Policy 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 National Drug Control Policy office and chief advisor to the President on anti-drug matters, I am charged with producing the *National Drug Control Strategy*, which directs the Nation's anti-drug efforts and programs, a budget, and guidelines for cooperation among Federal, state, and local entities. My position allows me to raise public awareness and to take action on drug issues affecting our Nation. The Obama Administration recognizes that addiction is a disease, and that prevention, treatment, and law enforcement must all be part of a comprehensive strategy to reduce drug use, get help to those who need it, and ensure public health and safety.

The *2010 National Drug Control Strategy (Strategy)*, released by President Obama in May 2010, seeks to reduce drug use and its consequences through an evidence based, public health approach to drug policy. This Administration's inaugural *Strategy* reflected a nine-month consultative effort with Congress, Federal agencies, state and local partners, and hundreds of concerned citizens and stakeholders. It serves as a bold call to action for all Americans who share the desire and responsibility to keep our citizens - especially our youth - safe, healthy, and protected from the enormous physical, psychological, sociological and economic costs of substance abuse.

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 reduce drug use and its consequences. Our efforts are balanced and incorporate new research and evidence-based approaches to better align policy with the realities of drug use in communities throughout this country. Research shows that addiction is a complex, biological, and psychological disease. It is chronic and progressive, and negatively affects individuals, families, communities, and our society as a whole. In 2009, over 23 million Americans ages 12 or older needed treatment for an

illicit drug or alcohol use problem. However, only 11% received the necessary treatment for their substance use disorder.¹

The 2010 *Strategy* included Action Items comprehensively addressing all areas of drug control. Since its introduction, 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 2010 *Strategy*. The 2011 *Strategy* addresses issues of concern to specific populations, including service members and their families, veterans, 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 about prescription drug abuse. Prescription drug abuse is the fastest-growing drug problem in the United States and is categorized 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.² The 2010 Monitoring the Future study – a national survey on youth drug use – found that six of the top ten substances used by 12th graders in the past year were pharmaceuticals.³ In addition, there has been a four-fold increase in addiction treatment admissions for individuals primarily abusing prescription pain killers from 1998 to 2008.⁴

The increase in the percentage of treatment admissions for abuse of pain relievers spans every age, gender, race, ethnicity, education, employment level, and region. We have also seen the estimated number of emergency department visits linked to non-medical use of prescription drugs double between 2004 and 2008, and this dramatic rise occurred among men and women of all age groups.⁵ Even more alarming is the fact 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 unintentional drug overdoses.⁶ In 17 states and the District of Columbia, drug-induced deaths are now the leading cause of injury death.⁷

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

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

² Substance Abuse and Mental Health Services Administration 2010. *Results from the 2009 National Survey on Drug Use and Health: National Findings*.

³ University of Michigan 2009 Monitoring the Future: A Synopsis of the 2009 Results of Trends in Teen Use of Illicit Drugs and Alcohol.

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

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

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

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

past month illicit drug use, largely driven by the abuse of prescription drugs (reported by 11%).⁸ According to the most recent survey from the Department of Justice, nearly 60% of the 140,000 veterans in Federal and state prisons are struggling with a substance use disorder, and 25% reported being under the influence of drugs at the time of their offense.⁹ Equally concerning is the fact that substance abuse affects many of the estimated 75,600 homeless veterans.¹⁰

There are two unique barriers to combating prescription drug abuse compared to illegal drugs, like heroin and cocaine: easy accessibility to the drugs, and low perception of risk. For instance, of persons aged 12 or older who used pain relievers non-medically between 2008 and 2009, nearly 70% obtained the drug they abused from a friend or relative.¹¹ 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 using illegal drugs, and believed that drugs obtained from a medicine cabinet or pharmacy as not as dangerous as drugs obtained from a drug dealer.¹²

Although potentially 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 for whom they were prescribed. A comprehensive, multifaceted approach is required to address this epidemic. Because the prescription drug abuse problem poses unique challenges, it is important to balance prevention, education, and enforcement with the need for legitimate access to controlled substances.

Any policy response must be approached thoughtfully and must 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, it has also led to the unintended consequence of increased medication abuse. The Administration has created an inclusive Prescription Drug Abuse Prevention Plan which brings together a variety of Federal, state, local, and tribal groups to reduce prescription drug diversion and abuse. Our prescription drug abuse prevention plan has four parts: education, prescription drug monitoring programs, proper medication disposal, and enforcement.

The first part of our response plan is education, to include mandatory prescriber education, as well as patient and parent education. A significant percentage of opioid analgesics are distributed in primary care offices and emergency rooms, and surveys of healthcare professionals and professional schools have shown significant gaps in educational training on

⁸ 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.

⁹ Office of Justice Programs/Bureau of Justice Statistics. *Veterans in State and Federal Prison, 2004*. U.S. Department of Justice. 2007. <http://bjs.ojp.usdoj.gov/content/pub/pdf/vsfp04.pdf>.

¹⁰ U.S. Department of Veterans Affairs Budget Request for Fiscal Year 2012. Statement of Secretary Eric Shinseki.

<http://veterans.house.gov/hearings/Testimony.aspx?TID=3785&Newsid=2279&Name=%20Hon.%20Eric%20K.%20Shinseki%20>

¹¹ Substance Abuse and Mental Health Services Administration 2010. *Results from the 2009 National Survey on Drug Use and Health: National Findings*.

¹² http://www.rwjf.org/files/research/Full_Teen_Report%205-16-06.pdf

pain management, substance abuse, and appropriate prescribing.¹³ Mandatory prescriber education is therefore essential. In addition, we should make sure that parents and patients are fully aware of the dangers and prevalence of prescription drug abuse, and educated about the safe use and proper storage and disposal of these medications. The second part of our plan is encouraging each state to have a prescription drug monitoring program. Prescription drug monitoring programs (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 tools for patient care, drug epidemic early warning systems (especially when combined with other data), drug diversion investigative tools, and insurance fraud investigative tools. Information contained in the PDMPs 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 an 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. While PDMPs vary from state to state on what data is collected, they can provide clinicians with quick access to information regarding controlled substance prescriptions that were written and dispensed to patients within a specific state.

Despite the benefits of PDMPs, many states still lack the program, and states that do operate a PDMP are currently unable to share prescription data between states. We believe all states should operate PDMPs with mechanisms in place for data sharing between states. There also must be high utilization among healthcare providers, and checking a PDMP should be a regular part of an office visit just like checking for insurance coverage.

The third part of our plan calls for proper medication disposal. Nearly 70% of people report getting their pain killers 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. Creating a convenient and consumer-friendly method for disposal of expired or unused prescription drugs will benefit public health, public safety, and the environment. In September 2010, DEA held a National Take-Back Day and collected over 120 tons of drugs at over 4,000 sites across the country in partnership with state and local law enforcement. With this overwhelming success, DEA will hold a second National Take-Back Day on Saturday, April 30th. 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. The DEA is now in the process of rule-making to make disposal of prescription drugs more convenient and accessible.

The fourth and final part of our prescription drug prevention plan is law enforcement. We will assist states in addressing “pill mills”, doctor shopping and other forms of diversion as 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

¹³ 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. http://www.cdc.gov/nchs/data/series/sr_13/sr13_163.pdf

states. We also will continue to support High-Intensity Drug Trafficking Areas (HIDTAs) as they address diversion and trafficking pharmaceuticals and listed chemicals. Lastly, we must ensure law enforcement has proper prescription drug abuse-related training programs.

In closing, I would like to 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.

Mrs. BONO MACK. Thank you.
Administrator Leonhart, 5 minutes.

STATEMENT OF MICHELE LEONHART

Ms. LEONHART. Chairman Bono Mack and Ranking Member Gonzalez, distinguished members of the subcommittee, 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 drugs 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 are 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 for the DEA.

I am especially alarmed that another contributing factor to the increase of 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 for non-medical users for abuse, accidental ingestion or illegal distribution for profit. The 2010 Partnership Attitude Tracking Study, PATS, as we call it, 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 manufacturing levels to the dispensing of these medications to patients, and 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 household medicine cabinets in a lawful and safe manner.

DEA is working diligently to promulgate disposal regulations, and in the interim, DEA launched a nationwide take-back initiative in September of last year, resulting in the collection of 121 tons of unwanted or expired medications, and I am pleased to announce that DEA is planning a second nationwide take-back initiative on April 30th, and we 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. By carrying out this obligation, DEA strives to minimize the diversion of pharmaceutical controlled substances for abuse while ensuring that such medications are fully

available to patients in accordance with the sound medical judgments of their physicians. In this manner, DEA is committed to balancing the need for 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 through the supply chain, and 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 are unique groups that combine the skills of special agents, diversion investigators, intelligence analysts and taskforce operators. TDS groups are dedicated solely towards investigating, disrupting and dismantling those individuals or organizations involved in diversion schemes, and as of today, DEA has 37 operational TDS groups across the country, and we plan to add an additional 26 more over the next few years.

One example of the effectiveness of these tactical diversion squads is Operation Pill Nation, which targeted rogue pain clinics in south Florida since February of last year and culminated in a series of major takedowns in February of this year. This led to 32 arrests including 12 doctors and five pain clinic owners. DEA also immediately suspended 63 DEA registrations and issued orders to show cause on six more, which resulted in the surrender of 29 DEA registration numbers, and this caused a ripple effect throughout south Florida and resulted in 50 more DEA registrations being surrendered, and in total, we closed down 38 clinics.

DEA recognizes that it can't solve this problem alone. DEA is working closely with our Federal, state, and local and private-sector partners as a part of the Administration's comprehensive approach to combating prescription drug abuse. Many States have also adopted prescription drug monitoring programs which are deemed to be a valuable tool in curbing diversion.

In closing, I want to commend the courage of those who are testifying later this morning for putting names and faces of loved ones to this problem, and I want to express my heartfelt sympathy on behalf of the men and women of DEA for their loss. I am keenly aware that many others possibly here even today have struggled with drug abuse by friends and family, and DEA joins in this fight.

So thank you for the opportunity to appear here today.

[The prepared statement of Ms. Leonhart follows:]



Department of Justice

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

BEFORE THE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

ENTITLED
"WARNING: THE GROWING DANGER OF PRESCRIPTION
DRUG DIVERSION"

PRESENTED ON
APRIL 14, 2011

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

**Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce
United State House of Representatives**

**“Warning: The Growing Danger of Prescription Drug Diversion”
April 14, 2011**

Chairman Bono-Mack, Ranking Member G. K. Butterfield, 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, 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.¹

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

- 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 room 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.² In this age group, prescription drug abuse is second only to marijuana use.³

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.⁴ 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, 1 in 4 teens admitted to using a prescription drug not prescribed to them by a doctor at some point in their lives.⁵ 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.⁶

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

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

³ Ibid, p. 14.

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

⁵ Partnership for a Drug-Free America, 2010 Partnership Attitude Tracking Study.

⁶ 2010 Partnership Attitude Tracking Study, p.18.

⁷ 2010 Monitoring the Future Study. University of Michigan, Ann Arbor.

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

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).⁹

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.).

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

⁹ *Clinical Journal of Pain*, December 2010, University of Washington, Hansen RN; Oster, G; Edelberg, J; Woody, GE; and Sullivan, SD

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

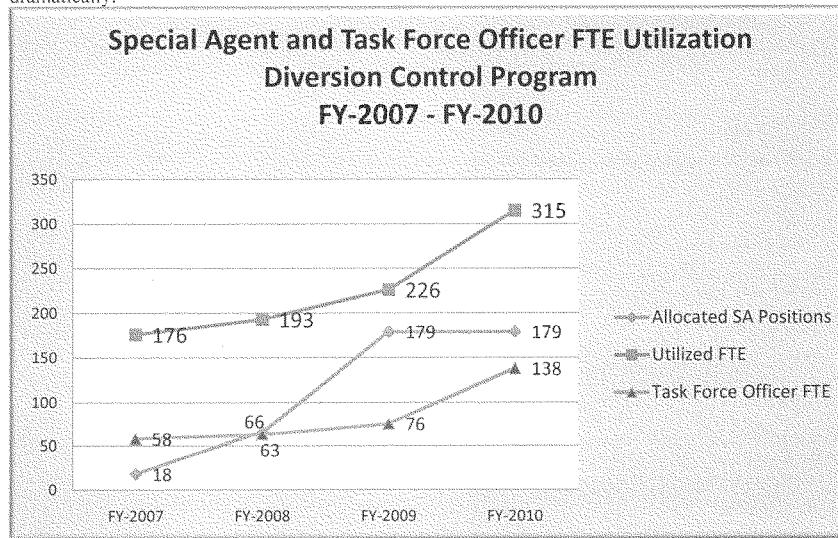
The substantial increase in the abuse of prescription drugs is fueled by many factors, including the development and marketing of new controlled substances, and ever-changing methods of diversion such as rogue Internet pharmacy schemes or rogue pain clinics. Attempts to prevent, detect, and reduce the 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 March 25, 2011, DEA had 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 requests 60 DI positions, 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 Controlled Substances Act (CSA) and its implementing regulations concerning suspicious orders. Since its inception in August 2005 through March 28, 2011, DEA has briefed 74 DEA-registered corporations/companies comprising 212 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 March 28, 2011, distributors have refused to sell controlled substances to approximately 1,390 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.

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 has requested an increase of 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.

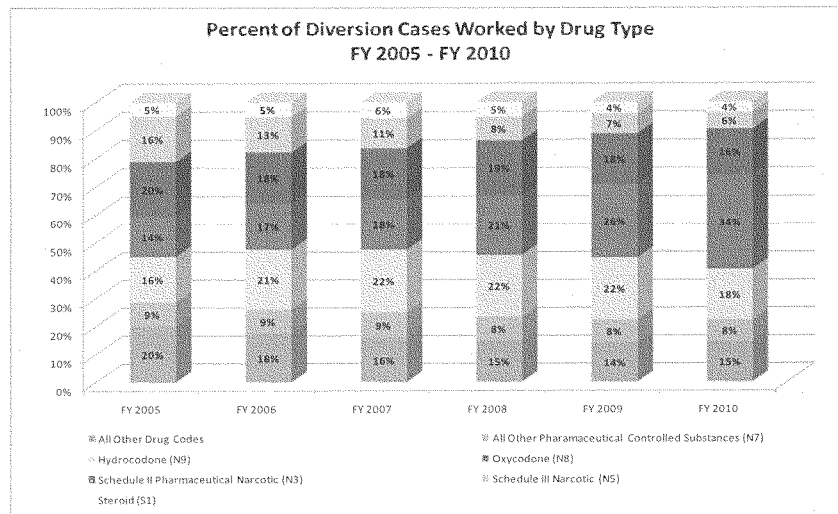
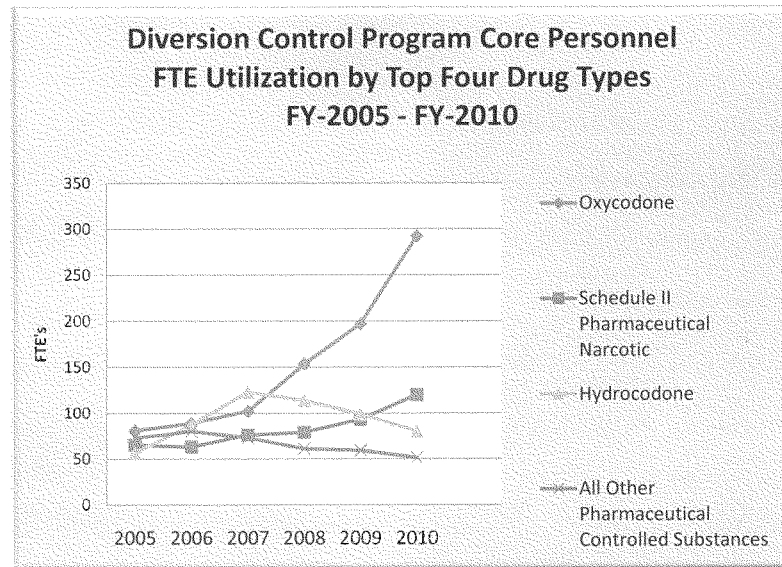
Level of Effort by Drug Type

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 exempted¹⁰ 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.

¹⁰ “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.

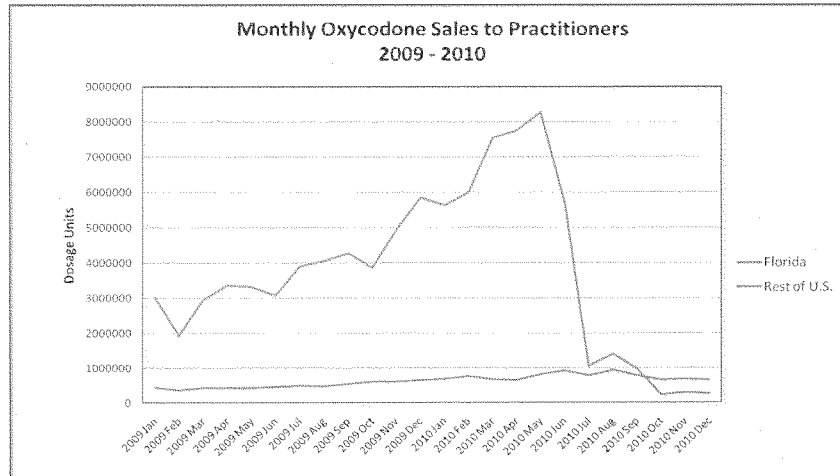


DEA, working with its state and local partners, has put forth a substantial investigative effort towards these rogue clinics which has been dubbed *Operation Pill Nation*. This operation involved the mobilization of eleven Tactical Diversion Squads from across the United States to marshal with the Miami 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:

- 21 search warrants executed at clinics, residences, and other locations in south Florida;
- 25 arrested on various federal and state drug and money laundering charges, of which 5 were medical doctors and 5 were pain clinic owners;
- Seizure of approximately \$7 million in assets. (\$3 million dollars in US currency, a variety of other real property, jewelry, and assets including 62 vehicles, some of which were exotic cars; and
- 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 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 (33 physicians, 1 distributor); Orders to Show Cause issued against 6 DEA registrations; 38 clinics closed; 32 arrests (12 physicians, 5 clinic owners and 15 clinic employees). Additionally, more than \$16.4 million in assets have been seized 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 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 2010 Partnership Attitude Tracking Study (PATs) noted that 51 percent of those surveyed believe that most teens get prescription drugs from their own family's medicine cabinets.¹¹ 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.¹²

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

¹¹ Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATs) Teens 2010 Report.

¹² 2010 National Drug Control Strategy, p. 32

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. In the interim, DEA is sponsoring another National Take-Back Initiative on April 30, 2011.

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 Bono-Mack, Ranking Member Butterfield, and distinguished Members of the Subcommittee, thank you for the opportunity to appear today to discuss this important issue.

Mrs. BONO MACK. I thank both of the panelists, and I will recognize myself for the first 5 minutes of questions, and I will begin by asking both of you to turn your attention to the charts on your right. Although the data is old—2007, 2006—would you both just, yes or no, is it fair to assume that the trend continues to grow at an alarming rate, that the numbers today are far worse than they were in 2006 and 2007?

Mr. KERLIKOWSKE. Yes.

Ms. LEONHART. Yes.

Mrs. BONO MACK. Thank you. Administrator Leonhart, you were specifically talking about Florida. Can you tell me how many doctors have been convicted or have had their DEA registration denied or revoked for over-prescribing schedule II prescription drugs? When Governor Scott points out that 98 of the 100 top prescribing doctors who prescribe these painkillers that are in Florida, doesn't that send up a huge warning flag?

Ms. LEONHART. Absolutely, Chairman. The actual numbers of doctors across the country that have been convicted or prosecuted, I can get you those numbers, but I can tell you that you are absolutely correct in that 90 of the top 100 are in Florida, and Operation Pill Nation identified those top doctors.

Mrs. BONO MACK. Can you tell me what took so long?

Ms. LEONHART. Well, I can tell you that the trends have changed. The pill situation, the pill mill situation in Florida is a really new phenomenon. We first targeted the Internet, which if you go back 4 and 5 years ago, drugs that we were finding on the street and we were asking where they came from, they were coming from the Internet, and it was unregulated, uncontrolled, and our first efforts were there. It is because of the Ryan Haight Act that Congress gave us and our actions going after those organizations and individuals dealing on the Internet that we were able to basically shut those rogue Internet sites down, and then we saw the shift over the last couple of years in Florida. We spent the last year identifying the pill mills and with a huge operation involving 12 of these tactical diversion squads over a period of a year were able to do those undercover buys that resulted in the takedown of Pill Nation, and we believe that that one consolidated takedown and actions over the past year will have a chilling effect on anyone attempting to open up a clinic or to continue in the same manner that they have continued over the past couple of years.

Mrs. BONO MACK. I see you have a chart on page 10 of your testimony that sort of reflects how effective the raids were, but I have a couple of questions for you just on basic math and perhaps to both of you. Some people will say that last year we took back 272 tons of unwanted prescription drugs. Does that mean we are over-prescribing 272 tons of these prescription drugs? And if that is the case, can you explain the quota system to me? It seems to me that there is simple math that you all are overlooking in a quota system. You both have the ability to determine how much of these painkillers are manufactured and pumped out into our society but the quota is just simply based upon demand? I will turn to both of you.

More specifically, if you look, Florida dispensed more than 41 million oxycodone pills. The second highest prescribing State dis-

pensed 1 million pills. Large States like California have dispensed fewer than 400,000. What a disparity. Doesn't that clearly indicate that there are probably 40 million extra pills in the supply chain if you look at that mathematical equation?

Mr. KERLIKOWSKE. Let me mention, I think, two things, and you bring up an excellent point on the quotas. So one thing is that the most recent data for all of 2010 for the first time in 8 years shows that the aggregate production of opioid painkillers actually flattened, so instead of seeing that incredibly steep increase in abuse and the increase in manufacturing, we also saw a flattening. I think as we brought more attention to this, it is going to be coming down.

The other concern would be trying to restrict particular quotas for particular drugs. We will just turn to a different drug with a different problem, and it could lead to subsequent abuse. So I think quotas is one answer and I think that it needs to be more robustly looked at, and I think those questions along with our FDA partners are important ones, but I also think that we are beginning to turn the corner on not only the aggregate amount of these painkillers that are produced but also on the registrants who will have to have the mandatory education, the number of scripts they write.

Ms. LEONHART. And I agree with Director Kerlikowske. A hundred and twenty-one tons of pills were collected at the take-back in September. There are a number of reasons, a number of things we need to look at. Over-prescribing, you brought up as an issue. I believe that is correct. I believe that it requires more education for the practitioners who are prescribing, more education for parents, more education for young adults and teens who are turning in amazing numbers to prescription drugs as their drug of choice, and DEA is looking at the entire spectrum, and we are striking at every level of the distribution chain, and our problem is that with quotas, you know, we have a job to make sure that there is enough medication produced and available for patients in need and we need to balance that with making sure that people that are not patients that have a medical reason for these drugs don't get it. So it is that balancing act, and the problem with quotas is also that no matter what we do there, there will still be a legitimate group of people that need that medication and so we try to get that target number.

Mrs. BONO MACK. Excuse me. My time is expired. I just wish I would hear you focus more on the people who are dying from these narcotics and painkillers than worrying about getting more out there. To me, the problem is 30,000 people a year are dying.

And with that, I need to yield to Mr. Gonzalez for 5 minutes.

Mr. GONZALEZ. Thank you very much, Madam Chair, and again, thanks to the witnesses. And I understand that once a drug is manufactured, there are only certain ways it gets out there to the consumer, and that is going to be—it is on the shelves of the hospitals or the pharmacist and then there is the prescription written by the doctor. So I want to talk about databases.

The first thing that occurs to me is that the most effective databases, and you have to have the assistance of all these individuals I just indicated. Those are the points of origin. So like you are going to deal with any problem, you have to figure out if you go

there first and try to control it the best you can, then we can deal with the other things that take the responsibilities of parents and such to make sure that there is not the availability of those drugs in the medicine cabinet and so on. And then there are some other issues but I will discuss it with another panel, and it is going to go to what the chairwoman was talking about, the amount of prescription drugs out there and what we can do.

But until we really have, in my opinion, a truly robust and very effective, widespread adoption of electronic medical records, health information technology, which is something that we have been attempting to do since I got here some years ago, I don't see how effective it is really going to be. Do you have any concerns about the abilities of all these different providers or points of origin to be able to access and to supply information in a manner that is timely and is going to be available and of course electronically based?

Mr. KERLIKOWSKE. You are absolutely right. I think it is a shame that when we have to have a chart that goes to the most recent data of 2006 or 2007. The President's Drug Control Strategy devoted an entire chapter to the fact that timely, robust, critical information, whether it is the Drug Abuse Warning Network, which is number of people brought into the emergency rooms, whether it is the number of people we test in only 10 jails in the country for the drug problems of people coming in to the jail regardless of what they were arrested for. All of that information is so helpful, and frankly, it is not timely and it is not as relevant as it should be and therefore it makes it difficult, I am sure for you in the policy-making area and it certainly makes it very difficult for us in that area. So we have devoted this entire chapter to strengthening these kinds of systems, and I agree with you, electronic health records will be an important step forward.

Mr. GONZALEZ. Administrator Leonhart?

Ms. LEONHART. I agree as well, and last June we started the e-prescribing. I had signed for that, and it went into effect in June and we are hoping that e-prescribing helps. I agree with you completely. And also, we do have 34 States that currently are using prescription drug monitoring program system and we see the value in doing that, how having a doctor or a pharmacist have the ability to look into a system and find out that someone has been doctor shopping or going from pharmacy to pharmacy has definitely assisted the States that have enacted those systems in preventing diversion.

Mr. GONZALEZ. And I know that we are always going to have this conflict. First of all, you have to respect confidentiality, the relationship of the patient with the doctor or the pharmacist, the professional and so on. How do we balance all that? I mean, my fear is that people—one of the greatest impediments is people don't like the fact that this kind of information is going to be shared or is going to be made available. Now, I just believe that if it is made available to the health care professional and in fact they act professionally, they are an incredible player or actor in this whole chain of how these drugs get out there. How do we balance the confidentiality aspects of it with, as we have said, a timely and robust database?

Mr. KERLIKOWSKIE. The PDMPs, I think the value in them is that they are designed by the States. So when the States enact them, they can put in the patient privacy and the confidentiality rules that they feel are best. They can also design them as to who has access to them. Some allow at certain points access by law enforcement agencies. But frankly, the practice of medicine is governed by the States, the boards of pharmacy and the medical boards in each of those States having access to those including routine reports that are generated from the PDMPs actually put the information in the hands of the people that have the power to regulate medicine within each particular State.

Ms. LEONHART. On your next panel, you have Governor Beshear here, and I know Kentucky is a State that implemented PDMPs, was very concerned about privacy issues and their systems have been up and running and have not had problems in that area, and as we look at the other 33 States that have PDMPs up and running, they have addressed those privacy issues and that has not been a deterrent that has worked and that is why nine additional States have moved and have pending legislation in their States and are moving towards PDMPs. They have worked those issues out.

Mr. GONZALEZ. Thank you very much. I yield back.

Mrs. BONO MACK. I thank the gentleman. The chair recognizes Mr. Guthrie for 5 minutes.

Mr. GUTHRIE. Thank you, Madam Chairman. In the interest of time, I just want to ask one question and throw it out to both of you.

I understand that prescription drugs are more accessible to people in the family. They get them from family members. You know, a parent may have OxyContin in the house where they wouldn't hopefully have one that you would typically get on the street without prescription drugs. But however, what level is the prescription drug trade also in organized crime, the drug cartels? You know, is it just doctors over-prescribing or is there a whole network like you have in other type of drug issues?

Ms. LEONHART. I can tell you from our enforcement cases, and we were surprised a few years back, we thought that they would act, there would be different organizations, they would act differently because they for the most part are from the medical profession, they are pharmacists, and actually they are organized. We learned from Florida, these pill mill organizations, they are organized just like other organized crime and other crime groups selling coke and heroin.

Mr. GUTHRIE. Are they the same groups? Are the cartels organizing the pill mills or is a different structure, I guess is my question?

Ms. LEONHART. I will say that they are for the most part different groups. We don't have a problem with prescription drugs coming from the Mexican drug cartels, for instance. This is one of those cases where the sources of supply are not in Columbia, are not in Mexico. The sources of supply are right here domestically.

Mr. KERLIKOWSKIE. I held a law enforcement roundtable last month in Buffalo, and one of the enforcement agents talked about a drug dealer in a particular section of the city in which heroin was

being dealt and then they had a subcomponent with a dealer dealing prescription drugs across the street.

Mr. GUTHRIE. Thank you, Madam Chairwoman. I will yield back in the interest of time.

Mrs. BONO MACK. Will the gentleman just yield for one quick question?

Mr. GUTHRIE. Yes, I will yield to the chairwoman.

Mrs. BONO MACK. Just briefly, can you explain how many people are dying from the illicit drugs any longer as compared to prescription drugs?

Mr. KERLIKOWSKE. The prescription drug overdose death, that is driving the numbers that have spiked so significantly. They cause more deaths than both heroin and cocaine combined.

Mrs. BONO MACK. Thank you, and the gentleman yields back so the chair recognizes Mr. Towns for 5 minutes.

Mr. TOWNS. Thank you very much.

Let me begin by—you mentioned the fact that there were 34 States using the monitoring system. Have you been able to detect that those States that are using the monitoring system, that the problem is not as severe in those States?

Mr. KERLIKOWSKE. There are two things that I think will be helpful, and one is that there is a recent evaluation done by the CDC through a contract, I believe, on prescription drug monitoring programs. They are relatively new. Some are used more and some are more robust than others. The other issue will be, how can they exchange information across State lines. All of the physicians that I have talked to and all the people that I have been privileged to be engaged with that have had these programs find them not only to be helpful in identifying doctors who may be over-prescribing but patients who may be doctor shopping, and the doctors themselves talk about it as a patient safety tool.

Ms. LEONHART. I will say that we are looking at the trends. Florida is ground zero for prescription drug abuse, and there is—

Mr. TOWNS. Do they monitor?

Ms. LEONHART. There is no current PDMP in place in Florida. As we took action over the last year in Operation Pill Nation, we are seeing these pill mills actually move and they are starting to show up in Georgia. Georgia is a State without a prescription drug monitoring program. So we are concerned. We believe that States that do enact prescription drug monitoring programs, that is one of the first things they can do to combat diversion in their States.

Mr. TOWNS. Is there any program in place to work with families that might be taking a certain type of medication that might be very susceptible to illegal use in terms of a drug, if it in a cabinet that is locked? Is there any kind of training program in place?

Mr. KERLIKOWSKE. And I think when you hear later on from General Dean and the CADCA group, and we fund through our partner SAMHSA 740 drug-free communities, part of those coalitions will be, part of their mission is to educate people about the dangers of the prescription drugs. There are now locking medicine cabinets that have been made available. There are pill containers that have locks. But we also think the important part is bringing this to the attention of people about what is inside. As the chairman mentioned, when you collect 121 tons of pills across the coun-

try in one 4-hour period, thanks to the leadership of DEA, that should be in my old job a clue that we have a problem.

Ms. LEONHART. We have been able to use the take-back initiative and will on April 30th do the same thing to make it not only be a way to safely dispose of your expired and unused medication but also to educate, and I attended one of the sites on September 25th for the take-back, talked to a number of people who showed up turning in their prescription drugs, and to a T they all said they didn't realize they had the medications stacking up in their medicine cabinet because they didn't want to flush it, they didn't want to throw it in the trash in case someone else could get it, they didn't know what to do with it. So the beauty of the take-back has been a way to educate, educate families about how to secure the medications, and overall having people realize that they don't need to hold on to that medication and that they have elderly in the home that could be confused and take the wrong medication and they have young adults in the home, and that is the number one source of supply for them.

Mr. TOWNS. Thank you very much, Madam Chair. I yield back.

Mrs. BONO MACK. I thank the gentleman. The chair recognizes Mr. McKinley for 5 minutes.

Mr. MCKINLEY. Thank you, Madam Chairman.

I am just curious. In the Appalachian area of this country that has such a high prevalence of misuse, why is that occurring? Is that because the medical community is abusing their prescription authority? I am just trying to get a sense of why is one area so highly using painkilling medicine?

Mr. KERLIKOWSKE. We just spent 4 days, 3 days in eastern Kentucky and 1 day in West Virginia, and spent a lot of time asking people and looking at that including interviewing 14 women who were in the jail system as a result, 13 of them for—

Mr. MCKINLEY. Can you speak up just a little bit, please?

Mr. KERLIKOWSKE. Thirteen of them as a result of prescription drugs, and what we found, particularly in Appalachia, was that, one, people all know each other and they sometimes share those drugs that are in their medicine cabinet, somebody has a back pain and somebody else shares and says here is something that I found helpful. The other problem came about as a result of people who had been prescribed a painkiller as a result of an injury, it could have been even a mining injury, and then ended up in a problem with that. It is a huge and significant problem and we couldn't have made the inroads in understanding it better without the support of Congressional staff that spent the 4 days with us there just less than 2 months ago.

Ms. LEONHART. And I would like to add that from our investigations and what we see, just as Kentucky, Ohio, Tennessee, we saw people that went down to Florida and would go to these pill mills. We saw that that is a major source of supply for the pills that are on the streets in West Virginia, junkies, people that, you know, busloads of people that would go down to Florida, go to all these pill mills, get as many pills as they can, return to your area and not only were some of them addicted themselves but they had multiple—

Mr. MCKINLEY. I am just struggling to understand why Appalachia. Why not Georgia? Why not Alabama? Why is it the Appalachia area is singled out for such high drug use, high painkiller use. I just wonder if the prescribing physicians are—if it is the prescribing physician. Maybe it is a pill mill. But what can we do? Because I struggle with it is just a region. I think it is a national issue.

Mr. KERLIKOWSKE. It is.

Mr. MCKINLEY. Because I think neighbors in New York City know their neighbors just as well as we do in West Virginia.

Mr. KERLIKOWSKE. And you are absolutely right. As my travels across the country have clearly shown, the prescription drug problem affects everyone regardless of race, ethnicity, gender or economic station in life. In particular, I think it gets more attention in Appalachia because of the abuse, and we heard a number of different reasons. I also think that it doesn't get quite the attention perhaps in some places because everyone that we met, they are community minded, they know each other, and there were no secrets. So if you had a friend or a relative that was suffering as a result of prescription drug abuse, other folks knew about it. But I think that bringing attention to it, I think the work that the Congressional staff has done in both places, West Virginia and Kentucky, will make a big difference.

Mr. MCKINLEY. Thank you. I yield back my time.

Mrs. BONO MACK. I thank the gentleman. The chair recognizes Mr. Harper for 5 minutes.

Mr. HARPER. Thank you, Madam Chair.

Director Kerlikowske, as you look at this issue, are PDMPs the only option out there for States to implement the sharing of this type of information?

Mr. KERLIKOWSKE. Right now for looking at doctors who may be over-prescribing or patients who may be doctor shopping, the only systems available are those state-run, statewide PDMPs.

Mr. HARPER. Well, are there any State PDMPs that stand out to you as a role model for other States to follow that you really are impressed with?

Mr. KERLIKOWSKE. As the Administrator also mentioned, I think we are both very impressed with what has happened in Kentucky.

Mr. HARPER. With that, I yield back, Madam Chair.

Mrs. BONO MACK. I thank the gentleman, and the chair now recognizes Ms. Blackburn for 5 minutes.

Mrs. BLACKBURN. Thank you so much, and I want to thank you all for being here. Very quickly, just a couple of things.

Listening to you, reading your opening statements, accessibility is the big problem, it seems, and you are trying to get into that, part of that, as I mentioned in my questions to you, looking at both the education components with individuals' physicians and I think also personal responsibility and parental participation in this.

Let me talk just a minute with you. Ms. Leonhart, you mentioned State monitoring systems, the problems in Florida, the pain clinics as being a problem. In Tennessee, I mean, we have been talking about over-prescribing by physicians since the days of Elvis, and, you know, how are you all working with that? If you are doing State monitoring systems, is there a method that you are

using to incentivize or grant to the States? What is your position on that and how are you helping with the local and the State component of that, and if you want to submit this in writing, because I know we are tight on time, that is fine. But listening to you, it seems if you going to say let us get to the crux of this, that getting to that linkage between your local and State agencies is part of the crux and dealing with that over-prescribing is another component.

Ms. LEONHART. We would be glad to submit to you after the hearing information on specifically what we are doing in Tennessee and know that the law enforcement officials in Tennessee have worked with us, are partnered with us to do what we can to help Tennessee and in many ways they were kind of ahead of everyone, Tennessee and Kentucky, when it came to use of the Internet. We learned from Kentucky and Tennessee, for instance, that there were all these deliveries being made to people who were ordering substances over the Internet. Working with them, they helped us develop an Internet strategy. They are up on the problem. They have worked with us on the problem. But I will provide additional information.

Mrs. BLACKBURN. That will be great, and articulate what you are doing with the grants and the incentive end.

Thank you. Yield back.

Mrs. BONO MACK. I thank the gentlelady. The chair recognizes Dr. Cassidy for 5 minutes.

Mr. CASSIDY. I will also submit a few extra questions for the record, but in the interest of time, I will limit myself.

Ms. Leonhart, in your testimony you refer to civil penalties levied against McKesson, CVS, Cardinal. So what is the role of these intermediaries and what is the role of the manufacturer in terms of controlling this problem?

Ms. LEONHART. Well, manufacturers and distributors have a part to play. They have responsibilities, and what we do at DEA is we make sure that we make them aware of methods of diversion and ways that their companies, their organizations can do more to prevent diversion. In these cases, our investigations showed over and over again that these companies were not doing enough to prevent diversion. So we used our administrative authorities working with U.S. Attorney's offices around the country. We have brought more civil—

Mr. CASSIDY. Well, let me ask you, I am sure there is supply chain control. Are they required to report to you that Smith's Pharmacy in Dade County is ordering 500 percent more prescription drugs than you would think normally such a pharmacy would?

Ms. LEONHART. Yes, they have a responsibility to report diversion. They have a responsibility to report any suspicious order.

Mr. CASSIDY. Define "diversion."

Ms. LEONHART. I am sorry.

Mr. CASSIDY. Define "diversion."

Ms. LEONHART. Diversion is where the controlled system for pharmaceuticals is not used, where pills and substances find their way outside of this closed distribution system. For instance, thefts, they are to report thefts and losses but they are also to report pharmacies or rogue pharmacies that are ordering from them and ordering amounts that changed or anything that raises a red flag

that they are outside of their normal practices. We have investigated many cases that have actually started from tips from the companies who have reported these suspicious orders.

Mr. CASSIDY. OK. Thank you very much.

Ms. LEONHART. And those that are not doing it, then we hold them responsible.

Mr. CASSIDY. I yield back.

Mrs. BONO MACK. I thank the gentleman, and the chair recognizes the gentleman from Washington, Mr. Inslee, for 5 minutes.

Mr. INSLEE. Thank you, Madam Chair. Thanks for letting me join you today.

Chief, thanks for your leadership here. I just wonder if you can give us an update on the implementation of our drug take-back legislation, and it is very timely. I just left Lisa Jackson, the EPA Administrator, and we were talking about endocrine disruptors in the water system that are changing the basic physiology of fish and frogs in rather disturbing ways. So we would like to know how we are doing on this.

Mr. KERLIKOWSKIE. Earlier, the remarks were made about truly what a bipartisan issue this is, and to see the legislation passed in both Houses and the President sign it and then DEA to be so involved and having public hearings already to look at how to restructure the way that pills can be safely disposed of and not causing environmental damage has been really heartening. We have had great cooperation from EPA. DEA is certainly the lead and I am sure the Administrator can mention that. But we are making good progress, and I think the other part is the interim steps that DEA has been taking through the drug take-backs. The next one will be April 30th for your calendar.

Mr. INSLEE. Thank you.

Ms. LEONHART. And I will add that we did hold a hearing a few months ago. Over 150 witnesses appeared. We took their information, their comments. We are working that, and we believe that we will actually have a proposed rule by the end of the summer. We will publish that proposed rule. That will go out for a comment period and we will then review all those comments and move forward with a final rule. But it is on track and comments have come in. We are reviewing them, and we want to especially thank you for participating in that.

Mr. INSLEE. So what would you describe as your biggest challenges to make this actually work? You know, law enforcement is stressed. We have had reductions in the COPS program, and everybody has budgetary issues. If you were going to describe challenges that perhaps we could help you with in any way, what would you say they are?

Ms. LEONHART. Well, making sure that law enforcement has the tools to combat this at every level of the distribution chain, but it is also doing what we can. One of your panels has a number of the community coalitions and the community groups, the prevention groups. It is making sure that they are getting the message out and they are getting the support to be able to do that. It is working with doctors and prescribers and the medical community. It is what Director Kerlikowski and I will be announcing next week with this new prescription plan.

Mr. KERLIKOWSKIE. Reauthorizing NASPER, removing the barrier that restricts the Veterans Administration from sharing prescription drug information, these are all things that Congress can actually do, requiring mandatory prescriber education, those things.

Mr. INSLEE. Thank you very much.

Mrs. BONO MACK. I thank the gentleman. The chair recognizes Mr. Kinzinger for 5 minutes.

Mr. KINZINGER. Thank you, Madam Chairwoman.

In the interest of time, I am going to keep this pretty short. For Ms. Leonhart, I have learned that certain companies are beginning to do a lot of reformulating of opiates drugs to make it more difficult for abusers to use and abuse the product. Do you believe reformulating has been effective in preventing the abuse of these drugs?

Ms. LEONHART. I appreciate the efforts in trying to reformulate so that they are not easily abused. However, I am concerned because we have seen with OxyContin that as soon as that was put out, we heard that even on the Internet they were announcing ways that you could go around that. So we are very concerned but we don't want to discourage industry from continuing to develop these drugs that can't be easily abused.

Mr. KINZINGER. So have there been for either of you any discussions about encouraging drug companies and generics to follow suit or is this something that you personally feel is ineffective and not really worth pursuing?

Ms. LEONHART. I believe it is worth pursuing.

Mr. KINZINGER. That is pretty much all I have unless you have something, sir. All right. I will yield back.

Mrs. BONO MACK. I thank the gentleman very much, and I believe that concludes this panel. I want to thank our witnesses very, very much for your hard work on this issue, certainly the boots on the ground who are working this day in and day out and risking their lives to keep our society safe. We thank them all very much. Again, appreciate your being here.

The subcommittee will take about a 5-minute recess while we switch panels.

[Recess.]

Mrs. BONO MACK. The hearing will come back to order, please. On our second panel today, we have two very distinguished witnesses who are both deeply involved in the issues of prescription drug abuse and prescription drug diversion, which obviously go hand and hand. We are honored to have Florida Governor Rick Scott and Kentucky Governor Steve Beshear with us today for a perspective on how this battle is faring in their States.

Without objection, I would like to yield 1 minute each to Mr. Stearns and to Mr. Guthrie for welcoming remarks. Mr. Stearns, you are recognized for 1 minute.

Mr. STEARNS. Good morning, and thank you, Madam Chair.

I am delighted to introduce my distinguished governor, Rick Scott, to testify today on prescription drug abuse. He is a U.S. naval veteran and a lawyer from Southern Methodist where he received his law degree. He started a business himself and met a payroll. He actually started Columbia Hospital Corporation and later became HCA. He has had experience with small business that

he and his wife and family and mother started to eventually become a large business. He was elected the governor in November 2010. He is the 45th governor in our State. He lives in Naples, Florida, with his wife, Ann, of 38 years and they have two lovely daughters, and I am certainly very proud to introduce Governor Rick Scott.

Thank you, Madam Chair.

Mrs. BONO MACK. And thank you. Mr. Guthrie, you are recognized for 1 minute to introduce your witness.

Mr. GUTHRIE. Thank you, Madam Chairman, and my voice is kind of raspy because Kentucky is in full splendor. Its bloom is there and it is a beautiful place to be, and I invite people to come. And in a month, we will have the world watching us, which we are excited about, with the Kentucky Derby.

But I am pleased to have Governor Beshear here, and I can speak for the whole delegation on our side that we worked together on this issue and we will work with our governor on this issue and make sure we move forward in Kentucky because it is a big issue. We have a great State, a beautiful State, but this is a problem that we are exposing here today and we are working to address.

And Governor Beshear has been involved in Kentucky politics since being elected president of his UK class, University of Kentucky, so just a few years ago he got started in politics. But he has been in the General Assembly, attorney general, lieutenant governor, and very active in civic life as an attorney in Lexington, and actually from West Kentucky, but practiced in the Lexington area. We are really pleased to have you here. Unfortunately, he got elected in 2007, I got elected here in 2008, so we only had a year that we worked together in Frankfort but enjoyed working with you and I am pleased to have you here today. Thank you.

Mrs. BONO MACK. I thank my colleagues, and also join them along with the entire subcommittee in welcoming the two of you today. You will each be recognized for 5 minutes. There are timers on either side of your table that will reflect green. As they turn yellow, that means you are, surprise, surprise, getting close to needing to wrap it up, and when it hits red, if you could come to a conclusion of your remarks as quickly as you can, we would appreciate it very much.

So Governor Scott, you are recognized for 5 minutes.

STATEMENTS OF RICK SCOTT, GOVERNOR, STATE OF FLORIDA; AND STEVE BESHEAR, GOVERNOR, COMMONWEALTH OF KENTUCKY

STATEMENT OF RICK SCOTT

Mr. SCOTT. Chairman Bono Mack and members of the subcommittee, thank you for convening this important hearing on the perils of the illegal distribution of prescription drugs. I ask that my full testimony be submitted for the record.

During my campaign and since becoming Florida's governor on January 4th, I have heard firsthand the heart-wrenching stories from family members and friends of those who have lost their livelihoods and tragically their loved ones to prescription drug addiction. So I have been working on solutions to this problem since

being elected. And Chairman Bono Mack, I know you have been personally touched by this epidemic.

Florida, like much of the Nation, has a long history in the fight against criminal drug distribution. The names of the drugs have changed but the problem has remained. Today, one of the most common names in the fight is oxycodone. Consider some of the statistics from my State and the scope of the problem becomes clear. Ninety-eight of the top 100 doctors dispensing oxycodone nationally are in Florida concentrated around Miami, Tampa and Orlando. A hundred and twenty-six million pills of oxycodone are dispensed through Florida pharmacies. By far, more oxycodone is dispensed in the State of Florida than in the rest of the Nation combined.

The targets for law enforcement have often been the street dealers and addicts, essentially the bottom level of the distribution chain. One tool that focuses on end users is a database focused on the patient level. This month in Florida, my Department of Health began implementation of such a database. While the database moves forward, I am working on satisfying the privacy concerns of law-abiding concerns. In 2009, the Associated Press reported a massive privacy breach when hackers broke into Virginia's prescription drug database. They obtained more than 8.2 million patient records and a total of nearly 36 million prescriptions. In Florida, I continue working with my legislative partners to find solution that protect patient privacy.

More important than computer databases, though, is focus on the resources of my administration on a law enforcement solution that starts at the top of the distribution chain instead of the bottom. Every day, we see that pharmaceutical manufacturers and wholesalers turned a blind eye when massive amounts of narcotics stream into the same regions of Florida. Meanwhile, unscrupulous doctors work with storefront pill mills masquerading as legitimate health clinics. At each level, there is an opportunity for law enforcement to intervene and stop the illegal flow of drugs into our communities.

In these first few months of my administration, I committed to provide a law enforcement solution, a statewide drug strike forces. It ensures open channels of communication and multi-agency cooperation. The goal is clear: target the sources of these drugs before they hit the streets. It gives our local sheriffs and police chiefs a statewide coordinated effort that provides intelligence, analytical and investigative support. As I speak to you today, local law enforcement strike teams are working to identify, investigate and apprehend those in the medical and pharmaceutical distribution chains. I also directed all the state agencies in Florida to identify investigative resources, licensing and registration information and analytical research that can be used by law enforcement. Florida Attorney General Pam Bondi is working with prosecutors across our State to ensure these criminals are prosecuted to the fullest extent of the law. I am grateful to all of these professionals for their commitment to this important work.

Not only are these efforts focused on Florida, we are also coordinating with other States to shut down a national prescription drug pipeline that some have called the Oxy Express. We are aggressively working to shut down the illegal supply of prescription drugs

from our State both inside and outside of Florida. Since the beginning of my administration, there have been more than 50 arrests around the State including a statewide sweep by law enforcement that raided 15 pill mills in three south Florida counties.

Just the other day, I was disappointed to learn that a deputy sheriff in south Florida was the first drug trafficking arrest made since the initiation of the strike force. It is too early to go into the details on this and other cases but I can tell you more investigations are underway and arrests will continue.

With my partners in the Florida Legislature, we will pass legislation in the next 3 weeks to prevent doctors from dispensing narcotics and require doctors to divest of their pharmacies. Doctors who have forsaken their commitment to people's health in exchange for the quick buck of unethical and criminal dispensing must be put to an end. We will also closely review the activities of wholesalers in Florida and we will put in place tough penalties for these manufacturers and distributors who fail to help us turn off the illegal supply chain.

Let me conclude by telling you that this strategy centered on a law enforcement solution and targeting the top of the distribution chain rather than the bottom will make a difference. I applaud this committee for taking a serious look at the issue and I want to ask you to also focus your energy at the sources of this problem. Together, if we hold the manufacturers, wholesalers, doctors and pharmacies accountable, we can win this fight. Thank you very much.

[The prepared statement of Mr. Scott follows:]

**The Honorable Governor Rick Scott
State of Florida
Testimony Before the United States House of Representatives
Energy and Commerce Committee
Subcommittee on Commerce, Manufacturing and Trade
Hearing on the Growing of Prescription Drug Diversion
April 14, 2011**

Chairman Bono Mack, Vice Chair Blackburn, Ranking Member Butterfield, and members of the subcommittee, I want to thank you for convening this important hearing on the perils of the illegal distribution of prescription drugs. This dangerous problem is destroying communities in my state and across the nation, so I thank you for your attention.

Last year, throughout my campaign, and in the months since I was sworn in as Florida's Governor, I have heard firsthand the heart wrenching stories from family members and friends of those who have lost their livelihoods, and, tragically, their loved ones to prescription drug addiction. And, Chairman Bono Mack I know you have been personally touched by this epidemic.

Florida, like much of the nation, has a long history of criminal drug enterprises. The drugs have ruined lives and threatened the safety of our fellow citizens. Across the decades, the names of the drugs have changed, but the problem has remained.

Today, one of the most common names when it comes to the diversion of legal pharmaceuticals for illegal use is Oxycodone. If you consider some of the statistics from my state, the scope of our problem is made clear.

Consider these facts that come from an analysis of the U.S. Drug Enforcement Agency's (DEA) data:

- 98 of the top 100 doctors dispensing Oxycodone nationally are in Florida – concentrated in the Miami, Tampa, and Orlando regions. (see Chart #1 attached)
- 126 million pills of Oxycodone are dispensed through Florida pharmacies – most of them are in or near the Tampa, Orlando, and Miami regions. (see Chart #2 attached)
- By far, more Oxycodone is dispensed in the state of Florida than in the rest of the nation. (see Chart #3)

When confronted with these numbers, a serious problem is plain to see. However, the nature of our response to the problem is sometimes less clear.

The targets for law enforcement have often been the street dealers and addicts – essentially the bottom level of the distribution chain. In fact, one tool that focuses on end users is a database focused on the patient level. This month in Florida, my Department of Health began implementation of such a database.

As the database implementation moves forward, I must draw your attention to a serious risk that I believe databases like this pose to the privacy of individuals – most of whom are law-abiding individuals.

As you know, in 2009 the Associated Press reported a massive privacy breach when hackers broke into Virginia's prescription-drug database. They obtained more than 8.2 million patient records and a total of nearly 36 million prescriptions.

So, while the database in Florida is brought online, I continue working with my legislative partners to find solutions that protect patient privacy.

More important than computer databases, though, is focusing the resources of my administration on a law enforcement solution that starts at the top of the distribution chain – instead of the bottom.

Every day, we see that pharmaceutical manufacturers and wholesalers turn a blind eye when massive amounts of narcotics stream into the same regions of Florida week after week. Meanwhile, unscrupulous doctors work with storefront pill mills masquerading as legitimate health clinics. Each of these levels (see Chart #4) provides an opportunity for law enforcement to intervene and stop the illegal flow of drugs into our communities.

Since my first days in office, I was told by law enforcement professionals at the state, county and local level that we needed a coordinated, law enforcement response to this criminal plague. Something that, according to law enforcement, had been lacking in Florida.

So, recently, I had the privilege of standing alongside representatives of Florida's law enforcement community, some of the best professionals in the nation, to initiate an immediate law enforcement response to criminal drug trafficking in Florida.

This action, the creation of a Statewide Drug Strike Force, meant that from the highest offices of statewide law enforcement down to the street cops in our cities, we would open the channels of communication and ensure multiagency cooperation. The goal is clear: target the sources of these drugs before they hit the streets.

Until recently, the burden of enforcement has primarily fallen on local jurisdictions. However, our local sheriffs and police chiefs simply cannot continue to tackle this mounting issue alone. They need the assistance of a statewide coordinated effort that provides intelligence, analytical, and investigative support.

Today in Florida, local law enforcement strike teams are working to identify, investigate, and apprehend those in the medical and pharmaceutical distribution chains who are facilitating the abuse of prescription drugs. Commissioner Gerald Bailey of Florida's Department of Law Enforcement serves as the statewide coordinator to support the work of local law enforcement, and local strike teams are co-led by Florida's sheriffs and police chiefs.

In addition, I directed all of the state agencies in Florida that are under my purview to identify investigative resources, licensing and registration information, and analytical research that can be used by law enforcement.

Specifically, I have directed the Florida Department of Health and the Agency for Health Care Administration to provide regulatory and licensing personnel; the Department of Business and Professional Regulation Division of Alcoholic Beverages and Tobacco to provide sworn investigators. Plus, my colleagues on the Florida Cabinet have authorized the Florida Highway Patrol's participation, and investigators from the Division of Insurance Fraud are supporting this effort. Attorney General Pam Bondi is working with prosecutors across our state to ensure these criminals are prosecuted to the fullest extent of the law. I am grateful to all of these professionals for their commitment to this important work.

Not only are these efforts focused on Florida, but we are also coordinating with other states to shutdown a national prescription drug pipeline that some have called the "Oxy Express."

In these first days, I can report that a strike force in Central Florida has already assisted in an out-of-state case last week. Just the other day, I was disappointed to learn that a Deputy Sheriff in South Florida was the first drug trafficking arrest made since the initiation of the Strike Force. At this point it is too early to go into details on these cases, but I can tell you investigations are underway and we expect arrests to continue.

I believe these efforts are the crucial and necessary tools to turn off the supply of drugs into and out of Florida. But there is more for Florida to do.

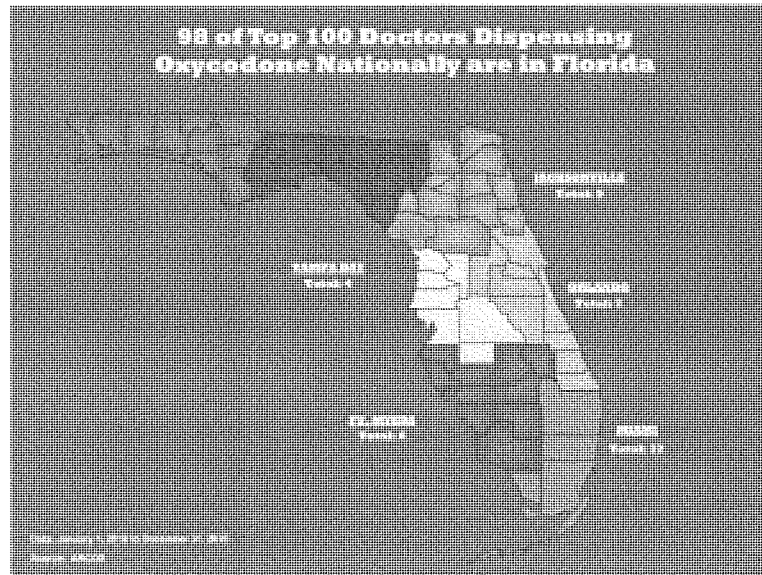
With my partners in the Florida Legislature, we are moving legislation to limit how doctors dispense narcotics and making sure doctors divest from pharmacies. The role of doctors who have forsaken their commitment to people's health in exchange for the quick buck of unethical and criminal dispensing cannot be overstated and absolutely must be put to an end.

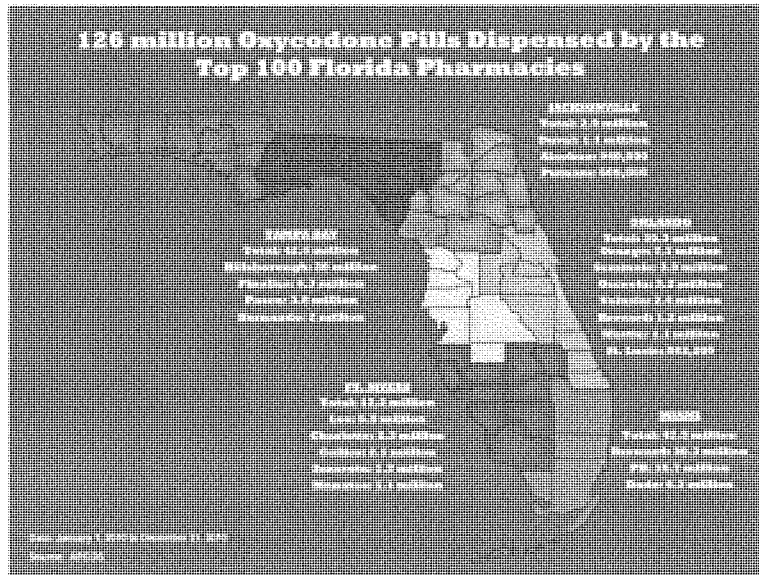
We will also closely review the activities of wholesalers in Florida, and we will put in place tough penalties for those manufacturers and distributors who fail to help us turn off the illegal supply chain.

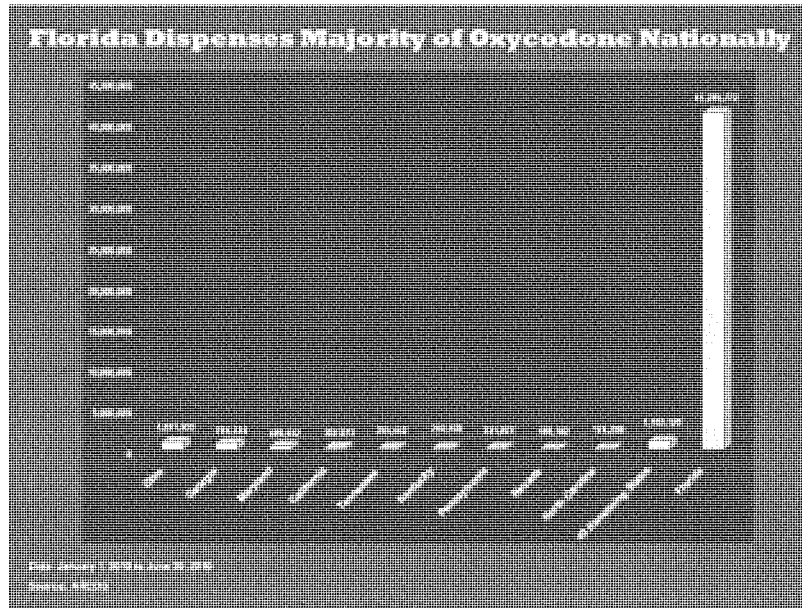
Let me conclude by telling you I believe we can fight this problem and, with the right strategy, I believe we can win. In my opinion, that strategy is centered on a law enforcement solution that focuses resources at the top of the distribution chain rather than the bottom.

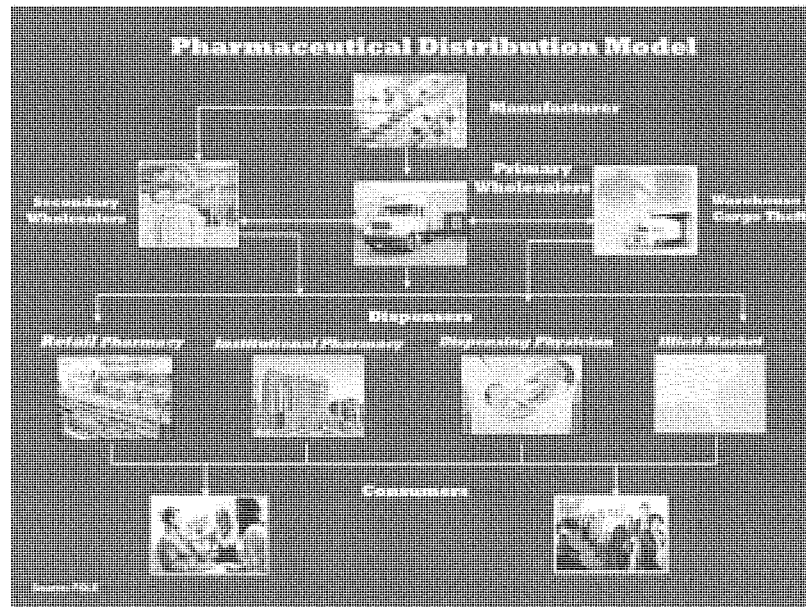
I applaud this committee for taking a serious look at the issue and would ask you to also focus your energy at the sources of this problem. Together, if we hold the manufacturers, wholesalers, doctors and pharmacies accountable, we can win this fight.

Thank you.









Mrs. BONO MACK. Thank you, Governor Scott.
Governor Beshear, you are recognized for 5 minutes.

STATEMENT OF STEVE BESHEAR

Mr. BESHEAR. Thank you, Madam Chairwoman, members of the committee. Thank you for allowing us to come here and discuss a national crisis that has been particularly destructive in Kentucky and in Appalachia in general, and that is the crisis of prescription drug abuse.

Let me be frank. Our people in Kentucky are dying. An average of 82 Kentuckians each month fall victim to drug overdoses, the majority related to prescription drugs. That is more than two people a day. To put that in perspective, more people in Kentucky die from overdoses than from car wrecks. Greater still is the number of families decimated by the financial and social toll of this illicit drug use. In the words of our law enforcement officials, medical professionals and coroners, what has long been a problem has become an epidemic.

Our response in Kentucky has been aggressive. We have ramped up enforcement. We have expanded the availability of treatment and we have implemented high-tech monitoring and recordkeeping while working to share that information with other States. Our prescription drug monitoring program called KASPER was created more than a decade ago as a tool for both the medical and law enforcement communities and is now available electronically. Singled out by the White House in 2006 as a national model, KASPER is inclusive and easily accessible. Furthermore, in 2005 Kentucky became one of the first States to require a doctor's examination for the writing of scripts for powerful painkillers and to require Internet pharmacies to be licensed in the State. Three years later, Congress passed the Ryan Haight Act.

But these innovative efforts have not been enough because as Kentucky has tightened its net, illicit drug users have found ready supplies of prescription drugs in other States with looser regulations, and we are not equipped to stop that. What is needed clear is an aggressive nationwide response, one that recognizes that this country's prescription drug strategy is only as strong as the weakest link in the chain.

I am here to push three thoughts. One, I urge Congress to continue providing resources to the Harold Rogers Prescription Drug Monitoring Grant Program so that the work toward data sharing among States can continue. We have come too far with that program to stop now. Forty-five States have authorized prescription drug monitoring programs and 34 are currently operating.

At this point I want to stop and salute the efforts of Congressman Harold Rogers of Kentucky. He has been a warrior on this issue of prescription drug abuse.

Secondly, training must be mandated for those who prescribe controlled substance, especially schedule II narcotics. These drugs and the risk of addiction and fatal overdoses must be more clearly understood by both doctors and patients. We can't leave this education simply to the pharmaceutical sales reps.

And three, the Department of Justice must focus more attention and resources on Florida, especially south Florida, to stop the flow

of prescription drugs. As Governor Scott and I have talked, it is a tremendous issue in his State and we both acknowledge that. Some 60 percent of the prescription drugs sold and consumed illegally in Kentucky come from the loosely regulated pain clinics in Florida with each trafficker bringing back on average more than \$10,000 worth of drugs. In 2009, Kentucky State Police arrested more than 500 people from eastern Kentucky in its largest drug roundup ever, and every single suspect had ties to Florida. These pill traffickers are not amateurs. They are sophisticated. They are well-organized operations. And the fight against them must be well organized as well.

I appreciate the very aggressive efforts that Governor Scott is implementing in Florida to attack this problem. I appreciate the fact that I believe now they are going ahead to implement the monitoring system that they passed a year or so ago.

And that, my friends, is good but it is a start. As we both know, it is just a start. It is one piece of a much larger strategy that we have to apply. This is a national problem that demands national solutions, and the sooner we come together to recognize that, the greater our success will be. Thank you.

[The prepared statement of Mr. Beshear follows:]



“Warning: The Growing Danger of Prescription Drug Diversion”

Presented by Governor Steven L. Beshear
Commonwealth of Kentucky
to the
Subcommittee on Commerce, Manufacturing, and Trade

April 14, 2011

The fastest growing, most prolific substance abuse issue facing our country is the diversion and abuse of prescription drugs. Nationwide, visits to emergency rooms by individuals using/abusing prescription drugs increased an astounding 98 percent from 2004 to 2009, according to the Drug Abuse Warning Network, a public health surveillance system that monitors drug-related visits to hospital emergency departments and drug-related deaths investigated by medical examiners and coroners.

The Commonwealth of Kentucky has not escaped the effects of this deadly phenomenon. In my home state, accidental deaths from prescription drug overdoses have skyrocketed, rising 34 percent in that same time period. Put in numeric terms, an average of 82 Kentuckians die every month from drug overdoses, which now surpass motor vehicle crashes as the leading cause of accidental death. As disturbing a picture as these numbers paint, they do not fully measure the problem: the statistics do not reflect drugged driving crashes that resulted in fatalities, nor the number of Kentuckians that overdosed in other states.

Throughout the past decade, Kentucky has implemented a number of program and policy initiatives in an effort to reverse this trend, including the development of a prescription drug monitoring program (PDMP). Created as a result of a task force headed by Congressman Chandler (then Attorney General of Kentucky) and recognized as a national model for its inclusive, easily accessible system, the Kentucky All Schedule Prescription Electronic Reporting system (KASPER) has been in place for more than 10

years, and allows prescribers to review the controlled substance prescription history of patients, and recognize the patterns of those who abuse and divert prescription drugs.

KASPER was upgraded in 2005 to eKASPER, making the system web accessible for faster, easier use. A 2010 survey of KASPER users indicated an overwhelming majority – 88.6 percent – of prescribers or dispensers have used a KASPER report to help with the clinical decision to deny medication to patients, compared to 58.4 percent in 2006 who had reported using KASPER in that process. The nearly 50 percent increase speaks to its use as a tool to identify potential controlled substance abuse and diversion.

Kentucky law enforcement officers became aware of large numbers of prescription drugs being shipped into the state from internet-based pharmacies. Prescriptions for powerful painkillers were being written by doctors who had never examined the patients, and filled by internet pharmacies whose only concern for the patients was their ability to pay by credit card. To respond to that tactic, Kentucky in 2005 became one of the first states to pass and enforce tough laws that required a doctor's examination for the writing of controlled substances, and required internet pharmacies to report to KASPER and be licensed in the state. Congress followed suit three years later, passing the Ryan Haight Act sponsored by Senator Feinstein to address the problem nationwide.

Kentucky medical and law enforcement officials soon identified a new trend in drug diversion: individuals and groups traveling to other states in an effort to avoid the scrutiny of KASPER, to obtain large amounts of prescription drugs from unscrupulous

doctors. In October 2009, during the state's largest drug bust, Kentucky law enforcement officials arrested more than 500 people in connection with diverting prescription drugs, all of whom had a Florida connection.

Thanks to support from the federal Harold Rogers Prescription Drug Monitoring Grant Program, Kentucky, along with Ohio, is developing a system allowing states with prescription monitoring programs to share data with authorized users.

Unfortunately, the state most prolific in providing prescription drugs to those who abuse and divert them currently has no prescription monitoring program. Since 2008, my office has worked with representatives of Florida's executive and legislative offices to provide information about the effectiveness of PDMPs, and encourage the development of a system in that state. In 2009 the Florida legislature approved the measure and start-up funding for the monitoring program; in late 2010, however, Florida's newly-elected Governor proposed to discontinue the program before it could become operational. We are glad to see from recent news reports that the project is moving forward and may be operational later this year.

The facts concerning Florida's impact on the accessibility of prescription drugs are clear. According to a report issued by a Broward County Florida Grand Jury in Spring 2009:

- In 2007 there were four pain clinics operating in Broward County, Florida; by 2009, that number had increased to 115, and continues to rise.
- During the last six months of 2008, the top 50 prescribers of oxycodone in the nation were located in the state of Florida – 33 in Broward County alone.
- In 2008, the Florida Medical Examiners Commission reported that there were 3,750 lethal dose reports of prescription drugs detected in deceased persons in the state of Florida, an average of more than 10 reported deaths per day.

In Kentucky, we continue to see that impact in human terms. Earlier this year, media reported the death resulting from overdose of a Kentucky mother who was found unresponsive in the rear of a vehicle during a routine traffic stop. According to reports, she was returning to Kentucky with two other people from a visit to a Florida pain clinic.

Kentucky has and will continue to use any and all means to reduce the prescription drug epidemic that grips us. We have increased treatment resources through public/private partnerships. We have expanded the availability of drug treatment in our prisons and jails, and Kentucky's Department of Corrections has increased its substance abuse expenditures from \$880,000 in FY 2005 to \$6.9 million in FY 2010. We will continue to refine and improve our programs and laws. We are reviewing legislative proposals for 2012 to include the regulation and licensing of pain clinics, as well as requiring all

prescribers of controlled substances to have an active account with the state's PDMP.

However, we are not an island. We live in a mobile society and that mobility limits the ability of any one state to be entirely successful on its own in addressing substance abuse issues. There are strategies that have a higher probability of success when implemented on a national level:

- I urge Congress to continue providing resources to the Harold Rogers Prescription Drug Monitoring Grant Program, so the critical work toward data sharing among the states can continue. We have come too far with that program to stop now.
- Prescribers of controlled substances, especially those treating pain with Schedule II narcotics, should be mandated to complete training related to those medications, as well as the disease of addiction. The University of Kentucky Center for Drug and Alcohol Research estimates that approximately 50 percent of all opioid addicts became addicted through a legitimate medical need. Since the recent reformulation of oxycodone (OxyContin), Kentucky has seen a shift in diversion to oxymorphone (Opana), a powerful narcotic with a significant risk of overdose death. Clearly, more prescriber and patient education is needed.

- The Department of Justice should investigate increasing resources to federal, state and local law enforcement and prosecutors in Florida – South Florida in particular – to address the threat that drugs obtained there will be diverted and abused on a regional scale. The High Intensity Drug Trafficking Areas (HIDTA) in Kentucky and South Florida identified this threat as early as 2007, and while these groups have used considerable resources to address the problem, evidence shows an increased effort is needed.

Our federal government has historically addressed drug threats at their origin; Columbia, Afghanistan and Mexico are examples of supply reduction efforts. Yet, as has been clearly demonstrated, the source of much of the prescription drugs that are destroying lives in my state, and in other states, is South Florida. An extreme effort should be made to immediately close down these drug dealing operations that masquerade as medicine.

Mrs. BONO MACK. I thank both our governors and recognize myself for the first 5 minutes.

I want to thank you both very much. I have encouragement that the two of you are sitting together, for those in the audience to recognize this is a bipartisan panel, and if you were to have only read your written testimony, you would have thought there would have been some sparks flying, but it seems that there is definitely a meeting of the minds here and a recognition first and foremost that the problem exists.

Governor Scott, congratulations on your recent election, but to you, I am encouraged to hear you are going to move forward now but I am also hoping you are going to continue to reject the \$1 million that Purdue Pharma offered you. Are you going to accept or reject that \$1 million Purdue Pharma offered you to fund a database?

Mr. SCOTT. We are not accepting it.

Mrs. BONO MACK. I thank you for that very much. Can you speak a little more as a businessman? You saw first and foremost that the law was being broken and you wanted to come at it from law enforcement. Can you speak a little bit more about this approach? Because I would love to see people go to jail. I would love to see some of these bad actors in handcuffs being taken off. Can you speak to your efforts a little bit more thoroughly from the law enforcement side?

Mr. SCOTT. Well, here is what we can do. We are in legislative session right now and so we have a very aggressive bill that is going forward that will help law enforcement, but in the meantime, we have a strike force. Our Florida Department of Law Enforcement, we took monies out of that budget right now and we took a lot of investigators from there, from the Department of Health and other agencies and provided help to each of our sheriffs and each of our police chiefs because they are just overwhelmed with this issue right now. At the State, we have got a lot more analytical and investigative research that we can do, so we are helping them deal with that. On top of that, we have a very aggressive attorney general. Attorney General Bondi is very aggressive on this issue and so we have done a good job with arrests so far. Eighty-seven percent of the oxycodone that comes out of the country comes out of Florida right now. So the strike force is going to have a big impact. But I think a bigger impact is going to be the fact that the doctors will not be able to both prescribe and dispense, so that will stop that. They are not going to be able to own the pharmacies. We are going to limit the number of prescriptions they can do a day. That will have a big impact. So it is just piece after piece after piece. And then of course, as we know, they will figure out something and then we will have to continue to change. But I think all those things put together with all the data that we are helping our local law enforcement will have a big impact.

Mrs. BONO MACK. Governor, do you need any help changing laws up here in Washington that you have found? Are you changing state law?

Mr. SCOTT. You know, I think that probably the biggest thing we need to look at is regulating these manufacturers and what should these drugs be allowed to be used for. So I think, you know, the

usage of it—I mean, the fact that you can prescribe for these things, you know, as Governor Beshear said, some of the things requiring the doctors to have to do a medical exam and all that, you know, that is already being done and it is never enough. There is always something else we are going to have to keep doing. But the first thing is, why are they even able to sell these things and for what purpose and should there be a much more limited purpose that these drugs can be used for.

Mrs. BONO MACK. Well, I look forward to working with you on these answers and moving forward, and I applaud that you are in the fight. I also would like to mention Governor Kasich as a third governor who has become very involved.

Governor Beshear, just a little bit of information. My parents met and fell in love before World War II at a little teeny tiny college called Berea, if you know Berea College in Kentucky. So it is a near and dear place to my heart.

But you also came in here sort of loaded for bear, ready to set your sights only on Florida, but can you speak a little bit about what you are hearing the governor say? You are encouraged about this willingness to cooperate?

Mr. BESHEAR. Listen, this is not a partisan issue. This is a life-and-death issue as we all know, and it requires us to work together. I don't know that there is ever going to be total solution to this problem. It is always going to be with us, but we can sure make a significant impact if we work together and bring all the tools that we have got and cooperate together. You mentioned Governor Kasich in Ohio. You know, we are working right now with Ohio trying to figure out how to share the information between our monitoring systems so that we can do an even better job than what we are doing.

Mrs. BONO MACK. For the sake of time, one of the biggest concerns of course is a privacy breach, and we are all very sensitive to that, and I think nowhere more so than in health care. Can you speak specifically how you are protecting that data and consumers can feel confident that they have privacy that they need?

Mr. BESHEAR. You know, we have had the system now for 10 years and we have got very strict privacy guidelines. It has a successful track record. It has never been breached. It is a felony for folks to breach that system. And it has worked. The integrity of the system has held together. I don't know of any system, whether it is with the CIA or the State Department or the Defense Department or our monitoring system that you can guarantee will never be breached, that will never find a way for somebody to hack into it. We obviously will continue to strengthen with the latest technology those security systems.

But is really a matter of weighing the issues here. You know, there is a slight risk always whether it is e-health records or whatever that some breach can occur, but when you are looking at 82 Kentuckians a month dying, when you are looking at about seven Floridians a day dying because of drug overdoses of legal prescription drugs, that is a pretty easy answer for me.

Mrs. BONO MACK. I thank you very much, and my time is expired. I recognize Ms. Blackburn for 5 minutes.

Mrs. BLACKBURN. I want to stay right there with the privacy and the online database issue because we are the committee of jurisdiction with telecommunications and the Internet. That is one of our subcommittees. And the privacy issue is one that we will do some work on this year. And Governor Beshear, you have had KASPER for 10 years, and I think it would be helpful to us as a committee as we consider both the larger privacy debate and as we look specifically at the prescription drug program to have some guidance from you all, some suggestions of what you think we could focus on.

And Governor Scott, let me just continue with the chairman's question to you. With these databases, what suggestions do you have and where are you seeing the problems? Have you all come up with a way to guard against the breaches and have you had any breaches?

Mr. SCOTT. Well, we just started to implement ours. When I came to office, there was a lawsuit that prevented us from implementing it. So we are just now getting started. And so what we are doing is, we are looking at what all the different States are doing with regard to privacy to come up with the best answer on dealing with that, because it is a big issue and we have people worried about it.

Mrs. BLACKBURN. All right. And Governor Beshear, did you say that you had or had not had a breach on your system?

Mr. BESHEAR. No, we have never had a breach.

Mrs. BLACKBURN. You have never had a breach in the 10 years?

Mr. BESHEAR. Right.

Mrs. BLACKBURN. So you feel like your firewalls—and do you do an opt-in or opt-out on information and data share? Get back to me on that. I know time is—

Mr. BESHEAR. I will. I am not sure on that.

Mrs. BLACKBURN. OK. Let us talk about education just a second because this is something with the prior panel as we had the DEA before us that we looked on just a little bit, and I think that it is important for us to continue to move forward with education. I would like for you each to give me just a 1-minute response on what you are doing with public education, with personal responsibility education, with parental education. I know in Florida the pain clinics are a problem that was recently discussed, and then you have a little bit of history, Governor Beshear, so if you all would talk about the education component, that would be helpful. Governor Scott first.

Mr. SCOTT. Sure. Well, what we are doing is, first off is making sure the public knows just through articles and things like that, make sure the public knows how big the problem is. I have done press conferences and things like that. I have brought it up through—we have had testimony in the legislature to talk about the issue. We spent a lot of time this legislative session going through what the problems are. So that is the biggest thing we are doing right now.

Mr. BESHEAR. Certainly the public education part of it in terms of talking about it publicly, and it is talked about a lot publicly in Kentucky right now, and I am glad of it because at least it is exposing all of our citizens to this dreaded problem. Also in our phar-

macy schools, in our medical schools, we are pushing to make sure that our doctors really understand, the ones that are coming out, and the pharmacists understand what they are really doing and that they don't get their information just from the drug reps, that they have the kind of information they need to handle these kinds of drugs very carefully and very effectively.

Mrs. BLACKBURN. Do you think most Kentuckians realize you have the KASPER system in place?

Mr. BESHEAR. I think there is probably a general knowledge we do, although it is probably not understood in terms of what it really does. But we are looking at strengthening that system. Right now, you know, doctors can voluntarily be in it or not be in it. I am thinking of beginning discussions about making that a little stronger.

Mrs. BLACKBURN. Having it be mandatory?

Mr. BESHEAR. Making that a little stronger. You know, I think doctors ought to be in that program.

Mrs. BLACKBURN. Thank you both, and I yield back in the interest of time.

Mrs. BONO MACK. I thank the gentlelady. The chair recognizes Mr. Stearns for 5 minutes.

Mr. STEARNS. Thank you, Madam Chair.

Governor Beshear, when you mentioned that more people are dying from overdose than automobile accidents, that is appalling. That is just a frightening statistic.

Governor Scott, earlier we had a Florida delegation, Madam Chair, so I heard some of the testimony from the governor, and I guess the question that came up when we had the delegation meeting, can pain clinics be subject to additional scrutiny before they are licensed to practice? Is that a place where we could start?

Mr. SCOTT. We are doing that now. We are doing it through—we already have where they have to be licensed so we are doing that. But it is not perfect. It is not easy to get around, but you can get around it. So that is actually one of the things that is in our bill. But the big thing is, think about this. We know the manufacturer, we know the distributor, we know the doctors that are distributing it. We ought to be able to stop this if we just keep tracking it. Now, people will change and there will be a new drug or something like that but this is a legal distribution system that is doing it the wrong way so we ought to be able to—if we track it all the way and have criminal penalties and civil penalties for everybody that is doing the wrong thing, I think we will have a dramatic impact in Florida for a period of time and then something will change.

Mr. STEARNS. Governor Beshear, anything you want to add to that?

Mr. BESHEAR. No. I think we need to be as aggressive as possible in all of these areas. We need to be aggressive in regulation of all of these folks and regulation of what the pharmaceutical companies can do in terms of who gets these drugs and how they are dispensed. We need to be very aggressive in the law enforcement area. And I think what Governor Scott is doing in Florida is showing that kind of commitment very quickly, and we have been doing that in Kentucky for some time also.

Mr. STEARNS. Intuitively, the relationship between the doctors and the pharmacies, is that anything that you as a governor, either one of you can do in terms of educating or threatening or somehow trying to influence the relationship between the pharmacy and the doctor, or is that sort of sacrosanct, that there is nothing you can do?

Mr. SCOTT. We are doing it in our bill. The doctor that prescribes will not be able to own a pharmacy.

Mr. STEARNS. Oh, that is good.

Mr. SCOTT. So we are going to completely separate it, and then we will have the data. We will be able to track all the way through. But I think stopping the ownership will have a significant impact.

Mr. STEARNS. Is there any State that has in place some of the things you have already talked about, Governor?

Mr. SCOTT. I haven't seen anybody that restricted the ownership of pharmacies.

Mr. STEARNS. Yes?

Mr. BESHEAR. One of the other things, and I am not sure how his laws are set up, but I appoint the doctors to the board of medical licensure and the pharmacists to the pharmacy regulatory board, and I have made it a very clear point before I appoint anybody, I have them come in and we talk about these kinds of issues, and I get a commitment from these folks to really bore in and try to address these kinds of issues as much as possible, and I think that is just another tool that we have to attack this problem.

Mr. STEARNS. Now, is there anything that the Federal Government, either one of you think we as legislators on the Federal side or perhaps direct the Federal agencies in some way that could make your job easier so we can stop these drugs from coming down the pipeline? So any suggestions you have would be very helpful. Governor Scott?

Mr. SCOTT. Sure. I think the biggest thing is, why—I mean, there ought to be restrictions on how these drugs can be used and what they can be prescribed for.

Mr. STEARNS. From the Federal level?

Mr. SCOTT. Yes.

Mr. STEARNS. From the FDA?

Mr. SCOTT. Right.

Mr. STEARNS. OK.

Mr. BESHEAR. Another area that I hope you all will pay particular attention to are continued funding for the Hal Rogers Act that is on the books now. That will help the States to share information and develop the systems to share information, and that will be effective in this battle, the HIDA, the Erns Jag awards and grants that are made that help us fight this specific problem. I know that just as Governor Scott and I are fighting budget battles every day, you all are too, but some things are more important than others and that is the way we all have to look at the way we balance our budget. That is what I do. That is what he does. And I just ask you in that priority, put this priority up there.

Mr. STEARNS. Well, I want to thank you. My time is expired. But I think the fact that both of you governors took the time to come up here to talk about this serious problem, I think is a commendation to you and also for us having this hearing, Madam Chairman,

because this shows that even though we are trying to reduce spending up here, this is a priority, I think, that is very serious in this country, and we have ways to stop it. So thank you for your testimony.

Mrs. BONO MACK. Thank you, Mr. Stearns. Mr. Guthrie, you are recognized for 5 minutes.

Mr. GUTHRIE. Thank you very much, Madam Chairwoman. And also your roots are from Muhlenberg County, or several generations back, I believe.

Mrs. BONO MACK. That is right.

Mr. GUTHRIE. Which is near where the governor is from, a couple counties over from where the governor is from. So thanks so much. And I did mention the first lady, she is from my area, so I should have mentioned that in the introduction. So I appreciate what she is doing as well for our State.

When we did KASPER, I remember it coming forth, and I will tell you, there is not a legislative session that doesn't go on, particularly the legislators from Appalachia, have always pushed what can we do to improve monitoring, interdiction. So the Kentucky leadership is focused on this and trying to help solve this problem.

If I remember some of the participation in the Medicaid, because it seems that the prescription drug problem is in areas that are heavily Medicaid as well, and I don't know if you know the correlation between that or if you have seen as well, Governor.

Mr. BESHEAR. Certainly, you know, prescription drugs are allowed under the Medicaid program obviously and every State is involved in that program, and you are going to have some abuse within that program, and we are very aggressive in the Medicaid area of trying to weed that out and at the same time educate people. You know, we are pushing in the Medicaid program the ability of our local health departments and those regional medical centers to educate our folks about the dangers of these narcotics. You know, so many of these people that end up being addicts start out as legitimate drug users, you know, that they need something for their pain or this or that, and they start out in a very legitimate way and then they end up being addicted and then they get into this cycle of buying the drugs illegally, and that just grows the problem.

Mr. GUTHRIE. And I know you weren't governor at the time, but when we passed KASPER, I don't remember Florida being such a big issue for us 10 years ago, but KASPER, did it just move—because I-75, wonderful highway, we love I-75 and people go to Florida and enjoy it and love it, but it also seems to be a pathway for the prescription drugs to come to Kentucky. Is that because we had KASPER because it helped curtail some of the problems we had so it just has moved?

Mr. BESHEAR. Sure. You know, before we had KASPER, they would just stay in Kentucky and get these drugs illegally, and we haven't cut all of that out. I don't want to even imply that. But we made a significant impact in it by having this monitoring system among several tools that we have, and the fact is, no State is an island, you know. Folks, if we stop them doing something in Kentucky but they can do it across the State line, they will go do it across the State line. And that is why it is so important for all of

us all across this country to find ways to address this. It doesn't have to be uniform everywhere but it has to be everywhere for this to really work.

Mr. GUTHRIE. Well, thanks. And I think I saw you on the news a couple of weeks ago. I know Florida is in session, and I guess a bill had seemed to have failed in Florida that might have addressed this, but it sounds like Florida does have a bill moving forward in the legislature now. I don't know if it stalled or whatever. I am glad to see you all together working on this because it is a problem for all of us. But what is going on in the Florida legislature to address the tracking or the similar KASPER deal?

Mr. SCOTT. Well, first off, the monitoring bill was passed last year, and there was a lawsuit that just got finished last Friday.

Mr. GUTHRIE. Maybe that is what you were referring to.

Mr. SCOTT. So that has finished. But we have a very good bill that looks like it is going to get out of both the house and the senate, which everybody has signed off on including the attorney general, who is very focused on this, and if you prescribe the drug, you can't dispense it out of your office. You can't own part of a pharmacy. There is a restriction on the number of prescriptions you can do a day. We have got tamper-resistant pads to write the prescriptions. We have got licensing of the pill mills and we have got criminal penalties, civil penalties going all the way up to the manufacturer. We are going to try to do everything we can to stop it. It is a big issue when 98 of the top 100 doctors in the country prescribing oxycodone are in Florida.

Mr. GUTHRIE. So are Florida's laws different? Because I-75, you have to go through Tennessee and Georgia to get to Florida. Are you all just so different? I know you are working on that? But is it so different now, the current status than Georgia or Tennessee? I mean, Kentuckians aren't going to Tennessee, they are going to Florida, so what is the difference, I guess?

Mr. SCOTT. Every State has been different.

Mr. BESHEAR. And what has happened is that some of this is starting to move to Georgia because Georgia doesn't have a monitoring system. Tennessee does. And that is, I think, initially what pushed it south, and you know, Georgia may be the next place that we really have to push hard to get them to address this situation.

Mr. GUTHRIE. Thanks, Governors. Thanks for making the trip to Washington today. I appreciate it. I have to yield back now. I am out of time.

Mrs. BONO MACK. I thank the gentleman. Mr. Harper, you are recognized for 5 minutes.

Mr. HARPER. Thank you, Madam Chair, and welcome to each of you, and it is an honor to have you here. This is a very important issue. We all have friends who have had their families devastated, primarily by young people who get those prescription drugs from their medicine cabinet at home. That seems to be a major problem.

So how do we solve the underlying problem here is that no matter what regulations we put on, which will be very helpful, how do we convince these young people not to use the drugs, not to take them? Are you doing anything in conjunction with, say, success in drug courts or any faith-based programs? Governor Beshear, I will ask you that first.

Mr. BESHEAR. Yes, we have drug courts, we have faith-based initiatives that all work in this area. Obviously a part of it is education, and we are pushing that both in the public school system as well as through faith-based initiatives. The other end of it is treatment and rehabilitation, and we took a significant step recently in Kentucky by revising a major part of our corrections system and our approach to corrections to put a lot of time and effort into treatment and rehabilitation so that we can stop recidivism and stop that revolving door to where folks just get out, you don't give them any help, you just turn them loose again, and, you know, within 30 days, they are out trying to buy the drugs again and they are back in. And we brought the Pew Foundation into Kentucky and had a bipartisan effort of Republicans and Democrats, our house, our senate, our supreme court, the court system as well as the governor all got together, and we have made some major changes that I think on that end of the spectrum will address the recidivism rate.

Mr. HARPER. And Governor Scott, your State dealing with drug courts or faith-based initiatives to help in this effort, what is the story there?

Mr. SCOTT. Well, the big thing we are doing since I have been in office is educate the public to make sure everybody gets on board, first off, making sure we get this legislation passed so that was very important to get that done. The strike force is very important. On top of that, just continuing to educate the public. The schools are educating the public. Also, the individual I put in charge of Department of Corrections is very focused on this and the same thing as Kentucky, very focused on the number of people that get out of prison and go right back and have the same problem. So he is somebody that is very focused on that issue.

Mr. HARPER. Well, obviously our goal is to make sure they never get into the court system in the first place and how do we encourage folks this is not the route to go?

Mr. SCOTT. Well, one thing we have done is, our juvenile justice is run by an individual from Miami. She came up to work with me, and she is focused on a program that she has worked for 20 years in Miami that has had a dramatic impact in stopping sort of the—the first time you get stopped for something, you don't end up in prison just because it ends up being a cycle. So all the things she has done starting with civil citations and starting with, if you get stopped for the first time, it is not just that issue. You might have an issue over food, shelter, family issues, things like that, and having a holistic approach to it to stop them from ultimately ending up in prison. So we are taking all the things that she is doing and spreading them across the State. On top of that, we have legislation that would allow us to do a civil citation program rather than immediately moving into a criminal program.

Mr. HARPER. And how you secure the prescriptions at someone's home so that no one other than the intended patient gets it is a really tough thing to do.

Mr. SCOTT. That is the hardest.

Mr. HARPER. I am interested in what you said about your task force that you have in place. How are you going to measure the

success of the mission of that task force? What are you anticipating or hoping for out of that?

Mr. SCOTT. Well, the numbers have to get better. We can't have 98 of the top 100 doctors, 126 million pills. It is basically, how do we stop basically all this happening in our State. But it is going to be arrests, it is going to be the number of prescriptions that are done. In the end, it is prescriptions and deaths.

Mr. HARPER. What about working in conjunction with your State medical association? What input have they given either of you?

Mr. SCOTT. Well, in our case, they are very focused. I am doing something similar because I have the opportunity to appoint the members of the board of medicine, so as I am going through that process and talking to individuals about those positions, I have talked to them about how important this issue is and the fact that they have got to be engaged and the board of medicine has to be engaged.

Mr. HARPER. Governor Beshear?

Mr. BESHEAR. Same thing here. You know, we are engaging the medical profession, the pharmacy profession as well as their regulatory boards, and you know, as I am sure Governor Scott would point out, those boards, their first duty is to protect the public and not just protect themselves, and we see a little bit of that in every regulatory environment whether that is lawyers, doctors, pharmacists, and I am a lawyer so I can say that about myself. But, you know, we have got to emphasize that their first duty is to the public and to protect the public, and it just comes down to appointing the right people.

Mr. HARPER. Thank you each for being here, and Madam Chair, I yield back.

Mrs. BONO MACK. I thank the gentleman. The chair recognizes Dr. Cassidy for 5 minutes.

Mr. CASSIDY. Thank you for being here, gentlemen. My pain doctors really like the PDMPs because they feel like the pill mills give everybody else a bad name. Now, that said, I gather from testimony that some of these PDMPs are robust and some of them are limited in ability.

Now, Governor Scott, clearly you have legitimate concerns regarding the privacy, but as much as you can say, and I gather Kentucky has a rather robust program, where do you imagine yours will be on the spectrum? And I just mention that because at the previous meeting, Florida was described as ground zero for the promulgation, if you will, or the source, if you will, for these drugs across the Nation.

Mr. SCOTT. Well, it is clearly ground zero, so it is a significant issue and things that are—Florida's problem is a problem for the whole country because we haven't stopped the abuse. So our database will be—what we are doing is, being one of the later States to do it, we will be able to take all the benefits, take all the knowledge from the other States, which is what we are doing, both to make sure we have the right information and also have the right privacy concerns that we can address, so we will be doing both of those. But on top of that, we are going to make sure we are tracking from the manufacturer to the wholesaler to the doctor, not just at the pharmacy after the fact, because after the fact is going to

be part of what we do but I think the biggest part is going to be, we are going to stop the distribution of it.

Mr. CASSIDY. I see that. OK. Now, let me ask you, my pain doctors also tell me part of the problem is that someone may live on the Pearl River borders between Louisiana and Mississippi, and I think there is a Pearl, Mississippi, and a Pearl, Louisiana, and they say live in one State and go to the other and they will get as much they can below the threshold here and then they will go back here, and they will do as well on the other side. Now, clearly, that just may require a Federal overlay, but as two fellows who obviously will be jealous and respective of States' prerogatives, how do we keep folks from popping across State borders to maximize—do you see where I am going with that, Governor Beshear?

Mr. BESHEAR. Well, first of all, both States need the monitoring program, and do both of them have that?

Mr. CASSIDY. They both do, but each is self-contained.

Mr. BESHEAR. Right, and they need to be doing what we are doing with Ohio right now. We are sitting down and trying to work out how to share information, and we are going to do that. Governor Kasich and I will end up—we will find a way to do that. And we are being helped by this Hal Rogers grant program. That is the money that has been provided to help States work to share information in these monitoring systems, and we need to continue that. We need that funding to continue doing this so that every State ultimately will be sharing across State lines. That is the only ultimate way that these programs will be as effective as possible.

Mr. CASSIDY. And so although you start off with Ohio, you share a border, you actually envision that eventually you may partner with Governor Scott, for example?

Mr. BESHEAR. Yes.

Mr. CASSIDY. And wherever there is a potential distribution, to be able to go there?

Mr. BESHEAR. Yes. We all need to partner eventually so that there is no place in this Nation that people can go and be able to do what they are doing now as freely as they do it.

Mr. CASSIDY. Now, Governor Scott, I have to admit, I am a gastroenterologist, which I tell people prepared me very well for Washington, D.C. So if what I am about to ask you seems very simplistic, it may be, but it seems like if you know who those 98 docs are, all you need to do is have an undercover person walk in. I am told these pill mills, you may \$250 or something for a visit. Five minutes later, you walk out with a handful of prescriptions. It seems like you could go to each of these and put them out of business for inappropriate prescribing. Why not?

Mr. SCOTT. The difficulty is that the smart ones, what they are doing is, it will appear legitimate. They will do the MRI, they will do the history, they will do all these things, and so it is not as easy as just walking in and saying that you are doing something wrong. You have to have—that is why we spent a lot of time on this legislation with the attorney general and with the sheriffs and the police chiefs to make sure that what we are passing is something they are going to be to convict with because they will do all the—everything I have been told, they will do all the basic things to make sure it is very difficult to stop them.

Mr. STEARNS. Will the gentleman yield just for one second?

Mr. CASSIDY. I will.

Mr. STEARNS. I would think if you just let out the word that you are going to do sting operations, I mean, I would think that would create a pale over those physicians that might retard them from doing this. So I know, Governor Scott, it sounds difficult but I think what the gentleman is saying is, the fact that these stings might or might not come would create some caution.

Mr. SCOTT. I think the difficulty is, there is a lot of money in this. There is a lot of money being made.

Mrs. BONO MACK. I thank the gentleman. We are fortunate to have the governors, I understand, until 10:15, so we would like to do a second round of questions until that point if my colleagues are so inclined, and I will recognize myself for the first 5 minutes and just point out a few things that I think are essential for this discussion.

First and foremost, it was my understanding that OxyContin was originally approved for severe cancer, late stages of cancer for severe pain yet the number-one prescriber today of OxyContin to children 12 and over is dentists, and I think that should be pointed out.

I would also like to talk a little bit about the parental education, words that keep coming up, and point out that we have two panels yet to speak who will show that parents of all walks of life are affected by this and that it is impossible to detect this problem until it is too late.

Governors, in your travels and your meetings with addicts and loved ones of addicts, first of all, would you be—I contend that OxyContin is heroin. Would you take big umbrage with that? Would you say that is about right, what you are seeing?

Mr. SCOTT. You know, you never know the definition, but I can tell you, we ought to really restrict what it can be prescribed for.

Mrs. BONO MACK. I have a bill that does just that, and I will be looking forward to working with you on that. You keep speaking also, Governor, about limiting all of these leftover pills in the medicine chest, and I keep wondering why we are prescribing, you know, hundreds of tons of pills a year that go unused. If patients don't want them, why are they getting out there? That is another question that I look forward to exploring with you.

And Governor Scott, I want to applaud you on your decision to reject the \$1 million from Purdue Pharma for your database. Just recently there was an article here that points out that the CDC authored a study where they linked these powerful painkillers to deaths and the University of Wisconsin School of Medicine released a study that disputed that and talked about liberalizing opioids, and lo and behold, financed by Purdue Pharma, and I would like to submit this article for the record.

[The information follows:]

Side Effects | A Journal Sentinel Watchdog Report

UW a force in pain drug growth

Research group receiving millions from pharmaceutical firms helped liberalize use of opioids

By [John Fauber](#) of the Journal Sentinel

April 2, 2011 [\(103\) Comments](#)

As an epidemic of narcotic painkiller abuse raged across America in 2006, researchers at the U.S. Centers for Disease Control and Prevention authored a critical study linking deaths from those drugs to an increase of up to 500% in the number of prescriptions written.

In that same medical journal, two researchers from the University of Wisconsin School of Medicine and Public Health took exception with those conclusions and warned against increasing regulation of the drugs.

The article did not disclose that their UW Pain & Policy Studies Group already had pocketed most of the \$2.5 million it would be paid over the years by the very companies that made the dangerous drugs - firms that stood to lose if prescribing rules were tightened, a Journal Sentinel investigation found.

Fueled by a continuous infusion of money from the manufacturers of drugs such as OxyContin over more than a decade, the UW research group has been a quiet force in the effort to liberalize the way those drugs are prescribed and viewed in the United States.

In addition, records show cozy personal financial relationships between drug makers and two officials with the UW Pain Group, Aaron Gilson and David Joranson. Those include helping a drug company win Food and Drug Administration approval for a new narcotic painkiller and working as speakers or consultants.

Gilson and Joranson refer to themselves as scientists, but neither are physicians. Gilson has a doctorate in social welfare; Joranson has a master's in social work.

For this article, the Journal Sentinel requested annual payments from pharmaceutical companies to the UW Pain Group and university records of annual reports listing outside income paid to Gilson and Joranson.

The narcotic painkiller industry's funding of the UW Pain Group is a unique twist on the drug and medical device industry's use of medical schools to sell more of its products, sometimes at the expense of patients.

The Journal Sentinel has documented in past articles how dozens of UW doctors hired themselves out as speakers for drug companies or were enriched by lucrative royalty and consulting deals with medical device

makers.

At the same time, the medical school itself has pulled in millions of dollars in pharmaceutical industry money to sponsor courses for doctors that sometimes were little more than advertising disguised as education, according to critics.

The university says the pain group's money comes with no strings attached, and that the group's goal is to improve pain care and access to opioids worldwide. The group says its mission is to "balance" international, national and state pain policies and to achieve availability of pain medications while minimizing diversion and abuse.

But doctors in the addiction and pain fields say the UW Pain Group pushed a pharmaceutical industry agenda not supported by rigorous science.

"They advocate for policies that benefit pharmaceutical companies and harm pain patients and the public health," said Andrew Kolodny, an expert on opioid addiction. "You have to wonder if they're doing this because their bread is buttered by big pharma."

Their efforts helped create a climate that vastly expanded unproven medical use of the often abused drugs, said Kolodny, chairman of psychiatry at the Maimonides Medical Center in New York.

Undisclosed conflicts

For doctors and consumers, it is critical to know about a researcher's financial ties to drug companies, but often those financial conflicts are not disclosed.

The Journal Sentinel identified several instances in which financial relationships between drug companies and the UW Pain Group were not disclosed in medical articles co-authored by group scientists.

By far the biggest chunk of money the UW Pain Group got was from Purdue Pharma. In 2007 the company was accused by the U.S. Department of Justice of fraudulently misleading doctors by claiming, with no proof, that its narcotic painkiller OxyContin was less addictive, less likely to cause withdrawal and less subject to abuse than other pain medications.

At the time, scores of deaths and an even greater number of addictions were attributed to OxyContin. The company and three of its executives pleaded guilty to various charges. A court imposed fines and restitution payments totaling \$635 million.

Between 1999 and 2010, Purdue paid the UW Pain Group about \$1.6 million, according to university records obtained by the Journal Sentinel through an open records request.

The UW Pain Group may have helped pave the way for OxyContin's widespread use.

In 1996, Joranson, who is listed as the founder and distinguished scientist of the group, was vice chairman and co-author of a committee that issued a consensus statement from the American Pain Society and the American Academy of Pain Medicine. The statement suggested that opioids were safe and effective for chronic, non-cancer pain and that the risk of addiction was low.

The committee chairman and co-author of the paper was J. David Haddox, then a paid speaker for Purdue Pharma and physician with Emory University School of Medicine who would become a Purdue Pharma executive three years later. Haddox now serves as vice president of health policy at Purdue Pharma. Critics say there is a lack of rigorous evidence supporting the use of opioids for long-term, non-cancer pain.

"People have gotten a little cavalier about things," said Roger Chou, an associate professor of medicine at Oregon Health & Science University. "A good portion of patients on opioids probably should not have been started on them. There are a lot of people who could be taken off these medications."

Indeed, doctors in the field say prescribing those drugs long term for non-cancer pain may provide modest benefit to some, but also can cause physical dependence, increased pain sensitivity, unintentional overdoses and even death.

Just months before the consensus statement was published, Purdue Pharma's OxyContin received FDA approval for use in the U.S. Its sales would skyrocket in the years to come, reaching \$3 billion last year, according to data from IMS Health, a drug market research firm.

UW's Joranson, who did not respond to email and voice mail requests to be interviewed, also teamed up with Purdue Pharma's Haddox in 2002 to co-author a paper warning state medical boards that fears of regulatory scrutiny could harm the efforts to manage pain in the U.S.

The paper, which also was authored by Gilson, of the UW Pain Group, made no mention of the money the group was getting from Purdue Pharma and other makers of narcotic painkillers.

UW response

In an email, Lisa Brunette, a UW spokeswoman, said the organization's drug industry funding was accepted as unrestricted educational grants and the group performed no work for the companies that provided the funding.

Brunette said the organization's mission is to improve the care of patients with pain and to focus on government policies that contribute to untreated pain.

"The medical use of opioid analgesics has been considered, for more than 50 years, as indispensable to the relief of pain and suffering," she said. "The United Nations acknowledged this in 1961, and the executive director of the U.N. Office on Drugs and Crime and the International Narcotics Control Board both reaffirmed this in 2010."

Gilson would only respond to questions sent by email.

Gilson said he disclosed conflicts of interests "if there was a requirement by the journals" to submit a conflict-of-interest disclosure form. He cited Medscape as an example of articles in which he submitted disclosure forms. He said he could not remember if it was required for other articles that appeared in publications years ago, but if it was, he submitted the forms.

Five Medscape articles by Gilson about opioids and pain stated that he "has disclosed no relevant financial relationships."

"Authors do not control how any journal or website chooses to present information in their publication," Gilson

wrote in an email response.

Katherine Hahn, a spokeswoman for WebMd, the parent of Medscape, said other articles disclosed that Gilson received personal income from drug companies. She could not explain why the five Medscape articles included in the Journal Sentinel investigation reported no relevant financial relationships.

Gilson also said the personal income he received from drug companies was declared appropriately to the university.

Haddox, the Purdue Pharma vice president, said it was "very jaundiced" to think the drug company was giving the UW Pain Group money to take positions that would allow the company to sell more of its drugs.

While the group's work may have helped increase sales of Purdue Pharma drugs, that was not the intent of the funding, he said.

"They are trying to promote balanced access to pain care, including the use of opioids," Haddox said. "We believe in the work they are doing."

Millions from companies

Not only has the UW Pain Group received millions from pharmaceutical companies, but Joranson and Gilson have been paid by drug makers or their contractors more than a dozen times for giving lectures, writing papers or other work.

That includes work Joranson did for DesignWrite, a New Jersey medical communications firm that was investigated by a U.S. Senate committee for its involvement in ghostwriting doctor education material that put a rosy spin on hormone therapy drugs, even after the drugs were found to cause breast cancer and also were linked to heart disease, blood clots and dementia. Joranson was not involved in the hormone therapy articles.

Journal Sentinel reports in 2009 documented how UW, DesignWrite, and Wyeth - the hormone therapy drug maker that funded the doctor education articles - created the Council on Hormone Education, a six-year long initiative that reached tens of thousands of doctors.

UW, which received \$1.5 million for sponsoring the program, took the articles off the Internet one day after the Journal Sentinel began asking questions about the propriety of the program.

In addition, Gilson was paid between \$10,000 and \$20,000 in 2008 to help Cephalon, a company that makes narcotic painkillers, obtain FDA approval for a new drug, according to UW records. At the time, UW did not require disclosure of the actual amount, only a range.

The five days of work he did for that money included attending an FDA approval hearing as a consultant on behalf of the company.

Between 2000 and 2004, Cephalon also paid \$25,000 to the UW Pain Group.

Like Purdue Pharma, Cephalon has been the target of a U.S. Justice Department investigation involving narcotic painkillers.

In 2008, it settled an investigation of off-label marketing of three of its drugs, including Actiq, a powerful painkilling product manufactured as a lollipop with the drug fentanyl.

The drug was approved for use only by cancer patients who no longer were getting pain relief from morphine-based drugs.

But Cephalon allegedly promoted the drug for non-cancer patients with conditions ranging from migraines to injuries. It also promoted Actiq for use in patients who were not opioid-tolerant and for whom it could have been life-threatening.

"These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients," according to a statement from the U.S. attorney's office that handled the case.

Cephalon agreed to pay a \$425 million penalty.

Advocacy for opioids

Throughout the 1990s, pain specialists, including researchers at the UW Pain Group, helped change the prevailing view in the medical community about the use of opioid analgesics, arguing that the risk of addiction to the drugs should not prevent their use in treating long-term, non-cancer pain.

The UW Pain Group's work has included chastising states with its annual "report cards" on policies restricting use of narcotic painkillers; writing medical articles supporting use of the drugs; and attempting to influence the Drug Enforcement Administration and the FDA about pain policy.

In 2008, the UW Pain Group wrote to DEA about the agency's proposed electronic prescribing system for controlled substances. It warned that the system likely would "create a cumbersome and overly strict system" that would be "an enormous burden of oversight for practitioners and pharmacies." The electronic prescribing system would give doctors the ability to write prescriptions electronically as a way to help maintain stricter controlled substance dispensing.

In 2009, the group warned the FDA that a moratorium on long-acting narcotic painkillers could hurt patients. Long-acting, or extended-release, opioids such as Purdue's OxyContin, are powerful painkillers that only have to be taken three times a day or less frequently.

Among the restrictions being considered by the FDA were a temporary moratorium on prescribing the drugs and a ban on OxyContin.

Throughout the 1990s and 2000s, as doctors became more willing to prescribe opioid analgesics for chronic conditions such as back pain, headache and fibromyalgia, prescriptions soared, though there are serious doubts about whether the drugs are beneficial for such conditions.

Pain specialists say there has been a lack of research showing that the drugs are safe and effective for treating non-cancer pain for many months or years.

One such critic, Jane Ballantyne, a professor of anesthesiology and pain medicine at the University of Washington, said the UW Pain Group played an important role in liberalizing use of the drugs.

"The drug companies have commandeered the good intentions of people like the Wisconsin group," she said. "Part of the way (drug companies) are so effective is they pick the message and the messenger."

But the concept of treating chronic pain with opioids was flawed, she said.

And it became an agenda that was not based on sound science, she said.

It was believed that if the drugs were good for treating pain in terminal cancer patients, they also would be beneficial for people with chronic conditions such as back pain. But rigorous studies proving that have not been done.

The drugs became so common that in 2007, 700 milligrams of morphine or its equivalent were prescribed, on average, for everyone in the country.

That's enough to give every man, woman and child round-the-clock dosing of Vicodin for three weeks.

Unintentional overdose deaths from opioid analgesics grew from 2,901 in 1999 to 11,499 in 2007, by far eclipsing deaths from heroin and cocaine combined. Opioid deaths follow a track that is almost identical to the growth in sales of the drugs. In addition, an estimated 1.9 million people abused the drugs or had dependence problems between 2007 and 2009.

Pain specialists who are against tighter regulation of opioids say that a major portion of the abuse and overdose problems have been in people who obtained the drugs illegally. However, critics say the massive increase in prescriptions for chronic and common ailments has contributed to illegal, recreational use of the drugs, as people with prescriptions sell or give away pills or the medications are taken from their medicine cabinets.

In addition, a considerable percentage of people who started out using the drugs for medical reasons end up abusing the drugs, doctors say.

Unproven uses

Pain experts say there is concern that the drugs may cause harm, including dependence and addiction.

Chou, of the Oregon Health & Science University, said OxyContin is one such drug that was marketed as being safer and not causing withdrawal.

"It turns out, that was not the case," he said.

Chou said the UW Pain Group clearly has staked a position that narcotic painkillers are appropriate for chronic pain.

He said there is a legitimate argument that they should not be taking money from the companies that make the drugs.

Consider one of the more influential papers written by UW Pain Group researchers, a 2000 study in the Journal of the American Medical Association.

In that paper, Joranson, Gilson and two other UW authors assured doctors around the country that increasing

prescriptions of narcotic painkillers were not contributing to drug abuse problems in America.

But the article, which looked at reports of abuse between 1990 and 1996, left out important data on one of most common and most abused opioid painkillers, hydrocodone. Big increases in hydrocodone had been reported in 1997 and 1998.

Hydrocodone is used in many pain products, including Vicodin, an often-abused drug. Former Green Bay Packers quarterback Brett Favre became addicted to Vicodin after first getting it from team doctors to relieve pain in 1992.

Critics of the article question why the hydrocodone data was not included because it is an opioid and it has been abused.

The hydrocodone data for 1997 and 1998 was available when the JAMA article was published in 2000, said Len Paulozzi, a physician and medical epidemiologist with the CDC.

"I don't have a good understanding of why they made those choices (to omit the hydrocodone data)," said Paulozzi, who points out the missing JAMA data in his slide presentation on America's prescription drug overdose epidemic.

In his email to the newspaper, Gilson said he and the other authors of the JAMA article explained in the article why they did not include hydrocodone. (It had to do with hydrocodone being a lower classification drug that was not indicated for severe pain.)

The 1996 data was the latest that was available to them, Gilson added.

Paulozzi said he believes the reassuring JAMA article had an influence on the prescribing habits of doctors.

Changing those habits will be difficult, doctors say.

But a group known as Physicians for Responsible Opioid Prescribing now is trying to undo the damage.

It includes a list of myths and warnings about long-term opioid therapy.

"It's not an easy thing to turn around," said Ballantyne, of the University of Washington.

This article is part of an ongoing series about how money and conflicts of interest affect medicine and patient care. John Fauber reported this story in a joint project of the Journal Sentinel and MedPage Today. MedPage Today provides a clinical perspective for physicians on breaking medical news at medpagetoday.com. Kristina Fiore, a staff writer with MedPage Today, and Ben Poston of the Journal Sentinel staff contributed to this report.

Find this article at:

<http://www.jsonline.com/watchdog/watchdogreports/119130114.html>

☐ Check the box to include the list of links referenced in the article.

Mrs. BONO MACK. And I think people need to start looking at the connection between these studies and these policies and the big money that you were just speaking about, Governor Scott.

Governor Beshear, clarification again if I might. You did say the number of fatalities in Kentucky from drug overdoses has now surpassed automobile accidents. Is that legal or illegal drugs, again?

Mr. BESHEAR. It is a combination but the majority of it is legal drugs, abuse of legal drugs.

Mrs. BONO MACK. Thank you. And then Governor Scott, as a businessman, when you look at the chart for the dramatic increase of opioid abuse, it is ironic that the trend line started screaming upward shortly after OxyContin was approved. As a businessman, does that look kind of fishy to you like it does to me?

Mr. SCOTT. Yes.

Mrs. BONO MACK. Thank you.

Mr. SCOTT. If you look at my testimony, you see how many—I mean, 87 percent of it coming out of Florida too and just the dramatic increase.

Mrs. BONO MACK. Thank you. And another point, as somebody who has spoken publicly about my family's problem with this or being involved with this disease of addiction—and it is a disease and I am happy that Congressman Harper brought up that side, that they shouldn't be necessarily in the courts but we should treat it as a disease first and foremost. But as governors, when you meet the families that are suffering, aren't these just normal families, regular families? I can show you stacks and stacks, I know you have pictures too, of kids who are in their senior year of high school, one family whose son died just a week before his graduation from high school, and he was an all-star athlete, on the dean's list. Everything is right about these kids. Do you believe like I do that when these kids get access to these powerful painkillers they don't stand a prayer in the ability to stay off of them?

Mr. BESHEAR. This cuts across income brackets, it cuts across every bracket. This is a problem that everybody is having, and I don't know that there is anyone in my State or any other State anymore that doesn't know somebody, whether it is in their own family or a friend or another family that has been affected by this.

Mr. SCOTT. Yes. A good friend of mine's 18-year-old just died 2 weeks ago of an overdose, and he found her. It would be horrible. But it impacts everybody.

Mrs. BONO MACK. Was your friend aware that his daughter was using?

Mr. SCOTT. He had found out, sent her to a program. What happens to a lot of people is that, you know, the kids turn 18, they don't have to be in a problem.

Mrs. BONO MACK. There is a mother who will speak to that on the next panel, to that very thing.

Have either one of you ever met somebody who wanted to be addicted?

Mr. SCOTT. No. I have a family member that has been addicted his whole life, never beat it. He started at a young age and never beat.

Mrs. BONO MACK. And it is a lifelong struggle. Again, I thank you two very much. I look forward to our continued working relationship. Again, I appreciate your courage in being here today.

I will now yield to Ms. Blackburn for 5 minutes.

Mrs. BLACKBURN. Just a follow-on. Governor Beshear, you mentioned you were thinking about putting your program as a mandate, and as I have sat here listening to you all respond to the questions, I am thinking, you know, it must be very difficult, and you may have some guidance for having a program that is an option for your pharmacists and your physicians, and it seems as if those who are illegally prescribing or illegitimately prescribing, over-prescribing, would choose not to use the system. So I wonder what—if you would just explain a little bit about what has led you to that, and as Governor Scott is setting his program up, what would you advise him? Would you advise him for it to be a mandate from the get-go?

Mr. BESHEAR. Well, I am going to be sitting down with our medical licensure board and our medical association and the dentists and the pharmacists and talk about this, but so far it has proven effective the way it is set up in that the doctors that are using it can actually detect other doctors even if they are not using it that are over-prescribing and are abusing the system as well as being able to detect those who—

Mrs. BLACKBURN. So you are using it as an accountability tool even for those that are outside of the system?

Mr. BESHEAR. Yes.

Mrs. BLACKBURN. OK. That is great. Now, how do you pay for your system and what is the cost of it each year?

Mr. BESHEAR. It is paid for by State funds.

Mrs. BLACKBURN. Taxpayer dollars?

Mr. BESHEAR. Taxpayer dollars, and I am not sure, I can't tell you offhand what it costs.

Mrs. BLACKBURN. If you would submit that?

Mr. BESHEAR. It costs a fraction of what it costs to handle the problem the other way.

Mrs. BLACKBURN. All right. And Governor Scott, you said you are not taking a grant that was offered to you so how do you all intend to pay for your system?

Mr. SCOTT. We have funding from other individuals and companies that are putting the money up.

Mrs. BLACKBURN. Are they pharmaceutical companies or—

Mr. SCOTT. No. We have got 2 years of funding right now. We are just starting to implement ours.

Mrs. BLACKBURN. Correct.

Mr. SCOTT. But no, it is not pharmaceutical companies.

Mrs. BLACKBURN. So it is private funding?

Mr. SCOTT. Right.

Mrs. BLACKBURN. So there is no taxpayer dollar involved?

Mr. SCOTT. No.

Mrs. BLACKBURN. OK. Thank you. I yield back.

Mrs. BONO MACK. The chair recognizes Mr. Guthrie for 5 minutes.

Mr. GUTHRIE. Thank you, Madam Chairwoman.

Again, I think that if I remember the problem, we were trying to define it in the legislature, it seemed to be Medicaid, you know, where if you have private insurance and they limit how many prescriptions you can get over and over, and we had to address that with the Medicaid but it just seemed that is where a lot of the prescriptions were coming, not everyone. It cuts across all swaths of people. But the concentration of it was. And you weren't here, Governor Beshear, earlier but Mr. McKinley asked the question to the panel before, to the DEA, about why does Appalachia seem to be in a bigger—you know, because it is not only Appalachia using drugs in Kentucky, I can tell you that. In my area, though, it is methamphetamine. So every time we would show up in Frankfort for our legislative sessions, groups of us were trying to fight meth and other groups were fighting this. But it does seem the prescription drug part of it is concentrated in Appalachia where in my area it is the illegal manufacture of meth. I don't know the answer to that, and I thought it was a good question. I don't know if you all have looked at that way, why Appalachia seems to be more on the prescription side. Maybe it is I-75 access to Florida versus our area is not that way. I don't know.

Mr. BESHEAR. Well, it is obviously a nationwide problem. There are, I think, concentrations of prescription drug abuse in some places. There are concentrations of things like meth—

Mr. GUTHRIE. In my area.

Mr. BESHEAR [continuing]. And illegal drugs in other places, but obviously it blankets the United States and it is getting worse, not better.

Mr. GUTHRIE. You know, when we come to Washington and talk about problems in our State, we have to do that, but obviously we have—and you are the governor of my favorite State and obviously a beautiful place, but we have to talk about these problems and we have to get together and try to solve them. So thank you very much for being here today.

Mr. BESHEAR. Well, the first step is to recognize that we have got the problem.

Mr. GUTHRIE. I think Governor Scott wants to comment.

Mr. SCOTT. Somebody just told me that there are no State taxpayer dollars but we are going to get some dollars from the Hal Rogers Federal grant, but there is no State taxpayer dollars.

Mrs. BONO MACK. Thank you for the clarification.

Mr. GUTHRIE. If you want my time, Madam Chairwoman, I will yield you my time back.

Mrs. BONO MACK. Oh, thank you. I was taking it anyway.

Mr. GUTHRIE. OK. Go ahead.

Mrs. BONO MACK. I think an important issue is whether or not there was other pharmaceutical money involved, which is a question we debate here on many things, but in this specific instance, I thought the Purdue Pharma, your decision on that was a good one, and I applaud both of you to wrap it up and to thank you for your time today and your spirit and the willingness to truly address this problem. We are not going to end it. We are not going to solve it entirely. But I do believe good, innocent people are suffering, and crime, it is a very basic situation for me. The FDA approves and regulates and the DEA is supposed to control, and with

statistics like that, it shows that we are failing, and it is time to stop. Too many people are dying and too many of our constituents, and more and more of my colleagues would have participated today. I know Congressman Vern Buchanan is very interested now, Congressmen from Massachusetts are very interested. This is not only Kentucky and Florida, it is nationwide, and as the panels go on, we will focus on California and what is happening. So Florida, don't feel that it is all you because it is throughout the country.

But thank you, gentlemen, very much. I look forward to working with you.

At this point the subcommittee will take a very brief recess to seat the third panel.

[Recess.]

Mrs. BONO MACK. The subcommittee will come back to order, please. I thank the staff for being so quick in switching the panels over.

On our third panel, as you can see, we have seven witnesses as I introduce them all at once. First is Phil Bauer, surviving father of Mark Bauer. Phil serves on the Parent Advisory Board for the Partnership for a Drug-Free America. Our next witnesses are Kathy and Courtney Creedon, surviving mother and sister of Ryan Creedon. Kathy is also Founder of Mothers against Prescription Drug Abuse, and I am blessed and lucky enough to call them my own constituents. Also testifying will be April Rovero, surviving mother of Joey Rovero and Founder of the National Coalition against Prescription Drug Abuse. Our next panelist is Dan Harris, who overcame a prescription drug addiction to gain custody of his children. He is a drug court graduate and also a constituent of mine. And finally, we are pleased to have Dr. Carol Boyd and Dr. Amelia Arria, who are widely respected nationally for their insight into addiction. On a personal note, staff told me to say what I already said about how proud I am to have some constituents on this panel.

So welcome to each and every one of you. I really appreciate your being here. If you can see the timer boxes down there, it is just like a traffic light, green, yellow and red. You know what they mean. The total time you are allotted will be 5 minutes each, so we are now going to recognize Phil Bauer for 5 minutes.

STATEMENTS OF PHIL BAUER, FATHER OF MARK BAUER AND PARENTS ADVISORY BOARD MEMBER, PARTNERSHIP AT DRUGFREE.ORG; KATHY CREEDON, MOTHER OF RYAN CREEDON AND FOUNDER, MOTHERS AGAINST PRESCRIPTION DRUG ABUSE, ACCOMPANIED BY COURTNEY CREEDON, SISTER OF RYAN CREEDON; APRIL ROVERO, MOTHER OF JOEY ROVERO AND FOUNDER, NATIONAL COALITION AGAINST PRESCRIPTION DRUG ABUSE, AND PARENT AMBASSADOR, PARTNERSHIP AT DRUGFREE.ORG; DAN HARRISON, DRUG COURT GRADUATE; CAROL J. BOYD, PH.D., R.N., F.A.A.N, DIRECTOR, INSTITUTE FOR RESEARCH ON WOMEN AND GENDER, PROFESSOR OF NURSING, UNIVERSITY OF MICHIGAN, ANN ARBOR; AND AMELIA M. ARRIA, PH.D., DIRECTOR, CENTER ON YOUNG ADULT HEALTH AND DEVELOPMENT, UNIVERSITY OF MARYLAND

STATEMENT OF PHIL BAUER

Mr. BAUER. Good morning, Chairman Bono Mack, Ranking Member Butterfield and members of the subcommittee. My name is Phil and I am from York, Pennsylvania, and I am here today speaking as a dad.

If you were to ask any parent what their biggest fear in life is, their worst nightmare, most would tell it would be losing a child. We are living that nightmare and it is worse than we ever could have imagined.

Our youngest son, Mark, died from prescription drugs. His death was preventable and avoidable, and I believe the underlying cause was ignorance: my ignorance. Of all the things I worried about as a dad, abuse of medicine wasn't among them. Unfortunately, there are many people who continue to underestimate the dangers of abusing prescription drugs and, as I know all too well, ignorance can be fatal.

On June 4, 2004, my wife Cookie and I, along with our oldest son Brian, attended the high school graduation of our youngest son Mark. As you know, there are many emotions that come with graduation, and it is a significant milestone and accomplishment in a young person's life, and the emotions are not just for the graduate but for their families as well—pride, happiness, relief, fear, sadness. It is a transition in life, and some refer to it as the beginning.

The words I would use to describe our emotions at Mark's graduation are devastation, emptiness and confusion. It marked the end of our son's life. I can remember so well sitting there and staring at an empty chair where Mark should have been sitting with his cap and gown draped over the back of the chair, and his diploma and yearbook laying on the seat, but Mark wasn't there.

On May 28, 2004, on what would have been his last day of high school, just one week before graduation, Mark died. That morning, I responded to my wife's screams and went to see what was wrong, and she said that she couldn't wake Mark up. I started CPR and Cookie called 911. When the emergency personnel arrived, we followed the ambulance to the hospital, were escorted to the little room, and then heard the words that our son was dead. We went back to see him to try to say our goodbyes, and we cried on his lifeless body. For Cookie and I, life as we knew it ended that day.

In his room that morning, we found a clear plastic bag of loose pills. They weren't his, nor did they belong to anyone else in our family. There were seven different types of pills in the bag, and 119 pills in all. When the toxicology report came back 3 months later, it was consistent with what we found in the bag in his room. Mark died from a lethal mix of oxycodone, acetaminophen, morphine and stimulants.

Just to give you a little background of our family, when our sons were born, they became the focal point of our lives. Their mom quit work and became a stay-at-home mom, and she has been a terrific mom. To me, being their dad has been the most rewarding and important part of my life. I was a diaper-changing, bath giving, story-reading, full-service dad. I took them everywhere I went, diaper bag and all, and we were together constantly. Throughout the school years, our sons never came home to an empty house.

Mark was quiet and an introvert. He didn't let many people into his life; you had to bring him into yours. When people took the time to get to know him they found a wonderful, caring person. Never much for words, he had a terrific sense of humor and could make you laugh just by his expressions and mannerisms. He loved sports, especially basketball, and was an avid weightlifter from the time he was 11. In the later stages of his life, Mark was 5-foot-9, 175 pounds. He could dunk a basketball and bench-press 400 lbs. Besides sports, he loved his family, friends, the Outer Banks of North Carolina, puppies, Star Wars, playing video games, any Leslie Nielson movie, shopping with his mom, and making fun of his dad.

One thing we will never know is why Mark chose to take these pills. We don't know if he was abusing prescription drugs to get high or self-medicate or to self-regulate. We also don't know if he had an addiction problem that went undetected, or if this was just an opportunity that presented itself. I know now that abuse of medicine can lead to the same dependence and addiction as that of illicit drugs. They can also be lethal on the first use, especially if mixed with other substances.

Unfortunately, there are still many people who underestimate the dangers of abusing prescription drugs. They believe that abusing these medicines is safer than using illicit drugs yet it is causing more deaths in our country than heroin and cocaine combined, and filling up our treatment centers. Based on the numbers from the CDC, on an average day in the United States, 31 people will die from prescription painkillers alone.

From the motivation and inspiration that I draw from Mark's life and death, I have dedicated myself to do anything possible to raise awareness about prescription drug abuse. I have learned so much about this issue over the past several years and have had many mentors. My journey has included forging partnerships with organizations and agencies which share my passion and commitment to combat this issue. I am pleased and grateful to have the opportunity to now serve on the Parent Advisory Board of The Partnership at DrugFree.org and to help promote and support their wonderful tools for parents.

I have also had many opportunities to speak on this topic at national conferences, to law enforcement, to health care professionals,

to community groups and parent groups throughout Pennsylvania, and to high school students. I plan to continue these efforts as long as I am able. Abuse and misuse of prescription drugs is devastating too many families, causing crime and other social issues, filling our treatment centers, and killing too many of our children.

There is no way to tell someone what it is like to lose a child. You either know what it is like or you don't, and I truly hope you don't. I am committed to do anything I can to help others avoid the devastation that Cookie and I live with every day. Today, I would like to offer my assistance to this subcommittee, if there is anything at all that I can do to support or promote your efforts to combat this public health crisis. Thank you.

[The prepared statement of Mr. Bauer follows:]

**Testimony of Philip G. Bauer
Parent Advisory Board Member
Partnership at Drugfree.org, York, Pennsylvania**

before the

**Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
United States House of Representatives**

**“Warning: The Growing Danger of Prescription Drug Diversion”
April 14, 2011**

Summary of Testimony

When prescription drugs are diverted, and used for non-medical purposes, it comes with the same consequences as that of heroin, cocaine or any other street drug. It can lead to dependence or drug addiction, and brings with it the same social impact as illicit drugs.

Of greatest concern is the toll that prescription drug abuse is taking on our young people. What motivates teens to engage in prescription drug abuse? Ultimately, their desire for get high, to self medicate, or to self regulate, and it outweighs their perception of the risks. Availability and ease of access is fueling this public health crisis.

According to The Partnership at Drugfree.org:

- 12 to 17 year olds abuse prescription drugs more than they abuse ecstasy, crack/cocaine, heroin, and methamphetamine combined
- Every day, 2,500 teenagers use a prescription drug to get high for the first time.
- 60% of teens who have abused prescription painkillers did so before age 15
- There are as many new abusers age 12 to 17 of prescription drugs as there are of marijuana

The abuse of prescription painkillers now cause more deaths than heroin and cocaine combined.

**Testimony of Philip G. Bauer
Parent Advisory Board Member
Partnership at Drugfree.org, York, Pennsylvania**

before the

**Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
United States House of Representatives**

**“Warning: The Growing Danger of Prescription Drug Diversion”
April 14, 2011**

Good morning Chairman Bono Mack, Ranking Member Butterfield, and members of the subcommittee. My name is Phil Bauer and I'm from York, Pennsylvania. I am here today speaking as a dad.

If you were to ask any parent what their biggest fear in life is - their worst nightmare - most would say that it would be losing a child. We are living that nightmare, and it is worse than we could ever have imagined. Our youngest son Mark died from prescription drugs. His death was preventable and avoidable, and I believe the underlying cause was ignorance – my ignorance. Of all the things I worried about as a dad, abuse of medicine wasn't among them. I just didn't think about it... and now my son is dead and there is nothing I can do about it. Unfortunately, there are many people who continue to underestimate the dangers of abusing prescription drugs and, as I know all too well, ignorance can be fatal.

On June 4, 2004, my wife Cookie and I, along with our oldest son Brian, attended the high school

graduation of our youngest son Mark. As you know, graduating from high school is a significant milestone in a young person's life. There are many emotions during that time, not only for the graduate, but for their family as well – pride, happiness, relief, fear, sadness. It is a transition in life, and some refer to it as the beginning.

The words I would use to describe our emotions at Mark's graduation are devastation, emptiness and confusion. It marked the end of our son's life. I can remember staring at the chair where Mark should have been sitting – his cap & gown draped over the back, and his diploma and yearbook laying on the seat – but Mark wasn't there.

On May 28, 2004, Mark died on what would have been his last day of high school, just one week prior to graduation. That morning, I responded to my wife's screams and went to see what was wrong. She said that she couldn't wake Mark up. Cookie called 911 and I started CPR. When emergency personnel arrived, we followed the ambulance to the hospital, were escorted to the “little room”, and then heard the words that our son was dead. We went back to see him and to say our goodbyes – and we cried on his lifeless body. For Cookie and I, life as we knew it ended that day.

In his room that morning, we found a clear plastic bag of loose pills. They weren't his, nor did they belong to anyone else in our house. There were 7 different types of pills in the bag – and 119 pills in all. When the toxicology report came back 3 months later, it was consistent with the pills found in his room. Mark died from a lethal mix of oxycodone, acetaminophen, morphine and stimulants.

Let me give you a little background of our family. When our sons were born, they became the focal point of our lives. Their mom quit work and became a stay-at-home mom. She has been a terrific mom! To me, being their dad has been the most rewarding part of my life. I was a diaper-changing,

bath giving, story-reading, “full service” dad. I took them everywhere I went and we were together constantly. Throughout the school years, our sons never came home to an empty house.

Mark was quiet and an introvert. He didn’t let many people into his life; you had to bring him into yours. When people took the time to get to know him they found a wonderful, caring person. Never much for words, he had a terrific sense of humor and could make you laugh just by his expressions and mannerisms. He loved sports – especially basketball – and was an avid weightlifter from the time he was 11. In the later stages of his life, Mark was 5’9” and 175 lbs – he could dunk a basketball and bench-press 400 lbs. Besides sports, he loved his family, friends, the Outer Banks of North Carolina, puppies, Star Wars, playing video games, any Leslie Nielson movie, shopping with his mom, and making fun of his dad.

One thing we will never know is why Mark chose to take these pills. We don’t know if he was abusing prescription drugs to get high...to self medicate...or to self regulate. We also don’t know if he had an addiction problem that went undetected, or if this was just an opportunity that presented itself. I know now that abuse of medicine can lead to the same dependence and addiction as that of illicit drugs. They can also be lethal on the first use – especially if taken with other substances.

Unfortunately, there are still many people who under-estimate the dangers of abusing prescription drugs – they believe that abusing these medicines is safer than using illicit drugs – yet it’s causing more deaths in our country than heroin and cocaine combined, and filling up our treatment centers. Based on the numbers from the CDC, on an average day in the U.S. thirty-one people will die from prescription painkillers alone – and that’s not o.k.

From the motivation and inspiration that I draw from Mark's life and death, I have dedicated myself to do anything possible to raise awareness about prescription drug abuse. I have learned so much about this issue over the past several years – and have had many mentors. My journey has included forging partnerships with organizations and agencies which share my passion and commitment to combat this issue. I am pleased and grateful to have the opportunity to now serve on the Parent Advisory Board of The Partnership at Drug Free.org. - and to help promote and support their wonderful tools for parents.

I have also had many opportunities to speak on this topic at National conferences, to law enforcement, to health care professionals, to community groups and parent groups throughout Pennsylvania, and to high school students. I plan to continue these efforts as long as I am able. Abuse and misuse of prescription drugs is devastating too many families, causing crime and other social issues, filling our treatment centers, and killing too many of our children.

There is no way to tell someone what it's like to lose a child – you either know what it's like or you don't. I am committed to do anything I can do help others avoid the devastation that Cookie and I live with everyday. Today, I would like to offer my assistance to this committee - if there is anything at all that I can do to support or promote your efforts to address this public health crisis. Thank you.



*In loving memory of Mark Daniel Bauer
February 12, 1986 – May 28, 2004
<http://mark-bauer.virtual-memorials.com/>*



Mrs. BONO MACK. Thank you very much.
Ms. Creedon, you are recognized for 5 minutes.

STATEMENT OF KATHY CREEDON

Ms. KATHY CREEDON. Thank you. Good morning, everyone. Thank you, Chairman Bono Mack. I am so grateful to be here today, and I hope that my testimony provides valuable information that will help bring awareness about the epidemic of prescription drug abuse and diversion we currently face in our Nation.

My story is about the most severe consequences of abusing prescription drugs. I lost my son Ryan on September 4, 2009, to an overdose of OxyContin. He was just 21 years old, and I agreed to come here today because I know there are thousands of families who are struggling with the pain of this situation just like I am. I sit here before you today on behalf of all of us and hope for some victory. My daughter Courtney is here with me today available to answer any questions after my testimony.

So I just wanted to say that I fought relentlessly to save Ryan's life, but when addiction is present, it is like spinning your wheels to try to keep up with their compulsive behavior. I believe the science that says addiction is a disease and it is not a moral failure.

As my written testimony details, my son was easily able to obtain these medications from doctors. He didn't get his pills from my medicine cabinet. Once I realized he was getting medication through prescriptions and not on the streets, I thought I could stop it. He was an adult by this time, and HIPAA privacy laws made it difficult for me to communicate my concerns about him abusing pills to his doctors but that did not stop me. I was able to get my foot in the door more than once. However, my concerns were mostly ignored and Ryan still continued to receive OxyContin many times for something as simple as a backache. In some cases, even when doctors stopped prescribing OxyContin, they still prescribed other narcotics that a person with a history of drug addiction should never have had.

In the last 13 months of Ryan's life, I documented seven pages of medical records for visits to doctors, urgent care and emergency rooms. There were six near-death overdoses that always resulted in a 911 call and hospitalizations, once for 8 days in a lockdown facility. It was a life-or-death struggle for Ryan many times, and we lived in fear.

I saw my son's addiction progress rapidly once he became addicted to OxyContin. I believe that was the result of the aggressive off-label marketing practices of Purdue Pharma. He was never a candidate to receive such a powerful, addictive narcotic, and I feel he might be alive today if he had not discovered OxyContin. He made several attempts to get off the powerful opiate OxyContin but did not make it longer than 30 to 90 days at a time.

After my son's death, I had the opportunity to discuss all the careless mistakes made by the HMO that provided his care. I was told in that meeting that they were not aware of the dangers of OxyContin at the time my son was receiving it. They were told it was safer than other pain medications including methadone, morphine and fentanyl. That confirmed everything I had read regard-

ing lawsuits and Purdue Pharma, and now my family was a victim of their misleading practices.

In general, Kaiser Permanente, which was the HMO in our county, claims it was not aware of the abuse of prescription drugs taking place among our youth. I was quite surprised hearing that because I thought that if I knew, surely they should have known. I then realized how important it was to figure out a way to bring awareness of the situation to the medical community as well. I believe that this lack of understanding contributed to my son's death.

In addition to the fact that they continued prescribing him narcotics after they knew he was an addict, I feel that prescription education is so important. Ryan's addiction to OxyContin resulted in a felony conviction for altering a prescription at a pharmacy. He was obtaining prescriptions from many sources at the time that could have been averted if a prescription monitoring program was in place. Some of those drugs ended up on the streets. Ryan basically became a drug dealer to support his addiction to OxyContin. It was unbearable to see what was happening to my son, at what lengths addiction will take a person to.

So in closing, I would like to say I will not stop fighting for my son in his memory. As a result, I have joined with some mothers to create an organization to fight this epidemic. Our goal is to make a difference and to try to save lives by bringing awareness to as many people as possible. So I appeal to those of you in this room today from the bottom of my heart to help me make a difference.

I thank you all so much for being here, and I would like to request that each of you reach out to other Members of Congress, your colleagues, friends and family to spread the word about this epidemic, and please be open-minded and learn all you can. Together we can make a difference. Thank you.

[The prepared statement of Kathy Creedon follows:]

Witness Name: Kathy Creedon

“Warning: The Growing Danger of Prescription Drug Diversion” April 14, 2011

Subcommittee on Commerce, Manufacturing and Trade

Summary

Prescription drugs were responsible for the death of my son Ryan. I found out that when the disease of addiction is present it creates such uncontrollable behavior, that unless you have lived through it, or are educated, it is hard to understand. Ryan’s chances for recovery were greatly diminished, once he became addicted to Oxycontin. The aggressive off label marketing practices of Purdue Pharma made it easier for my son to be prescribed this medication, for unnecessary reasons. I was told Ryan’s HMO believed that it was a safer pain medication, compared to some other choices. Ryan’s pain did not require such a potent addictive drug. The severe withdrawal symptoms and expense of effective opiate withdrawal medications became an obstacle in my son’s recovery. The HMO providing Ryan’s medical care often lacked means of communication between physicians’s that allowed him to receive what he should not have had. When you combine a person with the disease of addiction, people with lack of follow through, and inappropriate prescribing, it created a situation that lead to the outcome I have to live with for the rest of my life. There were many times along the way that Ryan was prescribed Schedule II, III and IV controlled substances under the Controlled Substance Act. It is well documented in pharmaceutical literature they were not appropriate for someone with a history of drug abuse. My son’s life was in jeopardy every time he walked out of a pharmacy with another bottle of pills. This type of careless prescribing of medications progressed my son’s disease so severely, that I had to file a restraining order and he became homeless. He was taken by ambulance many times for drug overdoses, and I feared for his life each time. Privacy laws also became an obstacle. It was difficult to effectively communicate my son’s disease, to the people that needed to know, because he was an adult. When I did, they didn’t follow through and utilize the technology they had access to. A prescription monitoring program that utilizes real time would have averted many of the situations. There were times when Ryan’s prescriptions were sold on the streets. When I heard the Medical Director say to me, he did not know these drugs were being abused, I found it hard to believe. I assumed if I knew, he certainly should have known this, unfortunately this was not the case and contributed to my son’s death. So, I am here today, to bring awareness to you about this epidemic we have on our hands.

Witness Name: Kathy Creedon

“Warning: The Growing Danger of Prescription Drug Diversion April 14, 2011

Subcommittee on Commerce, Manufacturing and Trade

The Growing Danger of Prescription Drug Diversion is a topic that was a reality for my family and me for several years—it resulted in addiction, incarceration and death. My son Ryan died on September 4, 2009 from an overdose of Oxycontin. I value the opportunity to testify as a witness as I document my testimony of painful memories and facts of living with the disease of addiction.

Ryan inherited the disease of addiction. I soon learned that addiction is a progressive disease, and that it is so powerful that even the negative consequences of addiction don’t stop an addict from using drugs. I sent my son to a residential treatment facility just before his 18th birthday—it was not successful, as he resumed abusing drugs little by little. I later found out he was experimenting with Oxycontin, that he obtained from unknown sources by means of diversion. By the time he was 20 years old, he commonly lost jobs; he lost his drivers license and car, his apartment, and pretty much everything else of value. I remember getting phone calls from Ryan on several occasions, saying he didn’t know what was wrong with him, but that his body ached, and he was freezing one minute and hot the next. I thought he must have had the flu—he was fatigued, and his legs ached. It got so bad that we ended up at urgent care with an unknown diagnosis from the physician. At that time, Ryan did not realize that it was Oxycontin withdrawal that was responsible for the cause of these severe symptoms. He soon found out that the symptoms disappeared when he would take Oxycontin again: he was addicted. Oxycontin

would eventually steal my son's life, and though he was already abusing drugs, I feel that Ryan would still be alive if it weren't for Oxycontin.

He had to support his addiction, and was now beginning to sell drugs as a means to do so. He was not living at home, and started avoiding his family. This was not my loving son, the son that I had raised with morals and Christian values. He had begun leading a double life. He thought that if he lied to me, he would be protecting me from the world he was living in. As a mother, I found myself being consumed with trying to save my son's life, all while I had another child at home that needed parenting and attention—it was a difficult time to manage.

As time passed, Ryan found out that he could obtain a prescription for Oxycontin by simply stating to a physician in our area that he had some back pain. Even though Ryan had a prescription for OxyContin, he would often run out before he could get a refill, so he began to sell other drugs in order to support his addiction. Ryan also claimed that he had developed anxiety, and so he was prescribed Xanax (another potentially addictive drug). In my research, I found out that his anxiety could have been due to abrupt withdrawal of opiates.

The physician is currently under investigation by the California State Medical Board for prescribing issues. I have been told that he is no longer able to prescribe narcotics—a decision handed down by the DEA. In desperation to save my son's life, I reached out to a nurse at this doctor's office and managed to have several conversations with her and the doctor about my concerns regarding their prescribing practices. I also alerted them to my son's addiction. My concerns were overlooked and ignored, as they continued to prescribe addictive medications. I later received information from a recovering addict that this physician's office was an outlet for drug diversion practices. Ryan was known to have met other addicts in this office that he then

began selling drugs to.

At some point, when Ryan was receiving Oxycontin from the above physician, he stated he wanted to get off Oxycontin and admitted he had an addiction. However, he knew he could not tolerate the withdrawal symptoms. He had heard about Suboxone, a medication to treat opiate withdrawal. We located a physician approved to prescribe Suboxone and Ryan started treatment. It was very effective, but expensive with a combined cost of approximately \$600.00 a month for office visits and medication. After one month of treatment, Ryan compared the cost to Methadone (at approximately \$70.00 a month) and decided to go back to the above physician for Methadone and treat himself, against my recommendation. Within two months, that physician was again prescribing him Oxycontin, and Ryan was back into his full-blown addiction.

During the last months of Ryan's life he became eligible for medical insurance, and he utilized the benefits to feed his addiction. I have documented seven pages, including 72 entries of medical history for a thirteen-month period that I was able to obtain. This part of my testimony does not directly relate to the topic of this hearing. It indicates that prescription drugs prescribed even through legitimate means are subject to diversion when addiction is present. Ryan had now become proficient in the "ropes" of obtaining what he wanted from the attending physician. I feel that carelessness and ignorance of the danger of opioid abuse, along with lack of knowledge about addiction, created a situation that enabled my son's addiction. Again, like I did with the first physician, I begged my way into speaking with the person at this HMO facility that I thought could put a stop to this unnecessary prescribing to my son. I was fully aware of the HIPAA laws in place to protect my son's privacy, but I was desperate again to save my son's life. I was granted a face-to-face meeting with the facility director. I was told by this person that he would relay my concerns about Ryan's addiction to the physician Ryan had an appointment

with two days later. I felt relieved that this would put an end to Ryan's attempts to further his addiction with 100% free prescription drug coverage under his plan. Almost two months to the day after my conversation, it was necessary to make a 911 call...Ryan was in serious medical trouble. Once he was stabilized, he was admitted on a California Code 5150, an involuntary psychiatric hold for eight days. The diagnosis was Opiate (Oxycontin) and Benzodiazepine (Xanax) dependence. I later found out that he was prescribed Oxycontin, and Alprazolam (generic for Xanax) at the appointment I had tried to avert. I have read online from a reliable source backed up with references the following: Narcotics (Oxycontin) should never be combined with other types of drugs that depress the central nervous system, including benzodiazepine tranquilizers such as alprazolam (Xanax). Ryan was having a severe reaction that included hallucinations, most likely due to rapid dose reduction of one or both because he was abusing them. Yet, he continued to be prescribed Xanax. During the same appointment, he was referred to the pain management department, where he was again prescribed Oxycontin a few weeks later for 40 mg. of Oxycontin three times a day. In May 2007, Purdue Pharma, the manufacturer of Oxycontin, paid \$19.5 million in fines relating to the aggressive off label marketing practices. The company had encouraged more frequent dosing than the recommended interval of 12 hours, and did not fully disclose the risk of hazardous or harmful use. Apparently news of the fines did not reach the HMO that was responsible for Ryan's medical treatment. Ryan was prescribed OxyContin without a doctor verifying his claims of pain, either with an x-ray or MRI that would not have justified prescribing such a potent pain reliever. In the same two-month period, Ryan was arrested for a felony at the pharmacy on the premises, for altering a prescription for Oxycontin. I have seen multiple warnings that indicate that all patients receiving opioids should be routinely monitored for the signs of misuse, abuse or addiction. The

pharmacy, that alerted law enforcement resulting in the arrest, failed to comply with that warning and did not notify Ryan's primary care physician, who was, by the way, located in the same building. It was only six days later that Ryan went back to the same HMO and received 45 more Oxycontin. All this occurred after I had alerted the facility that my son was a drug addict and had a history of abusing narcotic medications.

Ryan also made visits to the local hospitals' emergency departments during this particular time period and received more Oxycontin. If a prescription-monitoring program were in place, this would not have happened. In addition to repeated visits to his primary care physician, the HMO authorized a referral to a psychiatric facility for his anxiety. Ryan began receiving prescriptions for the same medication from the primary care physician and the psychiatrist. In a ten day period, Ryan legally obtained 210 Alprazolam (generic for Xanax).

Situations like this repeated themselves until the day Ryan died. In fact, it got worse—there were five near death overdoses, each one of them occurred within 24 hours of Ryan being prescribed addictive drugs. My daughter and I had to live through what seemed like a nightmare, through every occasion, many of which could have been prevented. He did manage to get into treatment for addiction during the ten months prior to his death, but unfortunately after five weeks he was kicked out for abusing medication that he was prescribed while he was in a recovery program. When I questioned how this could happen, it was explained to me that privacy laws prevented the primary care physician at the HMO facility from knowing that Ryan was a patient in the drug treatment facility. So, for a sprained foot, Ryan was prescribed Vicodin, a narcotic pain reliever, and three other medications not appropriate for someone with a history of addiction, as indicated on the pharmacy information sheet. Ryan's disease must have prevented him from taking the responsibility to say he did not want a narcotic pain reliever. Dr. Drew, a

leading expert in addiction said that even when narcotics are appropriately prescribed to an addict, their life is in danger. It will change the addicts thinking and change their motivation. Ryan was back on the streets after this, and again, we were in fear of Ryan's life. Ryan's addiction took him to a place that is described perfectly by Dr. Nora Volkow, Director, National Institute on Drug Abuse: "On a personal level, as a physician I have never met an addicted person who chose to be addicted or who expected that this compulsive, uncontrollable behavior would emerge when they started taking drugs."

Ryan was admitted to the hospital several times, by way of ambulance due to an overdose. Once, while hospitalized he was interviewed by the hospital LCSW. The following is documented in a Summary of History: [Ryan] also admitted that he has a 7 year history of poly substance abuse, admitted being arrested for substance related issues, admitted his mother refused to allow him to return home and has obtained a restraining order for the patient because of his drug abuse. In the Impression/Assessment it states: He does not see himself as having a substance abuse problem and is unwilling to make any serious attempt to overcome his addiction to pain medications. Ryan often justified his addiction by stating he was only taking what the doctor gave him.

The day before Ryan died, he was prescribed 60 2 mg Alprazolam (generic for Xanax) to be taken 4 times a day, which is an extremely high dose, from the same HMO. His medical records should have showed that his tolerance would not have justified this amount, however, the records were apparently not referred to. I made a phone call one week after my son's death to inform the facility director, who I had my original meeting with almost a year earlier that my son had died. I

said, “with all the technology you have, this should have never happened.” I had been told almost a year earlier from the pharmacist who was involved in the prior arrest that “[he] won’t be getting any more prescriptions from this pharmacy.” But that was not the case. When I told the facility director about this exchange, he replied something to the effect that the pharmacy was his safety net and he does not know why it happened, and, that I was right, it should not have happened. He told me he would look into it and call me back. I never got that phone call.

As a result of all this history, and a failed attempt to file a lawsuit after my son’s death I needed answers. I was notified about six months after my son died that the HMO responsible for his medical care wanted to meet with me. In reviewing the medical history, here is the conclusion of those meetings in brief:

1. One of physicians said that he was not aware of the abuse among young people, and he was surprised after it was brought to his attention.
2. I was told that when Ryan was being prescribed Oxycontin they did not know about the dangers and believed the drug representatives.
3. I was told that their hands are tied with HIPPA laws, especially for addiction. They stated that more transparency is needed between primary care and psychiatry providers, and communication with family members.
4. I was told that Oxycontin was touted as a new safer drug than Morphine, Fentanyl and Methadone.
5. When I asked why Ryan was prescribed 2mg, 4 times a day, the day before he died, they said that Ryan was very convincing in getting what he wanted, to which I replied, “So if your child

comes to you before dinner and wants a cookie, you give it to him? Who is in charge of the situation?"

6. It was discussed, that the pendulum had swung over the years from physicians being afraid to prescribe narcotics to the opposite direction when pain management experts said, we must make our patients comfortable.

Mrs. BONO MACK. Thank you, and Courtney. I appreciate your being here to take questions at the end if we have them, but we will go to Ms. Rovero for your 5 minutes of questioning.

STATEMENT OF APRIL ROVERO

Ms. ROVERO. Chairman Bono Mack and Ranking Member Butterfield and members of the subcommittee, thank you so much for having me here today.

On December 18, 2009, just a week before Christmas, my husband and I received the devastating and inconceivable news from a Tempe Police Department detective that our youngest son, Joey Rovero, had had been found dead by friends in his apartment off campus near Arizona State University, where he attended college. Over the next few days, as we worked to get his body returned home to California, where we live, and funeral arrangements made so we could bury him the day after Christmas, a story began to unfold that we were completely stunned by.

We learned that Joey had been invited by a couple of students from ASU that he knew to travel with them on a 6-hour journey from Arizona to Rowland Heights, California, on December 9th, which was just 9 days earlier than his death, to visit a doctor who was well known for freely prescribing narcotic medications. All three students walked into this doctor's office together after the 6-hour drive and all they all walked out a short time later with prescriptions in hand. Joey's prescriptions, the first time she had ever seen him and after just a \$75 payment to her, cash, and an X-ray that showed no problems in hand for him, was prescribed 90 30-milligram tablets of Roxicodone, 90 350-milligram tablets of Soma and 30 2-milligram tablets of Xanax. He and his friends were directed to a pharmacy that was at least 35 miles away from this doctor's office. They drove there together and all of them had their prescriptions filled with absolutely no questions asked. We have since learned that both the doctor and the pharmacy had been under investigation for at least 2-1/2 years before Joey died. The DEA has since revoked her registration. The medical board has moved to revoke her license, and that is in process, and criminal prosecution is expected for Joey's death, among several others for this doctor.

Joey had never been previously treated for any of the conditions that were cited in his medical record by the doctor as the basis for the prescriptions that he received that day, and there was absolutely no indication that she counseled him on how dangerous these medications could be if they are misused or abused, especially with alcohol. So again, just 9 days after he saw her, he was dead, and that was after partying with friends in a college, a typical college setting, wee into the morning. Joey went to sleep and he simply didn't wake up.

The coroner's report indicated that he died from low levels of Xanax and moderate levels of Roxicodone mixed with alcohol. His level of alcohol was .013. So he didn't have huge amounts in his system. The medical examiner indicated that none of the individual ingredients were lethal but all of them in combination were. So it was the polymix that was the problem.

Joey was due home for winter break the day after he died, and the Christmas we expected to share with him never happened. Instead, we somehow managed to get through the most awful week of our lives. Stunned, shocked and grieving, we picked out a gravesite, coffin and clothes for Joey to be buried in. I had to write an obituary for a young man who had not had time to develop the lifetime achievements that he should have been able to cite.

Through it all we struggled to understand how this could have happened to him, how our perfectly normal family could have been dealt such a blow. There are really no words that can adequately describe what my husband, Joey's brother and all of the other members of our family have experienced with his death. He was my husband's only biological child, and his brother is now left with no sibling. As his mother, I truly feel as though a part of me is gone and just ripped away from me forever. Our lives were irrevocably changed the night that he died.

Joey wasn't a troubled young man. I want you to know that. He was a senior at ASU just 5 months away from graduating. He was a gifted athlete and a good student, even making the dean's list at ASU in the fall of 2008. He worked every summer. He made money. He spent it wisely. He had a loving and caring relationship with all of his family members. He had tons of friends all over the country, and over 200 of them appeared at his funeral to support us and to honor Joey. His life has affected them also dramatically.

Unfortunately, tragedy struck once again 9 months to the day after my son's death when one of his two college roommates shot and killed himself in front of his girlfriend after a heavy night of drinking and prescription drug abuse. This problem has just continued to manifest itself in that college environment. There have been six young men that have died over the course of the last year at that university alone.

In addition to that, as we have heard today, in Florida we lost seven people a day, and over 32,000 people a year die from adverse reactions to medications, so something simply has to be done with this epidemic.

It is extremely important to me that I do whatever I can to make a difference. We formed our National Coalition Against Prescription Drug Abuse, and I speak everywhere I possibly can to parents, students, educators and community leaders about this problem.

One thing that I wanted to point out that hasn't been mentioned today. I have a whole list of recommendations, many of them have been talked about today. I think the one that I really want to make sure is mentioned is that the pharmaceutical industry has been allowed over time to expand its influence over virtually every facet of American life using its near-unlimited financial resources to influence the FDA and other governmental agencies, our educational research facilities, our legislators, unfortunately, and most alarmingly, our physicians and other medical providers. They are influencing medical research, drug trials and are compensating doctors to prescribe medications they want to become their next blockbuster drug. The spider web of influence needs to be dismantled.

Thank you very much for having me here today.

[The prepared statement of Ms. Rovero follows:]

**Testimony of April J. Rovero, Founder/President
National Coalition Against Prescription Drug Abuse, San Ramon, CA**

before the

**Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
United States House of Representatives**

“Warning: The Growing Danger of Prescription Drug Diversion”

April 14, 2011

Summary of Testimony

My family is just one among thousands that has been severely affected by the current prescription drug abuse epidemic. The death of my son, a senior attending Arizona State University, was completely shocking and devastating to everyone who knew him. We had no idea that Joey, like so many of his college friends, had started recreationally using prescription drugs. We didn’t know that prescription drug abuse is very prevalent on campuses and elsewhere across our country. We never would have guessed that over 32,000 deaths a year are attributed to adverse reactions to prescription medications, that 7 people die each day in Florida alone and that prescription drug overdoses have overtaken traffic accidents as the leading cause of accidental death in at least 17 states.

Before our son died, we were obviously living in a bubble, like so many others I talk with these days about prescription drug abuse. We had never heard of terms such as “dirty doctor”, “dirty pharmacy” and “pill mill”, and still find it incredulous that we’ve been so impacted them. Fortunately for us, our family was completely free of all substance abuse issues before Joey died, but that also meant that we didn’t know what to be on the alert for. We had not noticed mention of this epidemic in the media or heard about it from friends or other people we knew. So, there was no way to know that we needed to educate ourselves and share what we learned with our son, who was living 900 miles away from home in an environment ripe for abuse. It’s hard to believe now that we were once so naïve and uninformed.

After learning that the majority of people aren’t any more aware about this epidemic than we were, we decided to found the National Coalition Against Prescription Drug Abuse (www.ncapda.org) to increase public awareness about prescription drug dangers. Although there are complex factors that contribute to this epidemic, we strongly believe that community education, improved prescribing controls, nationwide PDMP deployment, affordable recovery treatment options, physician training, diversion management and improved control over marketing of pharmaceuticals are all critical to saving our youth, already dubbed “Generation RX”.

**Testimony of April J. Rovero, Founder/President
National Coalition Against Prescription Drug Abuse, San Ramon, CA
before the
Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
United States House of Representatives
“Warning: The Growing Danger of Prescription Drug Diversion”
April 14, 2011**

Chairman Bono Mack, Ranking Member Butterfield, and Members of the Subcommittee:

On December 18, 2009, my husband and I received the devastating and inconceivable news from a Detective with the Tempe, AZ Police Department that our youngest son, Joseph John Rovero, III (Joey), had been found dead by friends in his apartment off campus near Arizona State University (ASU), where he was attending college. Over the next few days, as we worked to get his body returned home to California, and funeral arrangements made so we could bury him the day after Christmas, a story began to unfold that we were completely stunned by.

We learned that Joey had been invited by two other ASU students to travel with them on a six hour road trip from Arizona to Rowland Heights, California on December 9, 2009, to visit Dr. Lisa Tseng, a licensed and practicing Osteopathic doctor. All three students walked into her office together after their 6 hour drive and all walked out a short time later with prescriptions in hand. Joey’s prescriptions included ninety 30mg. tablets of Roxicodone, ninety 350 mg. tablets of Soma and thirty 2 mg. tablets of Xanax. He and his “friends” were told by Tseng that they had to fill their prescriptions at Pacifica Pharmacy, which was about 35 miles from her office. They drove there together and all of them had their prescriptions filled with no questions asked. We’ve since learned that both the doctor and pharmacy had been under investigation by the DEA for at least 2 ½ years before Joey died.

Joey had never been previously treated for any of the conditions that were cited in Dr. Tseng’s medical record as the basis for what she prescribed for him that day. There was no indication in her records that she counseled Joey about how dangerous these medications can be if they are misused or abused, especially with alcohol. Joey died just nine days after his visit to Dr. Tseng. After partying with his college friends into the early hours of the morning, Joey went to sleep and never woke up.

The Coroner’s report indicated that he died from low levels of Xanax and moderate levels of Roxicodone, combined with an alcohol level of .013. The report stated that Joey “died from the

combined toxic effects of multiple drugs, including Ethanol, Oxycodone and Alprazolam. None of the drugs was present at a concentration that would have been individually lethal. However, each of the drugs has central nervous system depressant effects that would have been additive when taken together. There is no indication that the decedent intended to die on this occasion when he took the drugs in combination. Therefore, the manner of death will be classified as accident". The medications prescribed by Dr. Lisa Tseng proved to be a lethal weapon for Joey.

Joey had been due home for Winter break the day after he died, and the Christmas we expected to share with him never happened. Instead, we somehow managed to get through the most awful week of our lives. Stunned, shocked and grieving, we picked out a gravesite, coffin and clothes for Joey to be buried in. An obituary had to be written for a young man who had not had time to develop the lifetime achievements we should have been able to cite. Through it all we struggled to understand how this could have happened to Joey - how our perfectly normal family could have been dealt such a blow.

There are really no words that can adequately describe what my husband, Joey's brother and all of the other members of our family have experienced with Joey's death. He was my husband's only biological child, and his brother is now left with no sibling. As his mother, I truly feel as though a piece of me has been ripped away - forever. Our lives were irrevocably changed the night that we learned Joey had died. I can't believe any of us will ever fully recover from this tragedy that was so senseless and completely avoidable.

Joey was not a troubled young man - far from it. He was a senior at ASU and was just 5 months from graduating. He was a gifted athlete and a good student, even making the Dean's List at ASU in the Fall of 2008, his GPA over 3.5 that semester. He worked every summer and during every school break. He had a loving and caring relationship with all of his family members. Joey was extremely popular and he had friends all over the country who all seemed to feel as though he was their best friend. He was the one they went to for advice and counsel, and was known for being completely honest and non-judgmental. Over 200 of those friends attended his funeral, many of them missing Christmas with their families to travel from long distances to be with us that day. Joey's death has significantly impacted their lives, too.

Unfortunately, tragedy struck once again nine months to the day of Joey's death when one of his two college roommates shot and killed himself in front of his girlfriend after a heavy night of drinking and prescription drug abuse. This young man had struggled immensely with Joey's death and his own addiction to Xanax and Oxycodone. Joey and John are just two of six ASU students who have died from prescription drug-related causes this past year - all bright young men with very promising lives

ahead of them who are now gone forever. Every single week I learn about more deaths from prescription drug abuse, and each one is another dagger to my heart. In Florida alone, we lose seven people a day from overdoses and over 32,000 people a year die of adverse reactions to medications. Something simply must be done to end this epidemic.

It's extremely important to me that I do whatever I can to help other families avoid the devastation mine has experienced. Since Joey's death, I've worked hard to educate myself about the prescription drug abuse/misuse epidemic and all of the various aspects and contributors to it. It became quickly obvious to me that there is a general lack of awareness about how dangerous these drugs can be. Most people assume that they are safer than illicit drugs because a doctor prescribes them, but it's imperative that we spread the word that they simply aren't.

Determining that education could help reduce the death and addiction toll from prescription drugs, my family founded the National Coalition Against Prescription Drug Abuse (NCAPDA) in March, 2010. NCAPDA's primary focus is to increase public awareness and to stimulate and support legislative action that can reduce deaths and addiction due to prescription drugs.

Losing a child is the very worst nightmare a parent can experience. No one can possibly fully understand how impacting it is unless you've experienced it yourself. Not only do you find it terribly painful to recount all the wonderful years you had with them, you lament the "what ifs" and "should have beens" that you'll never experience with them. What career would they have developed after college graduation; who would they have married? What about those precious unborn grandchildren - what would they have looked like and what mark would they have made in this world? You worry about what will happen to you when you grow old. Who will be there who you can trust to be your advocate as your health fails and you need the support you thought would be there for you? You have to come to terms with the awful truth that you will have to live the rest of your life with a piece of your own life's puzzle missing.

No parent should ever have to live this new life my husband and I are now forced to endure, without the beautiful son we created together. I'm doing all I can to help others avoid what we've experienced by sharing Joey's story with students, parents, educators, medical professionals, community leaders and legislators throughout the country. Prescription drug abuse has become a multi-faceted epidemic that is going to take all of us to tackle. We've got to take action now to stem the tide of death, crime and addiction that has left no American community unaffected.

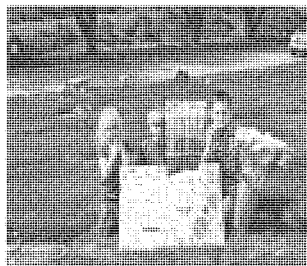
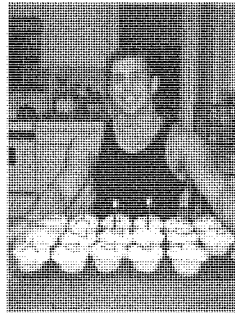
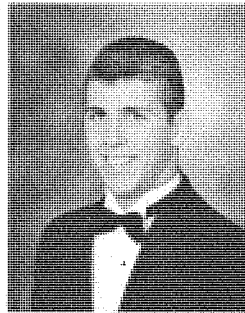
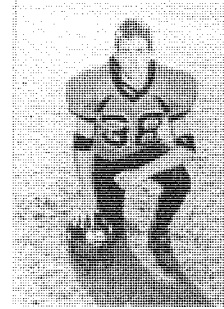
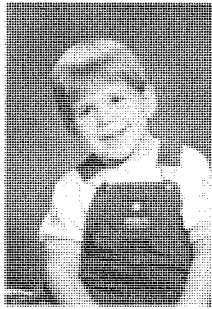
Please let me know if there is anything I can do to support your efforts in addressing the tough issues surrounding the prescription drug abuse epidemic. I simply can't stand idly by while it destroys more American families and their communities. I hope you can't either, because the next statistic could be someone **YOU** love. Please don't think it can't happen to you - it can and does happen to the best of families. I know that now from personal experience.

I respectfully ask that YOU consider how you can help facilitate the following actions to help put an end to the prescription drug abuse epidemic:

1. Most adults and youth don't understand how dangerous some prescription drugs can be, especially when misused/abused. They believe they must be safer than illegal drugs because a doctor prescribed them. Please help increase public awareness by providing funding to federal and grassroots agencies with a demonstrated ability to educate adults and youth about the dangers of prescription drug abuse.
2. Strong, highly addictive opiate analgesics such as Oxycodone are currently being prescribed routinely for moderate to severe pain. This prescribing range is far too wide and is resulting in severe over-prescribing by doctors and hospitals. These drugs should only be prescribed for patients with severe pain. Please establish laws that better manage how opiate analgesics are prescribed.
3. Not all states have fully operational Prescription Drug Monitoring Programs (PDMP), and those that are operational don't have interstate functionality. Please establish adequate funding sources for states that need help in establishing these systems. Mandate use of their PDMP by doctors and pharmacists so that "doctor shoppers" can be helped and over-prescribing doctors can be shut down.
4. The prescription drug epidemic has resulted in a dramatic increase in the number of addicts who need treatment, and many simply can't afford to get the help they need. The impact on our communities is enormous in terms of increased crime levels and human suffering. Crime increases as addicts become criminals to support their drug habits. Families become emotionally and financially bankrupt as they deal with their loved one's typically long road to recovery. It's crucial that more affordable drug treatment and care options be established throughout the country to deal with this escalating problem. Please find a way to fund these essential resources.

5. Although most doctors haven't been adequately trained in pain management, they are not restricted from prescribing (and often over-prescribing), very strong, addictive pain medications. Please establish laws requiring that physicians complete adequate, mandatory pain management training in order to prescribe these drugs to their patients with pain.
6. America's colleges and universities are not adequately educating their students about the dangers of prescription drug abuse. Given the college party scene, which often includes excessive drinking and illicit or prescription drug abuse, it's critical that students understand the dangers of misusing, abusing and mixing these substances. Please provide the resources necessary to initiate a national campaign aimed at college students to help save the lives of our country's future leaders.
7. Although the Drug Enforcement Agency (DEA) and local law enforcement agencies are working diligently on multiple fronts to manage prescription drug diversion, it is simply taking far too long to shut down "pill mills" and "dirty doctors" throughout the country. The longer they stay in business, the more lives are lost. Please drive action to streamline processes and to establish special inter-agency task forces to that can more quickly identify and stop unscrupulous medical providers.
8. The United States and New Zealand are the only countries in the world that allow prescription drug commercials to air on network television stations. Despite Pharma's rhetoric that they are simply trying to educate the public about important health issues, these commercials are nothing more than clever marketing tools. Please initiate the action needed to put an end to these harmful advertisements.
9. The pharmaceutical industry has been allowed over time to expand its influence over virtually every facet of American life, using its near unlimited financial resources to influence the FDA and other governmental agencies, our educational research facilities, our legislators and most alarmingly, our physicians and other medical providers. They are influencing medical research, drug trials and are compensating doctors to prescribe the medications they want to become their next blockbuster drug. This spider web of influence needs to be dismantled. Please establish an unbiased Federal task force to examine every facet of the pharmaceutical industry's marketing and development practices and take action necessary to protect end their sphere of influence.

JOSEPH JOHN ROVERO, III (Joey)
3.9.88 RIP 12.18.09



www.ncapda.org



Mrs. BONO MACK. Thank you, Ms. Rovero.

Mr. Harrison, you are recognized for the 5 minutes, and please do try to keep an eye on that red light for me.

STATEMENT OF DAN HARRISON

Mr. HARRISON. Thank you, Chairwoman Bono Mack, Ranking Member Butterfield and distinguished members of Commerce, Manufacturing and Trade Subcommittee for giving me this opportunity to speak before you today. I am very honored to be here.

My name is Dan Harrison. I am a tribal member of the Muskogee Creek Nation of Oklahoma. I currently reside in Palm Springs, California, for the past 20 years. I worked as a structural ironworker and achieved apprenticeship status. In September of 1995, I took a fall on a construction site. My fall not only resulted in a severe back injury but led to a life of addiction.

After injuring my back, I went on disability for a couple of months, then finally went to an orthopedic surgeon, and I was told that I would need to have surgery which could result in never achieving 100 percent mobility. I chose not to have the surgery and developed my own solution of physical therapy and pain medication. After 90 days, I stopped going to physical therapy and started drinking to intensify the effects of the pain medication.

As the days went on, my drinking and opiate use increased and my life started spiraling out of control. During this time, my wife and I separated, and I shared custody of our two daughters. In 1999, I remarried and soon after my third child was born. This all occurred while I had severe dependence on opiates and alcohol. The drugs are what got me through the day. I never had to go back to the doctor's office after my initial injury. I developed such a strong relationship with the doctor that I needed only to call and they would refill my prescription with no questions asked. I would go into local emergency rooms where the doctor would see me and wave me back for regular pain injections. I rarely had to resort to the streets for my medications. Depending on what type of narcotic I wanted and the method of administering it resulted in which doctor I would call.

In October of 2008, I decided I wanted to fight for full custody of my daughters. I felt that the mother was not caring for them the way I felt they should be cared for. I decided to call Child Protective Services. After the investigation, they were removed from the mother's care. When the caseworker showed up unannounced at my home, I had several cabinets full of prescription medication. When I was confronted, I admitted to the recent use of OxyContin, Vicodin, morphine, Lortab, Demerol, Dilaudid and marijuana.

After hearing myself admit to the amount of drugs in my system and seeing the caseworker's response, I knew it was time to make a change. The only way I would ever get custody of my daughters was to get help. I entered the Family Preservation Court, otherwise known as Family Dependency Treatment Court. The Family Preservation Court applies the drug court model to child welfare cases that involve an allegation of child abuse or neglect related to substance abuse. The Family Preservation Court seeks to do what is in the best interest of the family by providing a safe and secure environment for the child while intensively intervening in the treat-

ment of the parents' substance abuse and other comorbidity issues. This approach also results in better collaboration between agencies and better compliance with treatment and other family court orders necessary to improve child protective case outcomes.

Since graduating from the program, I have learned that there are 2,500 drug courts including over 300 family dependency treatment courts in the United States. I am humbled to know that now over 120,000 addicted people a year have the opportunity for treatment and restoration in these courts, and I hope that somebody they are available to everyone who needs them. These courts have been proven to cut up to 40 percent of the crime rate and produce up to \$27 for every dollar invested.

When I first entered the Family Preservation Court, I had not accepted my problem. I was a little uneasy with myself or calling the CPS since the investigation turned on me. However, after my intake and sharing my history with the family preservation counselor, I realized how bad things had gotten. Through the Family Preservation Court, upon counseling and obtained guidance in educating my daughters about the addiction, I participated in parenting courses that taught me to effectively communicate with my children, how to create healthy boundaries. I was given support by my counselors and peers throughout my struggles with the reunification process.

In 2010, I graduated from the Family Preservation Court. Today I am thankful that I called the CPS. Without their intervention, I would not be here today. Family Preservation Court has helped me realize I needed to get help for myself as well as my family. As a result of completing the program and completing other parenting courses, I have vowed to work diligently with the program and CPS side by side to work to do some outreach work for the ones that are still suffering from prescription drug use in the local community as well as the tribal community in southern California.

I thank you for allowing me to come here and share just a little bit of my story. I realize today that I am a miracle that sits here because of my addiction and going through the process of my recovery, I realized how serious this epidemic is today.

So thank you for inviting me here today to share my story. I am very humbled by that. Thank you very much.

[The prepared statement of Mr. Harrison follows:]

**U.S. House of Representatives, Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
“Warning: The Growing Danger of Prescription Drug Diversion”**

April 14, 2011

Summary of Testimony of Dan Harrison, Drug Court Graduate

My name is Dan Harrison. In September 1995, I took a horrible fall at a construction site. My fall not only resulted in a severe back injury, but it led to a life of addiction. The drugs are what got me through the day. I never had to go back to a doctor's office after my initial injury. I developed such a strong relationship with my doctors that I would only need to call and they would refill my prescription with no questions asked.

In October of 2008 I decided I wanted to fight for full custody of my two daughters. I decided to call Child Protective Services (CPS) and after an investigation the children were removed from their mother's care. But when the case worker showed up unannounced to my house she saw my "pharmacy". The only way I would ever get custody of my daughters was to get help. I entered the Family Preservation Court, otherwise known as Family Dependency Treatment Court.

The Family Preservation Court (FPC) applies the Drug Court model to child welfare cases that involve an allegation of child abuse or neglect related to substance abuse. The FPC seeks to do what is in the best interest of the family by providing a safe and secure environment for the child while intensively intervening and treating the parent's substance abuse and other co-morbidity issues. Since graduating I have learned that there are over 2,500 Drug Courts, including over 300 Family Dependency Treatment Courts in the United States. I am humbled to know that over 120,000 addicted people a year have the opportunity for treatment and restoration in these courts and I hope that someday they are available to everyone who needs them. These courts have been proven to cut crime up to 45% and produce up to 27\$ for every 1\$ invested.

I now have full custody of both my daughters and I am an active parent in their lives. I am able to be my daughters' role model and they now look up to me. For the first time in their lives, my daughters now say, "Dad, I am proud of you."

**U.S. House of Representatives, Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
“Warning: The Growing Danger of Prescription Drug Diversion”**

April 14, 2011

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During this time, my wife and I separated, and shared custody of our two daughters. In 1999, I remarried and soon after had a baby boy. This all occurred while I had a severe dependence on opiates and alcohol. The drugs are what got me through the day. I

never had to go back to a doctor's office after my initial injury. I developed such a strong relationship with my doctors that I would only need to call and they would refill my prescription with no questions asked. I would go into a local emergency room where the doctor would see me and wave me back for my regular pain injections. I rarely had to resort to the streets to get my next fix. Depending on what type of narcotic I wanted and the method of administration of the drug resulted in which doctor I would call.

In October of 2008 I decided I wanted to fight for full custody of my two daughters. I felt that their mother was not caring for them the way I felt they should be cared for. I decided to call Child Protective Services (CPS) and after the investigation they were removed from their mother's care. When the case worker showed up unannounced to my house she saw my "pharmacy". I had two cabinets full of prescription medication. When confronted, I admitted to recent use of Oxycontin, Morphine, Lortabs, Demerol, dilaudid and Marijuana. After hearing myself admit to the amount of drugs in my system and seeing the case worker's response, I knew it was time to make a change. The only way I would ever get custody of my daughters was to get help. I entered the Family Preservation Court, otherwise known as Family Dependency Treatment Court.

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When I first entered the Family Preservation Court, I had not accepted my problem and I was very angry at myself for calling CPS since I was the one being sent to treatment. However, after my intake and sharing my history with the FPC counselor, I realized how bad things had gotten. Through the FPC, I was able to get help with setting my daughters, and myself, up with counseling and obtain guidance on educating my daughters about addiction. I participated in parenting courses that taught me how to effectively communicate with my children and how create healthy boundaries. I was given support from my counselors and peers throughout my struggles with the reunification process. In March 2010, I graduated from the Family Preservation Court.

Today I am thankful that I called CPS. Without CPS intervening and getting me enrolled in Family Preservation Court, I would not be in my daughters' lives today. I now have full custody of both my daughters and I am an active parent in their lives. I participate in ongoing counseling with my daughters and I am able to communicate honestly and openly with them. I received my GED and worked in social services at my reservation running family "talking" circles for youth and their families. I also work for a fire prevention and suppression program where I supervise 11 workers. Now, I am the co-owner and consultant for Power Shaver, a GSA approved energy saving system. Thanks to the Family Preservation Court, I am able to make decisions and better choices for my family. I have since come back to the Family Preservation Court as a mentor by co-leading parent support groups and mentoring other families going through the reunification process.

I am able to be my daughters' role model and they now look up to me. For the first time in their lives, my daughters now say, "Dad, I am proud of you."

ⁱ Aos et al. (2006). *Evidence-based public policy options to reduce future prison construction, criminal justice costs, and crime rates*. Olympia: Washington State Institute for Public Policy; Lattimer (2006). *A meta-analytic examination of drug treatment courts: Do they reduce recidivism?* Canada Dept. of Justice; Lowenkamp et al. (2005). Are drug courts effective: A meta-analytic review. *Journal of Community Corrections*, Fall, 5-28; Shaffer (2006). *Reconsidering drug court effectiveness: A meta-analytic review*. Las Vegas, NV: Dept. of Criminal Justice, University of Nevada; Wilson, et al. (2006). A systematic review of drug court effects on recidivism. *Journal of Experimental Criminology*, 2, 459-487.

ⁱⁱ Carey, S.M., Finigan, M., Crumpton, D., & Waller, M. (2006). California drug courts: Outcomes, costs and promising practices: An overview of phase II in a statewide study, *Journal of Psychoactive Drugs, SARC Supplement 3*, 345-356; Loman, L.A. (2004). A cost-benefit analysis of the St. Louis City Adult Felony Drug Court, St. Louis, MO: Institute of Applied Research; Finigan, M., Carey, S.M., & Cox, A.

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Mrs. BONO MACK. Thank you, Mr. Harrison.
Dr. Boyd, you are recognized.

STATEMENT OF CAROL BOYD

Ms. BOYD. Thank you. Thank you for inviting me today. My comments draw on my research that is primarily funded by the NIH, among other sources. I have been studying this for the past 10 years.

You have heard today that over the past 15 years, prescriptions for controlled medications have nearly doubled for adolescents and young adults, and these come from office visits, from ER visits and, significantly in this age group, from oral surgeons. And once the youth have the pills in their hand, they are at risk for diverting them. Approximately 10 percent of adolescents in a given year have diverted their pain medicine. Fifteen percent have diverted their stimulant medications. And like other researchers, we find that girls are more likely to divert by loaning and giving and boys are more likely to divert by selling. There are also socioeconomic differences among these adolescents.

Approximately 10 percent of all youth will divert their pills to their parents. Overall, one in six adolescents with legal prescriptions will be approached in a given year to divert their medicines, and in some cases, they will be asked to rent them. It is usually stimulants in this age group that are being diverted but not exclusively. We have found that the more elite the school and the more elite the university, the more likely diversion is to occur, and again, it is often stimulants. This is not to say that opiates are not the problem either, though.

Motives to divert as well as to use diverted medications are wide ranging, and it should not be assumed that the motives always involve getting high. Indeed, motives are one of the reasons that this problem is so difficult to prevent. So I would like to share with three cases from our own studies, and they highlight what we found in our research.

The first one is a 16-year-old teen. She is an honor student. She was going to homecoming. She had a new boyfriend. Four hours before the event, she got a migraine headache, and she went to her mother and her mother gave her one of her own hydrocodone tablets that she had leftover from her hysterectomy. The teen took it, went to the event. When I interviewed her, she had had a great time and she did not use hydrocodone again.

The second case, a 15-year-old boy attends an elite high school and he is having trouble getting his work done. His best friend has a prescription for Adderall and keeps it on the dresser in the house. And when his friend leaves the house, his friend takes the Adderall. When I talked to this young man, he said well, you know, everyone in my school is using it, everyone uses it to study.

And then in the third case, this is a high school girl. She did have a history of alcohol abuse. She was given an oxycodone tablet from her girlfriend, who had also gotten it for oral surgery. She wanted to experiment to see what it does. Now, this is a girl that also was abusing alcohol. She crushed and snorted the pill and she found herself continuing to use what she called Oxy when she wanted to party with her friend.

Now, these cases represent what we have found in our research. First, diversion in this age group usually occurs among family and friends. Two, there are gender differences. Three, it usually involves one primary prescription and it is often from oral surgeons and dentists. Four, the diverted medicine is often started for the purpose of self-treatment so that you see youth thinking that they are going to use it for a headache or that they are going to study harder but then once they start using it, they have it available to them. And finally, the controlled medications are readily available. They are advertised on television. We do advertise controlled medications on television with direct-to-consumer marketing. And they are not stored properly nor are they disposed of, and I hear this time and again from youth.

The adolescent girl that was in my case three is the one that is at the absolute highest risk. She is a poly-drug user and she is using for recreational purposes. It is these sensation-seeking youth that our data find have the biggest problems and are at the greatest risk for drug addiction and death.

Most social scientists end their talk by saying we need more data, and I am going to tell you that as well. It is difficult to understand why a country such as ours has data from 2006. We need regional data. We need national data that has more nuance, that tells us the complexity of the problem.

But policymakers can also do something. The FDA has recently stipulated that medicine bottles need to carry the schedule on them. I called my son, who has a prescription for Adderall, before I came here today and I said did you pick up your prescription bottle, and he said yes, and I said, well, what about the labeling, did it look different. No, he said, it doesn't look any different. I said come on, Joseph, look, see if it looks different; oh, yes, maybe. This isn't enough. I have a prescription that tells me on the back not to use it with grapefruit juice. These prescription bottles need to be clearly labeled that it is unlawful to share the medication, that they need to be stored correctly, and how they need to be disposed of.

The solution to this problem lies in the recognition that it is far more complex than actually street drug use, and it is going to require cooperation with pharmaceutical companies, health care providers, families, young people and policymakers. Thank you.

[The prepared statement of Ms. Boyd follows:]

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Introduction:

The misuse and abuse of controlled medications by young people is an increasing problem in the United States (U.S.) with annual rates for nonmedical use approaching 8% for adolescents of 12-17 years (SAMHSA, 2010). Approximately 5% of 12th graders reported using OxyContin® and 8% reported Vicodin® in the previous year (Johnston, et al 2010). It is not only pain medications that are abused, stimulants such as Ritalin® and Adderall® are also misused, with approximately 3% of 12th graders using Ritalin® and 6% using Adderall®. Focusing on 12- to 17 year olds is important because it is the age when controlled medications often are prescribed and concomitantly, when users are least likely to be aware of legal and health risks associated with their diversion and/or nonmedical use.

In this testimony, the term “nonmedical use” is used to mean the use of a controlled (schedule CII-CV) medication in a manner unintended by the prescriber. Typically these medications fall into one of several drug classes including: pain, stimulant, anti-anxiety and sleep. And as we know, many of the medications in these classes carry an increased risk of abuse and addiction. Likewise, when diversion of controlled medications is used here, it refers to the exchange of controlled medications that leads to their use by people other those intended by the prescribing clinician or the use under conditions associated with doctor shopping/ misrepresentation of medical problems or by theft (Boyd et al 2007).

Availability and Diversion:

Over the past 15 years, prescriptions for controlled medication have nearly doubled in adolescent and young adult U.S. populations. Fortuna and colleagues (2010) reported that between 1994 and 2007, controlled medications were prescribed in a greater number of doctor visits (and in increasing proportions). For adolescents, in 1994 approximately 6% of the doctor's visits resulted in a prescription for a controlled medication; however, by 2007 it was 11% of the visits. This was also true for young adults, in 1994 approximately 8% of the visits resulted in a prescription for a controlled medication and by 2007 it almost doubled to approximately 16%. This increase was seen in male and female patients, in office and emergency visits, and in injury related as well as non-injury visits. Fortuna and colleagues reported that the most commonly prescribed were pain medications.

National and regional data show that most nonmedical users get their pills from peers and/or parents and siblings (Boyd, et al, 2007; McCabe et al, 2004; SAMHSA, 2010). Our data show that although most adolescents use their medications correctly, some adolescents divert their own medications to friends and family members (Boyd et al 2007). Approximately 10% of adolescents have diverted pain medications and 15% stimulant medications. Like other researchers (Daniel et al 2003), we found that girls, when compared to boys, reported higher lifetime rates for giving or loaning medications (27.5% vs. 17.4%) and they were significantly more likely to divert to their girlfriends (64.0% vs. 21.2%). In contrast, boys were more likely to divert their controlled medications to their male friends (45.5% vs. 25.6%). Approximately 10% divert their pills to their parents. Overall, 13% of adolescents in our most current studies divert their controlled medicines and approximately 16% of adolescents with legal prescriptions are asked to divert, it is usually stimulants that are requested.

Case Examples:

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Motives to divert as well as to use diverted medications are wide ranging and it should not be assumed that all motives involve “getting high” (Boyd & McCabe, 2008; Boyd et al 2009). Indeed, motives are one of the reasons that nonmedical use of controlled medications is so difficult to prevent. Below are several scenarios that come from our research, with each scenario addressing a specific type of diversion.

CASE 1: A 16-year-old teen, an honor student, is planning to attend “Homecoming” with her new boyfriend. Four hours before the event, she develops a severe migraine headache. In tears, she asks her mother for help. Her mother gives her a hydrocodone tablet (left over from her own surgery). The teen went to the event and “had a great time.”

CASE 2: A 15 year old at an elite high school is having trouble getting his school work done and he wants to do well on his final exams. His best friend has a prescription for a stimulant to treat ADHD and his friend keeps the pill bottle on his bedroom dresser. When his friend leaves the bedroom, the 15 year old takes several of the Adderall®, justifying it by saying “everyone uses them to study”.

CASE 3: A young man works as a line-cook in a restaurant. During work, he slices-off the upper part of his finger. The manager takes the young man to the nearest ED; on the drive to the hospital the manager gives him a Vicodin® saying, “you will be waiting a long time, you will need this”. The young man takes it. The ED surgeon gives him a prescription for Vicodin® and tells him to see his primary care provider in one week.

CASE 4: A high school girl is given an oxycodone tablet by her girl friend; she wants to experiment to see “what it does”. She crushes the pill and snorts it and finds herself continuing to purchase the “Oxy” from a friend when she wants to party.

These cases represent what research has shown about diversion and all of the scenarios represent illegal behavior: 1) Diversion usually occurs among family and friends (Boyd, et al 2007; McCabe et al 2004); 2) It usually involves one primary prescription (SAMHSA, 2006); 3) Diverted medicine is often used for the purpose for which it was developed (e.g. pain medicines to treat pain) (Boyd, et al 2006^a; Boyd et al 2006^b); and 4) controlled medications are readily available to the adolescent because they are neither stored properly nor are they disposed of in a timely manner. And finally, for the adolescents such as the girl in the 4th case, the risks are even higher. These young people are using for recreational purposes, mixing the pills with alcohol and seeking more and more pills (Boyd, et al 2009; McCabe et al, 2007) and the adolescents sensation-seek most often develop other problem behaviors including drug abuse (Boyd 2009; McCabe et al, 2007).

Conclusion:

Most social scientists end their papers by noting more research is needed to understand diversion and nonmedical use. The national studies funded by the NIH do not ask detailed enough questions about diversion. We glean little from them. And while the regional studies provide greater details, they lack generalizability. Researchers also conclude that the problem lies with

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doctors, dentists and other prescribers. Failing to adequately educate patients and their parents, as well as evidence of over-prescribing are issues that need further professional attention. However, policy makers also have a role. Recently, a new Federal Regulation (21CFR1302) was established, mandating among other things, that prescription bottles that contain controlled medications be clearly labeled with a symbol designating its schedule (e.g. CII-CIV) along with a special sealing requirement. This is an important first step but it is not enough. The bottles should include information about proper storage, proper disposal and the risks associated with allowing others to use the medication.

If all it took was symbols on bottles or lecturing adolescents, the problems of nonmedical use and diversion could be solved. However, educating adolescents about the dangers of these medications is unlikely to be effective because they see too many of their friends with prescriptions. The solution to this problem lies in the recognition that it is far more complex than street drug use and involves all aspects of our society – our pharmaceutical companies, our health care providers, our families, our young people and equally as important, our policy makers.

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Original article

Adolescents' Nonmedical Use of Prescription Medications and Other Problem Behaviors

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Purpose: This study examines adolescent nonmedical use of prescription medications (NUPM) and its relationship to other problem behaviors.**Methods:** A secondary analysis was conducted with data gathered from 912 adolescents in 2007. Four mutually exclusive groups were created from the data. Adolescents who: 1) did not use controlled prescription medications (nonusers); 2) used their own controlled medications as prescribed (medical-users); 3) engaged in nonmedical use for self-treatment motivations (self-treaters), and 4) engaged in nonmedical use for sensation-seeking motivations (sensation-seekers). These four groups were compared on problem behaviors as well as depression and impulsivity.**Results:** Approximately 10.9% of the sample engaged in NUPM and 36.8% had a legal prescription for a controlled medication. Sensation-seekers were more likely to engage in most problem behaviors when compared with all other groups; impulsivity and depression was variable among groups.**Conclusions:** The findings suggest there are different subtypes of nonmedical users of prescription medications. © 2009 Society for Adolescent Medicine. All rights reserved.**Keywords:** Nonmedical use prescription medications (NUPM); Adolescents' prescription drug abuse; Problem behaviors

Nonmedical use of prescription medications (NUPM) is an emerging problem behavior that is associated with diversion and poly-drug abuse [1–12]. Given that NUPM prevalence rates are high in populations under 25 years and that NUPM is associated with other forms of drug abuse [1–3,6–10], it is critical that this form of substance use be studied.

Two national surveys provide epidemiological data on nonmedical use of prescription medications (NUPM) among adolescents in the United States. These studies—the *National Survey on Drug Use and Health* (NSDUH) and *Monitoring the Future* (MTF)—include measures of NUPM in annual population surveys of substance use behaviors.

In the NSDUH [13], “prescription-type” medications are separated into four classes: pain relievers, stimulants, sedatives, and tranquilizers. Twelve percent (12%) of youth aged 12–17 report the nonmedical use of prescription-type medications in their lifetimes, while 8.3% report past-year use and 3.3% report past-month use. *Monitoring the Future* [14,15] assesses NUPM among 8th, 10th, and 12th grade students in the U.S and reveals that since the early 1990s, the nonmedical use of narcotics has increased with 9% of 12th graders reporting NUPM within the past year [14].

Legitimate medical use of controlled prescription medication (particularly opioids) has also increased in the past decade [16]. Data from the ARCOS system indicate a substantial rise in the distribution of some controlled medications to youth between 2000 and 2005 [17]; however, the relationship between the rise in NUPM and increased medical use remains unclear, although youth data from

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Canada reveals a robust relationship between medical and nonmedical use of a controlled stimulants [18,19].

Jessor et al developed the Problem Behavior Theory [20–24] in part to explain the co-occurrence of problem behaviors during adolescence. Problem Behavior Theory stipulates that a problem behavior is “behavior that departs from the norms of the larger society,” a behavior that is either disapproved of by social institutions and/or elicits some form of social response (e.g. reproof, probation, incarceration). Problem behaviors that co-occur are considered part of problem behavior syndrome, which includes substance use, early sexual activity, delinquency, school truancy, and other socially deviant behaviors. Impulsiveness is a factor that has been found to influence problem behaviors such as substance abuse [25] and there appears to be a connection between sensation-seeking and substance use [26].

Problem Behavior Theory provides a useful model for understanding the strong association among various adolescent behaviors that are viewed by society as “deviant.” A question remains, however, about adolescents’ nonmedical use of prescription medications. Does it represent an isolated—albeit risky—behavior, or is it part of a larger set of problem behaviors? The answer may lie in an adolescent’s motivation to engage in nonmedical use.

This current study builds on our earlier work [2,7]. Four mutually exclusive groups were compared: those adolescents who 1) never used controlled prescription medications (nonusers); 2) used their own controlled medications prescribed to them (medical users); 3) engaged in nonmedical use for self-treatment motivations (self-treaters); and 4) engaged in nonmedical use for experimental or sensation-seeking motivations (sensation-seekers). Given that impulsivity and depression often occur as precursors to problem behaviors, we assessed the relationship of group membership with impulsivity and depression.

We conducted this research with the following hypotheses: 1) Adolescents who engage in NUPM for sensation-seeking motivations will be significantly more likely to report additional problem behaviors when compared with adolescents who are self-treaters, medical users, or nonusers; and 2) adolescents who engage in NUPM for self-treatment or sensation-seeking motivations will be significantly more likely to have higher impulsivity and depression scores compared with adolescents who are characterized as nonusers.

Methods

This secondary analysis used 2007 cross-sectional data from one school district in southeastern Michigan. All students (1514) in grades 7–12 attending the district’s middle and high schools were recruited; 968 students returned their consent forms and thus, participated in the study (64% response rate). University IRB approval and a NIH Certificate of Confidentiality were obtained.

The Secondary Student Life Survey, a Web-based survey, involves a procedure described in earlier studies [1–6], and relies on the use of hooded computers in classrooms. For classes

with lower reading levels, research assistants read with students. The web-based survey method was selected because they have been shown to increase the reporting of highly sensitive behaviors compared with pencil-and-paper surveys [27,28].

Study sample

The final 2007 sample consisted of 912 respondents in grades 7–12. To create our four mutually exclusive groups, we selected those who answered questions about prescription medications, including never having used. If respondents checked “rather not say” to any of the prescription medication questions they were excluded ($n = 41$). Furthermore, 15 respondents reported NUPM for reasons other than sensation-seeking or self-treatment with pain medications (e.g., “it helps me sleep” or “for other reasons.”) These 15 cases were dropped given the ambiguity surrounding their motives.

Approximately half of respondents were female (52.6%) with 53.8% being African-American and 43.5% being white. At the time of the survey, respondents’ average age was 15 ($SD = 1.74$). Fifteen percent of the sample was in the 7th grade, 17.4% in 8th grade, 21.4% in 9th grade, 18.9% in 10th grade, 14.8% in 11th grade and 12.1% was in 12th grade.

Measurement

Demographic information was collected (Table 1). Parental education was a nominal variable with the following categories: “less than high school” (1), “completed high school” (2), “some college” (3), “completed college” (4), “graduate or professional school” (5), or “don’t know/not applicable” or “rather not say.” Both mother’s and father’s education were entered when used as covariates; hereafter, these variables are referred to as parental education.

For the questions related to problem behavior variables respondents were given an option to endorse “rather not say.” If a student endorsed “rather not say,” the data were coded as missing.

Binge drinking was assessed with a question adapted from MTF [15] and the College Alcohol Study [29]: “Over the past two weeks, on how many occasions have you had four (five for males) or more drinks in a row...?” Response options were: “none” (0), “once” (1), “twice” (2), “3–5 times” (3), “6–9 times” (4), “10 or more times” (5).

Illicit drug use was assessed with 10 items adapted from the MTF study (marijuana, cocaine, LSD, other psychedelics, crystal methamphetamine, heroin, inhalants, ecstasy, GHB, and Rohypnol®). A count of the number of drugs reported for the past year was used to create an index of illicit drug use.

Gambling was measured with a single item: “On how many occasions have you gambled for money in the past 12 months?” The response options were: “never” (0), “1–2” (1), “3–5” (2), “6–9” (3), and “10+” (4).

School discipline was measured with three items that asked about past year detention, suspension, and other forms of school-based discipline. Response options included: “never” (0), “1–3 times” (1), “4–6 times” (2), “7–9 times” (3), and “10 or more times” (4). The three items were summed to create an ordinal index of school discipline.

Sexual activity included four frequency items summed to create a measure of consensual sexual activity involving physical contact [30]. It was assessed with, “Please indicate how often you have engaged in the following activities: kissing someone you were interested in, making out, touching private parts, and having sexual intercourse.” Response options were: “never” (0), “once” (1), “two or three times” (2), and “four or more times” (3).

Depression was measured by the Center for Epidemiological Studies Depression Scale [31]. The scale is a sum of how often each of 20 symptoms is reported in the past two weeks, with response options ranging from rarely (or none of the time) to most or all of the time, with a possible scale range from 0 to 60. The alpha coefficient for these 20 items was .84.

Impulsivity was measured with the Impulsivity subscale, part of the Impulsivity/Sensation-Seeking scale (Imp-SS) of the Zuckerman-Kuhlman Personality Questionnaire [32,33]. The seven-item scale assesses lack of planning and impulsivity and has a true-false format with score ranging from 0 to 7. The Imp/SS has a reported alpha coefficient of .72 [32].

Medical and nonmedical use of prescription medication were assessed as in previous studies [1,2,3,6]. Medical use was measured with the question: “Based on a health professional’s prescription, on how many occasions in your lifetime [also asked in the past 12 months] have you used the following types of drugs...” Nonmedical use was measured with the question: “On how many occasions in your lifetime [also in the past 12 months] have you used the following types of drugs not prescribed to you?”... The drug classes (with trade and generic names included for examples) for both questions were: (a) sleeping medication; (b) sedative/anxiety medication; (c) stimulant medication; and (d) pain medication. Response options ranged from “no occasions” to “40+ occasions” (and “rather not say”). Respondents’ answers to each question were dichotomized to create a variable that indicated whether they used each medication in the past year.

Motivations to engage in NUPM were adapted from the MTF and possible motives used in previous research [2,7,11,34]. Respondents who reported any lifetime NUPM were asked to provide the reasons why they used each of the four drug classes nonmedically. Respondents were given a list of motivations and asked to check all that apply. Five motivations were listed for all four drug classes: 1) “because it gives me a high”; 2) “counteracts effects of other drugs”; 3) “is safer than street drugs”; 4) “experimentation”; and 5) “because I’m addicted.” In addition, for the anxiety/sedative and sleeping drug classes, two other motivations were

provided: “because it helps me sleep” and “because it helps decrease anxiety.” For stimulant medications, these additional motivations were provided: “to help with concentration,” “to help with alertness,” “to help me study,” and “to lose weight.” For pain medications, the motivation “to relieve pain” was also provided.

Data analyses

Data analyses included 912 respondents and all statistical analyses were carried out using SPSS 14.0. Prior to hypothesis testing, univariate and bivariate analyses were conducted. A four-level group variable was created with the aforementioned medical use, nonmedical use, and motivations to engage in NUPM items.

1. Respondents were characterized as *nonusers* if they reported no prescription medication use, either medical or nonmedical, in the past year.
2. Respondents were characterized as *medical users* if they reported having a prescription for a controlled medication during the past year but reported never engaging in NUPM.
3. Respondents were characterized as *self-treaters* if they reported past year nonmedical use for therapeutic reasons only. Self-treaters reported using pain medication because “it relieves pain”; sedative/anxiety medication because “it helps decrease anxiety” or “it helps me sleep”; sleep medications because “it helps me sleep,” or stimulants because “it helps me concentrate,” “it helps increase my alertness,” or “it helps me study.”
4. Respondents were characterized as *sensation-seekers* if they reported past year nonmedical use for motivations such as: “it gives me a high” and “it is safer than street drugs and “experimentation.” Any endorsement of sensation-seeking motives resulted in the respondent being classified as a sensation-seeker even if self-treatment motives were also endorsed.

Finally, 15 respondents reported NUPM for reasons other than sensation-seeking or self-treatment. The two reasons offered were “it helps me sleep” or for “other” reasons. These cases were dropped from the analyses given the ambiguity surrounding their motives to use pain medications.

To better understand how respondent characteristics related to group membership (i.e., nonusers, medical users, sensation-seekers, self-treaters), chi-square tests were used to examine group membership by gender, race, and parental education, and a one-way ANOVA was used to examine group membership by age. These analyses were followed by MANOVA to test the hypotheses. MANOVA was used to determine whether group membership (sensation-seekers, self-treaters, medical users, nonusers) predicted higher scores on problem behaviors, impulsivity, and depression. Age, race, gender, and parental education were entered as covariates to control for any effect on problem behaviors; in turn, the covariance matrices generated by MANOVA took into account possible correlations

among the various problem behaviors. Given that the school discipline variable was skewed, this variable was corrected with a log transformation prior to its inclusion in the hypothesis testing. The MANOVA test was followed by post-hoc comparison tests to determine which of the groups were different from each other; post hoc tests were adjusted for all pairwise comparisons using the Bonferroni correction.

Results

Over one-third of the sample (36.8%) reported having a legal prescription for at least one of the four controlled drug classes within the previous 12 months (Table 2); however, 546 (59.9%) respondents reported “no annual use” of prescription medications. A total of 71 respondents (7.8%) reported nonmedical use for self-treatment motivations in the past year and 28 (3.1%) reported motivations related to sensation-seeking. Pain medication was the most frequently reported controlled medication used in the past year, both medically (32.5%) and nonmedically (10%). There were other forms of substance use as well: 148 respondents (16.2%) had used at least one illicit drug in their lifetimes, with approximately 8.7% of the sample reporting at least one binge drinking episode in the preceding two weeks (Table 3).

Analyses revealed demographic differences in both medical and nonmedical use by gender, race, and age. A greater percentage of males reported no use of any prescription medications (males = 67%, females = 54%), and female respondents (10.7%) reported greater nonmedical use for self-treating motives than males (4.4%, $\chi^2 (3) = 22.72$,

$P < .001$). A larger percentage of white respondents (5.8%) reported sensation-seeking motives when compared with African-American/nonwhite respondents (1%, $\chi^2 (3) = 22.69$, $P < .001$). Finally, sensation-seekers ($mean = 15.96$ $SD = 1.35$) tended to be older than nonusers ($mean = 14.84$ $SD = 1.76$), $F (3,911) = 4.85$, $P = .002$. There were no differences in parental education between users and nonusers of prescription medication.

We found significant associations of age, race, gender, and father's education for several of the problem behaviors (Table 4). For instance, males scored higher than females in gambling, amount disciplined, sexual activity, and impulsivity (gambling: males $mean = 2.33$, $SD = 1.78$, females $mean = 1.32$, $SD = .81$), $F (1, 887) = 124.17$, $p < .001$; amount disciplined: males $mean = 4.03$, $SD = 1.60$, females $mean = 3.65$, $SD = 1.17$), $F (1, 907) = 16.71$, $p < .001$; sexual activity: males $mean = 6.56$, $SD = 4.26$, females $mean = 5.78$, $SD = 3.47$), $F (1, 870) = 8.86$, $p = .003$; impulsivity: males $mean = 14.77$, $SD = 3.89$, females $mean = 14.26$, $SD = 3.63$), $F (1, 910) = 4.17$, $p = .04$). Father's education, but not mother's, had a significant association with depression $F (3, 904) = 6.96$, $p = .04$; those who did not know or would rather not say ($mean = 14.62$ $SD = 8.29$) and those whose fathers had less than or completed high school ($mean = 14.04$ $SD = 8.92$) reported greater depression than those with fathers who had some or completed college ($mean = 12.28$ $SD = 8.50$) and completed graduate education ($mean = 10.18$ $SD = 6.35$).

Table 5 provides a summary of the MANOVA analyses used to test the study hypotheses. The first hypothesis, which

Table 1
Sample characteristics

Characteristic		Sample		Non-respondent Population		
		% (n)	Mean (SD)	% (n)	χ^2	p Value
Sex	Female	52.6% (480)		45.5% (274)	7.35	.007
	Male	47.4% (432)		54.5% (328)		
	Total	100% (912)		100% (602)		
Age			14.97 (1.74)			
Race	Black	53.8% (490)		65.6% (395)	25.36	< .001
	White	43.5% (396)		31.9% (192)		
	Asian American	1.4% (13)		1.0% (6)		
	Hispanic or Latino/a	.7% (6)		1.3% (8)		
	American Indian or Alaskan Native	.7% (6)		0.2% (1)		
	Total	100% (911)				
Mother's/female guardian's highest level of education	Less than high school	5.6% (45)				
	Completed high school	26.7% (216)				
	Some college	27.9% (226)				
	Completed college	25.7% (208)				
	Graduate school	14.2% (115)				
Father's/male guardian's highest level of education	Total	100% (810)				
	Less than high school	10.6% (77)				
	Completed high school	33.2% (242)				
	Some college	22.8% (166)				
	Completed college	24.1% (176)				
	Graduate school	9.3% (68)				
	Total	100% (729)				

Table 2
Prevalence of annual and lifetime medical and nonmedical use and motives

		Annual % (n)	Lifetime % (n)
Medical Use	Anxiety/Sedatives (n = 906)	2.5% (23)	4.7% (43)
	Stimulants (n = 907)	3.1% (28)	5.7% (52)
	Pain (n = 904)	32.5% (294)	43.3% (392)
	Sleep (n = 909)	7.4% (67)	15.0% (136)
	At least one (n = 912)	36.8% (336)	49.6% (452)
Nonmedical Use	Anxiety/Sedatives (n = 910)	1.3% (12)	2.0% (18)
	Stimulants (n = 907)	1.2% (11)	1.5% (14)
	Pain (n = 907)	10.0% (91)	14.6% (132)
	Sleep (n = 908)	2.5% (23)	4.5% (41)
	At least one (n = 912)	10.9% (99)	16.2% (148)
Groups* (n = 912)	No prescription use	59.9% (546)	N/A
	Medical use only	29.3% (267)	N/A
	Self-treaters	7.8% (71)	N/A
	Sensation-seekers	3.1% (28)	N/A

*Groups were created using annual report.

predicted that the sensation seekers would be significantly more likely to report problem behaviors than the three other groups, was supported. Specifically, sensation-seekers were more likely than self-treaters, medical-users, and nonusers to report using illicit drugs, gambling, binge drinking, and sexual activity. All of these group comparisons were significant at the $p < .05$ level, with the exception of the comparison between the sensation-seekers and self-treaters on sexual activity, which was significant at a trend level ($p = .07$). Although not predicted, medical-users were found to be significantly lower than the nonusers on number of times disciplined; however, this difference occurred only at a trend level ($p < .08$). No other group differences were found.

Results provided partial support for the second hypothesis, which predicted that the sensation-seekers would be significantly higher than the other groups on depression and impulsivity. The sensation-seekers were significantly higher than the nonusers and medical users on impulsivity, but there were no significant differences on impulsivity between the sensation-seekers and the self-treaters. Thus, all nonmedical users (whether self-treaters or sensation-seekers) had greater impulsivity than nonusers. In terms of depression, no significant differences were found among the four groups.

Discussion

Arguably, Problem Behavior Theory [PBT] is one of the most widely used and empirically validated frameworks to understand the co-occurrence of adolescent behaviors. Our results lend support to PBT and support to the proposition that motivations to engage in NUPM appear to be associated with adolescent problem behaviors. As hypothesized, this study demonstrated that sensation-seekers were statistically more likely to engage in a host of problem behaviors. While future research is necessary to better describe the nature of the relationship between NUPM and problem behaviors, it may well be that NUPM should be considered a type of adolescent

problem behavior that has come into prominence among youth of today.

There were no differences among the groups relative to depressive symptoms and this surprised us. Although sensation-seekers had higher depression mean scores than nonusers, medical-users or self-treaters (16.89 vs. 13.12, 13.51, and 13.06), the differences were not significant and thus, the hypothesis remains unsupported. There are several possible

Table 3
Frequencies and means of problem behaviors, depression, and impulsivity

		Sample % (n)
No. of illicit drugs used past year	0	83.8% (759)
	1	12.6% (114)
	2	2.1% (19)
	3 or more	1.5% (14)
	Total	100% (906)
No. of occasions gambled past year	Never	65.4% (581)
	1-2 occasions	16.5% (147)
	3-5 occasions	7.5% (67)
	6-9 occasions	3.5% (31)
	10 + occasions	7.1% (63)
No. occasions binge drank past 2 weeks	Total	100% (889)
	0	91.4% (787)
	1	4.2% (36)
	2	2.1% (18)
	3 or more	2.4% (20)
No. of times disciplined (past year) (possible range 0 to 12)	Total	100% (861)
	Mean (SD)	
	.84 (1.39)	
Sexual activity (possible range 0 to 12)	3.75 (3.43)	
Depression (CES-D) (possible range 0 to 60)	13.20 (8.54)	
Impulsivity (possible range 0 to 19)	10.60 (3.59)	

Table 4
Respondent characteristics and four mutually exclusive prescription medication groups

Respondent Characteristic	Non-users % (n)	Medical-users % (n)	Self-treaters % (n)	Sensation-seekers % (n)	df	χ^2	p Value
Sex					3	22.72	< .001
Female	53.6% (260)	32.8% (159)	10.7% (52)	2.9% (14)			
Male	67.0% (286)	25.3% (108)	4.4% (19)	3.3% (14)			
Race					3	22.69	< .001
White	56.3% (223)	31.8% (126)	6.1% (24)	5.8% (23)			
Black and other	62.5% (322)	27.4% (141)	9.1% (47)	1.0% (5)			
Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	df	F statistic	p Value
Age	14.84 (1.76)**	15.11 (1.73)	15.11 (1.64)	15.96 (1.35)**	3, 911	4.85	.002

** post hoc comparisons significant $p < .01$.

explanations for this unexpected finding regarding depression; measurement error, small cell sizes, and sample characteristics may all be factors.

Simoni-Wastila [35] observed that greater availability may be associated with an increase in NUPM. In support of Simoni-Wastila's observation, we found that girls were statistically more likely to be medical users (32.8% vs. 25.3%) and self-treaters (10.7% vs. 4.4%). However there were no statistical differences between girls and boys relative to sensation-seeking NUPM. We are not sure how to interpret these gendered findings, other than to note that girls are more likely to be prescribed medications and thus, the drugs may be more available for diversion. Further research is needed to examine gender differences and the differences between those who engage in nonmedical use for self-treatment vs. those who engage in it for sensation-seeking motivations.

The National Survey of Health and Drug Use [13] indicates that about 8.3% of 12–17-year-olds reported NUPM, this annual prevalence estimate is a bit lower than our finding of 11%. However, the differences between the NSDUH and our data may be related to several factors: 1) the NSDUH data were collected in the adolescents' homes while our survey was self-administered on hooded computers; 2) the NSDUH question to assess nonmedical use is a complex one that not only asks about nonprescribed use but also stipulates a broad motivation (i.e., "...or took only for the experience or feeling it caused"), whereas our question is more straightforward; 3) our sample was limited to one geographic region that

generally has higher rates of nonmedical use of prescription opioids (5.6%) when compared with the national average (4.9%) and thus, adolescent NUPM may reflect the higher use in their general environment [36]. Our higher prevalence estimates and the fact that our sample was disproportionately African-American somewhat constrains our ability to generalize. However, our data remind us that national drug studies may not adequately account for community differences in nonmedical use.

Nonmedical use of prescription medications, whether by a self-treater or sensation-seeker, represents an unacceptable health risk. Health providers should communicate with their adolescent patients about the health and safety risks associated with diverted medications and the legal risk associated with diverting their own medications. In a paper on prescription medication abuse in school settings, Apa-Hall [37] noted that "talking" to adolescents is not enough; rather, the message about nonmedical use should be reinforced with illustration and repetition, having patients paraphrase back what they have heard. In addition, all health providers – pediatricians, dentists, nurses, and pharmacists – should alert parents about the importance of "controlling and counting" their children's pills; most certainly, parents should restrict availability and not leave medicines on countertops or in unlocked medicine cabinets.

Generalizations should be made cautiously; the sample was drawn from one school district and relied on self-report. Respondents completed the survey in school; thus, problem

Table 5
Problem behaviors, depression, and impulsivity among past-year medical and nonmedical users

	Non-users (n = 484)		Medical-users (n = 237)		Self-treaters (n = 65)		Sensation-seekers (n = 26)		F (3, 335)	p Value
	M (SD)	B (SE)	M (SD)	B (SE)	M (SD)	B (SE)	M (SD)	B (SE)		
Illicit drugs	0.24 (0.08) ^a	0	0.33 (0.10) ^b	0.10 (0.11)	0.41 (0.17) ^c	0.17 (0.17)	3.07 (.23) ^{bhc}	2.84 (0.24)	47.73	< .001
Gambling	1.81 (0.133) ^a	0	2.09 (0.17) ^b	0.27 (0.18)	2.23 (0.29) ^c	0.42 (0.29)	3.33 (0.39) ^{bhc}	1.52 (0.40)	5.23	< .01
Binge drinking	0.20 (0.07) ^a	0	0.25 (0.09) ^b	0.05 (0.10)	0.40 (0.17) ^c	0.20 (0.17)	1.16 (.23) ^{bhc}	0.89 (0.13)	8.61	< .001
Disciplined	.49 (0.05) ^{ad}	0	0.37 (0.06) ^{bd}	0.12 (0.07)	0.49 (0.11) ^c	0.02 (0.12)	0.98 (0.15) ^{bhc}	0.49 (0.27)	5.23	< .01
Sexual activity	3.67 (0.24) ^a	0	4.00 (0.30) ^b	0.31 (0.33)	4.20 (0.54)	0.53 (0.55)	5.84 (0.74) ^{bh}	2.16 (0.76)	2.87	< .05
Depression	13.12 (0.75)	0	13.51 (0.93)	0.39 (1.05)	13.06 (1.70)	0.06 (1.17)	16.89 (2.32)	3.77 (2.38)	.86	NS
Impulsivity	4.02 (0.12) ^{ad}	0	4.20 (0.14) ^b	0.18 (0.16)	4.50 (0.26) ^{cd}	0.49 (0.27)	5.00 (0.36) ^{bhc}	0.98 (0.37)	3.19	< .05

Non-users were the reference group and set to "0" to avoid over-parameterization. Multivariate, $F(21,945) = 17.05, p < .001$; MANOVA only uses cases that have data for all variables, including control variables and dependent variables statistically controlling for age, race, gender and parental education.

Estimates with the same superscripts in a given row are significantly different from each other.

behaviors are likely underestimated since youth with problems are less likely to be in school [38]. We never assessed the quantity of the prescribed medications and this information would have provided an important context for understanding the extent to which NUPM occurs. Finally, the index to create our illicit drug measure did not take into account the frequency of consumption so all illicit drug use were weighted the same.

Despite the noted limitations, we believe this study reflects a reality; the use of controlled medications is an increasing behavior among adolescents [39]. However, our comments should not be construed as “anti-medication”; rather, we are concerned with the number of adolescents who self-treat. How is it that so many teens perceive themselves in need of potentially addictive medicines? An answer to this question may rest on determining: 1) the number of adolescents who do not have access to adequate medical care; 2) the number of self-treaters that if seen by a provider would receive a prescription for a controlled medication; and 3) the extent to which direct-to-consumer marketing contributes to adolescents’ attitudes about self-treatment.

To the best of our knowledge we are the first to examine subgroup differences among adolescents who engage in nonmedical use. In a recent commentary, Boyd and McCabe [40] argued that national representative data have treated all nonmedical users as a homogeneous group, failing to distinguish between those nonmedical users who use to self-treat versus to “get high.” We believe that studies such as this will help researchers to design better questions, thereby producing data that ultimately assist prevention experts in crafting more targeted messages.

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Medical and Nonmedical Use of Prescription Drugs among Secondary School Students

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Abstract

Purpose: The main objective of this study was to assess the prevalence of medical and nonmedical use of four categories of prescription drugs (opioid, stimulant, sleeping, and sedative/anxiety medication) in a racially diverse sample of secondary public school students in the Detroit metropolitan area. A secondary objective was to examine the association between the use of four categories of prescription medications and illicit drug use and probable drug abuse.

Methods: In 2005, a Web-based survey was self-administered by 1086 secondary school students in grades seven through 12.

Results: The sample consisted of 54% female, 52% White, 45% African American, and 3% from other racial categories. Forty-eight percent of the sample reported no lifetime use of four categories of prescription drugs (nonusers), 31.5% reported medically prescribed use only (medical users), 17.5% reported both medical and nonmedical use (medical/nonmedical users) and 3.3% reported nonmedical use only (nonmedical users). Multivariate analyses indicated that medical/nonmedical users and nonmedical users were significantly more likely than nonusers to report illicit drug use and probable drug abuse. Medical users generally reported similar or increased odds of illicit drug use and probable drug abuse than non-users.

Conclusions: These findings provide evidence that nonmedical use of prescription drugs represents a problem behavior among secondary school students. © 2007 Society for Adolescent Medicine. All rights reserved.

Keywords:

Prescription drugs; Epidemiology; Drug abuse; Adolescents; Survey research; School-based research

The medical and nonmedical use of prescription drugs such as benzodiazepines, opioid analgesics, and stimulants has increased among adolescents and young adults in the United States during the past decade [1–11]. According to the Monitoring the Future Study (MTF), the nonmedical use of several prescription medications by 12th graders in the United States is at its highest level in the past 15 years [1,2]. Because prescription drugs are necessary for the treatment

of many pediatric disorders including anxiety, sleep, and attention deficit hyperactivity disorder (ADHD), any examination of the nonmedical use and abuse of prescription drugs should occur within the larger context of proper medical use. With appropriate medical use considered, there are at least three studies that have examined nonmedical use among adolescents [12–14]; however, these earlier studies limited their focus to either stimulant or pain medications. To date, there are few (if any) investigations examining secondary students' reports of medical and nonmedical use of all four of the most abused classes of prescription drugs (i.e., opioid, stimulant, sleeping, and sedative/anxiety medications).

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In 2001, Poulin reported on a sample of secondary school students and found that nonmedical use of prescription stimulants was directly correlated to the number of prescription users in a particular school class who reported giving away their stimulant medication [14]. Although there were some limitations in the measures used by Poulin, the investigation represented one of the first attempts to examine medical and nonmedical use of prescription stimulants at the school class level [14]. In two subsequent studies, McCabe and colleagues reported that secondary school students who properly use prescription stimulant or pain medications were not at greater risk for substance use than nonusers [12,13]. For example, students who used their prescription stimulants for ADHD (e.g., Ritalin®, Adderall®, etc.) did not report higher rates of alcohol, marijuana, and other illicit drug use than nonstimulant-using peers; however, students who reported nonmedical use of prescription stimulants had significantly higher rates of alcohol, marijuana, and other illicit drug use when compared with students who did not use prescription stimulant medication [13]. These stimulant findings are similar to those reported by Boyd and colleagues for prescription opioid analgesics. Boyd and colleagues found that secondary students who reported medical use of prescription opioids (used as prescribed) were no more likely to use substances than their nonopioid-using counterparts; however, secondary school students who reported nonmedical use had significantly higher rates of alcohol, marijuana, and other illicit drug use than their nonopioid using counterparts [12]. Despite growing evidence suggesting significant associations between prescription medication use and other drugs, there is limited information regarding these associations among secondary students.

The current study builds on earlier studies and assesses medical and nonmedical use of four different classes of abusable prescription drugs (i.e., opioid, stimulant, sleeping, and sedative/anxiety medications) in a probability-based sample of secondary school students in a Detroit-area public school district. The specific objectives of this study were to examine the prevalence of the following: 1) medical use of four classes of prescription drugs, 2) nonmedical use of four classes of prescription drugs, and 3) illicit drug use and probable drug abuse based on use of four classes of prescription drugs.

Methods

The present study was conducted during a 1-week period in May 2005, drawing on the entire population of 1594 middle school and high school students from a public school district in the Detroit metropolitan area (seventh through 12th grades). The study received approval from the University of Michigan Institutional Review Board and a Certificate of Confidentiality was obtained from the National Institutes of Health. All parents in the school district were

sent letters explaining that their child's participation was voluntary, describing the relevance of the study, and assuring that all responses would be kept confidential. Seventy-three percent of parents gave informed consent. The survey was conducted over the internet from school-based computer labs and students were excused from class to complete the survey. All participants were informed that a private research firm, unaffiliated with the school district, was contracted to set up the Web survey as well as store and maintain data to ensure students' responses were kept completely confidential.

The Web-based survey method was used in part because computer-based approaches have been shown to have certain advantages relative to hardcopy surveys such as faster turnaround time and improved reporting of highly sensitive and illegal behaviors [15,16]. The Web survey was maintained on a hosted secure Internet site running under the secure sockets layer (SSL) protocol to insure respondent data were safely transmitted between the respondent's browser and the server. Students were given sheets with a unique preassigned PIN number that allowed them to access the Web survey and these sheets were destroyed immediately after the survey administration; school officials and staff were unable to access any personally identifiable information connected with the data of any respondent. The survey took approximately 22 minutes to complete, and survey administration was supervised by staff from the University of Michigan, the public school district, and a private research firm. The project achieved a participation rate of 94% for students in the seventh through 12th grades whose parents gave informed consent, and the main reason for nonresponse was absenteeism on the days of survey administration. The final response rate for this Web-based survey was 68% based on guideline #2 of the American Association for Public Opinion Research (AAPOR); this guideline asserts that the response rate should be calculated by dividing the number of completed and partial cases by the number of all eligible respondents [17].

Measures

Medical use of prescription medication. Medical use of prescription medication was measured using the following question: "Based on a health professional's (e.g., doctor, dentist, nurse) prescription, on how many occasions in your lifetime have you used the following types of drugs?" A separate question was asked for each of the following four classes of prescription drugs: (a) Sleeping medication (e.g., Ambien, Halcion, Restoril, temazepam, triazolam); (b) Sedative/anxiety medication (e.g., Ativan, Xanax, Valium, Klonopin, diazepam, lorazepam); (c) Stimulant medication for ADHD (e.g., Ritalin, Dexedrine, Adderall, Concerta, methylphenidate); (d) Pain medication (i.e., opioids such as Vicodin, OxyContin, Tylenol 3 with codeine, Percocet, Darvocet, morphine, hydrocodone, oxycodone). The

response scale for each question was (1) Never, (2) 1–2 occasions, (3) 3–5 occasions, (4) 6–9 occasions, (5) 10–19 occasions, (6) 20–39 occasions, and (7) 40 or more occasions.

Nonmedical use of prescription medication. Nonmedical use of prescription medication was assessed by asking the following question: “Sometimes people use prescription drugs that were meant for other people, even when their own health professional (e.g., doctor, dentist, nurse) has not prescribed it for them. On how many occasions in your lifetime have you used the following types of drugs, not prescribed to you?” There were separate questions for each of the following four classes of prescription drugs: (a) Sleeping medication (e.g., Ambien, Halcion, Restoril, temazepam, triazolam); (b) Sedative/anxiety medication (e.g., Ativan, Xanax, Valium, Klonopin, diazepam, lorazepam); (c) Stimulant medication for ADHD (e.g., Ritalin, Dexedrine, Adderall, Concerta, methylphenidate); (d) Pain medication (i.e., opioids such as Vicodin, OxyContin, Tylenol 3 with codeine, Percocet, Darvocet, morphine, hydrocodone, oxycodone). The response scale for each question was the same as for medical use.

Prescription drug use status. Prescription drug use status was assessed by creating four distinct groups of lifetime prescription medication use: (1) individuals who never used one or more of the four classes of prescription medication (nonusers, $n = 499$); (2) individuals who only used one or more of the four classes of prescription medication as prescribed by their physicians (medical user only, $n = 329$); (3) individuals who used one or more of the four classes of prescription medication as prescribed by their physicians, as well as prescription medication that was not prescribed to them (both medical and nonmedical user, $n = 183$); (4) individuals who only used one or more of the four classes of prescription medication that was not prescribed to them (nonmedical user only, $n = 35$). Similar four-level indicator variables were developed for each specific drug class.

Drug Abuse Screening Test, Short Form (DAST-10). The Drug Abuse Screening Test, Short Form (DAST-10) is a self-report instrument that can be used in clinical and non-clinical settings to screen for probable drug abuse or dependence on a wide variety of substances other than alcohol [17]. Respondents who used drugs other than alcohol in the past 12 months were asked whether they had experienced 10 drug-related items in the past 12 months (e.g., inability to stop using drugs, simultaneous polydrug use, illegal activities to obtain drugs, blackouts as a result of drug use, medical problems as a result of drug use, withdrawal symptoms, felt bad or guilty about drug use, family complaints about drug use, and family avoidance due to drug use). Based on the objectives of the present study, we removed the item regarding “non-medical reasons” for drug use resulting in nine DAST items. Based on previous research, if

a respondent positively endorsed two or more DAST items, this was considered a “positive” screening test result, denoting risk for probable drug abuse or dependence [18–20]. Cronbach’s alpha was .80 for the nine DAST items.

Data analysis

Data analyses included 1086 respondents, and all statistical analyses were performed using SPSS 13.0 (SPSS Inc., Chicago, IL). Chi-square tests were used to compare the prevalence of medical use and nonmedical use according to student characteristics. Chi-square tests and multiple logistic regression models were used to compare illicit drug use and DAST scores across the following four mutually exclusive groups of lifetime and past-year prescription medication users: (1) no use, (2) medical use only, (3) both medical and nonmedical use, and (4) nonmedical use only. Multiple logistic regression models used nonusers as the reference group and were adjusted for gender, race/ethnicity, and grade level. Interactions between demographic characteristics (e.g., gender, race/ethnicity, and grade level) were examined in the multiple logistic regression models. Adjusted odds ratios (AOR) and 95% confidence intervals (95% CI) were reported.

Sample

The final sample consisted of 1086 secondary school students, and the demographic characteristics resembled the characteristics of the overall student population. The grade level distribution did not significantly differ between the final sample (37% in seventh–eighth grade and 63% in ninth–12th grade) and the overall student population (35% in seventh–eighth grade and 65% in ninth–12th grade). The final sample contained a higher proportion of females (54%) than in the overall student population (51%) ($\chi^2 = 10.5$, $df = 1$, $p < .01$). The racial distribution of the final sample was 52% White, 45% African American, and 3% from other racial categories, whereas the racial distribution of the overall student population was 48% White, 49% African American, and 3% other racial categories ($\chi^2 = 26.7$, $df = 2$, $p < .01$).

Results

The lifetime prevalence of medical use was 49.0% for any of the four categories of prescription medications. The most common medically used prescription drug class among secondary school students was pain medication (44.9%), followed by sleeping (13.9%), sedative/anxiety (6.1%), and stimulant medications (6.0%). There were notable gender differences; within any of the four classes, females were significantly more likely than males to report lifetime medically prescribed use (56.4% vs. 40.2%, $\chi^2 = 27.4$, $df = 1$, $p < .001$), pain medication (53.1% vs. 35.0%, $\chi^2 = 34.0$, $df = 1$, $p < .001$), sleeping medication (16.2% vs. 11.2%, $\chi^2 = 5.5$, $df = 1$, $p < .05$), and sedative/anxiety medication

Table 1
Zero-order correlations between lifetime frequency of medical and nonmedical use of prescription drugs

Variable	1.	2.	3.	4.	5.	6.	7.	8.	M	SD	Range
1. Frequency of lifetime stimulant medical use	—								1.21	.99	1–7
2. Frequency of lifetime stimulant nonmedical use	.34**	—							1.07	.55	1–7
3. Frequency of lifetime pain medical use	.18**	.14**	—						2.12	1.70	1–7
4. Frequency of lifetime pain nonmedical use	.24**	.45**	.38**	—					1.37	1.03	1–7
5. Frequency of lifetime sedative medical use	.46**	.51**	.23**	.33**	—				1.14	.73	1–7
6. Frequency of lifetime sedative nonmedical use	.40**	.84**	.21**	.49**	.62**	—			1.09	.60	1–7
7. Frequency of lifetime sleeping medical use	.34**	.31**	.38**	.36**	.43**	.48**	—		1.33	1.07	1–7
8. Frequency of lifetime sleeping nonmedical use	.33**	.71**	.20**	.52**	.48**	.76**	.45**	—	1.15	.73	1–7

Note: Sample sizes varied due to missing data (range = 1030–1046).

** $p < .01$.

(7.6% vs. 4.4%, $\chi^2 = 4.5$, $df = 1$, $p < .05$). There were also some significant racial differences; White students were significantly more likely than African American students to report medical use of sedative/anxiety medication (8.8% vs. 3.0%, $\chi^2 = 14.2$, $df = 1$, $p < .001$) and stimulant medication (8.0% vs. 3.5%, $\chi^2 = 9.0$, $df = 1$, $p < .01$). Older students in grades nine–12 were more likely than students in grades seven to eight to report medical use of sedative/anxiety medication (7.3% vs. 4.1%, $\chi^2 = 4.2$, $df = 1$, $p < .05$) and pain medication (48.9% vs. 38.1%, $\chi^2 = 11.4$, $df = 1$, $p < .01$). The correlations among frequencies of lifetime medical and nonmedical use of prescription drugs ranged from .14 to .84, with most correlations between .30 and .50 (Table 1).

For any drug category studied, the lifetime prevalence of nonmedical use was 20.9%. The lifetime prevalence of nonmedical use was highest for pain medication (17.7%), followed by sleeping (5.9%), sedative/anxiety (3.5%), and stimulant medications (2.4%). Females were significantly more likely than males to report nonmedical use of pain medication (22.2% vs. 12.3%, $\chi^2 = 17.6$, $df = 1$, $p < .001$). White students were more likely than African American students to report nonmedical use of prescription sedative/anxiety (4.5% vs. 2.2%, $\chi^2 = 4.2$, $df = 1$, $p < .05$) and stimulant medications (3.3% vs. 1.3%, $\chi^2 = 4.2$, $df = 1$, $p < .05$). Finally, students in grades nine–12 were more likely than students in grades seven to eight to report nonmedical use of sedative/anxiety (4.5% vs. 1.8%, $\chi^2 = 5.3$, $df = 1$, $p < .05$) and pain medications (20.9% vs. 12.1%, $\chi^2 = 12.9$, $df = 1$, $p < .001$).

As illustrated in Table 2, approximately 48% ($n = 499$) of students never used an abusable prescription drug (lifetime nonuser). 31.5% ($n = 329$) used prescription medication as prescribed by their physicians (lifetime medical user only), 17.5% ($n = 183$) used both prescription medication as prescribed by their physicians as well as used an abusable prescription medication that was not prescribed to them (lifetime medical and nonmedical user), and 3.3% ($n = 35$) used an abusable prescription medication that was not prescribed to them (lifetime nonmedical user only).

Bivariate analyses indicated significant gender differ-

ences in lifetime medical and nonmedical use of four classes of prescription drugs (Table 3). There were no significant racial differences in the lifetime use of prescription medication; predictably, grade level was significantly associated with lifetime use of prescription drugs.

Bivariate analyses were used to examine the associations among lifetime prescription drug use, past-year illicit drug use, and DAST scores. Chi-square analysis revealed significant associations between lifetime prescription drug use status and each measure of past-year illicit drug use and probable drug abuse as measured by the DAST ($p < .001$). Multivariate logistic regression results reinforced the biva-

Table 2
Frequency distributions of lifetime prescription drug use

Lifetime prescription drug use status	Sample size (n)	Sample size (%)
Four classes of prescription drugs*		
Nonuser	499	47.7
Medical user only	329	31.5
Medical and nonmedical user	183	17.5
Nonmedical user only	35	3.3
Pain medication		
Nonuser	535	51.9
Medical user only	313	30.4
Medical and nonmedical user	147	14.3
Nonmedical user only	35	3.4
Sleeping medication		
Nonuser	872	83.9
Medical user only	106	10.2
Medical and nonmedical user	36	3.5
Nonmedical user only	25	2.4
Sedative/anxiety medication		
Nonuser	964	92.7
Medical user only	39	3.8
Medical and nonmedical user	25	2.4
Nonmedical user only	12	1.2
Stimulant medication		
Nonuser	962	92.9
Medical user only	50	4.8
Medical and nonmedical user	12	1.2
Nonmedical user only	12	1.2

* Four classes of prescription drugs include pain, sleeping, sedative/anxiety and stimulant medications.

Table 3
Demographic characteristics based on lifetime use of four classes of prescription drugs

	Nonuser (n = 499) %	Medical use only (n = 329) %	Medical/nonmedical use (n = 183) %	Nonmedical use only (n = 35) %	Differences based on chi-square
					χ^2 (df) p-value
Gender					
Female	46.0	58.2	70.5	57.1	35.24 (3) $p < .001$
Male	54.0	41.8	29.5	42.9	
Race/ethnicity					
White	51.2	56.4	50.3	51.4	NS
African American	45.4	41.2	45.4	45.7	
Other	3.4	2.4	4.4	2.9	
Grade level					
7th–8th grade	41.9	36.5	24.0	31.4	18.81 (3) $p < .001$
9th–12th grade	58.1	63.5	76.0	68.6	

riate findings; the odds of reporting illicit drug use and probable drug abuse were considerably higher among individuals who reported lifetime nonmedical use only of prescription drugs after adjusting for gender, race/ethnicity and

grade level (Table 4). The heightened risk for illicit drug use and probable drug abuse among lifetime nonmedical users of prescription drugs held steady across each of the four classes of prescription drugs. In addition, illicit drug use and

Table 4
Prevalence of drug use and misuse based on lifetime use of four classes of prescription drugs

Prescription drug use status	Past-year DAST (positive screening) two or more items		Past-year marijuana use		Past-year illicit drug use other than marijuana ^a	
	%	AOR ^b (95% CI)	%	AOR ^b (95% CI)	%	AOR ^b (95% CI)
Four prescription drug classes ^c						
Nonuser	5.0	—	13.5	—	2.6	—
Medical user only	7.3	1.5 (.8–2.8)	19.9	1.5 (1.0–2.2)*	6.1	2.6 (1.3–5.4)**
Medical and nonmedical user	20.9	5.2 (2.9–9.1)***	33.0	2.6 (1.7–4.0)***	12.0	6.5 (3.1–13.7)***
Nonmedical user only	22.9	6.7 (2.7–16.8)***	21.2	1.7 (.7–4.2)	11.4	5.7 (1.7–19.1)**
Pain medication						
Nonuser	5.2	—	13.7	—	3.0	—
Medical user only	8.0	1.6 (.9–2.8)	21.7	1.6 (1.1–2.4)*	5.8	2.3 (1.1–4.6)*
Medical and nonmedical user	21.8	5.3 (3.0–9.4)***	33.3	2.6 (1.6–4.1)***	12.2	5.9 (2.8–12.4)***
Nonmedical user only	22.9	6.1 (2.5–15.2)***	18.2	1.3 (.5–3.4)	14.3	6.4 (2.1–19.3)**
Sleeping medication						
Nonuser	6.7	—	16.5	—	3.7	—
Medical user only	14.2	2.4 (1.3–4.5)**	30.0	2.5 (1.6–4.2)***	9.4	2.7 (1.3–5.8)*
Medical and nonmedical user	44.4	11.0 (5.3–23.0)***	45.7	4.4 (2.1–9.3)***	30.6	12.4 (5.4–28.2)***
Nonmedical user only	25.0	5.8 (2.1–16.0)**	33.3	3.6 (1.4–9.1)**	24.0	9.0 (3.2–25.0)***
Sedative/anxiety medication						
Nonuser	7.4	—	17.2	—	4.4	—
Medical user only	15.4	2.2 (.9–5.7)	28.9	1.6 (.8–3.5)	7.7	2.1 (.6–7.4)
Medical and nonmedical user	54.2	14.6 (6.0–35.4)***	68.0	8.9 (3.6–22.2)***	44.0	23.3 (9.2–59.1)***
Nonmedical user only	41.7	8.7 (2.6–29.3)***	41.7	3.1 (1.0–10.3)	25.0	7.6 (1.9–31.1)**
Stimulant medication						
Nonuser	6.5	—	17.2	—	4.0	—
Medical user only	30.0	6.0 (3.0–11.8)***	27.1	1.7 (.9–3.5)	14.0	3.5 (1.4–8.4)**
Medical and nonmedical user	72.7	31.0 (7.7–125.1)***	91.7	52.0 (6.1–439.8)***	58.3	36.7 (10.4–130.2)***
Nonmedical user only	75.0	44.5 (11.3–174.9)***	66.7	11.9 (3.4–42.3)***	50.0	22.4 (6.7–74.5)***

—reference group.

^a Past-year illicit drug index consists of summing annual use of cocaine, LSD, other psychedelics, inhalants, ecstasy, crystal methamphetamine, heroin, and GHB.

^b Odds ratios (AOR) are adjusted for gender, race/ethnicity and grade level (odds ratios for these variables were not shown).

^c Four classes of prescription drugs included pain, stimulant, sleeping, and sedative/anxiety medications.

* $p < .05$; ** $p < .01$; *** $p < .001$ based on logistic regression results.

probable drug abuse among individuals who reported both lifetime medical and nonmedical use of prescription drugs were similar to individuals who reported only lifetime nonmedical use. Individuals who reported only lifetime medical use generally reported similar or increased odds of illicit drug use and probable drug abuse (DAST score) than individuals who reported no lifetime use of prescription drugs. Finally, we tested for interactions involving gender, racial/ethnic, and grade level variables and generally found no evidence for interactions between these variables and prescription drug use status in accounting for probable drug abuse.

The past-year use of four classes of prescription drugs was as follows: 59.7% ($n = 623$) of students never used an abusable prescription drug (past-year nonuser), 26.5% ($n = 276$) used prescription medication as prescribed (past-year medical user only), 10.6% ($n = 111$) used both prescription medication as prescribed as well as an abusable prescription medication that was not prescribed (past-year medical and nonmedical user), and 3.2% ($n = 28$) used an abusable prescription medication that was not prescribed (past-year nonmedical user only). The association between past-year prescription drug use status and probable drug abuse was examined using chi-square analysis that revealed significant associations ($p < .001$). The prevalence of experiencing two or more DAST items was 5.5% among past-year nonusers, 6.9% for past-year medical users only, 29.1% for past-year medical and nonmedical users and 27.3% for past-year nonmedical users only.

The logistic regression results supported the bivariate findings because the odds of experiencing two or more DAST items did not differ significantly between past-year medical users and past-year nonusers after adjusting for gender, race/ethnicity, and grade level. In contrast, past-year medical and nonmedical users were over seven times more likely than past-year nonusers to experience two or more DAST items (AOR = 7.7, 95% CI = 4.3–13.7, $p < .001$). Similarly, past-year nonmedical users were over seven times more likely than past-year nonusers to experience two or more DAST items (AOR = 7.6, 95% CI = 3.2–18.4, $p < .001$).

Finally, we examined whether higher frequencies of nonmedical use of each prescription drug class (lifetime and past-year) were positively associated with illicit drug use and probable drug abuse (lifetime and past-year). Bivariate correlations revealed significant positive associations between frequencies of nonmedical use for each class of prescription drugs and illicit drug use and probable drug abuse ($p < .001$).

Discussion

In the present study, the lifetime prevalence rate of nonmedical use within the four prescription drug classes was 20.9%; this was higher than the lifetime prevalence of

nonmedical use for the same four prescription drug classes (13.5%) among persons 12 to 17 years of age nationally in 2004 [3]. Notably, the prevalence of nonmedical use of prescription opioids was higher than state and national averages, whereas the prevalence of nonmedical use of prescription stimulants was lower [1,3,21,22]. For example, in this study the lifetime prevalence of nonmedical use of prescription opioids was 17.7% and this is contrasted to national and state data that indicate 11.4% of persons 12 to 17 years and 14.3% of Michigan residents (12 years or older) reported lifetime nonmedical use of prescription opioids [1,21].

The lifetime prevalence rates of medical use of prescription drugs reported here were similar to the prevalence rates and increasing prescribing patterns for U.S. youth [11,23–25]. For example, the lifetime prevalence of medical use of prescription stimulants for ADHD was 6.0% in the present study; this is similar to data that suggest 5.0% of youth aged 5 to 17 years in the state of Michigan [23] and 4.3% of U.S. youth between 4 and 17 years of age are prescribed stimulant medication [25]. The gender differences in medical use of prescription drugs resembled national patterns [7,11,26]; adolescent girls were more likely to report medical use of prescription opioids, sedative/anxiety medication, and sleeping medication. We also found boys were more likely to report medical use of prescription stimulants for ADHD, but the difference was not statistically significant. Although these gender differences have been found in prescribing patterns in previous research with secondary school students, these prior studies did not consider the association with nonmedical use.

Seven of every 10 secondary students who reported medical and nonmedical use of prescription drugs were female. The increased rates of nonmedical use among female medical users could be the result of greater medical exposure to medications or, alternatively, it could be due to possible under-treatment of conditions that result in girls obtaining prescription medications from friends, family members, or others to self-treat. After all, the leading sources of prescription drugs among adolescent nonmedical users are peers and family members [12,27,28], and this suggests that nonmedical use among adolescents should be considered within the larger context of medical availability.

The racial differences in medical and nonmedical use of prescription drugs found here are notable relative to previous research. The higher rates of medical and nonmedical use of stimulant and sedative/anxiety medications among White youth were similar to the racial differences in both prescribing patterns [23–25] and nonmedical use of stimulant medications [1,13,22]. Although we found no difference between White and African American students, national findings indicate lifetime nonmedical use of prescription opioid medications was higher among White 12th grade students (15.9%) than among African American (3.5%) 12th grade students [1]. Furthermore, we did not find

Our data indicate that nonmedical use of prescription drugs represents a problem behavior among secondary school students. Approximately one in every five secondary school adolescents reported nonmedical use of prescription drugs and these youth were at greater risk for probable drug abuse or dependence than their peers. This study also found that a higher frequency of nonmedical use of prescription drugs is positively associated with probable drug abuse or dependence. The high rates of drug-use-related problems among nonmedical users of prescription medication provide support for targeting prescription drug abuse in prevention and intervention efforts among adolescents.

Approximately three in every 10 students in the school district failed to complete the survey and this may lead to biased findings; however, concern regarding nonresponse bias was somewhat lessened because the demographic characteristics of the final sample resembled the student population. Some of our analyses were limited by the small number of students who reported medical and nonmedical use of some prescription drugs. Finally, although the DAST has been used in clinical and nonclinical settings, the instrument has not been used widely in adolescent populations. Further validation of the DAST using Web-based survey research and standard clinical interviews is needed to confirm optimal cut-points for sensitivity and specificity among adolescents.

ical use of prescription drugs and reinforces the need for educational efforts directed at patients and their families. Data from the present study also support the importance of compliance with medication management and suggest that proper medical monitoring may be helpful in reducing non-medical use of prescription drugs by adolescents.

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Adolescents' Motivations to Abuse Prescription Medications

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ABSTRACT

OBJECTIVES. Our goals were to (1) determine adolescents' motivations (reasons) for engaging in the nonmedical (illicit) use of 4 classes of prescription medications and (2) examine whether motivations were associated with a higher risk for substance abuse problems.

RESPONDENTS. The 2005 sample ($N = 1086$) was derived from one ethnically diverse school district in southeastern Michigan and included 7th- through 12th-grade students.

METHODS. Data were collected by using a self-administered, Web-based survey that included questions about drug use and the motivations to engage in nonmedical use of prescription medication.

RESULTS. Twelve percent of the respondents had engaged in nonmedical use of opioid pain medications in the past year: 3% for sleeping, 2% as a sedative and/or for anxiety, and 2% as stimulants. The reasons for engaging in the nonmedical use of prescription medications varied by drug classification. For opioid analgesics, when the number of motives increased, so too did the likelihood of a positive Drug Abuse Screening Test score. For every additional motive endorsed, the Drug Abuse Screening Test increased by a factor of 1.8. Two groups of students were compared (at-risk versus self-treatment); those who endorsed multiple motivations for non-medical use of opioids (at-risk group) were significantly more likely to have elevated Drug Abuse Screening Test scores when compared with those who were in the self-treatment group. Those in the at-risk group also were significantly more likely to engage in marijuana and alcohol use.

CONCLUSION. The findings from this exploratory study warrant additional research because several motivations for the nonmedical use of prescription medications seem associated with a greater likelihood of substance abuse problems.

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Dr Boyd had full access to all the data reported in this study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Key Words

nonmedical prescription drug use, adolescents' prescription medication abuse

Abbreviations

DAST-10—Drug Abuse Screening Test
PIN—personal identification number
df—degrees of freedom

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ACCORDING TO THE National Survey on Drug Use and Health 2004 data,¹ ~9% of adolescents aged 12 to 17 years used prescription drugs for nonmedical purposes in the past year, including 7% who used pain medication, 2% stimulant medication, 2% tranquilizers, and 0.5% sedatives; however, the motivations to abuse these prescription drugs were not assessed. In fact, despite ample evidence that the nonmedical use of prescription medications is increasing in the United States, little research exists on adolescents' motivations for this form of drug use.

BACKGROUND

Daniel et al² found gender differences in their sample of 9- to 18-year-olds who took a mail survey (764 girls and 804 boys). Their study was based on data from 2 questions: "Have you ever shared your prescription medication with others?" and "Have you ever borrowed prescription medication from another?" and a follow-up question that provided 14 reasons for borrowing or sharing prescription drugs. They sought to determine how often children and adolescents share prescription medications. Approximately 20% of the girls and 13% of the boys reported borrowing and/or sharing prescribed medications in their lifetimes, a statistically significant gender difference. Of the girls, 16% reported borrowing prescription drugs from others, and 15% reported sharing their prescriptions; notably, 7% of the girls aged 15 through 18 years had shared medications >3 times. Respondents did not indicate what drugs were being borrowed or shared; therefore, it was difficult to determine if respondents were talking about acne soap or psychotropic medications.

In an exploratory study of 1017 middle and high school students attending school in 2003, researchers asked nonmedical users of prescription pain medication to provide a reason for their abuse of these medications.³ Twenty-two percent of the girls and 10% of the boys reported lifetime nonmedical use of pain medications. Thirty-four percent of the students received diverted pain medications from family members, and the reasons offered were often to relieve pain for problems such as migraines and menstrual cramps. In a study of asthma-inhaler abuse, Boyd et al⁴ found that students who misused their prescription asthma inhalers were more likely to smoke cigarettes and marijuana, as well as more likely to drink alcohol and abuse illicit drugs. Unlike with opioid analgesics, there were no gender differences in prescription asthma-inhaler misuse, indicating that gender differences may vary by drug classification.

Teter et al⁵ examined the motives to abuse prescription stimulants in a random sample of 9161 undergraduate college students, 8% of whom had used prescription stimulants nonmedically in their lifetimes. Using the Student Life Survey,⁶ a Web-based survey, these researchers asked students ($n = 689$) to endorse their

reasons for abusing prescription stimulants. The most prevalent motivations were to (1) help with concentration, (2) increase alertness, and (3) provide a high; motivations did not vary by gender. To determine why students were abusing prescription stimulants, Hall et al⁷ studied 370 undergraduates and found no gender differences in motivations; 13% indicated that they had taken stimulants that were not prescribed to them. Twenty-seven percent of the students reported taking the drugs during finals week, 15% before tests, and 12% when they partied. Four of the 10 students who had been prescribed stimulants also indicated that they used them nonmedically.

Particularly relevant are the trends in medical prescription rates and the increase in prescription medications.⁸ Several studies have reported recent increases in US prescription rates of abusable medications including psychotropic,⁹ stimulant,¹⁰⁻¹¹ and opioid analgesics.¹⁴ Between 1992 and 2002, opioid prescriptions increased by 222%, benzodiazepines by 49%, and stimulants by 368%.⁸ Empirical evidence, albeit limited, suggests that an increase in the medical use of prescription medications will lead to increases in misuse and/or the nonmedical use of these drugs.^{15,16}

Poulin,¹⁷ in fact, found that nonmedical use of stimulants was directly correlated to the number of prescription users in a student's school class or grade level. In a self-report study of 13 549 Canadian students, Poulin reported that of the 7th-, 9th-, 10th-, and 12th-graders who were prescribed stimulants, ~15% reported giving away their medications. Seven percent reported selling their stimulant medications, 4.3% experienced theft, and 3% were forced to give someone their medications.¹⁷

METHODS

The purpose for this 2005 exploratory study was to examine the motives reported by 1086 youth between the ages of 12 and 18 years from a community in southeastern Michigan. We aimed to determine the reasons for abusing 4 classes of scheduled prescription medications: sleep aids, sedatives/anxiolytic agents, stimulants, and opioid analgesics. We also aimed to determine if the types of motivations were associated with a higher risk for other substance abuse problems as indicated by the 10-item Drug Abuse Screening Test (DAST-10).

A Web-based random-sample survey was conducted in the school setting with 7th- through 12th-grade students. After receiving human subject review board approval and a certificate of confidentiality, we sent consent forms to the parents of all students in 7th to 12th grades. The public school district required that all parents complete and return a consent form (active consent) before the student was allowed to participate; 73% of the students returned a consent form and were allowed to participate. Of these eligible students, 94%

took the survey. The final response rate for this Web-based survey was based on the American Association for Public Opinion Research guidelines (RR2)¹⁸; thus, our response rate was 68% for the 2005 data collection.

The survey was conducted over the Internet in computer laboratories with hooded computers; when students arrived at the laboratory, research assistants greeted their class and provided each student with a sheet of paper with a preassigned personal identification number (PIN). Students were told to sit at a computer terminal and sign on to the Web survey using their unique PIN. Two research assistants supervised each of the 4 computer laboratories. The first page of the survey provided a brief description of the study, an informed consent box, and basic instructions. The survey took ~22 minutes to complete. The Web survey was maintained on a hosted, secure Internet site running under the secure sockets layer (SSL) protocol. Unique PINs were preassigned to 1086 students to allow them to confidentially access the Web survey.

Sample

In May 2005, we studied 7th- through 12th-graders who attended schools in a public school district in the Detroit, Michigan, metropolitan area. Our sample included 54% boys and 46% girls; 52% of the respondents were white, 45% were black, and 3% were from other racial groups. Approximately 18% of the students were in 7th grade, 18% in 8th grade, 23% in 9th grade, 16% in 10th grade, 12% in 11th grade, and 12% in 12th grade. This public school district was an ideal study site because it provided a racially diverse sample of students.

Definitions

One problem with existing research pertaining to prescription drug abuse (or the nonmedical use of prescription medications) is that the terms "use," "misuse," and "abuse" are used in particularized ways depending on the authors' disciplines. In this article, the following definitions are presumed: "Nonmedical use," "prescription drug abuse," or "illicit use" of prescription medications (drugs) is defined as the use of prescription medication to create an altered state, to "get high," or for reasons (or by people) other than those (or for whom) intended by the prescribing clinician. In contrast, "medical misuse" (or noncompliant use) of prescription medication involves the use of a prescribed medication by a person (and for the purpose) intended by the prescribing clinician; however, in the case of misuse (unlike medical use), the medication is not used in the prescribed dose and/or is not taken within a prescribed time interval.

Measurements

Nonmedical use of prescription medication was assessed by asking about the occasions the nonprescribed medications were used. Lifetime and 12-month use was as-

sessed, and there were separate questions for each of the following prescription drugs analyzed here: (a) sleeping medication (eg, Ambien, Halcion, Restoril, etc); (b) sedative/anxiety medication (eg, Ativan, Xanax, Valium, Klonopin, etc); (c) stimulant medication (eg, Ritalin, Dexedrine, Adderall, Concerta, etc); and (d) pain medication (eg, Vicodin, OxyContin, Tylenol 3 with codeine, etc). Respondents could endorse "never" or "don't know/rather not say" or endorse the affirmative with the number of occasions.

Medical use of prescription medication was assessed by asking, "Based on a health professional's prescription, on how many occasions in your lifetime (and past 12 months) have you used the following types of drugs?" Respondents had similar response categories as indicated above (for nonmedical use).

Motivations to engage in nonmedical prescription medication abuse were assessed by asking youth to provide the reasons why they used each prescription medication nonmedically. Respondents were given a list of motivations and were asked to check all that applied (see Figs 1–4 for the items). If respondents only endorsed the motivation that is consistent with the drug's pharmaceutical indication, they were characterized as demonstrating self-treatment motivations. If they endorsed other motivations, they were characterized as demonstrating at-risk motivations.

Alcohol and marijuana use was assessed by asking about alcohol and drug use through a series of questions used in a national study of 8th-, 10th-, and 12th-grade students.¹⁹ Measures of lifetime, past-year, and past-month alcohol and other drug use were used. Moreover, a gender-sensitive measure of binge drinking was included to measure the frequency of at least one binge-drinking episode (ie, at least 4 drinks in one sitting for girls and at least 5 drinks in one sitting for boys) within the past 2 weeks.

Risk of substance abuse was assessed with a modified version of the DAST-10, a self-report instrument that can be used in nonclinical settings to screen for potential abuse and dependence to various drugs other than alcohol (eg, all illegal drugs and prescription medication abuse).²⁰ Originally modified from the Michigan Alcohol Screening Test, the DAST-10 has acceptable internal consistency (Cronbach's $\alpha = .86$) and test-retest reliability of .70.²¹

For this study, using Web-based skip logic, students who admitted to the use of drugs received the DAST-10. Because the first question on the DAST-10 pertains to drug use without medical reasons, it was assumed to be endorsed by this subsample of nonmedical prescription drug-using respondents. It is for this reason that we made the cutoff higher for a positive DAST-10 score. If a student positively endorsed ≥ 3 DAST-10 items, we considered it a "positive" score, denoting a moderate level of risk for substance abuse.²¹

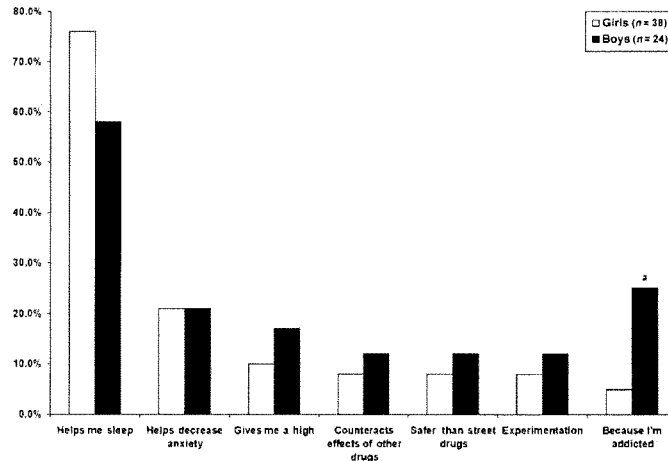


FIGURE 1
Reasons for nonmedical use of prescription sleeping medication according to gender ($n = 62$ lifetime nonmedical sleeping medication users). ^a $P < .05$.

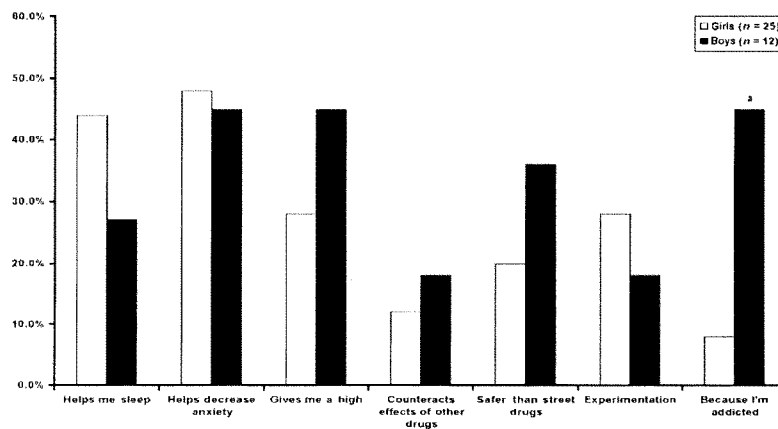


FIGURE 2
Reasons for nonmedical use of prescription sedative/anxiolytic medication according to gender ($n = 37$ lifetime nonmedical sedative/anxiolytic users). ^a $P < .05$.

Data Analysis

Data analysis included 1086 respondents, and all statistical analyses were conducted by using SPSS 14.0 (SPSS Inc, Chicago, IL). To determine the prevalence rates, the number of students reporting the behavior was divided

by the total number of students responding to the question. To determine if the motivation to engage in the nonmedical use of prescription medication predicted a positive DAST-10 score, we created a motives index for each of the 4 drug classes; this index was treated as a

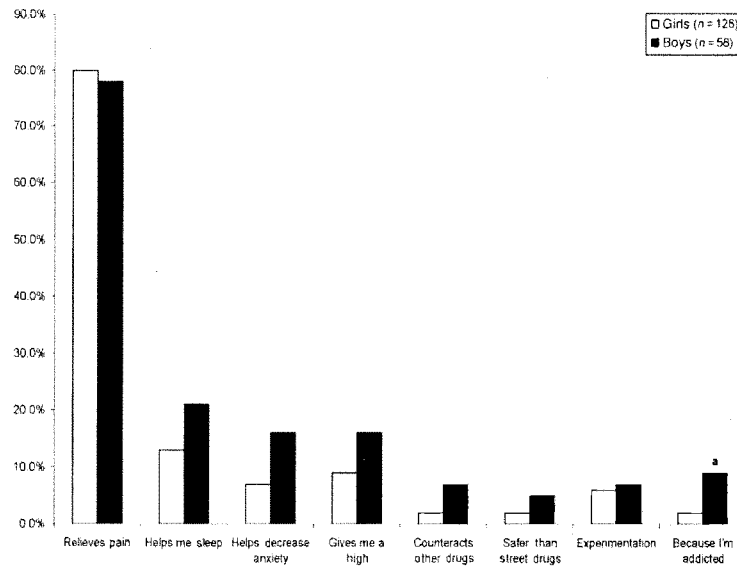


FIGURE 3
Reasons for nonmedical use of prescription pain medications according to gender ($n = 184$ lifetime nonmedical pain medication users). $^1P < .05$.

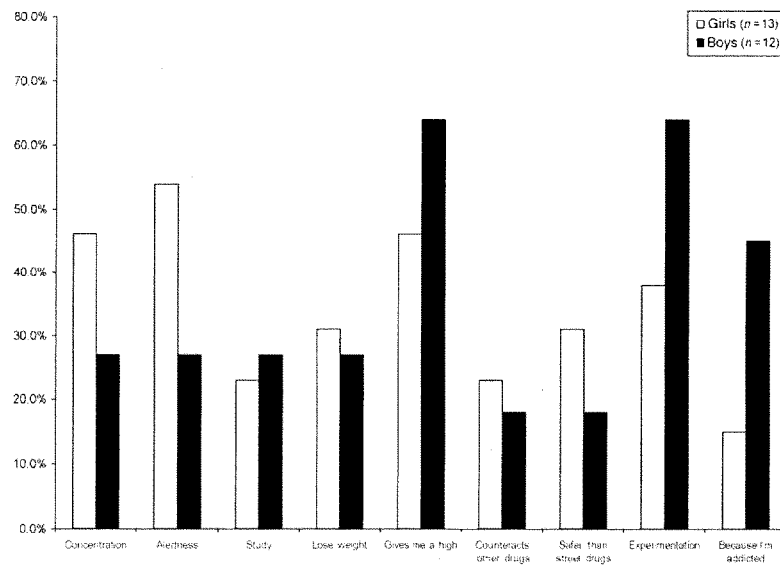


FIGURE 4
Reasons for nonmedical use of prescription stimulant medications according to gender ($n = 25$ lifetime nonmedical stimulant medication users).

TABLE 1 Past-Year Prevalence of Medical and Nonmedical Prescription Medication Use

Characteristics (N = 1086 ^a)	Sleeping Medication		Sedative/Anxiety Medication		Stimulant Medication for ADHD		Pain Medication	
	Medical Use, n (%)	NMPD Use, n (%)	Medical Use, n (%)	NMPD Use, n (%)	Medical Use, n (%)	NMPD Use, n (%)	Medical Use, n (%)	NMPD Use, n (%)
Overall	91 (9)	56 (5)	45 (4)	17 (2)	56 (5)	18 (2)	346 (34)	126 (12)
Gender								
Female (n = 586)	59 (10)	21 (4)	23 (4)	10 (2)	13 (2)	10 (2)	235 (42)	85 (15)
Male (n = 498)	32 (7)	15 (3)	12 (2)	7 (1)	23 (5)	8 (1)	110 (23)	41 (9)
Ethnicity								
Black (n = 484)	36 (8)	11 (2)	9 (2)	4 (1)	9 (2)	4 (1)	159 (35)	63 (14)
White (n = 565)	54 (10)	22 (4)	24 (4)	12 (2)	25 (5)	13 (2)	175 (32)	59 (11)
Other (n = 37)	1 (3)	3 (9)	2 (6)	1 (3)	2 (6)	1 (3)	11 (33)	4 (12)

NMPD indicates nonmedical prescription medication; ADHD, attention-deficit/hyperactivity disorder.

^a There were 2 cases with missing data on gender and race/ethnicity. Because of the missing data, the denominator for the overall prevalence rates was not always 1086.

TABLE 2 Self-treatment Group Compared to At-Risk Group Using DAST-10 Scores

Drug Classification	N	Mean	df	P (2-Tailed)
Sleep aids				
Self-treatment (0–2 drug use problems on DAST-10)	24	1.2	44	.06
At risk (≥ 3 drug use problems on DAST-10)	22	2.1		
Sedatives/anxiolytic agents				
Self-treatment (0–2 drug use problems on DAST-10)	12	1.3	27	.109
At risk (≥ 3 drug use problems on DAST-10)	17	2.6		
Pain relievers				
Self-treatment (0–2 drug use problems on DAST-10)	90	1.1	138	.000
At risk (≥ 3 drug use problems on DAST-10)	50	2.0		
Stimulants				
Self-treatment (0–2 drug use problems on DAST-10)	5	2.6	21	.611
At risk (≥ 3 drug use problems on DAST-10)	18	3.4		

TABLE 3 DAST-10 Responses (N = 338)

In the Past 12 mo.	Yes, %	No, %
Have you ever used drugs other than those required for medical reasons?	42	58
Have you used more than one drug at a time?	19	81
Are you always able to stop using drugs when you want?	80	20
Have you had blackouts or flashbacks as a result of drug use?	10	90
Have you ever felt bad or guilty about your drug use?	28	72
Have family members ever complained about your involvement with drugs?	26	85
Have you stayed away from your family because of your use of drugs?	10	90
Have you engaged in illegal activities in order to obtain drugs?	14	86
Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	10	90
Have you had medical problems as a result of your drug use (eg, memory loss, convulsions, bleeding)?	8	92

correlate of a positive DAST-10 score. We used the DAST-10 as a dichotomous variable, using the 3-plus endorsement as the cutoff for a positive score; <3 was considered to be a negative score. Finally, because opioid analgesics were the most likely prescription medication to be used, we focused on students who reported this form of drug use. We created 2 groups: a self-treatment group, defined as students who only used opioid analgesics nonmedically to relieve pain; and an at-risk group,

defined as students who used opioid analgesics for other reasons as well.

RESULTS

Twelve percent of the students engaged in the nonmedical use of opioid pain medications in the previous 12 months; 3% of the students had nonmedically used sleeping medications, 2% sedatives/anxiolytic agents, and 2% stimulants. There were no gender differences in these prevalence rates with the exception of that for pain medications; girls were significantly more likely to nonmedically use opioid analgesics ($\chi^2 = 9.9$; degrees of freedom [df] = 1; $P < .01$). There were also no gender differences in motivations with one exception: boys were more likely to report being addicted (as a reason for nonmedical use) for 3 of the 4 drug classes. However, the subsample numbers were small, and this finding should be interpreted cautiously.

As expected, motivations varied by drug classification. Some of the motives endorsed by our respondents were consistent with the diagnostic indications for the respective medications. For instance, 75% of the students who nonmedically used sleeping medications (in the previous 12 months) did so for help sleeping, and that was their sole reason. However, students' motives to nonmedically use pain medications were more diverse than for sleeping medications. Although 69% used them solely

for pain control and 79% endorsed pain relief as at least one motivation, other motives were endorsed. In addition, 11% endorsed using these medications to get high. This was not as true for stimulants: 29% endorsed only one motive to use stimulants (that is, to help with concentration or alertness), and 21% endorsed either 2 or 3 motivations, the most frequently mentioned of which were because it gives a high, to help concentrate, and to increase alertness. As with sleeping and stimulant medications, very few students had used sedative/anxiolytic medications nonmedically in the previous 12 months. The most frequently cited motivations for their use were to help with sleep, to decrease anxiety, and to get high.

Of the 338 respondents who admitted to any lifetime drug use, 20% answered "no" when asked: "In the past 12 months, are you always able to stop using drugs when you want to?" We also found evidence that the nonmedical use of prescription medications is associated with an increase in general substance abuse problems, particularly with the opioid analgesics.

For opioid analgesics, when the number of motives increased, so too did the likelihood of a positive DAST-10 score. For every additional motive endorsed, the odds of a positive score on the DAST-10 increased by a factor of 1.8. With logistic regression, our analysis indicated that the pain use-motive index still predicted higher odds of a positive score on the DAST-10 even when age, gender, and race were statistically controlled (adjusted odds ratio: 1.8; 95% confidence interval: 1.2–2.6). Although the subsamples for the other medications were too small to run multivariate analyses, we assessed whether those with a positive score on the DAST-10 reported more of each type of motive.

Two groups of nonmedical prescription opioid users were compared: those who self-medicated for pain ($n = 86$) and those who endorsed other reasons for nonmedical use ($n = 41$). Results showed that scores on the DAST-10 were significantly higher in the at-risk group (mean: 3.90) compared with the self-treatment group (mean: 1.67) ($t_{125} = 6.3$; $P < .01$). Analyses also indicated that past-year frequency of marijuana use was significantly higher in the at-risk group (mean: 4.03) compared with the self-treatment group (mean: 2.90) ($t_{63} = 2.1$; $P < .05$). This group difference was also observed for alcohol abuse: alcohol use (lifetime, past year, and past month) was higher in the at-risk group (eg, past year use: at-risk group mean: 3.82 versus self-treatment group mean: 2.75 [$t_{117} = 3.1$; $P < .01$]). The maximum number of drinks in a 2-hour period in the past year was significantly higher in the at-risk group (mean: 5.15) compared with that in the self-treatment group (mean: 2.84) ($t_{114} = 2.5$; $P < .05$).

When the total DAST-10 scores were compared, there were no significant gender differences. However, there was one item on the DAST-10 that revealed a gender difference: boys were more likely to have engaged in

illicit activity to obtain drugs than girls ($\chi^2 = 5$; $df = 2$; $P = .02$). Unfortunately, because the subsamples were small for the other 3 drug classes, we were unable to run multivariate analyses for the sleeping, sedative/anxiolytic, and stimulant medications.

DISCUSSION

It was noted earlier that ~9% of US youth aged 12 to 17 reported the nonmedical use of prescription medications in 2004, with 7% reporting the nonmedical use of opioid analgesics.¹ The overall prevalence in our 2005 sample was much higher; in fact, the nonmedical use of prescription medication was 14%, with 12% reporting the nonmedical use of opioid analgesics. The differences between the national data and our prevalence rates could be related to several design factors: The study populations were clearly different. Our sample came from one ethnically diverse public school district in which the entire 7th through 12th grades were invited to participate. Our study is contrasted with studies that used national, stratified random sampling of 8th-, 10th-, and 12th-graders¹⁹ or household surveys⁴ in which either paper-and-pencil questionnaires or computer-assisted surveys were administered. School-based surveys and Web-based approaches to data collection have produced higher estimates of drug use than household surveys, which may be a factor in the discrepancy here.²²

Respondents often endorsed reasons for nonmedical use that were consistent with the therapeutic indications for each drug class. For instance, 79% of the respondents endorsed pain relief for the nonmedical use of pain medications, 69% endorsed "helps with sleep" for the nonmedical use of sleeping medications, and 46% endorsed "decreasing anxiety" as a reason to take sedatives/anxiolytic agents. Thus, respondents admitted to self-treating their pain, sleep, and anxiety problems. The nonmedical use of stimulant medications was a bit different: students were just as likely to endorse "to get high" or "experimentation" as they were to endorse to "help with concentration" or "increase my alertness."

Our previous studies of nonmedical opioid and asthma-inhaler use demonstrated the relationship between nonmedical prescription drug use and other forms of substance abuse among adolescents^{3,4}; this study lends support to our earlier findings by examining the risk of substance abuse problems associated with nonmedical prescription drug use. Although endorsing only one motivation for nonmedical use was not necessarily associated with an elevated DAST-10 score, every additional motivation carried a greater likelihood of scoring higher on the DAST-10. The greater the number of motivations (endorsed by individual respondents), the more likely they were to be at risk for substance abuse/dependence problems. However, there may be at least 2 distinct groups of nonmedical prescription medication users: those who self-medicate and those who use for other

reasons, including to experiment and get high. The latter group seems to be at greater risk for other forms of substance abuse. It is also possible that some nonmedical users are attempting to enhance their performance; the nonmedical use of prescription medications for the purpose of enhancing performance needs additional study as well.

The nonmedical use of prescription medications may be a form of drug use that challenges traditional ideas about adolescent substance abusers. If future research supports the conceptualization of separate groups (differentiated by their motivations to use), then substance abuse-prevention programs may have to reconsider their approaches when addressing the nonmedical use of prescription medications. In fact, the preponderance of self-treating reasons endorsed by our sample may explain why effective and well-studied programs such as Life Skills²³ are not effective in reducing the nonmedical use of prescription medications.

Compton and Volkow,²⁴ in their commentary on opioid analgesics, hypothesize that prescription opioid analgesics are abused because of modeling by family members and social networks. Correspondingly, in a review by the National Center on Addiction and Substance Abuse,⁷ it was noted that "friendly sharing" is commonplace among family members and friends. Our worry is that this behavior sends the message that self-treating is normative and safe, a message that is reinforced by the ever-present marketing of prescription medications.

The nonmedical use of prescription drugs clearly signifies an increasing health problem among US youth, and this increase should impart a sense of urgency.^{1,3,4,24-27} We believe that the findings from this exploratory study warrant additional research, particularly because motivations for the nonmedical use of prescription medications seem associated with a greater likelihood of substance abuse problems. However, this was an exploratory study of students from 1 community, and generalizations are constrained. The study relied on self-report and, thus, may have resulted in underestimates; students who are consistently absent from school are known to have higher rates of illicit substance use.¹⁹ Finally, this study relied on survey data collected for a larger study; thus, the items in the original questionnaire present some limitations. For instance, we did not ask about the quantity and frequency of the prescribed medications, nor did we ask students about their medical diagnoses; this information would have provided perspective on the motivations.

Future research is needed to determine if friendly sharing among family and friends poses a risk for developing substance abuse problems and to further evaluate which nonmedical prescription drug users are at greatest risk for developing further substance abuse problems. Most certainly, we must better understand the reasons

for nonmedical use if we are to prevent prescription drug abuse from becoming an epidemic.²⁷

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CHANGE IN FEDERAL RULES BACKS SINGLE-SEX PUBLIC EDUCATION

"The . . . administration is giving public school districts broad new latitude to expand the number of single-sex classes, and even schools, in what is widely considered the most significant policy change on the issue since a landmark federal law barring sex discrimination in education more than 30 years ago. Two years in the making, the new rules, announced today by the Education Department, will allow school districts to create single-sex schools and classes as long as enrollment is voluntary. School districts that go that route must also make coeducational schools and classes of 'substantially equal' quality available for members of the excluded sex. The federal action is likely to accelerate efforts by public school systems to experiment with single-sex education, particularly among charter schools. Across the nation, the number of public schools exclusively for boys or girls has risen from 3 in 1955 to 241 today, said Leonard Sax, executive director of the National Association for Single Sex Schools. That is a tiny fraction of the approximately 93,000 public schools across the country."

Schemo DJ. *New York Times*. October 25, 2006
Noted by JFL, MD

Adolescents' Motivations to Abuse Prescription Medications

Carol J. Boyd, Sean Esteban McCabe, James A. Cranford and Amy Young

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Prescription Drug Abuse and Diversion Among Adolescents in a Southeast Michigan School District

Carol J. Boyd, PhD, MSN, RN; Sean Esteban McCabe, PhD, MSW; James A. Cranford, PhD; Amy Young, PhD

Objectives: To determine the prevalence of medical use of 4 classes of prescription medications relative to non-medical use (illicit use), to examine the relative rates among the 4 drug classes, and to assess whether gender differences exist in the trading, selling, loaning, or giving away of medications.

Design: A Web-based survey was administered to 7th- to 12th-grade students residing in 1 ethnically diverse school district; a 68% response rate was achieved.

Setting: During a 3-week period in May 2005, teachers brought students to their schools' computing center where students took the survey using a unique personal identification number to sign on to the survey.

Participants: There were 1086 secondary students, including 586 girls, 498 boys, 484 black students, and 565 white students.

Main Outcome Measures: Students were asked about their medical and nonmedical use of sleeping, sedative

or anxiety, stimulant, and pain medications. Diversion of prescription medication was assessed by determining who asked the student to divert his or her prescription and who received it.

Results: Thirty-six percent of students reported having a recent prescription for 1 of the 4 drug classes. A higher percentage of girls reported giving away their medications than boys (27.5% vs 17.4%, respectively; $\chi^2=6.7$; $P=.01$); girls were significantly more likely than boys to divert to female friends (64.0% vs 21.2%, respectively; $\chi^2=17.5$; $P<.001$) whereas boys were more likely than girls to divert to male friends (45.5% vs 25.6%, respectively; $\chi^2=4.4$; $P=.04$). Ten percent diverted their drugs to parents.

Conclusion: Physicians should discuss the proper use of prescription medications with their patients and their patients' families.

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THE NONMEDICAL USE OF PRESCRIPTION drugs—which ranges from medication noncompliance to compulsive abuse—represents an increasing problem among adolescents in the United States.¹⁻⁶ According to the 2004 National Survey on Drug Use and Health data,⁷ approximately 8.8% of adolescents aged 12 to 17 years used prescription drugs for nonmedical purposes in the past year, including approximately 7% who used pain medication, 2% stimulant medication, 2% tranquilizers, and 0.5% sedatives. However, the medical use of prescription medications and the diversion of these prescription medications were not fully addressed.

The aims of this descriptive, exploratory study were 2-fold. The first aim was to determine the prevalence of medical use of 4 classes of prescription medications relative to nonmedical use in an adolescent, ethnically diverse, school-based sample and to compare these relative rates among the 4 drug classes. The second aim was to exam-

ine whether gender differences exist in the trading, selling, loaning, or giving away of one's medications, that is, who received the students' diverted medications?

BACKGROUND

Data from the National Ambulatory Medical Care Survey⁸ reveal that for 14- to 18-year-olds, there was a 209% growth in the number of stimulant prescriptions and a 385% growth in the number of anxiety or sedative medications prescribed between 1994 and 2001. Poulin¹⁰ found that non-medical stimulant use was directly associated with the number of prescription users in the students' classroom or grade level. In a self-report study of 13 549 Canadian students (between 7th and 12th grades), Poulin¹⁰ found that of the students with prescribed stimulants, approximately 15% reported giving away their medications, 7% reported selling their stimulant medications, 4% experienced theft, and 3% were forced to give someone their medications.

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Daniel et al¹¹ observed gender differences in diversion patterns (n=210), reporting that approximately 20% of the girls and 13% of the boys borrowed and/or shared prescribed medications, representing a statistically significant gender difference in lifetime use. Of the girls, 16% borrowed and 15% shared their prescription medications; 7% of the older girls had shared prescription medications more than 3 times. Fifty-eight percent of the youth acknowledged at least 1 motivation for sharing drugs: 40% of the girls and 27% of the boys shared because the receiving person had a prescription for the drug but had run out. Thirty-three percent of the girls and 27% of the boys received their diverted drugs from a family member. In a study of stimulant use conducted by Musser et al,¹² children diagnosed with attention-deficit disorder or attention-deficit/hyperactivity disorder (n=161) and their school administrators were surveyed regarding stimulant use and abuse; 16% of the students had been approached to sell, give, or trade their stimulant medication.

In an earlier study of 10- to 18-year-olds, we found that when students reported the source of diverted opioid analgesics, more than 33% were from family and approximately 17% were from friends.² However, McCabe and Boyd¹³ found that college students were most likely to get diverted drugs from peers, and women were significantly more likely than men to get diverted prescription sedative or anxiety, sleeping, and pain medications from family members.

DEFINITIONS

One problem with existing research is that the terms *use*, *misuse*, and *abuse* are used in particularized ways depending on the author's discipline. In response to the idiosyncratic use of these terms, Compton and Volkow¹⁴ have called for authors to clearly specify their definitions.¹⁵ In this article, we assume the following: *nonmedical use*, *prescription drug abuse*, and *illegal use of prescription medications (drugs)* refer to the same phenomenon and are defined as the use of prescription medication to "get high," to create an altered state, or for reasons (or by routes) other than what the prescribing clinician intended. The use of someone else's prescription medication is illegal. *Diversion of prescription medications (drugs)* is defined as the exchange of prescription medications that leads to the use of these drugs by people other than for whom the prescribing clinician intended or under conditions associated with "doctor shopping," misrepresentation of medical problems, or theft.

METHODS

PROCEDURE

As part of a larger longitudinal project, this study received human subjects review board approval and a certificate of confidentiality. The public school district requires active consent before students are allowed to participate. Seventy-three percent of the parents returned the consent forms and agreed to let their children participate. Of the eligible students (with returned consent forms), 94% completed the survey. The final response rate was calculated using the American Association for Public Opin-

ion Research guideline 2; our response rate was 68% for the 2005 data collection used for this study.

The survey took approximately 22 minutes and was conducted over the Internet from school computer laboratories. Students were given a preassigned personal identification number that allowed them to sign on to the Web survey; this survey method was used because similar computer-based approaches have been found to improve the reporting of sensitive information.¹⁶⁻¹⁹ The Web survey was maintained on a hosted secure Internet site running under the Secure Sockets Layer protocol.

SAMPLE

During a 3-week period in May 2005, we drew on a population of 1594 students in 7th through 12th grades and obtained a sample of 1086 secondary students. Fifty-two percent of respondents were white, 45% were black, and 3% were from other racial groups. Sex was not quite equally distributed in the student sample: 54% of the students were girls and 46% were boys. Students included approximately 18% in 7th grade, 18% in 8th grade, 23% in 9th grade, 16% in 10th grade, 12% in 11th grade, and 12% in 12th grade.

MEASUREMENT

Many of the standard demographic, drug, and alcohol questions used in this study have been described in earlier publications.²⁻³ The following questions pertain directly to the aims of this study.

Medical use of prescription medication was measured using 2 questions, one that requested the number of lifetime occasions and the other the number of occasions during the previous year. We asked, "Based on a health professional's prescription, on how many occasions in your lifetime (or past 12 months) have you used the following types of drugs: (1) sleeping medication (eg, Ambien [Sanofi-aventis, Bridgewater, NJ], Halcion [Pharmacia and Upjohn Co, Kalamazoo, Mich], Restoril [Mallinckrodt Pharmaceuticals, Hazelwood, Mo], etc); (2) sedative or anxiety medication (eg, Ativan [Biovail Pharmaceuticals, Inc, Mississauga, Ontario], Xanax [Pfizer, Inc, New York, NY], Valium [Roche Laboratories, Inc, Nutley, NJ], Klonopin [Hoffmann-La Roche, Inc, Nutley, NJ], etc); (3) stimulant medication for attention-deficit/hyperactivity disorder (eg, Ritalin [Novartis Pharmaceuticals Corp, East Hanover, NJ], Adderall [Shire US, Inc, Wayne, Pa], Concerta [ALZA Corp, Mountain View, Calif], etc); and (4) pain medication (eg, Vicodin [Abbott Laboratories, Abbott Park, Ill], OxyContin [Purdue Pharma LP, Stamford, Conn], Tylenol 3 with codeine [Johnson & Johnson, New Brunswick, NJ], etc)?" The ordinal response scale provided a range from no occasions to 40 or more occasions. An index of medical use of prescription medication was created by summing the medically prescribed use of the 4 classes of prescription medication. A recent prescription was defined as having a legal prescription for a given medication within the past 12 months.

Nonmedical use of prescription medication was assessed by asking 2 questions, one for lifetime use and the other for use in the past 12 months. We asked, "Sometimes people use prescription drugs that were meant for other people, even when their own doctor has not prescribed it for them. On how many occasions in your lifetime (or past 12 months) have you used the following types of drugs, not prescribed to you?" There were separate questions for each of the following prescription drugs: (1) sleeping medication (eg, Ambien, Halcion, Restoril, etc); (2) sedative or anxiety medication (eg, Ativan, Xanax, Valium, Klonopin, etc); (3) stimulant medication for attention-deficit/hyperactivity disorder (eg, Ritalin, Adderall, Concerta, etc); and (4) pain medication (eg, Vicodin, OxyContin, Tylenol 3 with

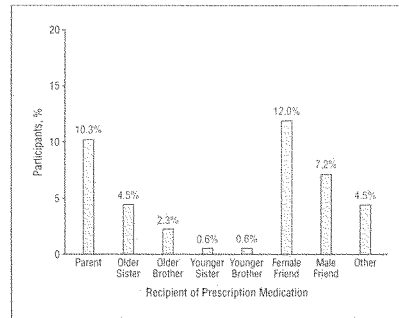


Figure 1. Percentages of participants (n=504 lifetime medication users) who gave or loaned their prescription medications to other individuals in the most recent episode.

codeine, etc). The response scale was the same as for the medical use of prescription medications. An index of nonmedical use of prescription medication was created by summing the nonmedical use of the 4 classes of prescription medication.

Requests to divert prescription medication were assessed using the following item: "On how many occasions in your lifetime (or past 12 months) have you been approached to sell, trade, or give away your prescription medication?" There were separate questions for each of the 4 drug classes mentioned in the previous questions. The response scale was the same as for the medical use of prescription medication. Students were also asked whether their pills had been taken against their will by force or threat.

Recipients of diverted medications were assessed using the following items (each was asked as a separate question): "In the most recent time that you (1) sold your pills, (2) traded any of your pills, or (3) loaned or gave away your medication to someone, who did you provide the medication to?" The list of possible recipients was based on our earlier work² (see **Figure 1** for a complete listing).

RESULTS

All of the statistical analyses were carried out using SPSS statistical software version 14.0 (SPSS, Inc, Chicago, Ill). Thirty-six percent of the students reported having a recent prescription for 1 of the 4 classes of prescription medications and 49% had received a prescription in their lifetimes. Opioid analgesic pain medications were the most widely used of the 4 drug classes, with approximately 45% of students having a prescription for them in their lifetimes and 33% having a prescription for them in the past 12 months. Results showed that 235 (41%) of the 586 girls and 110 (22%) of the 498 boys reported medical use of pain medications in the past year; this compares with 15% of girls and 9% of boys who had used prescription pain medication nonmedically. Girls were significantly more likely to have a prescription for these pain medications in the past year ($\chi^2=39.8$; $P<.001$) and were more likely to use them nonmedically in the past year as well ($\chi^2=9.9$; $P=.002$). When we considered the relationship between nonmedical and medical use, there were

disproportionately more nonmedical users of stimulant and sedative medications when compared with the other 2 prescription drug classes. Within the previous 12 months, 91 students had a prescription for sleeping medications and 36 had engaged in nonmedical use of sleeping medications; 35 students had a prescription for sedative medications and 17 had engaged in nonmedical use of sedatives; 36 students had a prescription for stimulant medications and 18 had engaged in nonmedical use of stimulants; and 348 students had a prescription for pain medications and 126 had engaged in nonmedical use of pain medications (**Table 1** and **Table 2**).

Current medical users (that is, students with legal prescriptions in the past 12 months) were statistically more likely ($P<.001$) to report being approached to divert their medications within the past year than students who had an earlier prescription (but not a current one). This relationship was supported even after controlling for sex, age, and race (odds ratio=2.9; 95% confidence interval=1.57-5.47; $P<.001$). In fact, there was some evidence of trading medications by the students; for instance, 465 students (10%) reported trading pain medications, 94 (15%) reported trading stimulant medications, 144 (10%) reported trading sleeping medications, and 94 (10%) reported trading sedative or anxiety medications, although the numbers were relatively low. Many fewer students reported selling their medications. However, students were most likely to give away or loan their medications rather than trade or sell: 466 students (25%) gave away or loaned their pain medications, 62 (21%) gave away or loaned their stimulant medications, 64 (20%) gave away or loaned their sleeping medications, and 64 (15%) gave away or loaned their sedative medications. Overall, 24% of students (with a legal prescription) gave away or loaned their prescription drugs to someone else, often a family member (eg, parents and siblings). A higher percentage of girls as compared with boys reported lifetime giving or loaning their sedative, stimulant, pain, and/or sleeping medications (27.5% vs 17.4%, respectively; $\chi^2=6.7$; $P=.01$). They also were significantly more likely than boys to divert to their female friends (64.0% vs 21.2%, respectively; $\chi^2=17.5$; $P<.001$) whereas boys were statistically more likely than girls to divert their prescription medications to their male friends (45.5% vs 25.6%, respectively; $\chi^2=4.4$; $P=.04$) (**Figure 2**).

We also asked students with prescription medications whether they had their pills taken away from them against their will or by force or threat. A relatively small number of students had experienced this type of event. We found that 145 (12%) of the students had their sleeping medications taken, 64 (14%) had their sedatives taken, 62 (11%) had their stimulants taken, and 13 (3%) had their pain medications taken.

COMMENT

Earlier this year, Markel,¹⁶ a pediatrician, noted that his colleagues are all too ready to blame parents, the Internet, and doctor shopping for the increased use of diverted prescription medications. According to Markel, these sources are not at the problem's root; rather, it is

Table 1. Prevalence of Medical and Illicit Use of Prescription Medications in the Previous 12 Months in 1086 Students*

Characteristic	Students Receiving Sleeping Medication, No. (%)		Students Receiving Sedative or Anxiety Medication, No. (%)		Students Receiving Stimulant Medication for ADHD, No. (%)		Students Receiving Pain Medication, No. (%)	
	Medical Use	Illicit Use	Medical Use	Illicit Use	Medical Use	Illicit Use	Medical Use	Illicit Use
Sex								
Female (n = 586)	59 (10)	21 (4)	23 (4)	10 (2)	13 (2)	10 (2)	235 (42)	85 (15)
Male (n = 498)	32 (7)	15 (3)	12 (2)	7 (1)	23 (5)	8 (1)	110 (23)	41 (9)
Age, y								
11-13 (n = 290)	26 (9)	6 (2)	6 (2)	3 (1)	9 (3)	4 (1)	77 (27)	20 (7)
14-16 (n = 580)	48 (8)	19 (3)	14 (2)	7 (1)	15 (3)	5 (<1)	196 (22)	74 (13)
≥ 17 (n = 214)	17 (8)	10 (5)	15 (7)	7 (3)	12 (6)	9 (4)	72 (34)	32 (15)
Overall	91 (9)	36 (3)	35 (3)	17 (2)	36 (3)	18 (2)	345 (33)	126 (12)

Abbreviation: ADHD, attention-deficit/hyperactivity disorder.

*There were 390 students who received prescription drugs for medical use in the past 12 months and 145 students who engaged in nonmedical use in the past 12 months. There were 2 cases with missing data on sex and race or ethnicity. Owing to missing data, the denominator for the overall prevalence rates was not always 1086.

Table 2. Students Approached to Sell, Trade, or Give Away Their Prescription Medications in Their Lifetime and in the Previous 12 Months

Approached for Medication	Students Overall, No. (%)	Girls, No. (%)	Boys, No. (%)	χ^2 Value
Sleeping medication				
Lifetime (n = 145; 92 girls)	25 (18)	16 (18)	9 (17)	0.03
Previous 12 mo (n = 25; 16 girls)*	14 (56)	8 (63)	6 (67)	0.04
Sedative or anxiety medication				
Lifetime (n = 64; 43 girls)	14 (23)	6 (15)	8 (38)	4.4†
Previous 12 mo (n = 14; 8 girls)*	12 (86)	5 (83)	7 (87)	0.05
Stimulant medication				
Lifetime (n = 62; 28 girls)	14 (23)	7 (26)	7 (21)	0.2
Previous 12 mo (n = 14; 7 girls)*	12 (86)	6 (86)	6 (86)	0.0
Pain medication				
Lifetime (n = 466; 299 girls)	104 (23)	71 (24)	32 (19)	1.4
Previous 12 mo (n = 104; 71 girls)*	85 (64)	49 (70)	16 (53)	2.6

*Indicates the total number of prescription medication users in the past 12 months who also reported being approached to sell, trade, or give away their prescription medications in their lifetime.

† $P < .05$.

physicians who too quickly write prescriptions for Schedule II and III medications. Although Markel raises an important point, there is another aspect to the problem—physicians are uncomfortable talking about potential medication abuse with their patients. Indeed, 47% of physicians report that it is difficult for them to discuss prescription drug abuse with their patients; this is in contrast to 41% who have difficulty discussing alcohol abuse and 18% who have difficulty discussing depression.¹⁷ Our data, albeit preliminary, indicate that physicians, nurses, and dentists must discuss the proper use of abusable medications; it appears that many middle school and high school students engage in exchanges that challenge traditional ways of educating about drug abuse. Physicians, nurses, and dentists should be at the forefront of any educational effort to combat this problem.

In this descriptive study of 1086 public school students, we found that almost half had received a prescription for a scheduled medication in their lifetimes; 1 in 3 students had a prescription in the previous year. Opioid analgesics were the most widely prescribed and the most

widely abused. Stimulant and sedative or anxiety medications had the highest illicit-medical use ratios. Diversion of prescription medication was common; between 29% and 62% of 390 students with legal prescriptions were approached to divert their medications within the previous year.

Our prevalence rates of nonmedical use of prescription drugs were higher than those in the 2004 National Survey on Drug Use and Health study,⁷ and unlike Johnston et al⁴, we found that girls often had higher rates of nonmedical prescription use, particularly of the opioid analgesics. The differences between these studies could be attributed to differences in question wording, data collection modality, and study population.¹⁸⁻²²

Similarly to Daniel et al,¹¹ we also found that girls were more likely to divert their medications. A higher percentage of girls reported lifetime giving or loaning of their sedative, stimulant, pain, and/or sleeping medications. Girls were also more likely to divert to their female friends whereas boys diverted to their male friends. We believe that these gender differences may have implications for

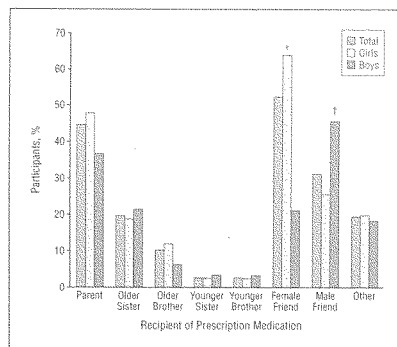


Figure 2. Sex comparison of percentages of participants ($n=119$ lifetime medication users who reported diversion) who diverted medications to different recipients. * $P<.01$. † $P<.05$.

drug prevention and education; thus, further investigation is needed into the possible reasons for and consequences of these same-sex exchanges. We were also intrigued by the students' willingness to give or loan their medications rather than to trade or sell them. Clearly, further research is needed to examine the motivations for the various types of diversion (giving away vs trading) and the context in which they occur.

There were no statistically significant gender, age, or race or ethnic differences in the likelihood of being approached to divert one's medications, although those with current prescriptions were more likely to be approached than those with previous prescriptions. This difference may be interpreted in 1 of 2 ways: (1) as prescription medications become more popular and abused, acquaintances are getting bolder about asking for them (either to buy or borrow); or (2) a recall bias is operating. Either way, more research is needed to explore whether requests to divert these abusable medications are increasing among adolescents.

To our knowledge, this is one of the few studies to examine the medical and nonmedical use of prescription drugs in the context of drug diversion and one of the first to use a random sample from an ethnically diverse student population. It is notable that so many in our sample engaged in the nonmedical use and diversion of prescription medications; in fact, given their propensity to divert their medications, availability appears high. A 16-year-old student speaking with one of us (C.J.B.) noted, "Pills are so easy to get; I can get Vicodin, Adderall, or Ritalin anytime I want at school." These controlled medications can be found everywhere—in medicine cabinets, on kitchen countertops, and in student backpacks. In earlier work,² we found that many students reported using diverted opioid medications they received from friends and family; they used the diverted drugs to relieve pain, help with sleep, and decrease anxiety. This raises the question about students' motivations to both nonmedically use and give away medications.

The findings of our study have several implications for professionals working with secondary school students. Physicians, nurses, and parents should be educated and should closely monitor the medical use, illicit use, and diversion of abusable prescription medications among secondary school students. In particular, parents can serve as gatekeepers in monitoring the dosage and frequency of use to detect possible signs of diversion. School teachers and other professionals can play an important role in monitoring whether students who are prescribed abusable medications are diverting or being approached to divert their medications. Finally, school administrators must enforce policies that require centralized medication monitoring. Too often, parents and students fail to report the medications they have been prescribed. School districts are encouraged to collect their own data to learn more about the drug use behaviors at their schools and to design appropriate practices and policies.

We believe that the findings from this descriptive study are timely and warrant further research, particularly because the nonmedical use of prescription medications is strongly associated with other forms of substance abuse,^{1,3,5,8} including selling drugs. However, our conclusions are constrained by several factors. Generalizations are limited because the sample was drawn from 1 school district. Also, the survey relied on the self-report of students and thus may have resulted in underestimates because students who are absent or drop out of school tend to report higher rates of illicit substance use.¹⁹ This study relies on survey data collected for a larger study; therefore, the items in the original questionnaire present some limitations. For instance, we never assessed the quantity and frequency of the prescribed medications, nor did we ask students about their medical diagnoses or who wrote the prescription (eg, a dentist or physician); this information would have provided an important context. Future research is needed to examine whether the findings from this study generalize to other school districts in the United States and to student populations in other countries.

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Author Contributions: Dr Boyd had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Boyd and McCabe. *Acquisition of data:* Boyd and Young. *Analysis and interpretation of data:* Boyd, McCabe, Cranford, and Young. *Drafting of the manuscript:* Boyd and McCabe. *Critical revision of the manuscript for important intellectual content:* Boyd, McCabe, Cranford, and Young. *Statistical analysis:* McCabe and Cranford. *Obtained funding:* Boyd and Young.

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"Asthma is a disease that has practically the same symptoms as passion except that with asthma it lasts longer."

—Anonymous, from JAMA. 1964;190:364.

Mrs. BONO MACK. Thank you.
Dr. Arria.

STATEMENT OF AMELIA ARRIA

Ms. ARRIA. Chairman Bono Mack, Ranking Member Butterfield, members of the subcommittee, thank you for this opportunity to testify on the problem as it manifest among our Nation's youth. I come at this issue as a researcher at the University of Maryland and the Treatment Research Institute in Philadelphia, but I am a mom too.

Since 2003, with my dedicated staff, I have led the College Life Study, a NIDA-funded study of more than 1,200 college students. Consider our findings regarding non-medical use. By the fourth year of college, 13 percent used a tranquilizer, 23 percent an analgesic and 30 percent a stimulant without a prescription. We found that more than one-third with prescriptions shared or sold their medications, usually to a friend. Most commonly diverted are stimulants such as Adderall with a 62 percent diversion rate. And individuals who divert prescription drugs are typically non-medical users themselves.

Let me sharpen the focus on this particular aspect of the problems, stimulants. They are widely available and attractive to students with high task demands, especially those experiencing academic difficulties. There is a popular assumption that taking stimulants non-medically confers an academic edge and is therefore beneficial. Headlines referencing smart drugs perpetuate the notion that non-medical prescription stimulant use increases academic performance. Scientific evidence tells us quite the opposite. It is not the academically successful students who use them but the unsuccessful ones. We know that non-medical users compared to non-users are more likely to be dependent on alcohol and/or marijuana, skip class more frequently and spend less time studying, and digging even deeper, we see that these academic problems are related to heavy drinking and marijuana use. What the research shows is that non-medical prescription stimulant use is an unsuccessful shortcut, an attempt to compensate for declining academic performance and is a red flag for an underlying alcohol or drug problem.

What can policymakers do about prescription drug abuse? The single best thing is to tighten the chain of custody that ultimately governs supply. For example, put in place better prescription monitoring programs, reform physician dosing practices and create timely surveillance databases. National data are often old and State-level data are not even available to researchers.

The prescription drug problem has complicated the landscape of existing drug threats. It does not occur in isolation. Individuals who use prescription drugs non-medically are very likely to be heavy drinkers and/or illicit drug users. Therefore, in addition to deal with this devastating symptom, we must redouble our efforts to develop innovative solutions to the root issue, that is, the larger public health problem of drug use and addiction in the United States.

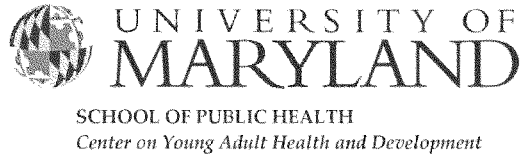
What specific strategies should be proposed? Today I recommend two things regarding prevention and intervention. One, modernize

the Nation's infrastructure for early detection. We can identify those who are at highest risk for drug problems, just like knowing who is at risk for other chronic health conditions, with an approach that involves standardized assessments, early intervention and promotes teamwork between parents, physicians and educators. We can put these young people back on track to fulfill their potential. To this end, NIH research has yielded valuable information about risk and resiliency, the interplay between genetics and the environment and the natural history and course of addiction. Effective solutions to this enormous public health threat will require continued funding for NIH research.

Number two: connect the dots between drug use and academic problems. This link cannot be ignored any longer. Making this connection loud and clear will get the attention of parents who want more than anything else to see their child succeed. Tacit approval by parents and students of underage drinking as normative and college as a 5-year party, especially when there are stimulants drugs as a last resort, is completely misguided by regrettably an all too common notion. Similarly, we must engage the leaders of our education system who are concerned about the high school dropout crisis and less than optimal college graduation rates. They must recognize the very real and contributory role of drug use to poor academic achievement. Sustaining our economy and navigating future challenges will require a clear mind and a sharp focus, which is inconsistent with underage drinking, excessive drinking, illicit and non-medical prescription drug use.

Again, thank you for shedding light on this continuing public health problem and allowing me to contribute to the discussion on solutions.

[The prepared statement of Ms. Arria follows:]



Testimony of Amelia M. Arria, Ph.D.

*Director, Center on Young Adult Health and Development
University of Maryland School of Public Health, College Park, MD
&
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*"Warning: The Growing Danger of Prescription Drug Diversion"
Subcommittee on Commerce, Manufacturing and Trade
United States House of Representatives
April 14, 2011*

Chairman Bono-Mack, Ranking Member Butterfield, Members of the Subcommittee, other distinguished guests and members of the audience: thank you for highlighting the seemingly intractable problem of prescription drug abuse in the United States— and for the opportunity for me to lend my voice to the others invited here today.

Today I testify on the problem as it manifests among our nation's youth, college age and even younger. And I come at this issue from my perspective as a researcher at the University of Maryland and the Treatment Research Institute in Philadelphia. Since 2003, with my dedicated staff, I have led the College Life Study, a NIDA-funded investigation of the health risk behaviors, including drinking and drug use, of more than 1200 young adults who were originally enrolled as college students. For eight years, on an annual basis, we have gathered a large amount of data from this cohort of young adults, whether or not they continue attending college. These data tell a compelling story that is consistent with the work of several others in our field.

The first major finding is that nonmedical prescription drug use among our nation's youth is a symptom of a much larger problem. It does not occur in isolation—individuals who use prescription drugs nonmedically are very likely to be heavy drinkers and/or users of illicit drugs. Although the prescription drug problem receives a lot of visibility because of some unique features, it is tightly linked to the larger drug abuse problem in the United States. We can and must deal with this “symptom”—because it is real, potentially dangerous, and threatens the futures of the youth of this nation. But even if policy makers, or practitioners, researchers, parents, or others—are successful in alleviating this manifestation of the problem, we must also address the root issue or in five years you will be calling another hearing to discuss a new manifestation of the same problem.

Consider the following findings from the College Life Study:

- By the fourth year of college, 13% of college students used a prescription tranquilizer nonmedically, that is, without having a legitimate prescription.
- By the same point, 23% had used prescription analgesics - again, non-medically;
- And, finally 30% nonmedically used prescription stimulants.

Importantly, the overlap with other drug use was significant. In the past year prior to being assessed, 88% of nonmedical stimulant users had used marijuana, 30% had used hallucinogens, and 15% had used cocaine.

Other findings from the College Life study show that nonmedical use is fueled by sharing or selling of prescription medications, usually between friends or acquaintances. More than one third of students in our study who had been prescribed any type of psychoactive medication diverted it to someone else at least once in their lifetime. The most commonly diverted class of prescription medications on college campuses are prescription stimulants, medications prescribed for ADHD, such as Adderall[®], Ritalin[®] and Concerta[®], with an estimated 61% of students with ADHD in our study diverting their medications to another person.

Let me sharpen the focus on this particular aspect of this problem—nonmedical use of prescription stimulants. We know that these drugs are widely available on college campuses for nonmedical use, owing in part to their ability to increase wakefulness. This particular class of drugs is attractive to college students with high task demands, and especially to those experiencing academic difficulties. There is a popular assumption—widely believed by the young adults themselves, and sometimes reinforced by the media—that taking stimulants non-medically confers an “academic edge,” and is therefore beneficial for passing exams and writing

papers. With headlines referencing “smart drugs” and “smart doping,” the popular media have perpetuated the general notion that nonmedical use of prescription stimulants increases academic performance and that stimulants are used nonmedically by the best students.

Scientific evidence tells us quite the opposite, however. Nonmedical prescription stimulant use is associated with lower academic performance; it is not primarily the academically successful students who use prescription stimulants nonmedically, but the academically unsuccessful students.

Compared to non-users, our data show that nonmedical users of prescription drugs are more likely to meet criteria for dependence on alcohol and marijuana, skip class more frequently, and spend less time studying. And digging even deeper to the root of this issue, we see that these academic performance problems are linked to heavy drinking and marijuana use. In summary, what the research shows is that nonmedical prescription stimulant use is an unsuccessful shortcut—an attempt to compensate for declining academic performance—and is really a “red flag” for a underlying alcohol and/or drug problem in a college student.

Although stimulant medications—when used safely under proper medical supervision for the treatment of ADHD—can be instrumental in achieving therapeutic goals related to academic performance, there is no basis for making the assumption that similar benefits are attained through nonmedical use.

It is necessary to dispel the powerful myths that parents, students and the media use to rationalize the nonmedical use of prescription stimulants. Prescribing physicians and college health centers need to emphasize why this behavior should be of concern, rather than a benign or normative behavior. In fact, the non-medical use of prescription stimulants should trigger an

assessment for possible underlying drug use, academic problems, and possible mental health issues.

Table 1 of my supplementary materials shows the relationship between non-medical prescription stimulant use and alcohol/illicit drug use—data taken from 15 separate studies. On the point of prescription drug diversion, research findings consistently show that individuals who divert prescription drugs share characteristics with individuals who use prescription drugs for nonmedical purposes, and often times are nonmedical users themselves. Again, we are not dealing with separate issues—they are tightly linked to one another and represent similar problems.

What can policy makers do to address this “symptom” of the issue? The single best thing is to help tighten the “chain of custody” that ultimately governs supply of prescription drugs. Putting better prescription monitoring programs in place is one critical thing policy makers can do.

But physicians also have roles to play—to reform their dosing practices, and be vigilant about underlying alcohol and drug issues when they prescribe psychoactive drugs to their adolescent and young adult patients.

Moreover, patients and parents need to do their part in tightening the supply chain by curtailing sharing of prescription medications among adults and becoming more aware of the whereabouts of leftover medication.

However, because the prescription drug problem has complicated the landscape of existing drug threats to our nation’s youth and young adults, we need to redouble our efforts to develop innovative solutions to the public health problem of drug abuse and addiction. What

specific strategies should be proposed? Today, I recommend two things related to prevention and early intervention:

1. Modernize the nation's infrastructure for early detection to address drug problems in youth and young adults. Decades of research tell us that we can identify those who are at highest-risk for drug problems, just like knowing who is at risk for other chronic health conditions. Youth who develop drug problems share certain identifiable characteristics. With an approach that involves standardized assessments, early intervention, and promotes teamwork between parents, physicians and educators, we can put these young people back on track to fulfill their potential. To this end, NIH research has yielded valuable information about the risk and resiliency factors involved in the various stages of youth drug involvement, the interplay between genetics and environment on the escalation of drug problems, and the natural history and course of addiction. Finding effective solutions to this enormous threat to public health will require continued funding for NIH research.

2. Connect the dots between drug use and academic problems. The link between drug use and educational outcomes cannot be ignored any longer. Making this connection loud and clear will get the attention of parents who want more than anything else to see their child succeed. Tacit approval by parents and students of underage drinking as normative and college as a "five year party", especially when there are stimulant drugs as a last-resort pathway to "success", is a completely misguided but, regrettably, an all too-common notion. Parents must be empowered to recognize a myth when they see one and respond with appropriate communication, emphasizing that attending class, completing assignments and using the time in college constructively is the best strategy to achieve superior academic performance.

Similarly, we must engage the leaders of our nation's education system who are concerned about the high school dropout crisis and less than optimal college graduation rates. With full recognition that academic problems can sometimes place a child at risk for drug use, we must also recognize the very real and contributory role of drug problems to poor academic achievement. Sustaining our economy and navigating future challenges will require a clear mind and sharp focus, which is inconsistent with underage and excessive drinking, and illicit and non-medical use of prescription drugs, among our nation's secondary school and college students.

Again, I thank the Chair, ranking member, and all other members of this Subcommittee for shedding light on this continuing public health problem and allowing me to contribute to the discussion on solutions.

Mrs. BONO MACK. Thank you. I thank you all the panelists very much. Certainly the parents who are hurting, I thank you for your advocacy and your passion turned towards helping others.

Dr. Boyd, the statistics I am looking at completely dispute what you are saying. As I look at the Drug Abuse Warning Network statistics as published by SAMHSA, you said that stimulants are the problem and you also say that opiate addiction has doubled. Did I not hear that correctly?

Ms. BOYD. No, that prescriptions for controlled medications for young adults and adolescents—I think this is what you are referring to—has nearly doubled since 2007.

Mrs. BONO MACK. Now, this is not specific to adolescents, but when I look at these numbers for the increase of emergency department visits, now, old data, but from 2004 to 2009 stimulants all together, again not specific to adolescents but I would think the trend would be similar, 20,490 admitted to ERs in the year 2004. That increased to 25,889 by 2009, a 5,000-person increase over those years, while oxycodone and combinations thereof, 41,701 in 2004. One would think that the crisis is similar, that that would double, but in fact it actually increased to 148,449. So you spent the bulk of your time talking about stimulants but I am not aware particularly, and I am sorry I don't have the data here, but would you say that the trend line for stimulants and fatalities for stimulants is similar to opiates and OxyContin?

Ms. BOYD. No, I wouldn't, and actually I did not intend to give the impression that I was mostly talking about stimulants actually. When I was speaking of the controlled medications, I was speaking of the four schedules and that for instance, 10 percent in our sample had diverted their pain medication where 15 percent had diverted stimulants.

Mrs. BONO MACK. Let me jump to Ms. Creedon here and even to Mr. Harrison, and thank God that you are here as a recovering addict. I am so proud of your courage. Thank you for being here. And to Kathy Creedon, this is the scientific community and you guys have lived it in the real world. Is this just diversion from the simple places they see? Ms. Creedon, in your testimony, I wish you had gone on a little bit more. You talk a great deal, and you mentioned you have seven pages of documentation that show the run-around and what they call the smurfing, the great lengths your son went to that had nothing to do with your medicine cabinet. Would you be willing to submit your seven pages and 72 entries of medical history? Would you be able to submit those things for the Congressional record so we can take a look at all of that? But are you hearing on the real street side of what is really happening out there in California and the homes? Is it paralleling what the scientists are saying here?

Ms. KATHY CREEDON. That the drugs are coming from parents' medicine cabinets? Is that the question?

Mrs. BONO MACK. Perhaps I just—I am a little on edge. It almost seems that you act as if the 16-year-old honor student was given hydrocodone, Dr. Boyd, and the teen went to the event, she had a great time but she never used hydrocodone again. So it seems to downplay, and you are acting as if the diversion is, well, Mom gave it to a 16-year-old, she had a great time at a party, and I just take

issue with that because this is a mother who never, ever dreamt of doing such a thing.

Ms. BOYD. Absolutely, but speaking as a social scientist, this is also happening so that when we look at the data on diversion, we see all kinds of diversion and we see that also parents are role modeling, share medications that are controlled. The mother shouldn't have had extra hydrocodone.

Mrs. BONO MACK. OK, but Ms. Creedon, you had no hydrocodone, you had no oxycodone. Can you speak a little bit about the great lengths your son went to that had nothing to do with this? You are like Ms. Rovero and Mr. Bauer, a loving parent doing your best to raise a teenager, or young Ms. Creedon.

Ms. COURTNEY CREEDON. If I can speak to this, I mean, I think the reputation certainly is out there, and we have heard a lot of that today that I guess there were some statistics floating around that most people get these drugs from their parents' medicine cabinets, but in our case, that did not happen. We never had any of these drugs in our house. My mother never condoned using drugs. I mean, when we do submit these records, I mean, Ryan went out of his way to visit every doctor imaginable and finagle every aspect of the system to make this work, and surprisingly, it wasn't that difficult. So it is kind of hard for us to sit here and hear people talk about I guess parent responsibility when really I think the bigger issue is responsibility or rather irresponsibility of the medical community in that none of these drugs came from our home. All of these drugs that Ryan used and the drugs he died from were obtained legally from licensed physicians.

Mrs. BONO MACK. Thank you. I have to yield now to the ranking member, Mr. Butterfield, but we will have a second and third round of questioning. So Mr. Butterfield is recognized.

Mr. BUTTERFIELD. Let me thank the chairman for convening this very important hearing today. Those of us on this side of the aisle are also acutely aware of the pervasive problem that we have with prescription drug abuse, and so the hearing today is very timely and I want to thank the witnesses for their testimony.

In my prior life, I was a trial judge in North Carolina. I did that for 15 years, and so I have seen and heard heart-wrenching stories for many years over my career, and I want to extend my personal condolences and concern to those families who have been directly affected.

I want to just ask one or two questions. I won't belabor this unnecessarily but let me start this way. Prescription drug abusers do so for a variety of reasons, and I think we recognize that today. There are many reasons that contribute to this problem. Some people use them recreationally, some seeking their euphoric, relaxing or energizing effects. Other people with or without a prescription use them inappropriately seeking to alleviate minor pain and treat a perceived illness or even to manage stress. Still other people use prescription drugs for their intended purpose but obtain them without a prescription.

To Dr. Arria and Dr. Boyd, do we have data in percentage terms which demonstrate either for the population as a whole or for high school- or college-age individuals why prescription drugs are being

used? In other words, for what reasons by percentage do young people decide to take prescription drugs without a prescription?

Ms. ARRIA. The percentages vary by class of prescription drugs, so for stimulants, I would say about three-quarters of people who use stimulants take them to increase concentration, to study and the scenario sort of plays itself out that I explained where they are having academic difficulties. Only a small percentage of them will crush stimulants to get high. On the analgesic side, many, many more, a higher percentage, probably about 80 percent, will use them to get high and a very small minority will use them because of curiosity reasons or for other reasons. And for the tranquilizers, we see a lot of self-medication going on where there might be an underlying mental health issue. So it varies by class, and that is for the college age-population, young adult populations. We do not have that level of data at the national level. The national survey on drug use and health does not collect that level of information for us.

Ms. BOYD. And I studied 12- to 17-year-olds so it is a younger group, and they are less likely to use any drugs, the 12-year-olds and 13-year-olds, so you see some differences. We also see differences by drug class, and they mimic much of what Dr. Aria said with the exception being the opioids where disproportionately the younger the child with the opioid, the more likely they say they are treating pain. Once they get older so that now they are into 11th and 12th grade, now when they are using diverted opioid medications, they are using it to experiment, to get high, to help them sleep, but that may be because they are using stimulants or they are drinking or partying, but so it would be for sensation-seeking or recreational reasons.

Mr. BUTTERFIELD. Can we quantify what percentage of users snort as opposed to crushing the medication? What percentage are snorting it? Do we know?

Ms. BOYD. Of 12- to 17-year-olds?

Mr. BUTTERFIELD. Well, your age group, yes.

Ms. BOYD. Relatively few are snorting it, and it depends by grade. Twelve-year-olds and 13-year-olds are not snorting it. We see about 5 to 10 percent snorting it by the time they get into high school.

Mr. BUTTERFIELD. What about combining it with alcohol?

Ms. BOYD. They all combine it with alcohol.

Mr. BUTTERFIELD. That is a common—

Ms. BOYD. Absolutely. Our data show that any youth that is using the opioid products to get high or to sensation seek or for recreational purposes are using other drugs as well, and they are also using other prescription medications.

Mr. BUTTERFIELD. Would that be the same in the older age groups as well, Dr. Arria?

Ms. ARRIA. What we find is that there is always a history of excessive drinking or a history of marijuana involvement, and in some cases they are using it at the same time concurrently during the same session. For instance, in our data, 88 percent of the non-medical prescription drug users had a history of marijuana use in the past year.

Mr. BUTTERFIELD. So there are similarities between the 12 to 17 and the 18 and above?

Ms. BOYD. There are, and particularly when you get to 16-, 17- and 18-year-olds. The younger ones, which I am also studying, who are in middle school, they do look different.

Mr. BUTTERFIELD. Well, let me thank you and thank all of you for your testimony. I yield back.

Mrs. BONO MACK. Thank you, and I do ask unanimous consent that the information that I requested from Ms. Creedon be allowed to be included in the record. No objection? OK. So ordered.

Mrs. BONO MACK. Dr. Arria, you keep mentioning the history, the history, the history of use. It is my belief as a mother who just got through high school that the powerful nature of these pain-killers that our kids do not have a chance. Can you speak to the adolescent brain, specifically what does happen when they get that tablet of OxyContin? Can you speak also to a pharm party and explain what that is?

Ms. ARRIA. Sure. I think it is very true that the addictive potential of opioid analgesics trump what we are talking about when we see marijuana, other drugs. So what really appears to be the issue is that because it is more typical for alcohol and marijuana to be used at younger ages, there are some people who are more predisposed to using substances. We know that. And the adolescent brain is more set up to take risks naturally, and so that combination of being an adolescent and having a propensity for addiction sets up a course where you get involved with alcohol and marijuana and then it exposes you to drug-using peers. Like I said, you begin to lose interest in other things, you get involved in prescription drugs and then you get a very, very highly addictive substance and that is what you are talking about when they don't stand a chance. So if they have a propensity for addiction plus they are in this age of adolescence—

Mrs. BONO MACK. I have no Ph.D., but I beg to differ that if they have a predisposition to addiction, because I believe that every human being—

Ms. ARRIA. I stand corrected.

Mrs. BONO MACK [continuing]. Has the potential to be addicted.

Ms. ARRIA. One hundred percent of people have some propensity for addiction.

Mrs. BONO MACK. I am sorry. Can you repeat that?

Ms. ARRIA. One hundred percent of people are at risk for addiction if they are exposed to addictive substances.

Mrs. BONO MACK. And then an adolescent then?

Ms. ARRIA. An adolescent would be even more so because of their risk-taking behaviors.

Mrs. BONO MACK. But risk-taking, a white pill to them is a lot less risky than meth?

Ms. ARRIA. Well, what we find is that in terms of, we have done studies on perceived risk and the risk of medications falls in between marijuana and cocaine, so they don't see it as less risky than marijuana. They see taking prescription drugs medically or non-medically as more risky than marijuana but less risky than cocaine, so that is where it falls.

Mrs. BONO MACK. Briefly, let me just lead you to the answer that I want to hear on another question, pharm parties. It is my understanding, is it not true, that kids now go to parties, throw bunches of pills into a bowl and grab whatever they can and swallow it to be risky?

Ms. ARRIA. We have heard of that happening. We are not sure how often it happens. What we do know is that the variety of drugs used is much—there is much more variety of different drugs used on the same occasion than there were years ago. That is what we know now.

Mrs. BONO MACK. Thank you.

Mr. Harrison, how helpful now is the medical community? If you walk into a pharmacy, do you have the ability to tell your pharmacist I am a recovering addict, please don't prescribe my drug of choice to me or help me if I do? Do you have that ability? Are they helpful to you now?

Mr. HARRISON. I went through a process of a second back surgery with a 12-month sobriety, and it was difficult for me to have them administer more intravenous drugs to me because I was going through recovery, but I haven't yet attempted to gain any access since my recovery, so I haven't attempted to talk to any doctors that I have dealt with in the past. Them knowing the severity of my injury, in the past, like I said, I had built a relationship with them and I see them from time to time in the community, and so access was real easy. But since my recovery, 30 months in recovery, and I haven't yet attempted to go back.

Mrs. BONO MACK. Well, congratulations on your 30 months.

Mr. Bauer, are you finding a good avenue for your advocacy and making a difference out there?

Mr. BAUER. Yes.

Mrs. BONO MACK. Good answer. Nice, short and sweet. OK. I will yield to Mr. Butterfield for the next 5 minutes.

Mr. BUTTERFIELD. Thank you very much, Madam Chairman.

During one of the earlier panels—and I apologize for not being here. I forewarned the chairman that I had another commitment this morning and I could not resolve. But during one of the panels this morning, a lot of time was devoted to discussing monitoring programs. I believe databases are an important tool that should be in our toolbox, but we need to treat the non-medical use of prescription drugs with many different tools, with multiple tools and treat it as a public health issue, not just a law enforcement issue. For example, we need better education of patients and parents and friends and doctors and dentists and every person in society.

Dr. Boyd, in your testimony you mentioned better labeling as one of those tools. Can you describe what you would envision to be on a label and would this be on all prescription drugs or just those that are the most risky if diverted?

Ms. BOYD. Well, I am also a nurse and I would like to see better labeling on all medications, but let me direct my attention to the controlled medications that are more likely to be diverted and abused. I would recommend that we label them that it is unlawful to distribute them. Many, many of the kids that I interview do not know, and parents do not know, that mother of the girl going to homecoming, she didn't know she was doing something illegal.

They should know it. It should be labeled on the bottom. There should also be directions on how to dispose of extra medicine that is left in the bottle so it is not sitting in the medicine cabinet. And finally, not only should they know where to dispose of it and that it is unlawful to distribute it but they should also know that it has addictive potential and abuse potential. Many medications I have gotten have been labeled more fully than the medications that are controlled.

Mr. BUTTERFIELD. All right. Let me come to the other end of the table. Ms. Creedon, aside from labeling—and I like Dr. Boyd's assessment of this—but aside from labeling, what can we do to increase public awareness of prescription drug abuse? We have got to become more proactive so other families do not have the tragedy that you have experienced. What can we do?

Ms. KATHY CREEDON. You know, that is a really good question. I don't know the answer yet but I intend to hopefully be able to make a difference by this organization that I have started and our goal is to reach out, first of all, to students in high schools, middle school, college age, the parents, and I really would like to reach out to the medical community as well because that was a specific problem in my son's, well, that led up to his death. In these seven pages, I document it, if I could just take a minute, in the beginning where my daughter and I had a face-to-face meeting with the director of the medical facility where we said to him, Ryan has an addiction problem, and like I said, because of privacy laws, we were not able to speak about certain things, you know, because of breaking laws. But he did tell me that he would go and speak to the physician that Ryan had an appointment with 2 days later. That conversation apparently never took place, and I just feel that if he would have taken our conversation seriously coming from a family member of Ryan's history of drug abuse, that could have stopped the other six pages of his hospitalizations and everything else that went on. So for me particularly, I feel that the medical community doesn't take addiction seriously because maybe they are just not aware, you know, of what a few pills can do to somebody. In my son's case, it led to his death.

Mr. BUTTERFIELD. What about public service announcements on TV channels that are watched by young people?

Ms. KATHY CREEDON. That is one of the things that we hope to be able to do.

Mr. BUTTERFIELD. MTV and BET and some of the other channels.

Ms. KATHY CREEDON. Absolutely. There are some things already being done directly to young people on the Web sites and things that they listen to about the dangers of prescription drug abuse.

Mr. BUTTERFIELD. We need to do it and we need to do it repetitively.

Ms. KATHY CREEDON. Exactly.

Mr. BUTTERFIELD. One thing we have learned in Congress, if you say something over and over and over again, people will listen and sometimes believe it.

Ms. KATHY CREEDON. And that is what I read in all the educator material that I have been researching lately is that it does have to be repetitive and so it would almost mean being present on a

high school property on a weekly basis just over and over telling them the dangers of the drugs before they go to a party on Friday night.

Mr. BUTTERFIELD. Thank you. Thank you again. I yield back.

Mrs. BONO MACK. All right. Thank you. We will do 5 more minutes and then we will conclude the panel and move on to the next, unless you would like another five, I am certainly fine with it.

Mr. BUTTERFIELD. We are going to have votes in about an hour.

Mrs. BONO MACK. Dr. Boyd, back to you. Labeling—my understanding through the years of my research on OxyContin that actually the label is what turned kids on to the ability for the misuse. I think that labeling is not going to be the answer. I don't know how old your son is, but I believe that it goes back to me to the DEA and the FDA and the supply chain and figuring out how this stuff is getting out there and why we are taking back hundreds of pounds of this stuff, whatever the astronomical number is. It has got to be beyond labeling.

Let me just jump to Ms. Creedon again. Again, your testimony is terrific, but you spoke about the medical community, your frustrations with them, but since Ryan's death you have worked with the medical community and the doctors overseeing the HMO, and it is my understanding that they did learn a lot from you and that they have agreed to change their prescribing practice for such powerful painkillers. Is that true, and have you followed up on that, that you are able to actually educate in your community, your HMO, and get a change?

Ms. KATHY CREEDON. Yes, that is true, and I was very happy that they were receptive to hearing the information. I printed out a lot of information from the Internet and shared it with them, and in fact, the medical director told me that he took the information that I gave him and presented it in front of a staff meeting that they had, and they in fact after my meeting made a policy within their organization that covers approximately 3,000 physicians and over 300,000 members that those physicians could no longer prescribe OxyContin for the patients unless they had fourth-stage cancer and they had tried everything else. So I feel that was a huge victory that the education that I gave them made that change, and I haven't been able to follow up with the outcome. I intend to do that, but I don't know right now if that is still happening.

Mrs. BONO MACK. I congratulate you on that, and it goes to Ms. Rovero, in your testimony you say the same thing. You say that your son had never been treated for any of the conditions listed on the doctor's record as the basis for her prescription for the powerful painkillers. Were you surprised by how easy it was for him to get access to those medications?

Ms. ROVERO. Not only surprised, I was shocked. I had never heard the term "pill mill." I had not heard about dirty doctors. This last year has been a complete education for me. Shocked, absolutely shocked, and I have learned that that is the case throughout the country. I talk now to parents all over the place, California to Florida, and it is happening. There are so many unscrupulous doctors out there that are giving it out, they are in a pill mill kind of environment, but it is not just those doctors, it is also those that are really well meaning but they are not really well educated about

pain management treatment. I have been told, I don't know if it is true for sure, but I have been told that doctors get less pain management training than veterinarians do, and that is horrifying to think about, but if it is true, my gosh.

Mrs. BONO MACK. Would you agree with that statement, Dr. Boyd, Dr. Arria? Do you know about the level of training that physicians do get before they can prescribe these things?

Ms. ARRIA. I know it has gotten better but I know that I can speak to the addiction medicine side. They really are not given proper training at the graduate medical education level on addictive disease.

Mrs. BONO MACK. Dr. Boyd?

Ms. BOYD. I agree with that. It is just inadequate.

Mrs. BONO MACK. Thank you. And I will just use my last minute. I think we agree with Ms. Creedon, Ms. Rovero, on trying to limit the scope on when it is prescribed. I think that is something we can push for in Washington. But I really just want to thank you all very much for your commitment, your advocacy to this, and I don't know where it is going to go. I am frustrated last night in my research to see that there was a Senate hearing in 2002 that is very much like the one we are holding today. I think that is frustrating, and I think we are failing. It is a tough time for budget cuts and we all have questions on how we spend our money, but we can do a better job and I think the American people want an effective government, and in this case, it is not being effective.

So I look forward to working with each and every one of you, and if you had another five, I am willing to yield to the gentleman. If not, we will take a quick recess and seat the next panel. Thank you very much.

[Recess.]

Mrs. BONO MACK. First up will be Sean Clarkin, Executive Vice President of Partnership for a Drug-Free America. Also joining us is General Arthur Dean, Chairman and CEO of the Community Anti-Drug Coalitions of America. Then we will have Dr. Coster, Senior Vice President of the Generic Pharmaceutical Association. Our fourth panelist is Kendra Martello, Assistant General Counsel, Pharmaceutical Research and Manufacturers of America. Also testifying, Michael Mayer, President of Frank Mayer and Associates. And our sixth witness is Patrick Coyne, Registered Nurse, testifying on behalf of the Oncology Nursing Society.

Welcome, everyone. Thank you much for being here today. I think you know the drill, 5 minutes, green, yellow, red. In America, we generally know what that means. So just please make sure you press the microphone to turn it on, and Mr. Clarkin, you are recognized for 5 minutes.

STATEMENTS OF SEAN CLARKIN, EXECUTIVE VICE PRESIDENT AND DIRECTOR OF STRATEGY, THE PARTNERSHIP AT DRUGFREE.ORG; ARTHUR T. DEAN, CHAIRMAN AND CEO, COMMUNITY ANTI-DRUG COALITIONS OF AMERICA; JOHN M. COSTER, PH.D., R.PH., SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, GENERIC PHARMACEUTICAL ASSOCIATION; KENDRA MARTELLO, ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; MICHAEL MAYER, PRESIDENT, MEDRETURN, LLC; AND PATRICK COYNE, R.N., M.S.N., CLINICAL DIRECTOR, THOMAS PALLIATIVE CARE UNIT, VIRGINIA COMMONWEALTH UNIVERSITY MEDICAL CENTER, ON BEHALF OF THE ONCOLOGY NURSING SOCIETY

STATEMENT OF SEAN CLARKIN

Mr. CLARKIN. Good morning, Chairman Bono Mack, Ranking Member Butterfield, members of the subcommittee, thank you for inviting me to testify about the problem of prescription drug abuse and the diversion of prescription medicine.

The abuse of prescription medications, legal substances of tremendous benefit if used appropriately, is the single most troubling phenomenon on today's drug landscape. According to the 2010 Partnership Attitude Tracking Study, the PATS study, one in four, 25 percent of teens, report 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, has used a prescription pain reliever not prescribed for them by a doctor.

Why have we as a Nation not been able to reduce this highly risky behavior? There are several reasons, many of which we have already heard today. The first is ready access. These substances are readily available to teens in their own medicine cabinets and the medicine cabinets of friends and family, and very often they are available for free. Nearly half, 47 percent, of teens in our PATS survey say that it is easy to get these drugs from parents' medicine cabinets, and more than a third say it is available everywhere.

Another reason is low perception of risk, the low perception of risk that is associated with abusing prescription drugs. Partnership research shows that less half of teens see great risk in trying prescription pain relievers such as Vicodin or OxyContin that a doctor did not prescribe for them. Low perception of risk coupled with easy availability is a recipe for an ongoing problem.

The third reason that we have heard a lot about, especially from Dr. Boyd, is the motivation to abuse. We have traditionally thought of teens abusing illegal drugs and alcohol either to party or to self-medication for some serious problem or disorder, adolescent depression, for example. But our research, like Dr. Boyd's, shows that teens appear to be abusing these drugs in a utilitarian way, using stimulants to help them cram for a test or to lose weight, pain relievers to escape some of the pressure they feel to perform academically, tranquilizers to wind down at the end of a stressful day. Once these substances have become integrated into teens' lived and abused as study or relaxation aids, it may become increasingly difficult to persuade teens that these are drugs are unnecessary or unsafe when taken without a prescription.

The fourth reason, and this is a particular focus of the partnerships, is the lack of parental activism in prevention of this behavior. Parents who are usually our most valuable ally in preventing teen drug use find it hard to understand the scale and purposefulness with which many of today's teens are abusing medications, and it is not immediately clear to these parents that the prime source of supply for abusable prescription drugs may well be their own medicine cabinet. Many parents themselves, moreover, are misusing or perhaps abusing prescription drugs without a prescription. In research that we did in 2007, 28 percent of parents said that they themselves had used a prescription drug without having a prescription for it, and 8 percent of those parents said that they had given their teenaged child a prescription drug that was not prescribed for them.

Finally, the reason we have not been able to reduce teen abuse of prescription medications is that our efforts as a Nation have been inadequate, at least to date. There simply has not been sufficient public attention or resources dedicated to this threat. The backdrop to all of this is that the national drug prevention infrastructure has been eroding for the past 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 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 to be able to mount the kind of effort that is necessary.

We know that if there is, when there is a well-funded effort to educate parents about the dangers of prescription drug abuse, we can increase awareness and we can make a difference. In the first half of 2008, the Office of National Drug Policy's National Youth Anti-Drug Media Campaign devoted \$14 million with which the media match was a \$28 million effort to a parent-targeted campaign aimed at raising awareness about the risks of medicine abuse and motivating parents to take action. The campaign actually in terms of parents' perceptions of the problem and intent to take action was demonstrably successful. This shows that a major public education campaign can help to turn the tide on this entrenched behavior. The media campaign's funding is in jeopardy and may even be eliminated in the coming year, so we can't assume that that campaign will be around to deliver this message. The private sector will need to help finance a campaign of the magnitude necessary to change the attitudes that underlie this behavior.

While the partnership is grateful for the unrestricted support we have received from a number of pharmaceutical 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 and other key stakeholders to first 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 adver-

tising and pointing viewers towards an objective and comprehensive online prevention resource. Second, we need to educate and enlist prescribers, pharmacists and other health care professionals. Third, we need to educate policymakers so that we can promote policies that will help reduce both the supply of and the demand for prescription drugs of abuse. And finally, implement an evaluation tool that would measure and hold this program accountable.

In conclusion, at the partnership 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 appreciate the time and the attention that the subcommittee is giving to raising awareness and looking for ways to reduce the abuse 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. Thank you very much.

[The prepared statement of Mr. Clarkin follows:]

Summary of Testimony of Sean Clarkin, The Partnership at Drugfree.org

The abuse of prescription medications – legal substances of tremendous benefit if used appropriately – is the single most troubling phenomenon on today's drug landscape. According to the 2010 Partnership Attitude Tracking Study sponsored by the MetLife Foundation, teen abuse of Rx medicines continues to be an area of major concern, with abuse rates holding steady over the past five years 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.

Why have we as a nation not been able to reduce this risky behavior? There are several reasons:

The first is availability. 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.

Another key factor is the relatively low perceived risk of abusing prescription drugs.

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.

A third aspect is the set of reasons why young people are abusing prescription medications.

Research conducted by the Partnership in 2007 suggests a wider range of motivations for young people's abuse of prescription drugs, including an emerging set of "life management" or "regulation" objectives.

Fourth is the fact that 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.

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.

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 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.

Testimony of Sean Clarkin, Executive Vice President

The Partnership at Drugfree.org

"Warning: The Growing Danger of Prescription Drug Diversion"

Subcommittee on Commerce, Manufacturing and Trade

United States House of Representatives

April 14, 2011

Chairman Bono-Mack, Ranking Member Butterfield, Members of the Subcommittee, thank you for inviting me to testify about the problem about prescription drug abuse and the diversion of prescription medications.

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 the Drug Enforcement Administration's first prescription drug "Take Back" day last fall -- where they collected 121 tons of pills from

4,000 locations in 50 states – and why we are supporting their next “Take Back” day on April 30. 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 he has been working with all of the national drug control agencies to develop a targeted strategy to address 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 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 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.

Mrs. BONO MACK. Thank you, Mr. Clarkin.
General Dean, you are recognized for your 5 minutes.

STATEMENT OF ARTHUR T. DEAN

Mr. DEAN. Chairman Bono Mack, Ranking Member Butterfield and other distinguished members of the subcommittee, thank you for the opportunity to testify today on behalf of Community Anti-Drug Coalitions of America, CADCA, and our more than 5,000 community coalitions nationwide. I am pleased to provide you with CADCA's perspective on the complex problem of prescription drug abuse.

CADCA has been on the front lines addressing prescription drug abuse for nearly 10 years. We have hosted town hall meetings, developed publications and toolkits for coalitions, and produced television programs on this subject. In 2009, we were fortunate enough to conduct a rally with over 1,000 community leaders on Capitol Hill to raise the awareness of over-the-counter as well as Rx abuse. CADCA recognizes that the misuse and abuse of prescription drugs is a multidimensional problem that demands comprehensive, coordinated solutions at all levels, local, State and national. Population-level changes in substance abuse including prescription drug abuse can be achieved by a comprehensive, data-driven approach. This approach mobilizes key community sectors that work together to educate, reduce access and availability, and change perceptions as well as social norms. Where this infrastructure is in place, communities have successfully prevented and pushed back against a variety of drug problems such as marijuana, methamphetamines, K2 and the misuse and abuse of prescription drugs.

The Drug-Free Community, DFC program is the best example of a comprehensive community-wide approach being taken to scale nationwide. Since 1998, the DFC program has been a central bipartisan component of our Nation's drug reduction strategy. A recent evaluation of the program found that youth drug, alcohol and tobacco use are significantly lower in DFC-funded communities than in communities without a DFC coalition.

CADCA trains DFC grantees and other community anti-drug coalitions to execute seven evidence-based strategies to effect community change for drug use. Coalitions across the country are implementing these strategies, and these strategies range from raising awareness to changing policies, and they are achieving measurable results and reducing local prescription drug abuse rates.

In the interest of time, I would like to share just one example from Caribou, Maine. The Aroostook coalition used a multisector approach to identify prescription drug problems and to craft a strategic action plan to address them. The coalition did the following: one, they implemented a comprehensive social marketing campaign; two, they provided training to health care providers about proper prescribing; three, promoted and funded a prescription drug take-back program; and four, created a monthly mailer for health care providers that lists individuals charged with prescription drug-related crimes in their communities. As a result of this data-driven multisector approach, the coalition achieved significant outcomes. Through the coalition's effort, the county has Maine's lowest rate of past 30-day prescription drug use among high school stu-

dents. Similar coalition examples are highlighted in my testimony, and I would invite those to your attention.

CADCA's primary message today to this committee is that community coalitions are evidence-based and effective and should be utilized as a major component of any prescription drug prevention strategy. We recommend that the coalition model be implemented in concert with a number of other key approaches. For example, CADCA supports the expansion of effective prescription drug monitoring programs to ensure adequate coverage in every State. The data from these programs can also help identify hot spots and appropriately direct the attention to other resources. We need enhanced education opportunities for training for medical and dental professions. We also need increased awareness and education about the danger, proper storage and disposal of drugs. We support enhanced opportunities to make prescription take-back programs routinely available. We strongly support increased law enforcement to remedy such things as pill mills. Our nation needs to embrace and enhance all these strategies. We need to expand the number of DFC-funded communities. And finally, we need to increase training at the local level so that more communities can effectively address this major public health and safety threat.

I thank you for the opportunity to testify before you today and applaud you for your great work. Thank you.

[The prepared statement of Mr. Dean follows:]

CADCA Summary Statement for Hearing Entitled: “Warning: The Growing Danger of Prescription Drug Diversion”

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.

“Warning: The Growing Danger of Prescription Drug Diversion”
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
Written Testimony of General Arthur T. Dean
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Chairwoman Bono Mack, Ranking Member Butterfield and other distinguished members of the Subcommittee on Commerce, Manufacturing and Trade, thank you for the opportunity to testify before you today on behalf of Community Anti-Drug Coalitions of America (CADCA) and our more than 5,000 coalition members nationwide. I am pleased to provide you with CADCA’s perspective on the growing danger of prescription drug diversion and critical role that drug prevention plays in mitigating this danger.

Having served in the military for 31 years and as the Chairman and CEO of CADCA for nearly 13 years, I have come to recognize the critically important role of prevention as the first line of defense in protecting individuals, families and communities from the devastating impact of drug abuse.

Prescription drug abuse, as most of us in this room are well aware, 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.¹

According to the most recent (2010) national Monitoring the Future (MTF) Survey,

¹ 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>

prescription drugs account for 8 of the top 14 most frequently abused drugs by our nation's youth.² Also according to MTF, 59.1 percent of 12th 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 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.

² 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>

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.

CADCA recognizes that the misuse and abuse of prescription drugs is a multi-dimensional problem that demands comprehensive, coordinated solutions.³ 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”.⁴ Successful prevention hinges on the extent to which schools, parents, law enforcement, business, the 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

³ 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.

⁴ 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.

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 data⁵; 2) build their prevention

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

capacity⁶; 3) develop a strategic plan⁷; 4) implement effective community prevention programs, policies and practices⁸; and 5) evaluate their efforts for outcomes.⁹

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 by researchers to categorize interventions.¹⁰ 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

⁶ Ibid.

⁷ 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. 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.

⁸ 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.

⁹ 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.

¹⁰ 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.

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 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.¹¹ 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 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.¹² 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.

¹¹ 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.

¹² 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>

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 increases¹³ (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 accessible a substance is the easier it is to abuse.¹⁴ 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*¹⁵, “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

¹³ 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.

¹⁴ Birckmayer, J.D., Boothroyd, R.L., 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.pire.org/documents/UnderageDrinking.doc>

¹⁵ 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>

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

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.

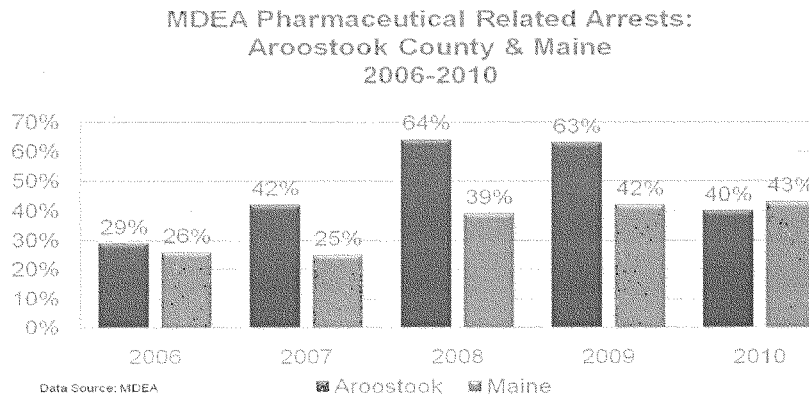
DFC coalitions have implemented a number of effective programs and strategies to reduce prescription drug abuse and have achieved measureable results. For example, in Caribou, Maine, the Aroostook Substance Abuse Prevention (ASAP) Coalition utilized a data-driven approach to identify prescription drug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

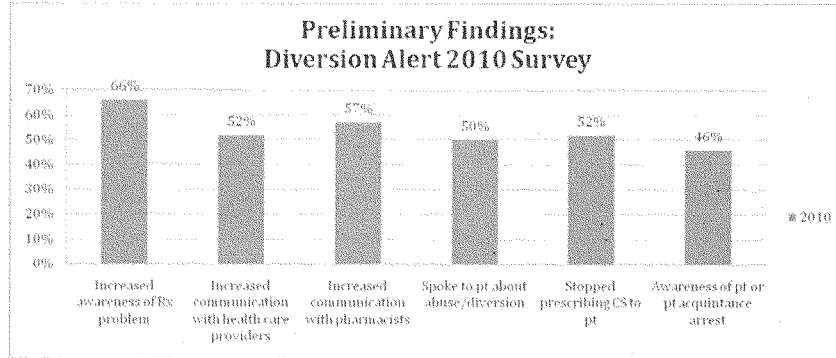
- created and disseminated to healthcare providers throughout the county, the Diversion Alert Program, which is a monthly mailer of individuals charged with prescription/illegal drug related crimes; and
- promoted and funded a prescription drug take back program.

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.

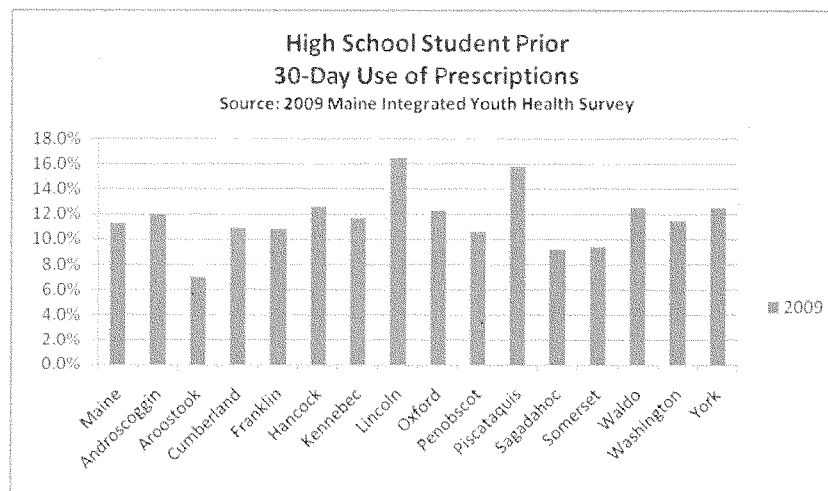
For instance, although the number of pharmaceutical related arrests in Aroostook County started out much higher than the statewide average in 2008 (64 percent in Aroostook County compared to 39 percent for the State), through its efforts, the coalition helped reduce this number to 40 percent in Aroostook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



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.

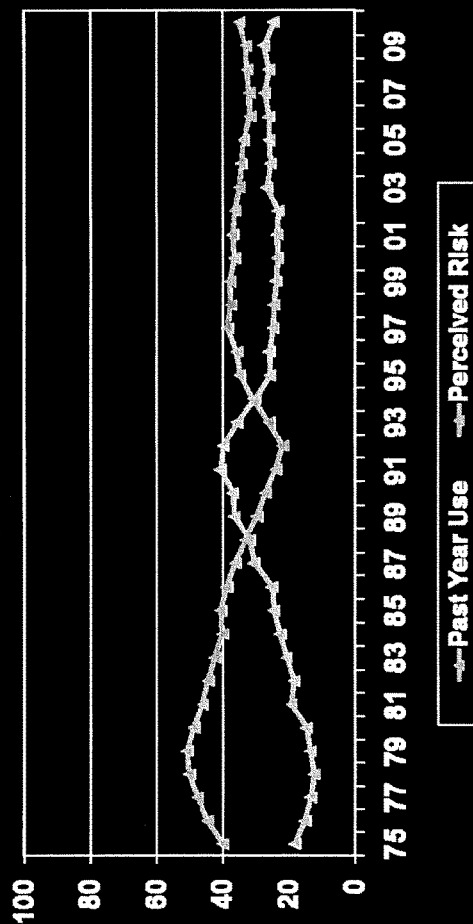
In addition, there is a great need for: (1) expansion of effective PDMP programs to ensure adequate coverage in every state, with both the enhanced abilities to begin to function with interoperability among states, as well as be a source of de-identified, aggregate data for use in identifying hot spots 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.

Thank you for the opportunity to testify on this subject of critical importance to our nation.

Attachment 1

12th 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 10th 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 10th 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 8th 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 12th 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 12th 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 8th 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.

Mrs. BONO MACK. Thank you, General, and we are honored that you are here, and I thank you for your service and that you came under the wire, because there is one person I couldn't gavel down, and that would be you, sir.

Mr. DEAN. And thank you for your great support and on a continuing basis. We appreciate it very much.

Mrs. BONO MACK. Thank you. I look forward to our continued work together.

Dr. Coster, you are recognized for 5 minutes.

STATEMENT OF JOHN COSTER

Mr. COSTER. Thank you. Good morning, Chairwoman Bono Mack, Ranking Member Butterfield, Congressman Lance, members of the subcommittee. I am John Coster, Senior Vice President of Government Affairs at the Generic Pharmaceutical Association and a licensed pharmacist. On behalf of GPhA and our member companies, thank you for calling this hearing and for the opportunity to testify.

Let me begin by giving some background on the role of the generic drug industry in the United States. About 75 percent of all prescriptions are filled with generic medications, although that percentage does vary by therapeutic class. We are proud that our industry helps make high-quality, safe, effective prescription medications more affordable for millions of Americans while saving the health care system billions of dollars each year.

GPhA's member companies manufacture FDA-approved generic versions of brand-name drugs in all therapeutic categories including prescription painkillers. We are as concerned as the members of this committee when medications that are made to improve lives or alleviate pain are abused. We believe that address this issue, as you have heard from the previous witnesses, will require a continued coordination among Federal and State agencies, State, local and Federal law enforcement, health professionals, drug manufacturers, pharmacists, patients and their families. Because it is a multifaceted problem, it requires a multifaceted solution.

As we work together to shape public policy to end the misuse of pain medications, we must recognize that the overwhelming majority of individuals including millions of seniors and cancer patients do rely on these important drugs for their proper pain treatment. We are absolutely committed to the safe and reliable manufacturing and delivery of generic drugs.

As an industry, we have invested millions of dollars into technologies and delivery systems to help assure that our products reach their destinations safely and securely. For example, with respect to opioid medications, the DEA has a closed system of distribution to prevent diversion. Our industry works with the DEA to assure that these products do not fall into the hands of abusers. For example, the DEA administers drug allotment and accountability systems to assure against the loss of diversion of controlled substances.

Recent studies suggest that the problem of prescription drug abuse stems not from drugs that have escaped legitimate supply chain or been obtained illegally through the black market but instead from those that were legally prescribed and available in the

home. Why are these medicines sitting in medicine cabinets? Shouldn't patients have already taken them? It is not uncommon to find many medicine cabinets in America are stocked with unused prescription drugs. Some of these may be for mild conditions such as allergy while others may be unused medications that were prescribed to treat the discomfort of a surgery. Many Americans have no recourse to return these unused medications, especially controlled substances, because Federal law prohibits the transfer of controlled substances from an ultimate user to anyone other than law enforcement. This will soon change as DEA implements the Safe and Secure Drug Disposal Act, which will permit ultimate users such as patients with excess controlled substances in their medicine cabinets to return them to DEA registrants such as willing pharmacists so they can be destroyed.

What has our industry been doing to help address this problem? In general, we have tried to support efforts that are dedicated to raising awareness to the dangers of prescription drug abuse as well as the need to properly dispose of unneeded or unwanted prescription medications. We think education is a key component to this. For example, we support efforts such as the American Medicine Chest Challenge, which is a community-based public health initiative with law enforcement partnership to raise awareness about the dangers of drug abuse. We are pleased to let you know that we will be partnering with PhRMA to produce a public service announcement that will promote the upcoming DEA Take Back Day on April 30th, which we hope will be as successful as the one from last fall.

We are also a board member of NCPIC, the National Council on Prescription Information and Education, a broad-based coalition on addressing raising awareness about prescription drug abuse. For example, NCPIC most recently developed a college resource kit to help educate students about the dangers of prescription drug misuse.

In addition, over the last few years our industry companies have focused efforts in this area by joining with the brand-name industry, patient groups and the FDA on working on a REMS program for long-acting and extended-release opioid medications. REMS are special programs that are used by FDA to help prevent adverse outcomes in patients. At this point, I don't believe the FDA has implemented that program yet.

Madam Chairwoman, we applaud you for the countless hours you have devoted to raising awareness about this issue and the great work you have done. With the cooperation of physicians, law enforcement and others, we can expand education efforts, keep our supply chain safe and secure, and help to ensure that patients and family members are not alone in this fight. We thank you for holding this hearing, and I would be happy to answer any questions you may have.

[The prepared statement of Mr. Coster follows:]



TESTIMONY OF

JOHN M. COSTER, Ph.D., R.Ph.

SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS

GENERIC PHARMACEUTICAL ASSOCIATION

**HEARING ON "WARNING: THE GROWING DANGER OF
PRESCRIPTION DRUG DIVERSION"**

BEFORE THE
ENERGY AND COMMERCE SUBCOMMITTEE ON COMMERCE,
MANUFACTURING AND TRADE

U.S. HOUSE OF REPRESENTATIVES
APRIL 14, 2011

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Testimony of John M. Coster, Ph.D., R.Ph. Senior Vice President,
Government Affairs Generic Pharmaceutical Association

IMPROVING LIVES FOR LESS®

Good morning Chairwoman Bono Mack, Ranking Member Butterfield, and Members of the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade.

My name is John Coster, Senior Vice President of Government Affairs at the Generic Pharmaceutical Association (GPhA) and a licensed pharmacist. On behalf of GPhA and our member companies, thank you for calling this hearing and for the opportunity to testify on the very important subject of prescription drug diversion. We applaud your leadership on this issue.

Background on Generic Drug Industry

Let me begin by giving some background on the role of the generic drug industry in the U.S. About 75 percent of all prescriptions are filled with generic medications. Yet, generics account for only about 22 percent of total drug spending. We are proud that our industry helps make high-quality, safe, effective prescription medicines more affordable for millions of Americans while saving the health care system billions of dollars each year.

In fact, based on a 2010 analysis by IMS Health, the use of generic drugs saved the government and other purchasers of prescription drugs more than \$824 billion over the past decade. Generics now save consumers and taxpayers about \$1 billion every three days. Through competition, generic manufacturers drive down costs and support public health by providing access to affordable medicine.

GPhA's member companies manufacture FDA-approved generic versions of brand name drugs in all therapeutic categories, including prescription pain killers. We are as concerned as the Members of this Committee when medications that are made to improve lives or alleviate pain are abused.

We believe that addressing this issue will require continued coordination among Federal and State agencies, state, local, and Federal law enforcement, health professionals, drug manufacturers, pharmacists, patients and their families. Because it is a multifaceted problem, it requires a multifaceted solution.

And as we work together to shape public policy to end the misuse of pain medications, we must recognize that the overwhelming majority of individuals, including millions of seniors and cancer patients, rely on these important drug products for the proper treatment of pain.

Security of Prescription Drug Supply Chain

GPhA member companies are absolutely committed to the safe and reliable manufacturing and delivery of generic drugs. As an industry, we have invested millions of dollars into technologies and delivery systems to help assure that our products reach their destination safely and securely.

For example, with respect to opioid pain medicines, under the Federal Controlled Substances Act, the DEA has a "closed" system of distribution to prevent diversion. Our industry works with the DEA to assure that these products do not fall into the hands of abusers. For example, the DEA administers drug allotment and accountability systems to ensure against the loss and diversion of controlled substances. In addition, we are required under DEA regulations to:

- Maintain steel vaults in our manufacturing facilities of specific shape and size to protect against theft;

- Build special cages to store controlled substances with ceiling and doors made of specific reinforced material, with certain alarm systems to protect against theft;
- Restrict access to areas which manufacture or hold controlled substances;
- Develop a system to identify suspicious orders of controlled substances to guard against them falling into the wrong hands.
- Utilize systems such as GPS tracking to continuously monitor the delivery of these controlled substances once they leave secure manufacturing and storage facilities.

Manufacturers typically ship to wholesalers or distributors, who in turn sell the drugs to all kinds of health care outlets, including pharmacies, hospitals, clinics, doctors' offices, nursing homes, mail order facilities and others for prescribing by physicians and dispensing to patients and consumers. Addressing the abuse and diversion issue will require cooperation of all these parties in the supply chain.

Main Source of Prescription Diversion

Recent studies suggest that the problem of prescription drug abuse in the U.S. today primarily stems not from drugs that have escaped the legitimate supply chain or been obtained illegally through the black market, but instead from those that were legally prescribed and available in the home.

According to the 2009 National Study of Drug Use and Health¹, 55 percent of people aged 12 or older who used pain relievers nonmedically in the previous year obtained those drugs from a friend or relative for free. In addition, another 10 percent bought their drugs from a friend or relative and 5 percent took them from a friend or relative without asking. That

means that close to 70 percent of people abusing prescription drugs were doing so with products they obtained from a friend or relative.

Why are people able to share these medications with others? Shouldn't they have already taken these medications? Medication non-compliance is a huge problem in the United States.

When medications go unused, it can cost the health care system billions of dollars in other medical interventions because of medication non-adherence. It is common to find that many medicine cabinets in America are stocked with unused prescription medications. Some of these may be for occasional mild conditions, such as allergy, while others may be unused medications that were prescribed to treat the discomfort from a surgery, such as a pain medication.

Many Americans have had no recourse to return these unused medications – especially controlled substances – because Federal law prohibits the transfer of controlled substances from an ultimate user to anyone other than law enforcement. That is, patients can't return unused controlled substances to pharmacies or other non law enforcement entities at this time.

This will soon change as DEA implements the Safe and Secure Drug Disposal Act of 2010, which will permit ultimate users – such as patients with excess controlled substances in their medicine cabinets – to return them to DEA registrants such as willing pharmacies – so they can be destroyed. The law also allows for such returns of controlled substances from nursing homes, which is also a source of controlled substance waste, as many nursing home patients expire or have their medication changed before all of it is used.

Congress also enacted a policy as part of the health care reform law, which would require that medications such as brand name pain killers only be dispensed to Part D patients in nursing homes in limited supplies so to avoid waste, prevent potential diversion, and reduce costs. As is evident, there are several ways that this issue must be addressed in order for us to continue to reduce the potential for diversion of these medications.

Generic Drug Industry Efforts to Reduce Diversion

What has our industry been doing to help address this problem? In general we have tried to support efforts that are dedicated to raising awareness to the dangers of prescription drug abuse as well as the need to properly dispose of unneeded or unwanted prescription medications.

We think that education is a key component to addressing this issue. For example, we help to support efforts such as the *American Medicine Chest Challenge*, which is a community-based public health initiative, with law enforcement partnership, to raise awareness about the dangers of drug abuse and provide a nationwide day of disposal for the collection of unwanted or expired medications. We are also members of SmartRx, an educational initiative that raises awareness about the proper way to dispose of unused or unwanted medicine. GPhA is also a Board Member of the National Council on Prescription Information and Education – known as NCPiE. This is a broad-based coalition focused on addressing and raising awareness about prescription drug abuse. For example, NCPiE most recently developed a College Resource Kit to help educate students about the dangerous of prescription drug misuse.

In addition, over the last few years, our industry companies have also focused efforts in this area by joining with the brand name industry, patient groups and the FDA on working on a REMS program for long acting and extended release opioid medications.

REMS – short for Risk Evaluation and Mitigation Strategies – are special programs that are used by the FDA to help prevent adverse outcomes in patients from prescription medications.

At this point, it is not clear how FDA intends to proceed with the REMS program for these products. We believe that an efficient, effective REMS could help improve the use of these medications and address some of the abuse problems that exist. We also believe that this REMS program could be enhanced by e-prescribing, which would give physicians more information about these medications at the point of prescribing.

Conclusion

Madame Chairwoman, we applaud you for the countless hours you have devoted to raising awareness about this issue and the great work you have done to help put an end to drug diversion and misuse. You know more than anyone that the problem of prescription drug abuse in this country is a multi-faceted issue that will require a multi-faceted solution.

With the cooperation of physicians, law enforcement and others we can expand education efforts and help to ensure that parents and family members are not alone in this fight. When 70 percent of people abusing prescription drugs in this country are getting those products directly from a friend or relative, it's going to take intervention and hard work from all of us at the most personal level to really make a difference.

Thank you, Madame Chairwoman, for holding this important hearing and I would be happy to answer any questions you may have.

¹ <http://oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf>

Mrs. BONO MACK. Thank you, Dr. Coster.
Ms. Martello.

STATEMENT OF KENDRA MARTELLO

Ms. MARTELLO. Good morning. Thank you, Madam Chairman and distinguished members of the subcommittee, Ranking Member Butterfield and Congressman Lance. My name is Kendra Martello and I am pleased to offer this testimony today on behalf of the Pharmaceutical Research and Manufacturers of America, or PhRMA. PhRMA's members represent America's leading pharmaceutical research and biotechnology companies. Last year, our members alone invested over \$49 billion in discovering and developing new medicines. Industry wide, research and investment reached more than \$67 billion last year, a record.

The prescription medicines our members research and develop are life-saving and life-enhancing medicines that allow patients to live longer, healthier and more productive lives when used appropriately and as intended. It is important as we consider the non-medical use of prescription medicines that we also balance the need to maintain patient access to these medicines for legitimate medical use.

We believe addressing the public health problem of prescription drug abuse is a shared responsibility. It requires a comprehensive, consistent and sustained approach and commitment from a wide range of stakeholders including prescribers and pharmacists. No one manufacturer, brand or generic, recognizing that approximately 75 percent of the prescriptions are for generic medicines, no one trade association and no one stakeholder group is solely responsible for implementing a solution that will truly be effective. We all must work together to achieve a common goal, and PhRMA and our member companies are committed to being part of the solution.

An important part of our educational message surrounds the appropriate use of medicines, which can reduce health care costs overall. Data also show that the majority who misuse or abuse prescription medicines do obtain them from a friend or a family member. We believe that education can have a significant impact in helping to inform the public and reducing the overall rates of prescription drug abuse. We have developed four simple messages as part of our education effort on this important issue.

First, take your medication exactly as prescribed. Second, store all medicines in a safe manner out of the sight and reach of children and adolescents in particular. Third, don't share your medicines with anyone including friends or relatives. And fourth, promptly dispose of any unused medicine in a safe manner, either through the household trash or an appropriate take-back program such as the one administered by the DEA. In fact, to help further this last message, PhRMA partnered with the U.S. Fish and Wildlife Service and the American Pharmacists Association in 2007 to create the Smart Disposal Program, which educates consumers about how they may safely dispose of most medicines through the household trash.

PhRMA and our member companies have also undertaken significant educational efforts regarding prescription drug abuse. For

example, we have recently worked with the Washington Health Foundation and the State Attorney General to develop education for college students and with Dare America to help educate students in grades 5 through 12. We also believe specific educational efforts must be targeted towards prescribers and pharmacists and could help them to detect and refer for treatment those who may be abusing prescription drugs.

Other ideas that could have a significant impact on reducing the rate of non-medical use of prescription drugs: first, increase the use of and improvements to State prescription drug monitoring programs which can be an important tool in preventing and detecting abusers and referring them for treatment. Second, reauthorize NASPER, which provides grants for these State monitoring tools and which is legislation that PhRMA has supported. Third, increase penalties for and enforcement against pill mills, medicine diverters and those who go outside the legitimate medical supply chain including rogue Internet drug sellers. Fourth, work with FDA and others to facilitate the development of medicines to treat addiction and mechanisms to make medicines less susceptible to abuse. And finally, work with the DEA as it develops regulations to allow ultimate users and long-term care facilities to return controlled substance for disposal.

In conclusion, prescription medicines when used as prescribed are critical to improving and extending patient health. However, when they are misused or abused, they can be dangerous and even deadly. No one solution to this public health problem exists. Education is of critical importance and it is a key first step but we must not stop there, and all stakeholders have a role to play in helping to develop solutions. We are committed to working with the subcommittee, members of Congress and other stakeholders on this important public health issue. Thank you.

[The prepared statement of Ms. Martello follows:]

**TESTIMONY OF THE PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA (PhRMA)
BEFORE THE HOUSE ENERGY & COMMERCE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
APRIL 14, 2011**

Madame Chair, my name is Kendra Martello, Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am pleased to present this testimony on behalf of PhRMA, which represents the country's leading pharmaceutical research and biotechnology companies. Our members are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives, and are leading the way in the search for new cures and treatments. Our members alone invested an estimated \$49.4 billion in 2010 in discovering and developing new medicines. Industry-wide research and investment reached a record \$67.4 billion in 2010.

I. Introduction

When used appropriately, under the direction and care of a licensed health care professional, prescription medicines can improve and save lives. However, when used inappropriately and not as intended, devastating consequences can result. According to the most recent national data, after marijuana, prescription medicines are the most abused substance.¹ Seven million Americans over age 12 reported using prescription drugs in the past month for non-medical reasons in 2009.² Among 12 to 17 year olds and 18 to 25 year olds, prescription drugs were the second most common drug of abuse in 2009, with 3.3% of 12 to 17 year olds and 6.3 % of 18 to 25 year olds reporting using prescription drugs non-medically in the past month.³ Of particular concern, there was an increase in recent nonmedical use of prescription drugs among 18 to 25 year olds between 2008 and 2009 from 5.9 to 6.3%--even more alarming when many are leaving college and entering the workforce with this dangerous behavior. According to treatment admissions data, opiates other than heroin increased from 1 percent of admissions aged 12 and older in 1998 to 6 percent in 2008, while other prescription medicines, such as tranquilizers and sedatives, each accounted for less than 1 percent of TEDS admissions between 1998 and 2008.⁴ In addition to the human toll on families, misuse and abuse of prescription drugs

¹ *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, SAMHSA (2010).

² Substance Abuse and Mental Health Services Administration, *Results from the 2009 National Survey on Drug Use and Health: National Findings*, September 2010.

³ *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, SAMHSA (2010).

⁴ Treatment Episode Data Set 1998-2008, National Admissions to Substance Abuse Treatment Services, SAMHSA, April 2010.

result in higher costs to the health care system in terms of avoidable hospitalizations, increased emergency room visits, and costs related to addiction treatment.

PhRMA supports efforts to bring attention to this issue and recognizes the identified need for broad stakeholder engagement to help respond to this important public health matter. PhRMA and our member companies are actively engaged in a range of efforts to help ensure that prescription medicines are used appropriately and to reduce prescription drug abuse. At the same time, it must be recognized that national data on the abuse of prescription drugs reinforces the importance of improving communications between providers and patients as well as the need to improve patient monitoring among all health care stakeholders. According to the National Institute on Drug Abuse (NIDA), the three types of prescription drugs most commonly abused are opioids, central nervous system (CNS) depressants, and stimulants.⁵ While many of the medicines included in these categories are produced by brand name or innovator manufacturers, it is important to recognize that among these drugs, in 2010, 88.5% of prescriptions were for generic drugs with only 11.5% of the prescriptions for brand name medicines.⁶ For opioids, 92.4% of 2010 prescriptions were for generics; for CNS depressants, 93.4%, and for stimulants, 47.4%.⁷ These statistics reinforce that addressing the problem of non-medical use of prescription drugs is a shared responsibility and there is no single solution. Instead, collaborative efforts must be undertaken between the federal government, PhRMA, the Generic Pharmaceutical Association, American Medical Association, and other relevant associations and stakeholder groups – including healthcare providers, law enforcement, faith-based and other community organizations, schools and colleges, parents, pharmacists, and state and local governments – to address this public health issue.

II. Background

It is critical that policies aimed at preventing prescription drug abuse do not unintentionally create barriers to patient access to needed medicines. PhRMA and its members urge that any evaluation of policies to help reduce misuse and abuse of prescription medicines must also ensure continued patient access to needed prescription medicines. Potential barriers to patient access include poor or insufficient training of health care workers regarding appropriate prescribing practices, unnecessarily restrictive drug control regulations and practices which may impede good clinical care, and fear among health workers of the potential for legal sanctions for legitimate medical practice which may lead to undertreatment (see, for example, Gatchel 2010).⁸ Articles in medical literature and patient groups have raised concerns about increasing physician hesitancy to prescribe certain medications. As just one example, a survey of physicians regarding pain management found “that concerns of potential abuse or addiction often affect how pain is

⁵ National Institute on Drug Abuse, Prescription Drugs: Abuse and Addiction, August 2005, 2010 NSDUH Methodology Section.

⁶ PhRMA analysis of retail claims data for January-December 2010 for the classes of most commonly abused prescription drugs based on SDI Health's Vector One National Audit (VONA), April 8, 2011.

⁷ PhRMA analysis of retail claims data for January-December 2010 for the classes of most commonly abused prescription drugs based on SDI Health's Vector One National Audit (VONA), April 8, 2011.

⁸ Gatchel, R.J. Is fear of prescription drug abuse resulting in sufferers of chronic pain being undertreated? Expert Rev. Neurotherapeutics 2010;10(5):637-39.

pharmacologically treated” by physicians.”⁹ The end result of such practices is that millions of Americans who suffer significant or chronic pain are likely being under-treated either due to inadequate training or concerns about the potential for prescription drug abuse.

Experts agree that appropriate use of medicines plays a central role in both the quality of health care patients receive and the quality of the lives they lead. Numerous studies have reported that appropriate prescribing of medication therapy and adherence to that therapy improves quality and outcomes, while often reducing total costs and use of other, often more expensive, health services.¹⁰ One study found that non-adherence has been shown to result in \$100 billion each year in excess hospitalizations alone.¹¹ Stakeholders from all sectors of health care, including researchers, payers, employers, patient advocates, and health care practitioners, agree that non-adherence is a serious problem that should be solved. Supporting better communication between providers and patients is a key step to improving adherence as well as enhancing the patient’s understanding about his or her disease or condition, its course, and its related target laboratory test values. Providers, when given support by the proper tools and systems, can play a central role in helping patients understand how to take their medicines properly. For instance, one main cause of preventable hospital readmissions is poor communication with patients during the discharge process, especially regarding medications.¹²

Public policy discussions about the appropriate role of prescription medicines in health care often assume that medicines are widely overused. The importance of ensuring appropriate use of medicines through appropriate training of health care providers cannot be overstated. As policies around prescription drug abuse are discussed, it is important to recognize that, while research indicating overuse of prescription drugs is limited, there is much evidence that large percentages of patients underuse needed medical care, including prescription medicines, for many serious health conditions. Efforts to stimulate better prescribing of and adherence to essential medications improves health, averting costly emergency department visits and hospitalizations, and improving quality of life and productivity.¹³

Long-term policy solutions to ensuring appropriate use and reducing the potential for abuse will require substantial ongoing education, training, and responsibility among a

⁹ McCarberg, BH et al. “The Impact of Pain on Quality of Life and the Unmet Needs of Pain Management: Results From Pain Sufferers and Physicians Participating in an Internet Survey,” *American Journal of Therapeutics* 2008;15(4): 312-20.,

¹⁰ Examples include, but are not limited to: W.H. Shrank, et al. “A Blueprint for Pharmacy Benefit Managers to Increase Value,” *American Journal of Managed Care*, February, 2009.; D. Cutler, et al., “The Value of Antihypertensive Drugs: A Perspective on Medical Innovation,” *Health Affairs*, January/ February 2007.; M. Cloutier, et al., “Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity,” *Pediatrics*, November 2006.; M. Sokol et al., “Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost,” *Medical Care*, June 2005.

¹¹ New England Healthcare Institute, “Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease,” A NEHI Research Brief, August 2009.

¹² B.W. Jack et al., “A Reengineered Hospital Discharge Program to Decrease Rehospitalization,” *Annals of Internal Medicine*, February 2009.

¹³ See, for example, M. Sokol et al., “Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost,” *Medical Care*, June 2005; B.W. Jack et al., “A Reengineered Hospital Discharge Program to Decrease Rehospitalization,” *Annals of Internal Medicine*, February 2009; New England Healthcare Institute, “Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease,” A NEHI Research Brief, August 2009.

broad range of stakeholders, including patients, physicians, nurses, pharmacists, insurers and others involved in health care delivery. Any policies to prevent prescription drug abuse must recognize and ensure that patients with a legitimate need continue to receive their medicines.

III. Selected Federal Activities

Overview of National Policy Related to Prescription Drug Abuse

The 2010 National Drug Control Strategy identifies a number of objectives related to the diversion, abuse, or misuse of, and addiction to, prescription drugs including:

- Regulating and monitoring the prescribing of drugs with potential for abuse;
- Shutting down illegal pharmacies and fraudulent clinics;
- Expanding prescription drug monitoring programs;
- Removing unused medications from the home;
- Informing the public of the risks of prescription drug abuse and overdose; and
- Working with physicians to achieve consensus standards on prescribing.¹⁴

PhRMA supports these efforts and a comprehensive approach involving a range of stakeholders to help address this public health issue.

Overview of Select Provisions from PPACA

There are a number of provisions in the recently enacted Patient Protection and Affordable Health Care Act (PPACA) that may impact efforts to reduce prescription drug abuse and which should be taken into consideration in ensuring a comprehensive approach to preventing prescription drug abuse. For example, section 4305 of PPACA¹⁵ establishes three strategies to advance research and treatment in the field of pain care. First, it required the Secretary to enter into an agreement with the Institute of Medicine (IOM)¹⁶ to examine the state of pain research and treatment and to establish an agenda for action to improve the state of pain care research, education, and clinical care.¹⁷ We understand that IOM is about to hold its fifth meeting on its consensus study “Advancing Pain Research, Care, and Education”¹⁸ and look forward to findings and recommendations from the consensus study, which must be submitted to Congress no later than June 30, 2011. Second, PPACA added section 409J to the PHSA to authorize the Pain Consortium of the National Institutes of Health (NIH) to enhance and coordinate basic and clinical research on the causes of and potential treatments for pain. Within one

¹⁴ ONDCP. 2010 National Drug Control Strategy (<http://www.whitehousedrugpolicy.gov/strategy>).

¹⁵ The Reconciliation Amendments did not modify this provision.

¹⁶ If the Institute of Medicine declines to participate, the Secretary may enter into an agreement with another appropriate entity. Pub. L. No. 111-148 § 4305(a)(3).

¹⁷ This section authorizes Congress to appropriate sums necessary to carry out the Conference on Pain for each of fiscal years 2010 and 2011. Pub. L. No. 111-148 § 4305(a)(5).

¹⁸ IOM Consensus Study “Advancing Pain Research, Care, and Education,” <http://www.iom.edu/Activities/PublicHealth/PainResearch.aspx>

year of enactment, the Secretary also must establish an Interagency Pain Research Coordinating Committee to coordinate all efforts within the Department of Health and Human Services (HHS) and other federal agencies that relate to pain research. Third, PPACA added section 759 to the PHSA to authorize the Secretary to make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.¹⁹

Other Relevant Federal Laws and Activities

Risk Evaluation and Mitigation Strategy (REMS) for Opioid Products: The Food and Drug Administration (FDA) has been considering the development of a REMS to reduce the abuse of long-acting and extended-release opioids, which are a critical treatment option for pain management. The proposed REMS has yet to be put in place but FDA is considering several elements such as prescriber training, information for patients, and periodic effectiveness assessments.

Prescription Drug Take-Back Programs: Some states and localities have organized a variety of different voluntary prescription drug take-back programs to help facilitate secure consumer disposal of unwanted or expired prescription medicines. These types of programs can take many forms: a one-day event with or without a law enforcement presence, a mail back program, or an ongoing collection event. The Drug Enforcement Administration (DEA) is currently drafting proposed regulations to permit an ultimate user to return a controlled substance for the purposes of disposal.

The DEA is planning a second voluntary national take-back day on April 30, 2011, which will consist of local events at which law enforcement officers will be present at all times to monitor the items collected, along with educational information on prescription drug abuse. Other voluntary one-day collection events exist as well, such as the America's Medicine Chest Challenge. That program, which occurred on November 13, 2010, also involved consumer education.

In addition, PhRMA believes that any prescription drug take-back program must adequately protect against the very real risks that prescription drugs, including controlled substances, could be diverted for abuse or misuse. Any take-back program must also be coupled with a comprehensive educational effort that instructs stakeholders on key issues regarding prescription drug abuse. Finally, we are concerned that ongoing collection events at local pharmacies could facilitate medicines fraud and abuse, particularly if a person who gained access to collected medicines, and then resold them to unscrupulous buyers, and/or attempted to bill government programs for collected and/or resold products.

¹⁹ This section authorizes Congress to appropriate sums necessary to carry out the award program for each of the fiscal years 2010 through 2012. Pub. L. No. 111-148 § 4305(c).

IV. Developing a Comprehensive and Balanced Approach to Prescription Drug Abuse: Discussion of Potential Policy Options

The nation's leading pharmaceutical research and biotechnology companies are dedicated to developing safe and effective medicines to save and improve the lives of patients. Our key goals are to promote health care access for all Americans, including a commitment to health care quality, increased emphasis on disease prevention, and continued medical progress through advances in research. Our industry is committed to helping to educate relevant stakeholders on the appropriate use of medicines and to preventing the abuse of prescription medicines, and we look forward to working with Congress, the Administration and other stakeholders on efforts to help reduce and prevent prescription drug misuse and abuse. Public policy related to preventing prescription medicine abuse must:

- 1) Educate the public regarding the dangers of misusing and abusing prescription medicines while also educating and equipping youth influencers (including parents, grandparents, teachers, and health care providers) and all health care stakeholders with the necessary knowledge and skills to deter abuse of prescription medicines, identify those in need of treatment, and provide appropriate treatment options when appropriate.
- 2) Any policies to prevent prescription drug abuse must recognize and ensure that patients with a legitimate health need continue to receive the medicines they are prescribed.
- 3) Require a comprehensive approach and sustained commitment from all relevant health care stakeholders ranging from federal, state, and local governments to innovator and generic drug companies, to the broad range of health care providers that interact with patients, to educators, family members, and others across the community.

PhRMA offers the following policy ideas for consideration as part of a comprehensive national strategy aimed at reducing and preventing prescription drug abuse.

Expand existing and develop additional educational and awareness efforts for the public, health care stakeholders, and others.

Existing educational efforts could be expanded and the development and implementation of additional outreach campaigns to educate all relevant stakeholders about prescription drug abuse should be considered. Framing the issue as one that implicates the public health could also help educate Americans about the dangers of abuse of prescription medicines. While education is an important first step, it must be sustained and consistent, and reach a multitude of audiences, to be truly effective. And, while education is of critical importance, we must not stop there.

As background, the 2010 National Drug Control Strategy identifies several targets for education: (1) the public about the risks of prescription drug abuse and overdose, (2)

physicians via consensus standards to inform prescribing practices, and (3) those involved in prescribing via prescription drug monitoring programs (PDMPs). While these are important groups, there are many more stakeholders who have a role to play in preventing and reducing prescription drug abuse.²⁰ Regarding physicians as an educational target, we expect that the results of the IOM consensus study will help inform potential revisions to quality standards in treatment guidelines by various physician specialties. We also recognize that a wide range of coalitions and collaborative efforts have been developed that focus on preventing prescription drug abuse. Additionally, use of measurable performance outcomes could also help facilitate the development of a robust national network of organizations with prevention of prescription drug abuse as their core mission, and could help facilitate the expansion of existing collaborative efforts among various stakeholders.

These efforts should be complemented by educational activities related to the appropriate use of medicines with the goal of all patients monitored and supported effectively across the health care system. All health care stakeholders – not just physicians and pharmacists – who have access to patients or patient data have a responsibility to promote appropriate use of medicines and help identify and prevent inappropriate prescribing and abuse.

Enhance efforts to promote prevention, screening, brief intervention and referral for treatment of prescription drug abuse throughout the health care system.

There are four key stages at which the problem of prescription drug abuse can be impacted: prevention, screening, early intervention, and treatment. Through PPACA, Congress recognized the importance of ensuring addiction and mental health benefits. This is an important first step that could be enhanced by the assessment of the adequacy of current screening efforts across health care stakeholders. Such an assessment could inform the development of more robust screening and intervention efforts. The development of a cross-cutting strategy to address prescription drug abuse could help ensure adequate resources and attention are devoted to prevention, screening, early intervention, and treatment. Adequate infrastructure investments in the health care system could help connect Americans to prevention, early screening, intervention and treatment options. At the same time, it is also critical to ensure that such efforts do not unintentionally reduce patient access to medicines or negatively impact their medical treatment.

Working with relevant stakeholders, Congress could also explore incentives for ensuring that screening for prescription drug abuse is incorporated into routine interactions in the health care system, e.g., screening could be incorporated into medical and dental visits by asking about substance abuse history, current prescription drug use, and reasons. In

²⁰ For example, in a Drug Benefit News article representatives of pharmacy benefit plans acknowledged that payers and plans have a large responsibility in addressing prescription drug abuse, and identified a number of potential areas for payers to focus on, including increasing the frequency of monitoring of patients using controlled prescription medicines, promoting the use of consensus guidelines, developing additional educational and awareness efforts, and making better use of medication history to identify potential prescription drug abuse. Drug Benefit News. PBMs, Payers Need More Focus on Curbing Spike in Rx Pain Med Abuse, July 30, 2010 (vol. 11, no. 15).

addition, all health care providers should be educated regarding the signs of addiction and to be alert to drug seeking behaviors, including "doctor shopping." As another example, the Centers for Medicaid and Medicare Services (CMS) could explore incentives for the use of electronic health records (EHRs) to allow pharmacy medication data to auto-populate EHRs to ensure that the use of EHR technology improves the quality of patient care. Identifying new ways to facilitate electronic exchange of pharmacy claims data, as well as other medical data, would facilitate a more accurate picture of the patient's medication history by allowing providers to view a patient's active medication list and history within the EHR, resolve any identified discrepancies, compare any new medications with the list, receive prompts about medication interactions or allergies, and easily share the updated and verified information with the patient and other appropriate providers.

We support related efforts by the Substance Abuse and Mental Health Services Administration (SAMHSA) to consider how health information technology can be incorporated into a broad range of activities that include but are not limited to exploring the use of pharmacy and medical provider information from individual State PDMPs, and NASPER to inform state and community treatment and prevention programs, including community coalitions, to identify and provide local, real time information regarding questionable prescribing practices.

Assess the effectiveness of PDMPs and explore enhancements.

Federal law provides grants to the states to create prescription drug monitoring programs (PDMPs), which are databases in which medical professionals enter information related to prescription medicines identified as controlled substances by the DEA. PDMPs can help prevent abusers from obtaining prescriptions from multiple doctors and help identify inappropriate prescribing patterns. According to the National Alliance for Model State Drug Laws, as of July 15, 2010, 43 states have enacted legislation enabling the establishment of a PDMP, of which, 33 states have operational programs.²¹

While federal law sets out certain parameters for states to receive grants for PDMPs, the specific attributes of PDMPs vary widely across the states. In addition, PDMPs vary in terms of the outcome measures of interest. For PDMPs applying for federal funding, the Bureau of Justice Assistance has identified the principal impact measure as simply a reduction in the rate at which members of the general population use prescription drugs inappropriately to be based on National Survey on Drug Use and Health prevalence data.²² Other PDMPs may identify as desired outcomes (1) an increase in the number of referrals to treatment, and (2) a reduction in the number of prescribers who engage in inappropriate behavior.

²¹ National Alliance for Model State Drug Laws. Status of State Prescription Drug Monitoring Programs. <http://www.namsdl.org/documents/StatusofStatesJuly152010.pdf>.

²² Bureau of Justice Assistance. Guidance for Harold Rogers Prescription Drug Monitoring Program (PDMP) Grantees on Responding to Performance Measures (<http://www.ojp.usdoj.gov/BJA/pdf/PDMPPerfMeasureGuide.pdf>).

Programs and initiatives to promote removal of unused and expired medicines from the home are generally implemented with the goal of reducing the misuse and abuse of pharmaceuticals by reducing the access to such medicines in the home and/or preventing accidental overdoses. To fully assess the benefit of a program and, by extension, its cost-effectiveness, we continue to urge evaluations of their efficacy relative to its stated goal. As such, any discussion of program outcomes should be augmented with a consideration of the programs' goals and their relationship with those measurable outcomes.

As part of a comprehensive strategy designed to reduce and/or prevent prescription drug abuse, the utility and effectiveness of PDMPs to assist in the identification of inappropriate prescribing practices and the identification of prescription drug abusers should be assessed. Key considerations with respect to assessing the utility of PDMPs in reducing or preventing prescription drug abuse include:

- Interoperability across state lines,
- Appropriately populated with data from prescribers,
- Adequate funding and routine updating to serve as a reliable data source,
- Operate as “real-time” databases or static data files,
- Outcome measures tracked by the state that are appropriately matched to identifiable policy goals such as increasing the number of referrals for treatment,
- Assessment of extent to which PDMPs are incorporated into health care providers' clinical practices,
- Assessment of provider perspectives on PDMP effectiveness and administrative burden;
- Detailed outcome assessments for providers using PDMPs versus those not using PDMPs, that is, how patient-level outcomes differ;²³
- An understanding regarding whether and to what extent PDMPs have impacted fraud and related criminal investigations, and
- Understanding any gaps in PDMP data resulting from mail-order and internet purchases.

Address challenges related to research and development of new medicines to treat addiction and medicines with reduced potential for abuse.

Congress could promote efforts, both in the public and private sector, to address challenges in the research, development and approval of new medicines that can treat addiction and medicines with a reduced potential for abuse. The federal agencies with key roles in the approval and oversight of prescription drugs could be regularly convened to share ideas and perspectives on their relevant roles in helping prevent prescription drug abuse and to help promote comprehensive policies that could help further the Administration's goal of reducing prescription drug abuse.

²³ Possible outcome measures could include, of those identified as abusing prescription medicines, what percentage are prosecuted and sentenced and do they have access to treatment, what percentage are referred to treatment, is there adequate treatment capacity in the community, do those identified have better treatment outcomes due to earlier intervention in the drug abuse cycle, do those identified have fewer emergency department visits and hospitalizations.

Another potential way to address challenges related to medication development would be for the FDA to provide additional guidance to sponsors on the clinical trial and approval requirements for products with abuse-resistant formulations/dosing regimens. At the same time, however, any new policies should not present potential barriers to patient access to needed medicines.

Medications to Treat Addictions

A number of promising medicines are in the pipeline to treat addiction ranging from vaccines for nicotine and cocaine addiction to medicines to treat alcoholism and opioid dependence, as well as combination medicines and personalized medicines. However, research and development of medicines remains costly, risky, and very challenging, and clinical trials are becoming more complex.²⁴ The complexities related to developing medicines to treat addiction are compounded by challenges related to clinical trial recruitment and retention, ensuring patient access to addiction medicines, and obtaining adequate reimbursement and coverage of addiction medicines. While it is important for the public and private sector to continue to explore ways to develop new medicines to treat addiction, it is equally important to ensure access to these medicines and other treatment services, including via education of the health care community regarding how to screen for and treat drug abuse. We urge an increased emphasis within HHS and with private payers to address this ongoing challenge and to continue to explore how to further incentivize research and development of medicines to treat addiction.

Medications with Reduced Potential for Abuse

The biopharmaceutical industry faces similar issues in the development of medicines that are abuse resistant or deterrent. Reformulations, for example, can decrease abuse potential but require substantial research and development investment to demonstrate safety and efficacy with no guarantee of approval by the FDA. The lack of clear standards for assessing tamper-resistance has resulted in an unpredictable regulatory process. In addition, once approved, there is no guarantee that pharmacy benefit managers will favorably place or include these products in their formularies. In developing a comprehensive prescription drug abuse policy, resolution of potential barriers to research and development in this area is an important element.

Promote the enforcement of existing laws that can help deter abuse of prescription drugs as a key law enforcement priority.

Congress is uniquely positioned to encourage state, local, and federal law enforcement officials to use their full arsenal of existing enforcement authorities to deter prescription drug abuse. By increasing the emphasis on the enforcement of existing laws, financial incentives for illegal activities will be reduced, and the risks for those seeking to divert and profit from the illegal sale of prescription medicines will be increased. Areas of focus could include:

²⁴ See, for example, J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007.

- Increased enforcement of existing prohibitions on sales of prescription drugs without a doctor's prescription or without an in-person medical evaluation could be encouraged.
- Consider limiting online sales of prescription medicines only to those Internet sites operating in compliance with all state pharmacy laws, per a recent report from the Joint Strategic Plan on Intellectual Property Enforcement, which references ongoing U.S. government efforts to prohibit paid advertising for illegal on-line pharmaceutical vendors and to explore means to ensure those operating in violation of relevant laws can be subject "to the full reach of law enforcement jurisdiction."²⁵
- Ensure adequate resources for training law enforcement in pursuing investigations in this area and promoting information-sharing across jurisdictions as appropriate to ensure successful investigation and prosecution of health care fraud.

Expand educational efforts related to the proper disposal of unused and expired prescription medicines and secure storage of prescription medicines.

As discussed previously, PhRMA believes that prompt and proper disposal of unused and expired medicines is an important tool to help prevent the diversion and abuse of prescription medicines. Equally important is the secure storage of prescription medicines for a number of reasons, including to help consumers organize and keep track of their prescription medicines and to ensure that a child, teenager, or even a stranger does not gain inappropriate access to prescription medicines. In addition, ensuring medicines are stored properly will prevent damage to medicines and help reduce the potential for accidental injury. Efforts such as the SMARxT DISPOSAL campaign, a partnership between PhRMA, the U.S. Fish and Wildlife Service and the American Pharmacists Association, educate consumers on how to quickly and easily dispose of any unused medicines in a safe and environmentally protective manner in their household trash.

V. Spotlight on Select Activities by PhRMA Related to Preventing Prescription Drug Abuse

As stated, PhRMA views increasing awareness and education as fundamental to the prevention of prescription drug abuse. We have worked collaboratively with the medical community, drug abuse prevention organizations, and others on educational efforts to prevent the misuse and abuse of prescription drugs. Select examples of PhRMA initiatives include those described below.

Development of a school curriculum to prevent abuse of prescription and over-the-counter drugs. The curriculum is comprised of components for students (in grades 5 through 12) as well as presentations for parents (information available at <http://www.dare-america.com/home/features/documents/RxOTCInfoFlyer.pdf>). This curriculum was created by D.A.R.E. America (Drug Abuse Resistance Education), with

²⁵ "2010 Joint Strategic Plan on Intellectual Property Enforcement," (June 2010), available at: < http://www.whitehouse.gov/sites/default/files/omb/assets/intellectualproperty/intellectualproperty_strategic_plan.pdf >, at 17.

the support and expertise of law enforcement officials; PhRMA; Abbott; the Consumer Healthcare Products Association (CHPA); and a number of other organizations, including the White House Office of National Drug Control Policy (ONDCP), the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), NIDA, the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT) and the Partnership for a Drugfree.org.

A tool kit and brochure to raise awareness of the dangers of abusing over-the-counter cough medicines, alcohol, and prescription drugs. In collaboration with the Community Anti-Drug Coalitions of America (CADCA) and CHPA, PhRMA developed a 16-page newspaper supplement distributed nationwide as well as online, entitled "Stay Smart, Don't Start: The Truth About Drugs and Alcohol" (available at <http://www.nieteacher.org/staysmart.pdf>) to educate youth and parents about the dangers of abusing over-the-counter cough medicine and prescription drugs as well as a brochure targeting teenagers entitled "The Real Truth About Rx and OTC Medicine Abuse" (available at <http://www.otcsafety.org/Media/129096000527317246.pdf>).

Study of health care provider attitudes in collaboration with Partnership for a Drug-Free America (PDFA). PhRMA and PDFA (now Partnership at Drug Free.org) assessed healthcare provider attitudes as to their need for more information on prescription drug abuse for their patients. Many specialties stated they received information through their journals or their respective professional associations but several groups expressed the need for more patient-friendly materials for use in the emergency room, dental offices, orthopedic offices, nurse practitioner locations, etc. Through these interviews, we were able to assess the need for additional materials and educational opportunities, as well as guide them to valuable resources within the prevention and treatment community.

Educational tools and guidelines to prevent the misuse and abuse of prescription medicines targeting undergraduate and graduate students. In collaboration with the Washington Health Foundation, a program to improve health for the people of Washington state, PhRMA along with a diverse group of stakeholders recently unveiled a new initiative that will help educate college students in Washington state about the proper use of medicines and provide resources to help prevent the abuse and misuse of prescription drugs and over-the-counter products. The tools and guidelines available online (available at <http://www.whf.org/my-health>) were developed by other young people and the site is exclusively maintained by current undergraduate and graduate student interns from across the state. Key elements of the Washington state initiative include the use of resident assistants in college dormitories to conduct peer-to-peer education and the use of university healthcare clinic staff to increase awareness of the misuse or abuse of prescription drugs.

Educational efforts related to the proper disposal of unused and expired prescription medicines and secure storage of prescription medicines. According to the 2009 National Household Survey on Drug Use and Health, 55.3 percent of those who reported non-medical use of prescription pain relievers reported that they obtained them

from a friend or relative for free, if you also include the number who reported buying them from a friend or relative, or taking them from a friend or relative without asking the percentage increases to 70.2 percent in 2008.²⁶ PhRMA supports educational efforts to promote prompt and responsible disposal of unused and expired prescription medicines. As a practical matter, any medicine that appears damaged, discolored, or otherwise different from when the prescription was initially filled should be disposed of promptly and properly. PhRMA partnered with the U.S. Fish and Wildlife Service and the American Pharmacists Association to create the SMARxT DISPOSAL program (see, for example, www.SMARxTDISPOSAL.net) to help educate consumers about how to properly and safely dispose of medicines in an environmentally-friendly manner. This educational program outlines how in just a few small steps, consumers can promptly, safely, quickly and easily dispose of any unused or expired medicines in their home.

VI. Conclusion

In conclusion, tackling the increasing problem of prescription drug abuse is a shared responsibility. There is no single solution that will effectively reduce or eliminate the rates of prescription drug misuse or abuse. PhRMA stands ready to engage in the dialogue around this public health issue and to work with relevant stakeholders to help address the problem.

Prescription medicines save and improve lives every day but when used inappropriately, devastating consequences can result. At the same time, patients need continued, uninterrupted access to the prescription medicines that allow them to live longer, healthier lives. Any policies in this area should not unintentionally create barriers to patient access to needed medicines. Appropriate use of medicines is an important issue to all of our member companies, and we look forward to working with the Subcommittee, members of Congress, and other stakeholders on these important issues.

²⁶ *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*. SAMHSA (2010).

²⁷ Substance Abuse and Mental Health Services Administration, *Results from the 2009 National Survey on Drug Use and Health: National Findings*, September 2010; table 6.47B.

Mrs. BONO MACK. Thank you.
Mr. Mayer.

STATEMENT OF MICHAEL S. MAYER

Mr. MAYER. Madam Chair, Ranking Member Butterfield and Mr. Lance, I appreciate the opportunity to appear before you today. I am here today representing MedReturn. MedReturn is a subsidiary of Frank Mayer and Associates, an 80-year-old family-owned company in Grafton, Wisconsin. Our core business is designing and manufacturing in-store displayers, merchandisers and interactive kiosks for Fortune 500 companies.

Our involvement in the issue of prescription drug abuse stems from the commitment to provide a safe, secure, sustainable and environmentally friendly way to help law enforcement agencies and communities collect unwanted or expired prescription medication and over-the-counter drugs.

The genesis of MedReturn began over 3 years ago when I challenged the associates in my company to research and develop new ideas. The challenge was called WITT, Wish I'd Thought of That. As we began investigating the prescription drug disposal issue, we quickly became aware of the management of prescription medication and drugs that sit unused or expired in our medicine cabinets. We began researching and looking for existing take-back programs and realized there was no consistent method or program available. Over a 2-1/2-year period, we developed, prototyped, presented, tested, improved and produced the MedReturn drug collection unit. Noting the importance of education, we incorporated a sizable graphic panel that States and communities can customize.

We launched MedReturn at the International Association of Chiefs of Police conference in October 2010. To date, our drug collection has been placed in 50 police and sheriffs departments across 11 States. We helped implement only the second county-wide ongoing drug collection program in the United States.

Attached statements from law enforcement agencies confirm the positive response of their communities to sustained drug collection. Lieutenant Tim Doney of the Medford, Oregon, Police Department notes usage of their program is so heavy, they are emptying the collection unit at least 4 days a week. Other e-mail feedback we have received illustrates the demand for permanent medicine return programs. Sheriff David Peterson of Waushara County, Wisconsin, reports collecting 200 to 250 pounds of medication in 3 months, and Lieutenant Wayne Strong believes the Madison, Wisconsin, Police Department has collected 230 pounds in that same time frame.

What started as an effort to supplement our core business has quickly evolved in a passionate desire to be a smart part of the solution to the prescription drug abuse problem. We have devoted and continue to devote significant amounts of time and money to let State and local law enforcement agencies and community groups know we are available to answer inquiries. We know the DEA is working toward finalizing regulations that implement the Secure and Responsible Drug Disposal Act of 2010. We have talked with hundreds of law enforcement officers. Many of them are asking us how to implement their programs. Others believe the collec-

tion and disposal process is too complicated. Others insist on recording and inventorying all collected medications and others don't realize the scope of the problem.

We believe a lack of understanding may be a deterrent to establishing a permanent take-back program. We also find a varied interpretation of what constitutes safe disposal. Some departments accept pills in a bottle while others want pills placed in plastic bags. Others will hold the collected contents until the annual Take Back Day. One officer admitted he collected the drugs but then flushed them down the toilet. Ideally, we would like to refer potential users of MedReturn to a central resource that outlines Federal and State requirements and best practices.

At MedReturn, our vision is a sustainable, nationwide program as widely available as plastic, glass and paper recycling are today. By our calculation, there are some 30,000 communities that could benefit from a take-back program. We are in the process of seeking corporate or foundation partners that might speed this process.

We appreciate the amount of attention prescription drug abuse is receiving from Members of Congress and the Administration. We hope you will continue to consider the challenges of those who want to establish a sustainable drug collection program at the grassroots level. We stand ready to serve as a resource in any way that is appropriate. Thank you.

[The prepared statement of Mr. Mayer follows:]

**Summary of the Testimony of Michael S. Mayer, President, MedReturn, LLC
Before the Subcommittee on Commerce, Manufacturing and Trade
Hearing - "Warning: The Growing Danger of Prescription Drug Diversion"
April 14, 2011**

Over a 2 ½ year period, our company developed, prototyped, presented, tested, improved and produced a safe, secure and sustainable enclosure, the MedReturn Drug Disposal Unit, to collect expired and unwanted prescription medication and over the counter drugs.

We began researching and looking for existing collection and take-back programs and realized there was no consistent method or program available.

What started as an effort to supplement our core business has quickly evolved into a passionate desire to be a small part of the solution to the prescription drug abuse problem.

Feedback we have received illustrates the demand for permanent medicine return programs and a successful response in communities that have implemented one.

As a result of our continued efforts, MedReturn is in touch with many people with a stake in drug abuse prevention at the grass roots level. This vantage point gives us insights into the challenges of implementing a sustainable prescription drug take-back program and the need for clear best practices.

We have talked with hundreds of law enforcement officers. Many of them are asking us for guidance to implement their programs. We believe for some lack of understanding of how to go about implementation may be a deterrent to establishing a permanent take back program.

We also find a varied interpretation at the state and local level of what constitutes safe disposal.

In an ideal world, we would like to be able to refer users of MedReturn to a resource that clearly outlines federal requirements and best practices, links to a state agency point of coordination and state disposal regulations, and enumerates sources of funding.

At MedReturn, our vision is a sustainable nation-wide program as widely available a practice as plastic, glass and paper recycling are today. By our rough calculation there are some 30,000 localities that could benefit from ongoing drug collection, and we have only begun to scratch the surface in this country.

We hope you will continue to consider the challenges of those who want to establish a sustainable drug collection program at the grass roots level. We stand ready to serve as a resource in any way that is appropriate.



**“Warning: The Growing Danger of
Prescription Drug Diversion”**

Subcommittee on Commerce, Manufacturing, and Trade
United States House of Representatives

April 14, 2011

9:00 a.m.

2123 Rayburn House Office Building

Written Statement of
Michael S. Mayer
President
MedReturn, LLC

Madame Chair, Ranking Member Butterfield and members of the Subcommittee on Commerce, Manufacturing and Trade, I appreciate the opportunity to appear before you today. I am Mike Mayer, President of MedReturn. Our involvement in the issue of prescription drug abuse stems from the commitment to provide a safe, secure, sustainable and environmentally friendly way to help law enforcement agencies and communities collect unwanted or expired prescription medication and over the counter drugs.

MedReturn is a subsidiary of Frank Mayer & Associates, Inc., an 80 year old, family-owned company in Grafton, WI a suburb of Milwaukee. Our core business is designing and manufacturing in-store displays, merchandisers and interactive kiosks for companies such as Walmart, Nintendo, LEGO, Walgreens and Microsoft, to name a few.

The genesis of MedReturn was over 3 years ago when I challenged the associates in my company to research and develop new ideas. The challenge was called WITT (Wish I'd Thought of That). As we began investigating the prescription drug disposal issue, we quickly became aware of the magnitude of prescription medication and drugs that sit unused or expired in our medicine cabinets. It is staggering to think that over 10 million prescriptions are filled on a daily basis. The impact of their diversion manifests itself in misuse, abuse and accidental poisonings. Improper disposal contributes to the pharmaceutical waste that ends up in our environment, and we are just beginning to study those consequences.

We began researching and looking for existing collection and take-back programs and realized there was no consistent method or program available. We discovered a pharmacy in Virginia that placed a fishbowl on a counter for the public; old mailboxes repainted; open bins and

barrels; mailback envelopes and law enforcement agencies that called officers off of the street to accept expired medications. Over a 2 ½ year period, we developed, prototyped, presented, tested, improved and produced a safe, secure and sustainable enclosure to collect expired and unwanted prescription medication and over the counter drugs. Noting the importance of education, we incorporated a sizeable graphics panel that states and localities can customize to fit their objectives and policies.

We launched MedReturn at the International Association of Chiefs of Police conference in October 2010. At the writing of this testimony, our drug collection unit has been placed in 50 police and sheriff's departments across 11 states. We have appended statements to our testimony from law enforcement agencies confirming the positive response of their communities to the availability of an ongoing collection program. Lieutenant Tim Doney of the Medford, Oregon Police Department notes usage of their program is so heavy they are emptying the collection unit at least four days a week.

Other email feedback we have received illustrates the demand for permanent medicine return programs. Sheriff David Peterson of Waushara County, Wisconsin reports collecting 200 to 250 pounds of medication in three months, and Lieutenant Wayne Strong believes the Madison, Wisconsin police department has collected 230 pounds in that time period.

We helped implement the second county-wide ongoing drug collection program in the US. In establishing that program, Lieutenant Rodney Galbraith of the Ozaukee County, Wisconsin Sheriff's Department said, "From my perspective if the take back program can prevent even one tragic overdose death then it will have been worth it." We are in discussion with a state

that wants to place 5 test units prior to implementing a state-wide program. And we continue to fulfill individual law enforcement orders on a daily basis.

What started as an effort to supplement our core business has quickly evolved into a passionate desire to be a small part of the solution to the prescription drug abuse problem. We have devoted and continue to devote significant amounts of time and money to let state and local law enforcement agencies and community groups know we are available and to answer their inquiries. We know the DEA is working toward finalizing regulations that implement the Secure and Responsible Drug Disposal Act of 2010 that members of this subcommittee supported. We also know it will be some time before the regulations and policies are in place. We applaud the DEA and White House Office on Drug Control Policy for establishing one-day take back programs while working to make sustainable programs commonplace.

This whole realm of government regulation is new to us. We are more accustomed to dealing with the exacting requirements of Underwriters Laboratories (UL) than federal and state governments. Nonetheless, we are here today because we would like the members of this subcommittee and all those who touch the issue of prescription drug take-back programs to know that it could be easier for law enforcement agencies and communities to implement an always available program than it currently is.

We see the implementation of medication collection programs as a great opportunity for members of the community to coalesce around the cause of protecting a vulnerable population, our teens and young adults. A true community-wide effort can enlist groups ranging from parents, school administrators, business people, anti-drug coalitions,

environmental interests, pharmacists, and law enforcement. In the end, it is law enforcement that is on the front lines of medication return.

Those of us in this room know that only law enforcement officers are allowed to receive unwanted or expired prescription drugs. We have talked with hundreds of law enforcement officers. Many of them are asking us how to implement their programs; others believe the collection and disposal process is too complicated; others insist on recording and inventorying all collected medications; and others don't realize the scope of the prescription drug abuse problem. We believe for some lack of understanding may be a deterrent to establishing a permanent take back program.

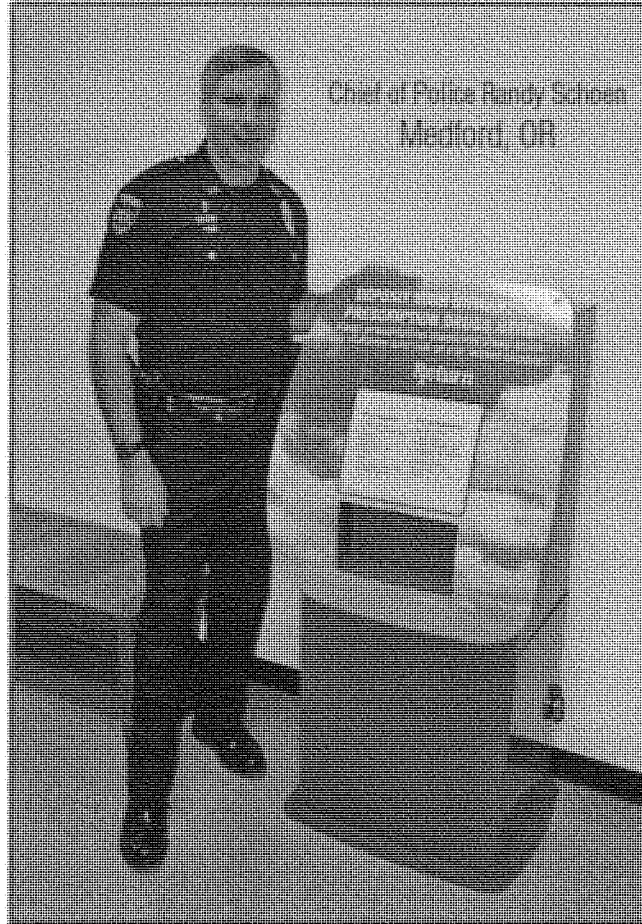
We also find a varied interpretation of what constitutes safe disposal. Some departments accept pills in the bottle (name removed or marked out because of HIPA laws) while others request individuals to empty just pill contents into a plastic bag before depositing into the collection unit. Others will hold the collected contents until the annual take-back day. One officer admitted that he collected the drugs to get them out of harm's way but then flushed them down the toilet.

In an ideal world, we would like to be able to refer users of MedReturn to a resource that clearly outlines federal requirements and best practices, links to a state agency point of coordination and state disposal regulations, and enumerates sources of funding. The Office of National Drug Control Policy has performed a helpful service listing an agency for each state that may be a touch point on this issue. Often these links lead to the home page of a state website, but quite a bit of searching is required to discover what may be going on in the area of

drug take-back at the state level. Local law enforcement sometimes doesn't realize they can look beyond the resources of law enforcement to implement a program. In reality there are many agencies that impact this issue, even though drug take back may not be a specifically enumerated activity.

The statistics illustrating the magnitude of prescription drug abuse are staggering. Over 27,000 drug abuse deaths occurred in 2007. Every day 2500 teens use prescription drugs non-medically for the first time. We know in the future states and communities will be able to move more quickly to establish permanent drug take back programs. At MedReturn, our vision is a sustainable nation-wide program as widely available a practice as plastic, glass and paper recycling are today. By our rough calculation there are some 30,000 localities that could benefit from ongoing drug collection, and we have only begun to scratch the surface in this country. We are in the process of seeking corporate or foundation partners that might speed this process along.

We appreciate the amount of attention prescription drug abuse is receiving from Members of Congress and the Administration. We hope you will continue to consider the challenges of those who want to establish a sustainable drug collection program at the grass roots level. We stand ready to serve as a resource in any way that is appropriate.



Contact

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President, MedReturn LLC
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Grafton, Wisconsin 53024

mike.mayer@medreturn.com
www.medreturn.com

Phone: 877 218-0990



POLICE INVESTIGATIONS



CITY OF MEDFORD

411 WEST 8TH STREET
MEDFORD, OR 97501PHONE: (541) 774-2230
FAX: (541) 774-2570
City Web Page: www.ci.medford.or.us
PoliceE-Mail: padmed@ci.medford.or.us

April 8, 2011

Re: Drug Collection Units/Turn-In Events**To Whom It May Concern:**

In the spring of 2010, the Medford Oregon Police Department was approached by the Jackson County Medical Alliance (Non-Profit/Philanthropic Organization) about partnering for a prescription drug turn-in event to be held at the Rogue Valley Mall. The idea behind the program was to get unused and expired prescription drugs out of the medicine cabinet and destroyed without having them litter our landfills and/or waterways/systems. This event was a huge success with almost 500 pounds collected.

In late September, we partnered with the DEA on the national turn-back day and again collected several hundred pounds.

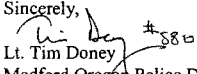
At that time, the Medford Police Department decided to research the purchase and installation of a dedicated and fixed prescription drug turn-in box/receptacle to be located in our lobby. In October 2010, department representatives attended the IACP conference in Orlando Florida and entered a drawing in which the department won a MedReturn Drug Collection Unit that has since been installed in our department lobby. This was advertised locally by the media and literally within the first 10-15 minutes after being installed, we had citizens dropping outdated/unused prescription medication in the box. It has seen a steady stream of discarded medications since that date which has necessitated that it be emptied no less than 4 days a week.

In November 2010, we participated in yet another community collection drive for unused/expired prescription medications and currently are in preparation for the upcoming April 30th National Turn-In event sponsored by the DEA.

This program is extremely popular with the community and media. In addition, we have been contacted by both local landfill and the wastewater treatment operators who have expressed their appreciation and support for this important program. We believe it lessens the chances of theft and abuse of prescription medications in addition to helping our environment by keeping the medications out of our landfills and waterways via the wastewater treatment system.

If I can be of further assistance, please contact me at 541-774-2205.

Sincerely,


Lt. Tim Doney #580
Medford Oregon Police Department
Tim.Doney@cityofmedford.org



Ozaukee County Sheriff's Office

Maury Straub, Sheriff

1201 S. Spring Street • P.O. Box 245 • Port Washington, Wisconsin 53074-0245

4/11/11

United States House of Representatives
Subcommittee on Manufacturing, Commerce and Trade
Washington DC, 20515

Greetings,

I was asked to provide comments on Ozaukee County's Law Enforcement initiative of taking back unused prescription medications at each law enforcement agency facility in Ozaukee County. In February of 2011 Ozaukee County Law Enforcement agencies adopted a county wide program utilizing a collection enclosure provided by MedReturn, a local manufacturing firm, which allows citizens to deposit unused medications at their local law enforcement agency.

As the commander of the Ozaukee County Sheriff's Department's Anti Drug Task Force I have found that the abuse of prescription medications has become one of the top two drug abuse problems in Ozaukee County. Prescription drug abuse is often a precursor to heroin abuse. The deadly combination of prescription medication and heroin overdoses are destroying the lives and families of too many Ozaukee County residents.

The program effectively allows families an environmental friendly option in disposing of unused medications in a timely fashion. It assures that family members, friends or other guest who may be an addict don't have an opportunity to get their hands on unused prescription medications.

From my perspective if the take back program can prevent even one tragic overdose death then it will have been worth it.

If I can be of any further assistance please feel free to contact me and thank you for the opportunity to share my comments.

Lt. Rodney Galbraith
Ozaukee County Sheriff's Department
Detective Bureau/Drug Unit
262-284-8468
262-238-8468



John H. Lucking, Jr.
Chief Of Police

SOLDOTNA POLICE DEPARTMENT

44510 Sterling Highway
Soldotna, Alaska 99669



TEL: (907) 262-4455
FAX: (907) 262-4427

April 10, 2011

Mr. Mike Mayer, President/COO
MedReturn, LLC
PO Box 902
Grafton, WI 53024

Dear Mr. Mayer,

In response to your query, I am writing to tell you that we are very pleased with the community response to our Drug Return Program. Since installing our Medreturn box in late January, we have taken in approximately 900 tablets of controlled substance prescription medication. We are pleased to know that these drugs will now be disposed of properly and we won't have to fear them causing contamination of local groundwater or our adjacent, world renowned Kenai River King Salmon habitat.

We recognized the need for a full time disposal site when we participated in the National Drug Return day last September and were inundated by citizens seeking to rid themselves of old medications. Your Medreturn box has provided the perfect depository for accepting the drugs from the public. Because it allows people to drop off drugs anonymously, they are not deterred by fear or embarrassment. We believe the program will reduce the numbers of children who accidentally ingest drugs, as well as reduce the number of pills which are illegally sold or otherwise abused in our city.

For more information of our program I would direct you to our website where you will find 2 references: http://www.ci.soldotna.ak.us/press_release_s.html and http://www.ci.soldotna.ak.us/drug_drop.html.

Respectfully,

John H. Lucking, Jr.
Soldotna Police Department
Chief of Police
44510 Sterling Hwy • Soldotna, AK 99669
(907) 262-4455 Fax: 1-866-596-2995



*"This message may contain confidential and/or
proprietary information and is intended for the
person/entity to which it was originally addressed.
Any use by others is strictly prohibited."*

Mike Mayer – President/COO

Mike represents the third generation of active family management in a company started by his grandfather in 1931. He brings over 25 years of experience in the point-of-purchase and merchandising industry, and has been instrumental in extending FMA's growth by directing FMA's successful entry into the interactive and kiosk marketplaces.

Frank Mayer & Associates, Inc.

President/COO 1996-present

MedReturn, LLC

President 2008-present

University of Wisconsin-Whitewater

1980-84

BA-Business Administration

TEC (The Executive Committee)

1998-present

Mrs. BONO MACK. Thank you, Mr. Mayer.
Mr. Coyne.

STATEMENT OF PATRICK COYNE

Mr. COYNE. Good morning, Madam Chair and distinguished members of the subcommittee. It is a great honor that I testify today regarding pain management and the potential implications for patients in need of pain relief from diagnosis to survivorship.

My name is Patrick Coyne. I have been a clinical nurse specialist for over 25 years, focusing on pain management and symptom control, typically in cancer patients. I am the Clinical Director of the Thomas Palliative Care Services within the Massey Cancer Center at Virginia Commonwealth University in Richmond. In my role, I care for individuals on a daily basis who are dealing with life-limiting diseases and significant issues with pain. The patients I care for are from all walks of life, living in both urban and rural areas throughout the Commonwealth. I also teach in the schools of nursing and schools of medicine in our university and beyond. Today I represent the Oncology Nurses Society, ONS, the largest professional oncology group in the United States composed of more than 35,000 nurses and other health care providers.

I would be naive not to recognize that the problem of opiate diversion is a very severe one and can destroy both patients, families and communities. More must be done to treat the significant issue. However, what about those patients who live daily with intractable, unrelenting pain? Daily, I encounter patients who will not see their next birthday and often travel hours to see someone within our institution for appropriate analgesia because their local health care provider is uncomfortable with prescribing the medications the patients need or fearful that their license may be revoked for using too much opiate pain medication.

This population of patients is frail, dealing with countless issues, which I hope I never have to, and often has no voice. I hope to be their voice and ensure their comfort. I also wish to support their privacy so that nobody needs to know about their illness unless they choose to release this information.

The challenges within pain management are many. Individuals respond differently to different medications including oxycodone. Many clinicians receive far inadequate training in prescribing analgesics, assessing pain and other treatment options and have false concerns regarding the role of analgesics. Certain areas in this country have limited resources for managing pain well. We know adequate pain management as demonstrated in several studies can increase both survival and quality of life for patients with life-limiting diseases. Caregivers often suffer from depression and financial impact when pain is poorly controlled. Pain is a serious and costly public health issue. Unmanaged pain is a tragedy. What really seems to be the tragedy is this patient population may suffer because of those conducting illegal activities.

Pain management is challenging in any population. Cancer patients fear pain as do their families, but what of cancer survivors who suffer daily in pain but are disease-free? Consider those individuals with pain from poor cardiac output, sickle cell disease or burn injuries as examples of just a few populations of patients who

may be at risk without the availability of certain opiates. Addiction and misuse of analgesics is exceedingly rare in patients in pain yet they may carry the burden and suffer the decisions made by others.

All discussion about the issue of opiate pain medications needs a balanced exploration of the risks but also the benefits of the medications when used appropriately. Limiting a pain medication, any medication, might take a very safe option away from countless patients living with moderate or severe pain. Education of prescribers is clearly needed to better assess pain and implement appropriate treatment options but limiting options may ruin many individuals' lives.

I have treated many patients with oxycodone, OxyContin and other analgesics, mostly cancer patients who have not tolerated other medications or did not get adequate relief from other opiate or non-opiate pain medications. Patients and their families need better education and support regarding the safe and appropriate use of, storage and disposal of medications. The needs of countless patients suffering in pain need to be part of this and any discussion.

I want to thank you for your time and commitment regarding this exceedingly important subject. I have devoted my life to pain management and I fear that many patients I care for may suffer if poor decisions are made regarding pain management, and I welcome your time and questions. Thank you very much.

[The prepared statement of Mr. Coyne follows:]

April 14, 2011
House of Representatives Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
“Warning: The Growing Danger of Prescription Drug Diversion” Hearing
Oncology Nursing Society Testimony
Delivered by Patrick Coyne, MSN, APN, FAAN

Good morning Madam Chair and distinguished members of the Subcommittee. It is with great honor I testify today regarding pain management, specifically H.R.1316, and its potential implications on patients in need of pain relief, from diagnosis through survivorship.

My name is Patrick Coyne and I have been a clinical nurse specialist for over 25 years focusing on pain management and symptom control, typically in cancer patients. I am the Clinical Director of the Thomas Palliative Care Services within Massey Cancer Center at Virginia Commonwealth University in Richmond, Virginia. In my role, I care for individuals on a daily basis who are dealing with life limiting diseases and significant issues with pain. The patients I care for are from all walks of life, ages, living in both urban and rural areas throughout our Commonwealth. I also teach within the schools of nursing and medicine within our University and beyond.

Today, I represent the Oncology Nursing Society (ONS). ONS is the largest professional oncology group in the United States, composed of more than 35,000 nurses and other health professionals. We exist to promote excellence in oncology nursing and the provision of quality care to those individuals affected by cancer. As part of its mission, the Society honors and maintains nursing’s historical and essential commitment to advocacy for the public good.

ONS maintains a long-standing commitment to ensuring that all people with cancer related pain have access to the quality pain and symptom management care, services, and therapies they need and deserve.

We represent the range of nurses involved in the delivery of cancer care, including registered nurses and advanced practice nurses. RNs administer pain medication and seek changes, as needed. Advanced practice nurses, such as nurse practitioners, prescribe and administer pain medication. In addition, our members work with patients and their caregivers to educate them about their treatments and therapies, side effects, and how to manage their symptoms and side effects, including nausea, pain, fatigue, etc.

We support patients and their caregivers throughout the cancer care continuum – from diagnosis through survivorship or end-of-life. As part of patient support and treatment education, our members assist patients and their family in the safe and effective management of pain.

Specifically, our organization believes that all people with legitimate need must be assured access to the pain medication and therapies that they and their health care providers deem most appropriate.

We recognize and appreciate that with the potential for abuse, our nation must maintain appropriate, yet reasonable, practices and regulations to ensure that these drugs do not fall into the wrong hands and are not abused.

ONS has a long-standing position that regulatory, legislative, economic, and other barriers to effective cancer pain management must be eliminated, but ONS also advocates steps must be taken to ensure that prescription pain medications, particularly opioids, do not fall into the wrong hands. It is this delicate balance that must be struck for patients, families, and society.

It would be naïve not to recognize that the problem of opioid diversion is a severe one, and can destroy families and communities. More must be done to treat this significant issue. However, what about those who live daily with intractable, unrelenting pain?

Daily, I encounter patients who will not see their next birthday and often travel hours to see someone within our institution for appropriate analgesics because their local health care provider is uncomfortable with prescribing the medications the patient needs or is fearful that their license may be revoked for using too much opioid pain medicine. This population of patients is frail, dealing with countless issues, which I hope never to have to, and often has no voice. I hope to be their voice and ensure their comfort. I also wish to support their privacy so that nobody needs to know about their illness, unless they choose to release this information.

The challenges within pain management are many. Individuals respond differently to different medications, including oxycodone. Many clinicians have received inadequate training in prescribing analgesics, assessing pain, other treatment options, and have false concerns regarding the role of analgesics. Certain areas in this country have limited resources for managing pain as well.

We now know that adequate pain management, as demonstrated in several studies, can increase both survival and quality of life for patients with life limiting diseases. Caregivers often suffer depression and financial impact when pain is poorly controlled. Pain is a serious and costly public health issue, unmanaged pain is a tragedy. What really seems to be the tragedy is that this patient population may suffer because of those conducting illegal activities.

Pain management is challenging in any population, cancer patients fear pain as do their families. But what of the cancer survivors who suffer in pain daily, but are disease free? Consider those individuals suffering from the pain of poor cardiac output, sickle cell disease, or burn injuries as examples of just a few populations of patients who would be at risk for suffering with increased pain without the availability of oxycodone (including its long-acting form, oxycontin). Addiction and misuse of analgesics is exceedingly rare

in those patients in pain yet they may carry the burden and suffer the decisions made within the Committee.

All discussions about the issue of opioid pain medications need a balanced exploration of the risks, but also the benefits, of these medications when used appropriately. Limiting a pain medication, any pain medication, might take a very safe option away from countless patients living with moderate or severe pain. Education of prescribers is clearly needed to better assess pain and implement appropriate treatment options, but limiting options may ruin many individuals' lives. I have treated many patients with oxycodone/oxycontin, including cancer patients, who have not tolerated, or did not get adequate pain relief from, other opioid or non-opioid pain medications. Patients and their families need better education and support regarding the safe and appropriate use of, storage and disposal of medications. The needs of countless patients suffering in pain need to be part of this discussion.

Thank you for your time and commitment regarding this exceedingly important subject. I've devoted my life to pain management and I fear that many patients I care for will suffer greatly if pain management options are taken away. I welcome your thoughts and questions, and again thank you for your time.

April 20, 2011

The Honorable Mary Bono Mack, Chair
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing and Trade
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515-6115

The Honorable G.K. Butterfield
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing and Trade
2125 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515-6115

Dear Chairwoman Bono Mack and Ranking Member Butterfield,

Thank you for inviting me to testify before your Committee last week. It was an honor to be a part of the important discussion regarding the future of medicinal oversight relating to pain relief. Having spent 25 years in pain management and symptom control, it is a subject to which I am deeply committed.

Your concerns about the lax of oversight in drug diversion is valid and more is required to reverse the very real, and tragic, effects of abuse. From enhanced education about the dangers of prescription drugs to the distribution through providers who "game" the system, it is imperative that we create and enforce a better paradigm for pharmaceuticals.

However, I again stress the need for access to appropriate medications for those in desperate need, particularly cancer patients, to these pain relief prescription drugs. Individual responses vary and geographic resources to adequate treatment options are limited as well. Combined, these forces often exclude large segments of America's most vulnerable populations from managing their severe pain for chronic diseases.

Discussions about opioid pain medications need a balanced exploration of the risks, but also require the benefits of these medications to be explained too. Restricting access to legal prescription medications may take a safe and effective option away from patients living with pain.

My work, and the work of tens of thousands of oncology nurses like me, revolves around the patients' needs. Please, consider their needs, and those of their families, as you continue to research medicinal diversion.

If I, or the Oncology Nursing Society, can be of any further assistance to your Committee, please let me know. I welcome the opportunity to work with you to define prescription drug abuse and help stop the unnecessary and preventable deaths this growing danger continues to take on our great country.

Again, thank you for allowing me to testify before your Committee.

Sincerely,

Patrick Coyne, MSN, APN, FAAN
PERSONAL ADDRESS
CITY, STATE, ZIP

Mrs. BONO MACK. Thank you to all of the panelists for your expert testimony.

Mr. Coyle, first of all, I applaud you in your efforts and think that we share the same goals. My father was suffering from the last stages of cancer just a couple of years ago, and I watched him go through it, so I appreciate what you see in a clinical setting. But at the same time, I have seen people suffering from opiate withdrawal, so I too care about those people and the pain that they suffer and the life of living with that addiction. Once you are an addict, as you know, you are an addict for the rest of your life. So hopefully we can continue to work to make sure that the people who you need to treat are treated to the best of your ability and we can also keep the drugs out of the hands of the bad guys.

And it goes to Ms. Martello. I keep hearing this reoccurring thing that it is coming from friends and family and medicine chests, and I can't believe that you all are serious when you think that is the big problem. You know, just this week there is an article about another prescription drug sting with 15 arrested in San Diego, California. Now, I will grant that they were arrested because they had prescription pills that they didn't have prescriptions for but they also had cocaine, methamphetamine and other street drugs, but can we take our head of the sand and quit acting like it is all grandma's medicine chest and admit the fact—and let me just go to Dr. Coster.

You are a licensed pharmacist. In 2008, the Partnership for a Drug-Free America or Drugfree.org's president, Steve Pasierb, he said in a Reuters interview, and I quote, "OxyContin is pharmaceutical heroin. There is really no difference between the two." Do you care to explain the difference pharmacologically between OxyContin and heroin, how far off it is?

Mr. COSTER. To be honest, Madam Chairman, it has been so long that I have been in pharmacy school, I would probably get it wrong if I did it, so if you like, we can provide you an explanation after, but at this point I probably wouldn't be able to do it.

Mrs. BONO MACK. Well, it is my understanding, it is one molecule off. I mean, that would be a fair characterization, and certainly you can submit that to me in writing later, but would you say that OxyContin and heroin the way they are consumed by the human body, the only difference is the delivery mechanism?

Mr. COSTER. You know, again, I wouldn't be able to comment on that, you know, from a pharmacological perspective. I wouldn't want to give you any incorrect information or inaccurate information, so again, if you like, I would be happy to provide whatever I can in writing after the hearing.

Mrs. BONO MACK. Well, it is my belief and my contention that they are pretty darn near the same, but to both you and Ms. Martello, you keep using "underadherence" and "medication non-compliance" and those terms in your testimony. When you talk about the problem with underadherence and noncompliance, are you lumping in therapeutics, antibiotics, other drugs into that category? Can you really say that there is a problem that people are not taking all 30 days of OxyContin when they are prescribed it?

Ms. MARTELLO. I think appropriate use of medicines can go a long way to helping patients improve their health conditions, and as I said in my testimony—

Mrs. BONO MACK. Including 30 days of OxyContin?

Ms. MARTELLO [continuing]. This is a shared responsibility. This is something that I think as we have heard throughout the testimony this morning, there are a variety of stakeholders that have a role to play.

Mrs. BONO MACK. Now, let me get back to this simple question. Are you saying that it is for the patient's benefit that they take 30 days' worth of painkillers like OxyContin?

Ms. MARTELLO. I think health care professionals are on the front line of this every day, and I think part of the educational effort that we can engage in—

Mrs. BONO MACK. No, this is a yes or no. And to Dr. Coster too, this is a yes or no.

Mr. COSTER. I mean, I can give you a personal experience if this helps. I had surgery a couple years ago, and when I left the physician said here is a prescription for, I can't remember if it was 30 or 50, for OxyContin, and I went to get it filled, and he said if you need them, take them. So I guess he thought that in my case I might need two or I might need, you know, a week's worth. So I think, and again, not to justify how these drugs are used, but some people, I guess some physicians feel like I will give you this quantity, and if you need them, take them, if you don't, they don't really tell them what to do with them. So I don't know if it is a yes or no answer but in terms of a personal—

Mrs. BONO MACK. No, the question is, is extending the life, extending the quality of life—you are lumping this in, it seems to me, with therapeutic drugs or antibiotic or something when you talk about underadherence of drugs.

Mr. COSTER. Again, in terms of like if you are taking a blood pressure medication where you absolutely have to take it every day or a cholesterol medication—

Mrs. BONO MACK. But we are not focused on those drugs today.

Mr. COSTER. No, I know that.

Mrs. BONO MACK. But we keep saying underadherence, underadherence.

Mr. COSTER. Again, I am not a prescriber, but in the case of pain, oftentimes you get prescribed a quantity of medication because a physician doesn't know, for example, how you are going to tolerate a certain procedure. He might say you might need for 5 days, you might need these for 10 days. Again, I am not justifying this. I am just saying as a pharmacist who has seen a lot of patients come in and fill prescriptions for pain where the patient says I may not need all these or why the doctor did give me all these, you are trained to tell the patient that the physician probably gave these to you because he is not sure how many you are going to actually need.

Mrs. BONO MACK. My time has expired, but we will come back to that, and I am sure Mr. Mayer is very appreciative of the over-prescriptions.

Mr. Butterfield, you are recognized for 5 minutes.

Mr. BUTTERFIELD. Thank you, Madam Chairman.

As we have heard, 70 percent of non-medical prescription drug users get those drugs from family or friends. It can be given to them, it can be sold. They can actually unfortunately steal it from others. We also know that the family medicine cabinet is bulging with unused and no longer needed medicines. Disposing of these medicines properly must be a priority and we must work to reduce their negative impact on the environment. When people do not have a safe place outside of the home where they can dispose of their unused drugs, they typically flush them, causing them to ultimately end up in our waterways.

Question: I understand that a number of communities have created take-back days in which medicines are safely collected by law enforcement. Also, the Secure and Responsible Drug Disposal Act sponsored in the House by Mr. Inslee of Washington will allow more people and places to collect these unused medicines. This question is for Mr. Clarkin. Does the partnership that you represent have any examples of times when a take-back operation works particularly well?

Mr. CLARKIN. Not specific instances in specific communities, but we first of all support the whole take-back program that the DEA has spearheaded in the most recent take-back initiative, I think it was pointed out earlier was terrifically successful in terms of the quantities of drugs that were actually brought back and safely disposed of, and we look forward to supporting the DEA at the April 30th take back.

Mr. BUTTERFIELD. Thank you.

Next to General Dean. Thank you for your service to our country. What branch were you a part of?

Mr. DEAN. The U.S. Army.

Mr. BUTTERFIELD. Ever stationed at Fort Bragg?

Mr. DEAN. [Inaudible.]

Mr. BUTTERFIELD. All right. And thank you for that. According to reporting by the North County California Times—I almost said North Carolina—the North County California Times a couple years ago, military doctors wrote service members nearly 3.8 million prescriptions for painkillers up from less than 900,000 10 years ago. The Defense Department estimates that abuse of prescription drugs in the military is double that of the general population. First of all, do you agree or disagree with that, that military drug abuse is more and probably twice as much?

Mrs. BONO MACK. Excuse me. General, would you please turn your microphone on?

Mr. DEAN. I agree that the military has a significant problem with this issue. I don't have the exact statistics on it.

Mr. BUTTERFIELD. But you have no reason to disagree with that statistic?

Mr. DEAN. I have every reason to agree with that.

Mr. BUTTERFIELD. And it appears that one study in 2009 even found that 20 percent of Marines had abused prescription drugs, mostly painkillers, at some point in the previous year. Our active service members face significant anxiety overseas and many live through pain every day when they are on duty, but if they develop a physical dependence or addiction to prescription drugs, it can fol-

low them back home to their civilian life, and I have seen it all of my life.

General, what should the Administration do with regard to training veterans hospitals to be on high alert for this type of abuse?

Mr. DEAN. I think it is a multifaceted approach that needs to be taken in order to assist our military members and their families and the communities that they reside in. I have had some discussions, my organization has, with the Army. I have another meeting scheduled with them in the very near future to address just this issue of helping them be more holistic in their approach of dealing with this issue that is not only soldier focused but also for the family members as well as the other civilians as well.

Mr. BUTTERFIELD. Are there other programs geared to prescription drug abuse by veterans? For example, veterans may receive health insurance from the Federal Government. Are the insurers instructed to be on the lookout for abuse and not simply for the sake of law enforcement but really to help the veteran?

Mr. DEAN. The answer is yes. I have a board member who runs the VA substance abuse center, the big VA center in Atlanta, Dr. Karen Drexler, and the VA has programs but the resources and the number of people that they have in my opinion—I am not speaking for the VA—needs to be expanded and there needs to be greater information provided and there need to be greater educational programs, but do they have the programs, yes, but my understanding would be that there needs to be a substantial enhancement in those programs.

Mr. BUTTERFIELD. Thank you. Thank you, one and all. I yield back.

Mrs. BONO MACK. Thank you, Mr. Butterfield. The chair recognizes Mr. Lance for 5 minutes.

Mr. LANCE. Thank you very much, Madam Chair, and good afternoon to you all. I find this testimony very interesting. I don't have the honor of representing Fort Bragg but I do represent the district in the United States that has more medical and pharmaceutical employment than any other district in this country, and certainly this is an issue in the district as well as across the country.

To Dr. Coster or to Ms. Martello or to both of you regarding the risk evaluation and mitigation strategy at the FDA, based upon your expertise, do you feel that it has contributed to the mitigation of prescription drug diversion and has there been any unforeseen consequence such as access issues for patients?

Ms. MARTELLO. When we look at policies in this area, certainly balancing the need between legitimate patient access and ensuring that the product's benefits continue to outweigh its risks is an important public health consideration and I think those are the issues that are currently being grappled with. The FDA has a variety of tools in its arsenal to make sure that the product's benefits continue to outweigh the risks of any product.

Mr. LANCE. Dr. Coster?

Mr. COSTER. Yes, sure. It is an excellent question, Congressman. There is so much focus and attention that has been placed on this program, and even though it has not yet been fully implemented by the FDA, I think just by the attention it has received, it has caused physicians to maybe look more closely on how they pre-

scribe and patients on what they do in terms of taking these medications, but I agree with Ms. Martello that any program put in place like this should assure that it doesn't interfere with the appropriate prescribing of these medications, the appropriate dispensing of them and that patients in pain are able to get them, and I think the agency itself is struggling with what that right balance is right now for these extended-release and long-acting opioid products.

Mr. LANCE. Thank you.

And to Ms. Martello, you state, and I agree with you, that you do not want to see barriers to patient access for needed prescription medicines. You highlight one potential barrier could be unnecessarily restrictive drug control regulations and practices. Could you give us in a little greater detail what you mean by that?

Ms. MARTELLO. I think health care providers play a pivotal role in helping to ensure that patients have access to the medicines that they need and so we would want to have health care providers and pharmacists frankly to be part of this conversation to help ensure that they can work with patients and counsel them on medication management and using medicines appropriately as prescribed.

Mr. LANCE. Thank you.

And to General Dean, thank you, sir, for your service to our Nation. Have you seen greater abuse given the fact that we now have military operations in the field in both Iraq and Afghanistan and has there been a tracking of this in relationship to other times when we have had our military personnel in combat situations?

Mr. DEAN. Well, as you know, I have been retired for a few years so I am giving you information from my perspective and not from within the Department of Defense, but clearly the protracted wars that we have been in and the extensive number of severely wounded soldiers and other member of the armed forces have contributed to an increased number of them needing and benefiting over a long period of time from these medicines, and as a result of that, it is clear, and my friends have told me, that there is an increasing number of them who unfortunately are now abusing them and they are trying to find ways to combat that. Just recently, we had an officer as senior as a three-star general admit that he was addicted to pain medicine. So it is an issue. I am not actively involved in it now. I am looking to work with the military services to help them build some procedures that would get at training and education around military bases that would help combat this, but it is a significant issue.

Mr. LANCE. Thank you very much. And Madam Chair, I yield back my remaining 4 seconds.

Mrs. BONO MACK. Thank you for your generosity. I recognize myself for 5 minutes again and say that it is so unfortunate, General, that we are hearing that this is truly carrying over into our troops, and it really makes a huge punctuation point on how important it is that we are doing this here today, so I thank you for your testimony and for being here.

Quickly, just to point out, thought, that the FDA does not currently have a REMS program for long-acting and extended-release opioids, so it is not currently in place, and I am wondering how long it will take for them to do it and how many deaths will it take

for them to do it, and I am curious, you know, fen-phen was taken off the market really quickly. If either one of the two pharmaceutical reps can explain to me why fen-phen would have been removed from the market or some of these drugs that are so quickly and what the difference is between that and these opioids that are now up to tens of thousands of deaths a year.

Ms. MARTELLO. It would be inappropriate for me to substitute my judgment for that of the independent scientific expert agency, the FDA, which evaluates the safety and efficacy of all marketed medicines, and so from my perspective, I think it would be inappropriate for me to comment on that.

Mrs. BONO MACK. OK, fine. Then let me use my time with somebody who can actually comment, if that is all right.

Mr. Clarkin, any of you, can you explain to me why the abusive opioid drugs because a problem so quickly, the trend lines screaming up there, anybody who is out there in the field in the real world?

Mr. CLARKIN. I think there is probably a combination of factors, and clearly supply has been a factor. I think the environment of marketing, direct-to-consumer marketing in the pharmaceutical industry, has expanded the abuse of prescription drugs not just prescription opioids.

Mrs. BONO MACK. In fairness, I have never seen an advertisement ever for OxyContin.

Mr. CLARKIN. That is correct, but my point is, that the direct-to-consumer advertising, and I think there is fairly robust literature on this, is creating a sense of a reliance on medicine to address a variety of different ills and so we see in our research, which I mentioned, and Dr. Boyd sees the same thing, an increasing reliance on the part of teens, at least, to be addressing not just to self-medicate or recreate with these substances but to address life management issues, and I think that is linked in some measure, not entirely but in some measure, to aggressive marketing.

Mrs. BONO MACK. Thank you. Does the partnership have any explanation just from an observing standpoint why rogue pharmacies specialize in hydrocodone versus oxycodone or other controlled substances yet the pill mills specialize in oxycodone instead? Has anybody figured out that discrepancy?

Mr. CLARKIN. I don't have an answer for you on that.

Mrs. BONO MACK. Anybody? No? OK. Mr. Mayer, the take-back program, what do you see as the key features of a successful, always available program?

Mr. MAYER. Local community support. Education is going to be the biggest key. Letting the communities, the public know that there is a sustainable take-back program within their community. The program that we put together, the county-wide program which is in our county actually was a combination of news media and support from local newspapers but it was also putting flyers in the pharmacies, letting individuals know when they pick up their prescriptions that they can dispose of unused, expired at the local law enforcement agencies.

Mrs. BONO MACK. Terrific. Thank you.

Mr. MAYER. Education is the key.

Mrs. BONO MACK. OK. Dr. Coster, when you see the statistics and graphs that Governor Scott presented earlier showing the disproportionate share of drugs dispensed from Florida and national statistics on drug diversion, do you think that the DEA and FDA quota system needs to be reevaluated in light of the high percentage of diversion, particularly in Florida?

Mr. COSTER. Well, I know the way the quota system works now. It is based on a combination of factors both in terms of what the data show in terms of demand, FDA data and other data that feed into DEA and then DEA then determines how much our individuals manufacturers can make. You know, in terms of the situation in Florida, it sounded like part of the issue down there was that they didn't have a prescription monitoring program which hopefully that will deter some of the abuse. But we are happy to talk with the committee and the DEA about whether the system needs to be recalibrated.

Mrs. BONO MACK. Let me just back that up. I am sorry. I am down to my last 15 seconds. You just said the quota is based upon the demand? Isn't that the problem here? If anybody wants it, then they are allowed to make it. That is the simple—that is it. That is the way you just explained it.

Mr. COSTER. Well, again, I am not intricately familiar with how the FDA determines its actual quotas so I just gave you a broad overview, so as I said, maybe it is time that that whole system is looked at again in terms of how those quotas are determined based upon what is happening in the State.

Mrs. BONO MACK. Thank you, Doctor.

Mr. Butterfield, you are recognized.

Mr. BUTTERFIELD. Thank you.

Let me drill down on prevention for just a moment if I can. If we can prevent abuse, we know we can save millions of dollars and, more importantly, we can save many, many precious lives. As prepared by the Office of National Drug Control Policy, the 2010 National Drug Control Strategy called for Federal, State, and local entities as well as non-governmental partners to seek earlier intervention opportunities in health care. One of the opportunities that the strategy highlights is working with physicians to achieve consensus standards on opiate painkiller prescribing.

Mr. Clarkin, I am going to go back to you. What do you believe are the best ways to seize this opportunity? How specifically should stakeholders unite around consensus standards? For example, should task forces or working groups that include doctors, nurses, pharmacists and others be created? What role can the partnership play in such a process?

Mr. CLARKIN. I think we have heard a lot today pointing to the need for prescriber education, first of all, on appropriate prescription of opioids and other medications. One of the measures that the partnership supports is the explicit linkage of education of prescribers to their DEA registration renewal every 3 years, so I believe that is an important piece and one that Director Kerlikowske also cited when he spoke here earlier. I think the dialog too between health care professionals, whether they are prescribers or pharmacists, the dialog between those health care professionals and consumers, particularly parents, needs to be much more mind-

ful of the risks of abuse, the risks of addiction, and I know one of the pieces that is under discussion as part of the long-term opioid REMS and one that the partnership supports is the adoption of effective prescriber-patient agreements at the point of prescription so that the patient very clearly understands the risks. First of all, there is a screener so that the doctor is aware if the patient indeed is particularly susceptible to addiction but the patient is also aware of the risks of abuse, the risks of addiction and the need to effectively safeguard meds and dispose of them appropriately.

Mr. BUTTERFIELD. Perfect timing. We have just been called to the floor. You heard the buzzer. I am going to have to yield back. Thank you.

Mrs. BONO MACK. I thank the gentleman. And does the gentleman from——

Mr. LANCE. I do not, Madam Chair, have any more questions. I yield to you.

Mrs. BONO MACK. I thank the gentleman for yielding back, and I believe that we should wrap this thing up.

Before I do, I would like to ask unanimous consent that these four items that we have previously discussed with the minority be included in the record.

Mr. BUTTERFIELD. No objection.
[The information follows:]



Boehringer Ingelheim Roxane, Inc.

April 11, 2011

The Honorable Michele Leonhart
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrisette Drive
Springfield, VA 22152

Dear Administrator Leonhart:

As President and CEO of Boehringer Ingelheim Roxane, Inc., I am writing to clarify the record regarding statements you made during a hearing before the House Appropriations Committee. We appreciate your attention to this important matter.

On Wednesday, March 16th, 2011, you testified before the Subcommittee on Commerce, Justice, Science and Related Agencies regarding funding for the Drug Enforcement Administration (DEA) as part of the President's 2012 budget. In an exchange with Congressman Graves and Chairman Wolf, you were asked about OxyContin abuse. You responded by saying the problem is not the abuse of the brand drug, OxyContin, but rather the generic version, oxycodone. Specifically, you pointed to Roxicodone® as the "most popular" [drug creating abuse issues]. When asked who manufactures the product, you cited Boehringer Ingelheim in Columbus, Ohio.

Boehringer Ingelheim Roxane, Inc. (BIRI), located in Columbus, Ohio, is a manufacturing subsidiary of Boehringer Ingelheim Corporation (BIC). BIRI predominately manufactures pharmaceuticals for BIC affiliates such as Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), and Roxane Laboratories, Inc. (RLI). BIRI also manufactures FDA approved pharmaceuticals for certain third parties under contract manufacturing agreements. One such product is Roxicodone® tablets.

While Roxicodone® tablets were originally owned and produced by RLI/BIRI beginning in 1982, the legal ownership of Roxicodone® has gone through several ownership changes through the years. Currently, Roxicodone® is owned by Xanodyne Pharmaceuticals, Inc., located in Newport, Kentucky, and it represents one version of oxycodone hydrochloride tablets available in the market today. Sales data provided by Wolters Kluwer Health indicate that at least 24 different companies currently sell oxycodone hydrochloride products. Additionally, this same sales data for the past twelve months (from March 2010 to February 2011) indicates that Roxicodone® represented a mere 0.42% of the total market share for oxycodone hydrochloride. Xanodyne was ranked eleventh out of the twenty four distributors who sold oxycodone hydrochloride in that time frame. It was stated during the hearing that Roxicodone® was the "main drug," [creating abuse issues], however considering that the market share for Roxicodone® is significantly less than 1% of the total market, we cannot understand how this can be the case. The market in which Roxicodone® is manufactured and sold is far too fragmented and complex to name a single firm as bearing responsibility for the scourge of abuse in a Congressional hearing.



There is a legitimate market demand for Roxicodone® and other oxycodone hydrochloride containing medications. These medications are available through highly regulated channels that allow physicians to treat patients appropriately for pain they could not otherwise treat with other pain medications. Boehringer Ingelheim and our subsidiary generics and manufacturing entities, comply with strict regulatory protocols laid out by the FDA and DEA. These standards include high demands on good manufacturing practices by the FDA, and rigid compliance to limits on quantity based on our ability to demonstrate proof of legitimate manufacturing demand.

We sympathize with the enormous challenges you face as the DEA Administrator. There is a long history of criminal activity by a small group of unlawful individuals running pill mills, physicians engaging in unethical prescribing practices, and demand from addicted users. We support measures like the National All Schedules Prescriptions Electronic Reporting Act (NASPER) that instituted the only program, authorized in statute, to assist states in combating the abuse of controlled substances through a prescription monitoring program. Unfortunately, as federal incentives went into effect, a number of states failed to adopt the program model. It has become increasingly clear that states failing to adopt the program are experiencing a dramatic increase in abuse and criminal activity.

Boehringer Ingelheim demands a high level of compliance for the controlled substances we manufacture. We appreciate this opportunity to clarify the record and, we welcome an opportunity to discuss these matters with you more fully.

Sincerely,

A handwritten signature in black ink, appearing to read "George Doyle", written over a horizontal line.

George Doyle
President and CEO
Boehringer Ingelheim Roxane, Inc.

cc: The Honorable Hal Rogers
Chairman, U.S. House of Representatives
Committee on Appropriations

The Honorable Norm Dicks
Ranking Member, U.S. House of Representatives
Committee on Appropriations

The Honorable Frank R. Wolf
Chairman U.S. House of Representatives
Subcommittee on Commerce, Justice, Science, and Regulated Agencies

The Honorable Chaka Fattah,
Ranking Member, U.S. House of Representatives
Subcommittee on Commerce, Justice, Science, and Regulated Agencies

Members of the U.S. House of Representatives
Subcommittee on Commerce, Justice, Science, and Regulated Agencies

**THE IMPORTANCE OF ON-DOSE
TECHNOLOGIES IN THE FIGHT AGAINST
MISUSE, ABUSE AND ILLEGAL DIVERSION
OF OPIOIDS**

A WHITE PAPER

By

John Glover, DPA

President John Glover Consulting, Inc.

*Vice President, Corporate Security, Bristol-Myers Squibb
Company (retired)*

*Executive Assistant Director for Administration, Federal Bureau
of Investigation (retired)*

Founding Member, Pharmaceutical Security Institute

**THE IMPORTANCE OF ON-DOSE TECHNOLOGIES IN THE FIGHT
AGAINST MISUSE, ABUSE AND ILLEGAL DIVERSION OF OPIOIDS**

By
John Glover, DPA

BACKGROUND

Opioids are regarded as safe and effective therapies for moderate to severe pain for many patients. However, opioids are subject to heightened regulation and classified by the U.S. Drug Enforcement Agency (DEA) as schedule II or schedule III controlled substances because of their high potential for abuse and addiction.

It is well-documented that the misuse, abuse, and illegal diversion of opioid pain medications and other Schedule II controlled substances (CII) are reaching epidemic proportions. Drug treatment admissions for prescription painkillers have increased more than 300 percent from 1995 to 2005.¹ Recent reports indicate that nationally, more than 7 million people abuse prescription drugs — more teens abuse prescription drugs than any other illicit drug, except marijuana; more than cocaine, heroin, and methamphetamine combined.² In addition, the number of deaths involving controlled prescription drugs, particularly opioid pain relievers (such as oxycodone, hydrocodone, methadone, morphine, and fentanyl), increased 66 percent from approximately 3,484 in 2001 to 5,789 in 2005, according to the Centers for Disease Control and Prevention (CDC).

Nationally, law enforcement reports indicate that criminal gangs have moved into the distribution and trafficking of approved CII and CIII medications.³ Many of the same distribution channels used to transport cocaine, heroin and other street drugs now distribute approved opioids and at times counterfeit versions of these medications. The tracing of diverted opioid medications is nearly impossible since criminals have penetrated the legitimate supply chain to divert legitimate product to illegitimate uses and have introduced illegitimate product into the legitimate supply chain.

¹ *Prescription For Danger: A Report On The Troubling Trend of Prescription And Over-The - Counter Drug Abuse Among The Nation's Teens*. Office of National Drug Control Policy; January 2008.

² *Ibid.*

³ *National Drug Threat Assessment 2009*. National Drug Intelligence Center; December 2008.

The Challenges of Illegally Diverted Opioids

The illegal diversion of opioids is a key factor in the misuse and abuse of these medications. While there are many factors that contribute to the action of illegal diversion, two key factors must be addressed if manufacturers, law enforcement, government agencies and regulators are going to make significant strides in reducing this illicit trade. The first factor is the lack of source information that can be gleaned from confiscated products following successful law enforcement activities. The second is the convoluted distribution system that allows cross-state shipping of opioid products from wholesalers to regional distribution centers, and ultimately retail pharmacies that may or may not be in close proximity to the regional distribution center.

From a law enforcement perspective, one of the most fundamental variables in a successful investigation is the amount of information investigators have on which to base their efforts. Unfortunately, in the case of illegally diverted opioids, the information at hand is usually quite minimal given that the medication is typically repackaged from its original container and the medication itself carries no information as to the intended site of distribution. This lack of on-dose source information presents a challenge for law enforcement and government agencies seeking to initiate investigations, which in turn hampers and prolongs investigations, thereby reducing the potential for a successful outcome.

Complicating this lack of information is the fact that the distribution system for opioids does not differ materially from that of non-scheduled products. Manufacturers ship large quantities of opioids to wholesalers, who in turn ship to their regional distribution centers to meet demand. Further, the regional distribution centers in turn service retail pharmacies that may or may not be geographically close in proximity to the distribution center. Opioids path through the supply chain is quite circuitous and provides various opportunities for diversion, increasing the burden on investigators and heightening the probability of a failed investigation.

Regulatory Response

The U.S. Food and Drug Administration (FDA) is using new authority to control drug misuse by classifying it as an adverse event. In 2007, the Food and Drug Administration Amendments Act was signed into law, giving FDA new authority to require a Risk Evaluation and Mitigation Strategies (REMS) for certain drugs and biological products.⁴ REMS are required to manage a known or potential serious risk associated with a product, which can include risks associated with drug abuse, overdose and withdrawal.

On September 5, 2008, FDA released its quarterly report of drugs and their potential related side effects which are under review by the agency. Utilizing new authority, FDA listed Oxycodone Hydrochloride Controlled-Release (OxyContin) with related side effects of misuse, abuse and overdose.⁵

On March 3, 2009, the FDA held a meeting with 16 manufacturers of opioid products to discuss a required REMS program “to ensure that the benefits of the drugs continue to outweigh the risks of: 1) use of certain opioid products in non-opioid-tolerant individuals; 2) abuse; and 3) overdose, both accidental and intentional.”⁶ The importance of addressing illegal diversion was underscored at this meeting by the FDA. The Agency identified diversion as a “surrogate marker” for misuse and abuse and emphasized the importance of addressing the issue in an opioid-specific REMS.

To date, REMS programs have focused on patient and prescriber education. While these elements will play an important role in an opioid-specific REMS, controlling the nefarious criminal elements, illicit diversion, and intentional misuse and abuse of opioid products will require a more specialized mitigation approach.

⁴ 21 U.S.C. § 355(p) (2007).

⁵ “Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS), January - March 2008.” Posted on the FDA web site, Sept. 5, 2008.

⁶

Industry Response

Opioid manufacturers have attempted to address the issue of illegal diversion by the use of on-package technologies such as Radio-frequency identification (RFID), which assists in the tracking of a package through the supply chain. These efforts have failed for multiple reasons including: the lack of supportive equipment and/or participation of downstream supply chain partners; the motivation of criminals to defeat traditional track and trace technologies such as RFID; and the fact that the vast majority of diverted, illicit product is not found in the original manufacturing package, but rather in plastic, zip-locked bags or other non-standard “packaging”.

On their own, package securing technologies, such as RFID and other on-package technologies including serialization and 2-D barcodes, are ineffective in addressing the issue of illegal diversion, and the misuse and abuse of opioids and other CII products.

REVISED RESPONSE MUST INCLUDE ON-DOSE TECHNOLOGIES

Newly available, state-of-the-art, on-dose technologies, such as NanoEncryption technology developed by NanoGuardian, can greatly assist in mitigating illicit diversion and intentional misuse and abuse by providing tracing information on each and every dose of a medication whether in a tablet, capsule, or vial form.

Dose-level tracing technology provides many benefits necessary for a successful opioid-specific REMS, including the following:

- On-dose technology does not require equipment or participation of downstream supply chain members to be effective;
- Since the technology resides on each and every dose of the medication, repackaging by criminals, as well as legitimate supply chain members, has no effect on the tracing information each dose can communicate to manufacturers, regulators, and law enforcement thereby greatly enhancing investigational activities and providing keen insight into the flow of illegally diverted product through the supply chain;

- The information associated with certain on-dose technologies is virtually unlimited and can include the capability to associate the drug dose with on-package technologies such as RFID creating a parent-child relationship between packaging and the specific dose.

This White Paper details how one such on-dose technology, NanoGuardian's NanoEncryption technology, could be implemented as a key element of an opioid-specific REMS. It will also discuss the ability of NanoGuardian's NanoEncryption to meet the requirements that elements of a REMS must:

- Commensurate with the specific serious risk listed in the labeling of the drug;
- Not be unduly burdensome on patient access to the drug;
- Be designed to be compatible with established distribution, procurement, and dispensing systems; and
- Have the ability for generic and innovator products to use a single shared system to implement the elements to assure safe use.

Employing On-Dose Technology as a Component of REMS

One goal of any diversion control system should be to ensure that at any point in the system, a product's original shipping destination from the manufacturer can be obtained in a rapid, discreet manner by appropriate authorities so that a determination may be made whether the product is where it was intended - both geographically and within the supply chain.

A comprehensive highly functioning diversion control system must include the following:

- ◆ The flexibility to run "sting" operations by manufacturers and law enforcement to identify and apprehend criminal gangs moving large volumes of diverted product;
- ◆ The ability to monitor sudden changes in purchasing patterns in regional areas; and
- ◆ Technology that does not alter the medication in any way by increasing the risk of adverse events or reducing efficacy.

Until recently, manufacturers have only had on-package technologies such as RFID to protect their brands from illegal diversion. RFID can provide two important functions; it can assist in managing and controlling inventory, and identify the intended recipient of fully packaged products. Unfortunately, given the dynamics of opioid diversion, packaging containing an RFID chip is rarely if ever accompanying the zip-locked baggie of confiscated product. As such, the diversion “protection” and information that on-package technologies provide is limited at best.

NanoGuardian’s NanoEncryption Technology

NanoGuardian’s on-dose NanoEncryption technology became commercially viable within the past year and can provide a significant resource to manufacturers and law enforcement in addressing the illegal diversion of opioids. In 2008, a NanoGuardian client received approval of its Supplemental New Drug Application (SNDA) for implementing NanoEncryption technology as a brand protection initiative.

NanoGuardian’s NanoEncryption technology provides on-dose layered security features at the overt, covert, and forensic level and can be applied directly to tablets, capsules and vial caps. NanoGuardian has perfected a way to impart these security features on each dose without adding any particles or chemical markers to the current product. The multi-layered security features enable NanoGuardian to provide a dual-protective benefit to manufacturers with a single technology. The overt and covert security features enable authentication at any point in the supply chain, while the forensic NanoCodes provide comprehensive tracing information on every single dose.

NanoGuardian’s NanoCodes can be associated with an unlimited amount of data including but not limited to product information (strength, expiration date), manufacturing information (location, date, batch and lot number), and distribution information (country, distributor, wholesaler, chain, RFID or 2-D Barcode). Since NanoGuardian’s on-dose protection always remains with the specific dose, even after numerous repackaging efforts, NanoGuardian provides comprehensive tracing information and brand integrity that traditional on-package and e-pedigree technologies cannot alone provide.

The unlimited dose-level information provided by NanoGuardian's NanoCodes can help address the current challenges facing law enforcement and government agencies. NanoGuardian's technology provides a crucial cornerstone to any investigation – information – and will improve the ability of all involved in the fight against illegal diversion.

NanoGuardian's program is also cost-effective at \$0.005 to \$0.01 per tablet/capsule NanoEncrypted, depending on volume. Compared to the devastating costs of diversion including the addiction of our youth, escalating crime related to addiction, and death from overdose; less than a penny per dose is a reasonable investment to provide a true weapon in the war against illegal diversion.

Proposed Use of NanoGuardian's NanoEncryption Technology

The on-dose distribution data contained with NanoGuardian's forensic-level NanoCodes will have significant benefit for investigators, especially when combined with a more restrictive distribution patterns for wholesalers. As such, the application of NanoEncryption technology should be employed as part of a restricted distribution scheme to provide optimal, practical control over highly diverted products. NanoGuardian's technology could be employed in the following manner:

1. Contrary to the traditional national-level wholesaler order system in use today and in order to gain a better awareness and understanding of regional opioid distribution patterns, wholesalers must present to manufacturers forecasted opioid demand for their Regional Wholesale Distribution Centers (RWDC). Given that there are approximately 110 Regional Wholesale Distribution Centers in the US, a region-based distribution model will provide significantly better understanding of regional opioid ordering patterns while having no impact on patient access to product for legitimate need.
2. After NanoEncryption, each and every opioid dose possesses a NanoCode that at the very least identifies the manufacturer's shipping date and the specific RWDC to which the product will be shipped.

3. Manufacturers ship opioid products containing the respective RWDC NanoCodes directly to the RWDC per the forecasted demand submitted by the wholesaler.
4. RWDC receive NanoEncrypted product and are responsible for maintaining strict records of quantities distributed to retail pharmacies and other licensed health care facilities.
5. Upon a successful seizure of illegally diverted product, law enforcement and government authorities are able to determine within 24 hours via the NanoCode the RWDC of original distribution and begin to investigate within the supply chain. If a bag of opioids seized in Florida possessed a NanoCode reflective of a Florida-based RWDC, the investigation would begin evaluating the local supply chain for leaks. If on the other hand, the Florida seizure had NanoCodes reflective of product that was originally shipped to a California-based RWDC, or perhaps another country, the investigation could look for interstate or international movement of product either legitimately or illegitimately.
6. The first Product Integrity Center containing the specialized decryption equipment required to read and decrypt the NanoCodes is located at NanoGuardian's headquarters near Chicago; however, NanoGuardian has expressed a willingness to work with DEA and FDA to house the specialized decryption equipment at their respective forensic centers. Manufacturers may also have specialized equipment designed for a desired manufacturing site.

National Implementation of the NanoGuardian Diversion Control System

A solution is not a solution if it cannot be implemented and the NanoGuardian Diversion Control System can be operational among all opioid manufacturers within the next 18 months, assuming SNDA approval is required for all dosage forms. This implementation time is reduced if CBE-30 regulatory filings are allowed by the FDA given that NanoGuardian's technology has already been the focus of an approved SNDA.

Implementation of the NanoGuardian Diversion Control System would require changes in the ordering and planning systems for manufacturers and wholesalers only (required with the move to better visible Regional Wholesale Distribution Centers) with no changes for pharmacies, patients or prescribers.

NanoGuardian Diversion Control System National Implementation Timeline

The timeline below assumes a July 1, 2009 start date and includes all 16 branded and generic manufactures of opioids contemplated in the REMS program. While all of manufactures could be ready by June 30, 2011, many manufactures could be ready before that date. Finally, additional resources and involvement from FDA and DEA could shorten the timelines.

Phase I – by June 30, 2011

- NanoEncryption initiated for all opioid sustained release products
- Initiate Regional Wholesale Distribution Center forecasting by wholesalers and associated product distribution by manufacturers for CII opioids
- Develop inter-agency law enforcement coordination protocols
- Develop tracking protocols for the proactive monitoring of diversion data in the marketplace

Phase II - after January 1, 2011

- Implement inter-agency law enforcement coordination protocols and diversion tracking protocols developed in Phase I
- Collect data and develop additional tactics to combat illegal diversion

Summary

The misuse and abuse of opioids and other CII-CIII medications is escalating at an alarming rate and is a growing national concern. The consequences are severe, often deadly, and at the heart lay illegal diversion. While manufacturers, law enforcement, and government agencies are working hard to address this concerning issue, recent trends suggest loudly that the criminals are winning the costly war of illegal diversion.

A successful outcome requires that all parties work together in addressing the issue of diversion and that the collective group embrace all available means necessary to stem the tide and begin realizing

a positive impact in averting illegal diversion. These means must include on-dose tracing technologies, such as NanoGuardian's NanoEncryption technology that provide invaluable information to investigators, despite an environment of multiple repackaging and deception. On-dose tracing technology provides law enforcement the essential source information it needs to launch successful investigations, which result in the arrest and imprisonment of those who are ultimately responsible for the misuse and abuse of opioid medications that is plaguing our country.

ABOUT THE AUTHOR - JOHN GLOVER

Dr. John Glover has a distinguished career spanning more than 35 years with the FBI, Bristol-Myers Squibb Company (NYSE: BMY), the Pharmaceutical Security Institute and the U.S. State Department's Overseas Security Advisory Council.

In March 1989, Dr. Glover retired from a distinguished career with the FBI, where he investigated, supervised and managed numerous successful high-profile investigations. During his tenure, he was designated executive assistant director for administration at FBI Headquarters in Washington, D.C., one of three direct reports to the director of the FBI.

Later, Dr. Glover served as vice president, corporate security for Bristol-Myers Squibb Company. Among his many accomplishments during this timeframe, Dr. Glover was instrumental in creating the Pharmaceutical Security Institute, an industry-wide, anti-counterfeiting body. He also served as co-chairman of the U.S. State Department's Overseas Security Advisory Council.

Today, Dr. Glover serves as president of John Glover Consulting, Inc., which provides consulting services to a very select number of prominent corporate and non-governmental entities.

Dr. Glover is also Chair of the Security Advisory Board for NanoGuardian.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug
Stores
For
U.S. House of Representatives
Energy and Commerce Committee
Commerce, Manufacturing, and Trade
Subcommittee
Hearing on
Warning: The Growing Danger of
Prescription Drug Diversion
April 14, 2011
9:00a.m.
2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
413 North Lee Street
Alexandria, VA 22314
703-549-3001
www.nacds.org

NACDS thanks the Committee for the opportunity to submit a statement for the hearing on “Warning: The Growing Danger of Prescription Drug Diversion.” NACDS and the chain pharmacy industry are committed to partnering with policymakers and others to work on viable strategies to prevent prescription drug diversion. Our members are engaged daily in activities with the goal of preventing drug diversion.

The National Association of Chain Drug Stores (NACDS) represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate 39,000 pharmacies, and employ more than 2.7 million employees, including 118,000 full-time pharmacists. They fill nearly 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their \$830 billion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.96 in other industries, for a total economic impact of \$1.57 trillion, equal to 11 percent of GDP. NACDS represents 137 chains that operate these pharmacies in neighborhoods across America, and NACDS members also include more than 900 pharmacy and consumer packaged goods suppliers and service providers, and over 60 international members from 23 countries. For more information about NACDS, visit www.NACDS.org.

NACDS and the chain pharmacy industry share the Committee’s concerns with the problem of prescription drug diversion. We believe that there are a variety of ways to help curb prescription drug diversion, and chain pharmacies actively work on many initiatives to reduce this problem. For instance, chain pharmacies participate in state controlled substance prescription drug monitoring programs. In addition, we are devoted to important initiatives to improve patients’ adherence to their prescribed medications. Chain pharmacies and their pharmacists work with their patients daily to provide them with information and counseling on the proper use of their prescription medications and

the importance of adhering to their prescription drug treatment. Further, NACDS and our member companies support policies that work to prevent illegitimate Internet drug sellers from selling or offering to sell drugs to U.S. consumers in violation of federal and state laws. We also support efforts to provide patients with means for disposal of their unwanted medications that are authorized by law enforcement.

NACDS and the chain pharmacy industry look forward to working with the Committee to address the problem of prescription drug diversion.

CONTROLLED PRESCRIPTION MONITORING PROGRAMS

NACDS and chain pharmacies support controlled substance prescription monitoring programs to help combat prescription drug diversion. Currently, about 35 states have operational monitoring programs and another 7 or 8 states are in various stages of program implementation. Recognizing the role these programs have in helping to prevent drug abuse and diversion, chain pharmacies actively support these programs. Pharmacies submit information on the controlled substances they dispense monthly, weekly, and daily depending on the particular state's program requirements. This information includes information on the patient, prescribed drug dosage and quantity and the prescriber. This information allows the state to conduct confidential reviews to determine any patterns of potential abuse or diversion.

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

NACDS and chain pharmacies support these programs as one of the links in the chain to help curb prescription drug abuse and diversion. We believe that these programs have

proven useful in preventing drug abuse and diversion at the prescriber, pharmacy and patient levels.

THE ROLE OF MEDICATION THERAPY MANAGEMENT (MTM)

Services provided by community pharmacists could assist with the prevention and reduction of prescription drug diversion. Pharmacists are uniquely qualified to provide Medication Therapy Management (MTM) services to patients, which help ensure that patients are prescribed the correct medications and that they are taking them properly. Unfortunately however, MTM services are infrequently compensated, which limits pharmacists' ability to provide these services to patients.

When patients are prescribed the correct medications, they are less likely to experience adverse effects, such as allergies and drug interactions. Thus, they are more likely to take their medications as directed, that is, to adhere to their therapy. Patient adherence to their medication therapy leaves fewer unused medications in medicine cabinets that can be diverted and abused by others. Properly reimbursing pharmacists for providing MTM services is a greatly underutilized tool for addressing the problems of prescription drug diversion.

Pharmacist MTM services and the improved medication adherence that can result also provide the dual benefits of improving patient health outcomes and reducing the use of other more costly healthcare services. Research has shown that an estimated one-third to one-half of all patients in the United States do not take their medication as prescribed. They may fail to take their prescription medications, take their medication incorrectly, or stop taking their medication altogether. These circumstances seriously undermine quality of life and quality of care, patient outcomes and the value of healthcare dollars spent. Poor medication adherence costs the U.S. approximately \$290 billion annually – 13% of total healthcare expenditures. Community pharmacies and their pharmacists are uniquely situated to assist patients in complying with their prescribed medication treatment and explaining the benefits of adherence. Programs such as ChecKmeds in North Carolina, a

program where community pharmacists provided MTM services involving nearly 27,000 seniors in 2008 and 2009, showed the benefits and savings by avoiding more costly health care services such as emergency rooms and hospitalizations and prescription drug savings. For every dollar spent in this program for pharmacist medication therapy management services, the benefit was \$13.55 in savings.

**TARGET ILLEGITIMATE INTERNET DRUG SELLERS WITH THE
CHOKEPOINT APPROACH**

NACDS also believes that an important link in the chain to stop drug diversion and abuse is addressing the problem of illegitimate Internet drug sellers. These illicit online drug sellers have websites that target U.S. consumers with ads to sell drugs often without any prescription required. They are almost without exception located outside of the U.S. yet have websites camouflaged to look like legitimate pharmacy websites. They operate in clear violation of U.S. state and federal laws and regulations that protect public health and safety. They sell drugs to consumers without the safety precautions of a legitimate prescriber-patient relationship, a valid prescription, and a licensed U.S. pharmacy.

These illegal Internet sites that profit from these illegitimate activities are often mistakenly referred to as Internet “pharmacies.” They are not pharmacies; they are *illegitimate Internet drug sellers*. They are not licensed as pharmacies by any U.S. jurisdiction, nor do they comply with any of the rigorous state and federal laws governing pharmacy licensure and the practice of pharmacy by pharmacists. Instead, these illegitimate Internet drug sellers are shipping unapproved, counterfeit, mislabeled, or adulterated products within or into the country.

We support targeting illegal Internet drug sellers through the *chokepoint approach*, rather than placing unwarranted burdens on legitimate, state licensed pharmacies that have associated branded Internet websites. Under the chokepoint approach, entities such as domain name registrars that issue websites, financial entities that handle payment transactions, Internet Service Providers that show the illegitimate websites on the

Internet, and common carriers that provide the mailing services would have authority to stop illicit transactions at their point of interaction with these bad actors.

**LAW ENFORCEMENT AUTHORIZED PROGRAMS FOR RETURN AND
DISPOSAL OF UNWANTED PRESCRIPTION DRUGS**

A further link in approaches to curb drug diversion and abuse is to provide consumers with appropriate means to return unwanted prescription drugs for disposal.

Finding a workable law enforcement authorized means for consumer disposal of unused and expired drug products is an important part of reducing drug diversion. While varying policy options have been proposed, NACDS supports the following principles for proper return and disposal of consumers' unwanted medications. These include protecting patient health and safety by maintaining a physical separation between pharmacies and locations that take back consumers' unwanted drugs. For example, drug take-back events sponsored by the Drug Enforcement Administration (DEA) provide for such separation and avoid the potential for returned medications to re-enter the drug distribution supply chain. In addition, we support policies where consumers have a reliable and readily available means to return their unwanted medications such as mail-back envelope programs that are sanctioned by law enforcement or the DEA. For example, the state of Maine has operated a DEA authorized drug mail-back program, funded through federal grants, where consumers are provided with pre-paid mail back envelopes distributed at pharmacies and other locations, to mail in their unwanted medications. In addition, at various locations across the U.S. law enforcement partners with pharmacies to provide drug take-back events to give consumers means to return their unwanted medications.

CONCLUSION

NACDS thanks the Committee for consideration of our comments on efforts to address the problem of drug diversion.



WWW.NCPANET.ORG

**Statement of the
National Community Pharmacists Association**

**Warning: The Growing Danger of
Prescription Drug Diversion**

**The U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and
Trade**

**April 14, 2011
8:00 a.m.**

Chairman Bono Mack, Vice-Chairman Blackburn, Ranking Member Butterfield 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, 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 Drug Control and Prevention, pain is a serious and costly public health issue, impacting 76.5 million Americans.¹ 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

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

serve as a vital reminder that efforts to curb abuse and diversion must be focused on proper disposal of these products.²

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 where consumers seek to return unused or expired medicines.³ 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,

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

³ January 2006 Washington Citizens for Resource Conservation (WCRC) SoundStats® Report

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 that 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 member's pharmacies become legal outlets to receive unused controlled substances.

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 are in compliance with DEA requirements.

In 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.

April 13, 2011

Re: H.R. 1316

The Honorable Mary Bono Mack
Chair, Commerce Subcommittee of the Energy and Commerce Committee
United States House of Representatives
Washington, DC 20510

And

House Commerce Subcommittee Members

Dear Madam Chairwoman:

The undersigned organizations, representing people living with pain, physicians, nurses, cancer patients, cancer survivors and other medical professionals, wish to remind legislators that in addition to helping curb abuse and misuse of extended release oxycodone pain medications, they must be careful not to diminish access to these effective pain treatments for people who need them. Pain is a serious and costly public health issue, and if untreated, can be devastating. Unmanaged pain impacts all areas of one's life including the ability to perform everyday tasks, sleep and even work. It affects more Americans than diabetes, heart disease and cancer combined. According to the CDC, 76.5 million Americans struggle with pain.

When pain is treated, many people can resume daily activities and become productive citizens. For many people with pain, opioids are an integral part of a comprehensive pain management plan to help relieve pain, restore functioning and improve quality of life and are not misused, abused or diverted.

The extent of the non-medical use of extended release of oxycodone, or any prescription opioid medication, is a serious public health issue that needs to be addressed. The strategy proposed in H.R. 1316, limiting the medications indicated use to only "severe" pain, would take a safe and effective medicine away from millions of people living with moderate pain. "Moderate" pain, for one who is living with chronic pain, can be a disabling curtailment to quality of life and function. The proposed strategy would not diminish the rate of abuse as drug seekers will shift to other options. Any part of the misuse/diversion problem attributable to prescribers and patients can be addressed through the kind of education proposed in the FDA Risk Evaluation Mitigation Strategy plan for extended release opioid medications. Prescribers need better education and skills to appropriately assess pain and implement treatment options and plans. Patients need better education in the use, safe storage and disposal of medications that pose abuse and misuse risks.

Hearings on the issue of opioid pain medicines need to offer balanced opinions about not only the associated risks but the benefits of these medicines when properly used. Living each day in pain is a

horrible existence. The needs of millions of people living in pain should be included when reviewing medicines designed to relieve pain.

We respectfully ask that the committee consider our remarks and expand the review to include the value of these medicines for people with pain who take these medicines as properly prescribed.

Thank you.

Respectfully submitted:

American Academy of Pain Management

American Cancer Society---Cancer Action Network

American Chronic Pain Association

American Pain Foundation

American Society for Pain Management Nursing

Cephalon

Citizens Advocacy Center

Inflexxion

International Association for Pain and Chemical Dependency

Lance Armstrong Foundation---LIVESTRONG

The Neuropathy Association

Reflex Sympathetic Dystrophy Syndrome Association

Cc: Commerce Subcommittee members

Mrs. BONO MACK. I thank the gentleman. And we also have statements from members who are not on the subcommittee that will be submitted for the record without objection.
[The information follows:]

Statement for the Record
Congressman Harold Rogers

House Committee on Energy & Commerce
Subcommittee on Commerce, Manufacturing, and Trade

April 14, 2011

“Warning: The Growing Danger of Prescription Drug Diversion”

As Co-Chairman of the Congressional Caucus on Prescription Drug Abuse, I would like to thank Caucus Co-Chair and Subcommittee Chairwoman Mary Bono Mack for holding this important hearing today. For over a decade ago, prescription drug diversion began to wreak havoc on communities in my region of Appalachian Kentucky. Local hospitals were experiencing more than an overdose per week, families had been overrun by pain pills, and a feeling of hopelessness had begun to pervade the entire region. These powerful drugs intended to *manage* pain were suddenly *creating* pain in the form of overdoses, crime and uncontrollable addiction. While the first wave hit Appalachia, this second wave is hitting America. Now the diversion of prescription pills is the fastest growing drug problem nationwide with abuse transcending state lines and socio-economic groups.

Ms. Bono Mack and the Members of the Subcommittee have assembled a talented group of federal policy-makers, state officials and Americans who have experienced first-hand the devastation wrought by the illicit diversion and abuse of these otherwise life-saving drugs. Today’s testimonies and the ensuing discussions will accomplish more than simply identify the tremendous scope of the problem and the dire implications for the next generation of Americans. I hope this hearing will facilitate ongoing conversations and enhanced collaboration among federal, state and local officials, advocacy organizations around the country, our health and law enforcement communities, and the men and women suffering or recovering from abuse about *solutions*.

Now that the nation’s attention has been turned to this epidemic, it is time to employ all of the resources and brainpower at our disposal to approach this challenge from a number of angles – prevention, treatment, education and law enforcement all will play a role in eliminating this scourge for good.

As Governor Beshear alluded in his remarks, state-run Prescription Drug Monitoring Programs (PDMPs) are among the most effective and accessible tools to combat prescription drug diversion and abuse, bridging the gap between legitimate medical need and potential misuse. PDMPs acknowledge that a family doctor, a neighborhood pharmacist and a local law enforcement officer are all critical to keeping these drugs from diversion or abuse. Monitoring programs track vital prescription data so that doctors and pharmacists know when a prescription is being abused and investigators can root out bad doctors who are aiding drug dealers and addicts.

In the Commonwealth, the Kentucky All Schedule Prescription Electronic Reporting System (KASPER) has had unprecedented success in bringing this problem under control. In 2008, KASPER processed nearly 418,000 requests for patient prescription information. Of the 94% which came from the medical community, including physicians, ER doctors and pharmacists, nearly three-quarters of them say KASPER is "important" in helping to ascertain patient intentions and patterns, and to feel comfortable writing prescriptions for patients truly in need of medical attention. In the same year, just over 11,000 KASPER requests came from the law enforcement community, and 96% of these KASPER users agree that the PDMP is an excellent tool for obtaining evidence in criminal investigations.

These reports create informed decision-making for good medicine and good law enforcement. I have heard anecdotally of countless occasions where KASPER has helped a doctor provide better patient care or a law enforcement official interrupt a crime. Since 2002, the U.S. Department of Justice Prescription Drug Monitoring Grant Program has awarded over \$55 million to nearly every state to plan, implement and enhance similar state-run programs. Because of these efforts, thirty-three other states are catching on with operational PDMPs. Nearly every other state, including three this year alone (Arkansas, Maryland, Montana), has passed authorizing legislation. Nationwide, since 2003, there has been a 2,596% increase in the number of prescription reports produced by state-run PDMPs annually. Important steps have recently been undertaken to facilitate interstate data exchange among these programs to reduce the doctor shopping we're experiencing, such as that between Florida and Kentucky.

Of note, I have expressed my continued frustration that an inordinate number of the drugs on Kentucky Main Streets are heralding from South Florida. In the first six months of 2010, 41.2 million doses of oxycodone were prescribed in Florida, whereas the total prescribed doses of oxycodone in every other state combined was 4.8 million. In other words, almost 90% of the oxycodone prescribed in the U.S. is ordered by Florida physicians. Last month, as a part of "Operation Pill Nation," DEA in Florida arrested 22 people and seized over \$2.5 million in assets during a takedown of rogue pain clinics. These arrests resulted from 340 undercover buys of prescription drugs, from over 60 doctors in more than 40 "pill mills." With impressive strides being made to enhance the PDMP model and integrate data-sharing, Florida's participation will be vital to the success of our nation in fighting this problem, helping addicts get treatment and prosecuting pushers. We need to shut down this pipeline across state lines, and I am heartened by recent news that the state is moving forward with its PDMP. In addition, I am proud to support legislation sponsored by Congressman Vern Buchanan of Florida that would employ the full gamut of federal resources to crack down even more aggressively on these pill mills.

While monitoring programs provide our medical and law enforcement communities with an important tool to identify abuse and diversion, buy-in from local communities might be the single most important factor in developing an anti-drug culture in towns across the country. I was proud to welcome Office of National Drug Control Policy (ONDCP) Director Gil Kerlikowske to my congressional district last month. When I showed him the front page of our local paper, there were some notable omission – no stories about the town fair or the community pot lock. The front page was chalk full of articles about prescription drug abuse – arrests, thefts, the abandonment of children, and tragically, deaths. This is sadly typical in Kentucky, where we are losing 82 people monthly to overdose. To spend a few days in my district, one would think

that the situation is truly cyclical and hopeless. However, while I believe the Director has appreciation for the challenges we're facing with the abuse of these drugs in Kentucky, I don't think he left with that impression that we can't pull ourselves out of this mess.

In Eastern Kentucky, we've been employing a multi-pronged approach to combating this abuse for years through Operation UNITE. Since inception, more than 4,500 addicts and non-violent offenders who have fallen prey to this scourge have participated in a UNITE-funded drug court or treatment program, restoring hope and creating opportunity. In addition, 188 schools in 36 southern and eastern Kentucky counties have a UNITE club, encouraging our children to remain drug-free and offering counseling programs. There are countless UNITE Community Coalitions throughout my congressional district, which support educational and faith-based conferences, medical symposiums, technical trainings and health care workshops. Many of these coalitions have received federal support through the Office of National Drug Control Policy (ONDCP) Drug-Free Communities Grant program. Operation UNITE is a bright star in our charge to empower our youth, create an anti-drug culture and knock out abuse for good, and a clear indication that our fight against drug abuse is rooted in small communities across the country. I am pleased that Director Kerlikowske had a desire and an opportunity to witness first-hand the positive impact of this program in our region.

Needless to say, we're positioning ourselves to tackle this issue, both locally and through state-level coordination. I look forward to next Tuesday when ONDCP will join top officials from the Department of Health and Human Services, Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA) to unveil the Administration's comprehensive plan for addressing the our fastest growing drug threat. I am encouraged by these important strides to bring relevant and interested stakeholders to the same table to work towards solutions for the short- and long-term. This will take a collaborative, multi-pronged effort -- law enforcement, treatment, education are all a part of the puzzle -- and I am grateful to have the opportunity to share my perspective with you in the course of this important hearing.

Thank you all for being here today.

Mrs. BONO MACK. I just wanted to say that as we wrap things up today, I want to thank all of our panelists as well as my colleagues and their staffs for their time and their commitment to this critically important issue.

If 30,000 Americans died every year from food poisoning, Congress would take action. If 30,000 Americans died from pesticide exposure, Congress would take action. And if 30,000 Americans died in airplane crashes every year, trust me, Congress would take action in a huge way. So why are the victims of prescription drug abuse treated differently? I don't have an answer, but I encourage everyone here to help us find one.

I remind members that they have 10 business days to submit questions for the record, and I ask the witnesses to please respond promptly to any questions they receive. Again, I thank you all and I look forward to our work together in the future.

The subcommittee hearing is now adjourned.

[Whereupon, at 12:35 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**Statement of the Honorable Fred Upton
Chairman, Committee on Energy & Commerce
April 14, 2011
Subcommittee on Commerce, Manufacturing and Trade
Hearing on “Warning: The Growing Danger of Prescription Drug Diversion”
(As Submitted for the Record)**

Thank you, Chairman Bono Mack, for holding this hearing. I know this is an issue of great personal importance to you, but it should also be of great personal importance to every parent in this country.

According to the CDC, accidental overdose from recreational and non-recreational drug use is second only to motor vehicle crashes as the leading cause of accidental death in the United States. More than 29,000 individuals lost their lives in 2007 due to accidental poisoning.

Tragically, our children fall victim to this growing trend. The Partnership for a Drug-Free America estimates that every day approximately 2,500 of our teens try prescription drugs for the first time. And what many parents may not realize is that kids are getting these prescription drugs from their own homes. According to a 2009 survey conducted by the HHS Substance Abuse and Mental Health Services Administration, nearly 70 percent of users said they got the pills from a friend or relative. In the worst cases, when these supplies of legal drugs dry up, many users turn to illicit drugs such as heroin.

These medications serve a critical purpose – they make life livable for severely ill or injured individuals who require pain medication to function in their daily lives and that supply should not be restricted. But I am concerned with what some medical experts believe is a trend of over-prescribing these drugs. Adding to that concern, these medications often sit around the medicine cabinet, unmonitored, because patients do not use their full supply and do not know how to properly dispose of the pills.

Education is a key component of addressing this issue. The medical community must ensure prescribers are educated about when to prescribe these medications and at what dosage. Patients must be educated about the dangers of these prescriptions if not used properly and the signs to look for so that pain treatment does not become addiction. And anyone who has these drugs in their homes must be warned against sharing them with others (even if they believe it is for a legitimate purpose), and they must be educated about how to properly store and dispose of these drugs. This basic information could help prevent some tragedies like those we will hear about today.

**Opening Statement of the Honorable Joe Barton
Chairman Emeritus, Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
“Caution: The Growing Danger of Prescription Drug
Diversion”
April 14, 2011**

Thank you Madame Chairwoman for holding this hearing. I would like to welcome Governors Beshear and Scott along with Administrator Leonhart, Director Kerlikowske and our other panelists.

Madame Chairwoman, the diversion of prescription drugs to users for whom the drugs were not prescribed and for uses other than the medicinal purpose of the drug is a growing problem in the United States and I applaud your effort to highlight this growing and tragic issue.

Being from border states, we are keenly aware of the porous nature of our border with Mexico. Unfortunately, people are not Mexico's only illegal export to the United States. In fact, Mexican border town pharmacies are a vital source of illegal pharmaceuticals seized in the Houston Field Division of the Drug Enforcement Agency. The DEA's interdiction efforts also show that prescription drug smuggling from Mexico, where these drugs can be sold over the counter, contributes to the illegal distribution of prescription medications in Texas.

I look forward to hearing from Governor Scott about his state's efforts to combat this illegal use of legal drugs by focusing not just on the users but also on their dealers and their sources at the top of the trafficking ladder. I also applaud his efforts to make privacy a priority as his state implements their patient database.

With that Madame Chairwoman, I yield back.

Statement from Representative John D. Dingell
House Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade hearing
“Warning: The Growing Danger of Prescription Drug Diversion.”
April 14, 2011

Madam Chairman, I commend you for holding today’s hearing. As you know firsthand, prescription drug abuse and diversion are a part of the nation’s growing pharmaceutical safety and security problem.

I strongly believe that we need to look further into how we can prevent abuses and safety lapses before they occur, helping to protect American consumers from inappropriate, unsafe or ineffective use of pharmaceuticals.

This is why I introduced H.R. 1483, the Drug Safety Enhancement Act, which would provide the FDA with needed authorities and resources to prevent the spread of counterfeit, adulterated and misbranded pharmaceuticals here and abroad.

This legislation would:

- Require manufacturers to implement improved quality and safety standards, including stronger supply chain management;
- Require manufacturers to notify FDA of counterfeits or safety concerns and to list drugs and drug components country of origin;
- Strengthen importers and customs brokers oversight;
- Arm FDA with administrative detention, destruction, and mandatory recall authorities, subpoena power, and clear extraterritorial jurisdiction;
- Strengthen criminal and civil penalties for crime deterrence;
- Increase FDA foreign manufacturing inspections to be on par with domestic facilities; and,
- Create new funding mechanisms for FDA inspectional activities, so globalization doesn’t burden US taxpayers.

While this Subcommittee does not have jurisdiction over the FDA, it is important that we recognize that the FDA serves a critical role in the safety of our pharmaceuticals. Not only do they monitor drugs coming across our borders, but they are responsible for approving new drugs entering the market here in the U.S. and communicating side effects or safety concerns about drugs with consumers.

More importantly, the FDA has been active in educating consumers about the misuse of prescription pain killers, producing educational documents and brochures to help consumers to educate themselves and their families about the dangers of addiction and misuse of prescription drugs.

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To help the FDA to continue this good work, we must ensure that have a steady, reliable stream of funding to carry out their duties.

I sincerely hope my colleagues on both sides of the aisle will work with me to provide FDA with the authority it needs to ensure safety of pharmaceuticals here and abroad.



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

June 28, 2011

The Honorable Mary Bono Mack
Chairwoman
Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce
United States House of Representatives
104 Cannon House Office Building
Washington, D.C. 20515

Dear Madam Chairman:

Enclosed please find my responses to the Questions for the Record pertaining to the April 14, 2011, hearing of the Committee on Energy and Commerce's Subcommittee on Commerce, Manufacturing, and Trade entitled, "*Warning: The Growing Danger of Prescription Drug Diversion.*"

I sincerely appreciated the opportunity the Subcommittee on Commerce, Manufacturing, and Trade provided me to discuss this important issue. If you have any further questions, please do not hesitate to contact me directly at (202) 395-6700, or have your staff contact Christine Leonard, Director of ONDCP's Office of Legislative Affairs, at (202) 395-7225.

Respectfully,

A handwritten signature in black ink, reading "R. Gil Kerlikowske".

R. Gil Kerlikowske
Director

Enclosure: Responses to Questions for the Record

cc: The Honorable G.K. Butterfield, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade, Committee on Energy and Commerce

Responses to Questions for the Record
 R. Gil Kerlikowske
 Director, Office of National Drug Control Policy
 Congressional House Committee on Energy and Commerce
 Subcommittee on Commerce, Manufacturing and Trade
 Re: April 14, 2011 Hearing on prescription drug abuse
 June 16, 2011

The Honorable Mary Bono Mack

1. Why did abuse of opioid drugs become a problem so quickly?

The misuse of prescription drugs has emerged as a critical public health issue to such an extent that the Centers for Disease Control and Prevention (CDC) has declared it an epidemic. The rate of unintentional drug overdose deaths has increased approximately five-fold since 1990, due in large part to opioid analgesics. In 2007, there were more such deaths due to opioid analgesics than cocaine and heroin combined. The proportion of all substance abuse treatment admissions aged 12 or older who reported any pain reliever abuse increased more than four-fold between 1998 and 2008. In 2009, emergency department (ED) visits resulting from the misuse or abuse of pharmaceuticals occurred at a rate of 405.4 visits per 100,000 population, compared with a rate of 317.1 per 100,000 population for illicit drugs. About half of the ED visits for misuse or abuse of pharmaceuticals involved pain relievers. Ease of access to and availability of prescription drugs are significant risk factors for drug abuse. This, combined with a perceived lack of risk from abusing prescription drugs, has contributed to an epidemic of prescription drug abuse. It is essential that we maintain appropriate access to pain medication for individuals suffering from chronic and acute pain, while recognizing the risk of diversion, misuse, and abuse of prescription drugs.

The patient advocacy and healthcare communities have sought to ensure adequate and comprehensive treatment for patients suffering from acute and chronic pain. Over the last decade, there has been a dramatic increase in the number of products available for the treatment of pain. In addition, the number of prescriptions filled for opioid pain relievers – some of the most powerful medications available – has increased dramatically. Average sales of opioids per person have increased from 74 milligrams in 1997 to 369 milligrams in 2007, a 402 percent increase.¹ In 2000, retail pharmacies dispensed 174 million prescriptions for opioids; by 2009, 257 million prescriptions were dispensed, an increase of 48 percent.² However, along with the increased legitimate use of these products, the misuse and abuse of prescription pain killers has reached unacceptably high levels. Opiate overdoses, once almost always due to heroin use, are now increasingly due to prescription painkillers.

¹ Manchikanti L., Fellow B, Ailani H, Pampati V. Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective. *Pain Physician*. 13:401-435. 2010.

² Based on data from SDI, Vector One: National. Years 2000-2009. Extracted June 2010. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM217510.pdf>

2. Why did the rogue pharmacies specialize in hydrocodone versus oxycodone or other controlled substances? Why do the pill mills specialize in oxycodone instead?

Most opiates are powerful drugs that affect the brain and nervous system to alter the body's normal systems by altering mood or blocking pain. Prescription controlled substances are classified in Schedule II, III, IV, and V, with Schedule II drugs having the most inventory and dispensing restrictions. Currently marketed hydrocodone products, although not as potent as oxycodone, are only available in combination with other active ingredients and are listed as Schedule III drugs, which allows for refills and the prescriber to call prescriptions in over the phone. In addition, hydrocodone is procured by pharmacies and medical offices through a less-stringent process and generally requires less inventory control at pharmacies. Oxycodone, a more potent opiate in Schedule II, has tighter ordering restrictions from wholesalers or distributors and inventory controls once in pharmacies.

3. Are pain drugs inherently habit forming? Is there work to develop better drugs for pain that have less potential for abuse?

Opioid pain medications come with risks for physiological dependence or of becoming "habit forming" after continued or regular use. This physiological dependency is not the same as addiction, and can be managed with appropriate medical oversight. These drugs work on the same brain mechanism as most other psychoactive drugs, including illicit drugs. Psychoactive medications such as these come with varying degrees of abuse liability, that is, the likelihood that people will abuse them to get high, alter their mood and perceptions, or just feel normal. Therefore, the system of medication regulation must balance the potential health benefits of medications with abuse liability against the potential for abuse. However, there is ongoing research, funded by both government and industry, to develop new formulations in an effort to maximize therapeutic benefit and minimize their risk of abuse.

4. How much of a problem is "drugged driving"?

The prevalence of drugged driving in our country poses a problem for drivers, their passengers, and the public. *The National Roadside Survey of Alcohol and Drug Use by Drivers*, a nationally representative survey conducted by the National Highway Traffic Safety Administration (NHTSA), found that in 2007, one in eight weekend, nighttime drivers tested positive for illegal drugs. Moreover, approximately one in eight high school seniors responding to the 2010 Monitoring the Future (MTF) study reported that in the two weeks prior to the survey interview, they had driven after smoking marijuana.

The most compelling evidence of the severity of the drugged driving threat was provided in data released by NHTSA in November 2010. According to the Fatality Analysis Reporting System (FARS), one in three (33 percent) of all drivers killed in traffic crashes in 2009 who were tested and the results reported, tested positive for drugs (illegal substances as well as over-the-counter and prescription medications). Even as the total number of drivers killed in motor vehicle crashes

declined 21 percent from 2005 to 2009, the involvement of drugs in fatal crashes increased by 5 percent over the same time period, though the data does not indicate level of impairment or whether drug use was the cause of the crash. Research does show, however, that drugs have adverse effects on judgment, reaction time, motor skills, and memory – critical skills for safe and responsible driving.

The Roadside Survey can be found online at www.nhtsa.dot.gov. MTF is available online at www.monitoringthefuture.org. More information about FARS can be found at <http://www.nhtsa.gov/FARS>.

5. Statistics show that the U.S. population consumes 80% of the world's opioid painkillers. We also have a large problem with abuse of opioid painkillers among a large population – including teens. When you look at the rest of the world and the lack of similar drug addiction problems or use for medical reasons, is it fair to ask whether we are over prescribing painkillers?

The ability of U.S. health care providers to treat pain has greatly improved. However, we need to carefully address over prescribing of pain medications. Action must be taken to stem the epidemic of prescription drug abuse, but there is no single answer to this complex problem. A comprehensive solution is needed to ensure the availability of opioid pain relievers for those who need them, while curtailing diversion and inappropriate use of prescription drugs. Too often, potentially dangerous prescription drugs are left unused and are easily available in unlocked medicine cabinets, where they are ripe for diversion and abuse. Further, far too few prescribers receive adequate training in appropriate prescribing of opioids, and most have little to no training on substance abuse during the course of their health care training. That is why we encourage proper disposal of medications and mandatory prescriber education.

6. Other than throwing more resources at the problem, are there steps that Congress can take to assist you in combating this enormous problem?

Yes. Congress took an important first step last year by passing the Secure and Responsible Drug Disposal Act of 2010, but additional actions can be taken.

We support strengthening state Prescription Drug Monitoring Programs (PDMPs) by reauthorizing the National All Schedules Prescription Electronic Reporting Act and passing legislation to allow the Departments of Veterans Affairs and Defense to share data with state PDMPs. In addition, as we recommended in our plan to combat prescription drug abuse, PDMPs should be funded. Mandatory prescriber education should be required for healthcare professionals who are registered with the DEA to prescribe controlled substances.



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

February 29, 2012

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Madam Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Michele Leonhart, Administrator of the Drug Enforcement Administration, before the Subcommittee on April 14, 2011, at a hearing entitled "Warning: The Growing Danger of Prescription Drug Diversion." We apologize for our delay and hope that this information is of assistance to the Subcommittee.

Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that from the perspective of the Administration's program there is no objection to submission of this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "mwe", is located below the "Sincerely," text.

Ronald Weich
Assistant Attorney General

Enclosure

cc: The Honorable G.K. Butterfield
Ranking Member

Questions for the Record to Administrator Leonhart

Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce Committee
U.S. House of Representatives

“Warning: The Growing Danger of Prescription Drug Diversion”

April 14, 2011

The Honorable Mary Bono Mack

1. Does the DEA consider any data - other than diverted drugs of which they have direct knowledge (e.g., a DEA drug bust) – when they calculate production quotas?

Response:

The Controlled Substances Act (CSA) requires the Drug Enforcement Administration (DEA) to establish quotas to provide for estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for reserve stocks. In estimating the legitimate need, DEA considers losses through diversion activities. Specifically, DEA considers known and reported thefts and losses, information from databases such as the System to Retrieve Information from Drug Evidence¹ (STRIDE) and the National Forensic Laboratory Information System (NFLIS),² and case seizures. DEA reviews information that the manufacturers and distributors are required to report into DEA's Automation of Reports and Consolidated Orders System (ARCOS). DEA also considers that particular registrants seeking individual procurement or manufacturing quotas may be known to be unlawfully diverting controlled substances. For example, when a registrant seeking a procurement quota or a manufacturing quota is under investigation for unlawful distribution, DEA will consider this factor in determining whether to grant or deny the quota request. Other than “diverted drugs of which DEA has direct knowledge,” DEA also considers the Food and Drug Administration (FDA) estimates of the stock needed, historic market trends, and net disposal (in the most basic terms, “net disposal” is the amount of the controlled substance that was actually used in previous years). The information provided by FDA for consideration can also include new products, new indications, voluntary recalls or withdrawals of specific products.

¹ STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits in the database are from the DEA, other federal agencies, and local law enforcement agencies. STRIDE is not a representative sample of drugs available in the United States, but reflects all evidence submitted to DEA laboratories for analysis, from both domestic and foreign sources.

² Implemented in 1997, NFLIS systematically collects results from drug analyses conducted by forensic laboratories and law enforcement entities. NFLIS data helps provide a comprehensive picture of our Nation's drug problem and is used in strategic and tactical drug control plans, policies, and operations. Through the assistance of a contractor, DEA is gathering information for the NFLIS through partnerships with forensic laboratories and law enforcement entities around the country.

This information can be used in conjunction with other information to calculate the legitimate medical needs in the United States.

a. Does DEA partner with State and local law enforcement to ascertain their knowledge of diverted drugs?

Response:

Regarding the diversion of pharmaceutical controlled substances, DEA works with its state and local counterparts in several ways. DEA regularly works with state and local law enforcement on diversion investigations. These opportunities involve the exchange of information on unilateral investigations as well as bilateral investigations. As of February 2012, DEA has 46 Tactical Diversion Squads (TDS) established across the United States that are operational, but some may not be fully staffed. 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 also participates in the National Methamphetamine and Pharmaceutical Initiative (NMPI). NMPI is a High Intensity Drug Trafficking Areas (HIDTA) initiative and receives funding through the Office of National Drug Control Policy's (ONDCP) HIDTA program. The NMPI maintains an Executive Board as well as coordinating an annual conference. The Executive Board is comprised of federal, state, and local law enforcement representatives. The annual conference is typically attended by more than 300 federal, state, and local law enforcement officials. These venues provide opportunities to exchange information on current trends and intelligence regarding the diversion of controlled substance pharmaceuticals. DEA is represented on the Executive Board as well as at the annual conference.

DEA also works with the state medical and pharmacy boards to ascertain information on current trends involving the diversion of controlled substance pharmaceuticals.

b. Does DEA gather statistics from its "drug take back" program?

Response:

DEA recognizes that the diversion and abuse of pharmaceutical controlled substances is a significant and growing problem in the United States. Every leading indicator shows substantial increases, over relatively short periods of time, in the use and abuse of these drugs.

A 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.

On September 25, 2010, DEA coordinated the first National Take-Back Initiative (NTBI). 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 removal of 122 tons of unwanted or expired medications from America's medicine cabinets. The second National Take-Back Initiative was held on April 30, 2011, and the third was held on October 29, 2011. Cumulatively, these three take-back initiatives have resulted in the collection and safe disposal of more than 498.5 tons of unwanted or expired medications.

DEA gathers statistics on the number of collection sites, law enforcement agencies that participate and the weight of drugs collected during the take-back initiative. DEA does not gather statistics regarding the type of drugs collected, i.e., what substances were collected.

- 2. What is the status of DEA's drug take-back regulations? And, as a part of those regulations, are you considering "non-traditional" take-back mechanisms that do not involve law enforcement at the forefront - to remove any intimidation or fear factor? If so, what kinds of take-back mechanisms are you considering?**

Response:

In October 2010, Congress passed and the President signed into law, the Secure and Responsible Drug Disposal Act of 2010. DEA is working diligently to promulgate the regulations implementing this Act. On January 19 and 20, 2011, DEA conducted a public meeting to hear from all interested parties on possible 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 consistent with the CSA. The hearing transcript is available on DEA's website: www.deadiversion.usdoj.gov. 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.

Once drafted, the proposed rule will be published in the Federal Register, and posted on DEA's website and www.regulations.gov. At that time, the public will have an opportunity to submit written comments in response to the proposed rule. DEA will carefully consider all timely comments in preparing a final rule for publication in the Federal Register.

Since the rulemaking process is underway, it would not be appropriate to further comment on what specific drug disposal methods are being considered.

- 3. What State level programs and industry-established programs exist to educate parents about the risks of prescription drugs?**

Response:

DEA works on several fronts to educate the general public and providers about prescription drug abuse including the abuse of prescription pain relievers. First, DEA works with the ONDCP to develop, finalize, and implement the National Drug Control Strategy. This serves as a template to help reduce drug abuse in America. The 2010 National Drug Control Strategy specifically addresses the growing problem of prescription drug abuse and sets forth several action items, to wit: "Educate Physicians About Opiate Painkiller Prescribing;" "Expand Prescription Drug Monitoring Programs and Promote Links among State Systems and to Electronic Health Records;" "Increase Prescription Return/Take-Back and Disposal Programs;" "Assist States to Address Doctor Shopping and Pill Mills;" "Drive Illegal Internet Pharmacies Out of Business;" and "Crack Down on Rogue Pain Clinics that Do Not Follow Appropriate Prescribing Practices."

DEA also works with the Department of Health and Human Services to coordinate and exchange information regarding prescription drug abuse. One such example was a two-day conference held in April 2011, by the Surgeon General regarding the abuse of prescription drugs. The Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS provides technical assistance through a program entitled, "Prevention of Prescription Drug Abuse in the Workplace." This program provides technical assistance to SAMHSA grantees, workplaces, and organizations nationwide to reduce prescription drug abuse. Part of the technical assistance includes information related to effective, science-based, successful model programs to educate parents at their workplace concerning the risk of prescription drug abuse.

Additionally, DEA works with a host of professional organizations regarding prescription drug abuse, specifically the National Association of Boards of Pharmacy, the Federation of State Medical Boards, the American Society of Interventional Pain Physicians, and the National Alliance of State Model Drug Laws. DEA routinely speaks about prescription drug abuse at national conferences held by these and other organizations.

DEA partners with the Community Anti-Drug Coalitions of America (CADCA) at their annual conference to provide hundreds of its members with information regarding prescription drug abuse. In January 2011, DEA helped CADCA develop an hour-long taped presentation on prescription drug abuse which will be aired nationwide to CADCA members.

Several divisional offices within DEA host regular Citizen's Academy classes. These classes are designed to inform members of the community about DEA. During these academy classes, DEA provides a segment on prescription drug abuse to educate attendees about this problem.

The Office of Diversion Control regularly meets with members of Congress or their staff to provide information on the current state of prescription drug abuse. Whenever called upon, DEA provides technical assistance to members of Congress regarding draft legislation specific to diversion and prescription drug abuse, examples of which include the Ryan Haight Act and the Secure and Responsible Drug Disposal Act.

Through its Public Affairs Section, DEA also responds to numerous media inquiries specific to prescription drug abuse. These inquiries include written responses, on camera/radio interviews as well as telephone interviews. These efforts inform the general public on the issue of prescription drug abuse.

DEA maintains several websites which provide the public with a significant amount of information relative to prescription drug abuse. (www.deadiversion.usdoj.gov, www.dea.gov, www.justthinktwice.com, and www.getsmartaboutdrugs.com.) The Office of Diversion Control also maintains a link on its web site that provides the results of criminal and administrative actions against practitioners who have abused their DEA registrations. This link may be accessed via "Info & Legal Resources," then "Cases Against Doctors."

The Office of Diversion Control regularly provides speakers at national, state, and community conferences to inform law enforcement personnel, judges, and the general public about prescription drug abuse. These conferences include, but are not limited to, the following: the National Methamphetamine and Pharmaceutical Initiative; the Law Enforcement Coordinating Committee Conference; the Northwest Alcohol Conference; the Drug, DUI & Mental Health Court Conference; the National Narcotics Officers Conference; the National Native American Law Enforcement Conference; and the National Association of Drug Court Professionals.

As part of their duties, Diversion Investigators conduct inspections and investigations of DEA registrants. This routine oversight helps to ensure that these registrants comply with the CSA and its implementing regulations thereby helping reduce diversion of controlled substance pharmaceuticals.

Finally, the Office of Diversion Control coordinates the National Take-Back initiative. This program is designed to rid medicine cabinets of stored expired and unwanted medications. DEA also provides Drug ID pamphlets and drug awareness booklets to the general public and professional associations. These initiatives involve a nation-wide public awareness campaign that helps inform the general public about prescription drug abuse and what they can do to help reduce this threat.

4. **Statistics show that the U.S. population consumes 80 percent of the world's opioid painkillers. We also have a large problem with abuse of opioid painkillers among a large population – including teens. When you look at the rest of the world and the lack of similar drug addiction problems or use for medical reasons, is it fair to ask whether we are over prescribing painkillers?**

Response:

There are many scientific studies and journal articles examining the use of opioids to treat chronic noncancer pain. The use of opioids to treat pain is primarily within the purview of medical professional licensing and regulating authorities. DEA's authority in this regard extends to ensuring that controlled substance prescriptions are issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice.

Controlled substance prescriptions are not issued for a legitimate medical purpose in the course of professional practice, for example, when practitioners intentionally or knowingly divert controlled substances using their DEA registrations.

- 5. If diversion data shows that 5 percent of legal drugs are diverted for non-medical uses, should production quotas be lowered correspondingly? Are the quotas currently reduced based on diversion data?**

Response:

The purpose of quotas is to provide for an adequate and uninterrupted supply of schedule I and II controlled substances necessary to fulfill the United States' estimated medical, scientific, research and industrial needs, lawful export requirements, and reserve stocks. DEA is obligated to set quotas at a level that will avoid a shortage for legitimate users. Some of the factors considered when setting quotas include total net disposal, trends in the national rate of net disposal, total actual or estimated inventories, and other factors such as changes in accepted medical use, economic and physical availability of raw materials, and emergencies. The calculations are based primarily on annual need assessments provided by the FDA and actual sales, disposal, and inventory numbers provided by industry. As discussed, DEA considers losses through diversion activities. Specifically, DEA considers known and reported thefts and losses, information from STRIDE and NFLIS, and case seizures. DEA also considers that particular registrants seeking quotas may be known to be unlawfully diverting controlled substances, which may trigger an administrative action or a civil or criminal investigation.

Reducing production quotas by a percentage of "legal drugs diverted for non-medical use" will reduce the amount of controlled substances available for lawful distribution, thereby adversely affecting legitimate users. Such a result is contrary to DEA's mandate in the CSA to provide an adequate and uninterrupted supply of controlled substances for the medical and other needs of the United States. It is important to note that reducing production quotas will not necessarily lead to reduced demand. Legitimate and illegitimate users often acquire controlled substances from the same source - through prescriptions or dispensations that may only be issued by practitioners acting in the usual course of professional practice.

DEA utilizes all of its regulatory, administrative, civil, and criminal authority to help ensure that DEA registrants adhere to all aspects of the CSA and implementing regulations. In doing so, sources of supply are kept in check and organizations that are responsible for diversion are disrupted or dismantled. These enforcement and regulatory efforts help reduce the amount of controlled substance pharmaceuticals that make their way into the illicit market. Though these efforts are needed to help reduce the illicit supply we must also work to reduce the illicit demand for controlled substance pharmaceuticals.

- 6. How many doctors have been convicted or had their DEA registration denied or revoked for overprescribing Schedule II prescription drugs?**

Response:

DEA maintains statistics on those arrested versus those convicted and therefore provides the following data. The specific charges may vary on a case by case basis, but many are for illegal distribution of controlled substances.

- In 2008, 34 practitioners were arrested by DEA for violations involving schedule II substances.
- In 2009, 36 practitioners were arrested by DEA for violations involving schedule II substances.
- In 2010, 19 practitioners were arrested by DEA for violations involving schedule II substances.

Despite these cases, the vast majority of the more than 810,000 DEA registered practitioners adhere to their responsibilities under the CSA and implementing regulations. DEA's authority regarding denial and revocation of a practitioner's DEA registration is outlined in 21 U.S.C. 823, 824. DEA's authority in this regard extends to ensuring that controlled substance prescriptions are issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice. Controlled substance prescriptions are not issued for a legitimate medical purpose in the course of professional practice when practitioners intentionally or knowingly divert controlled substances using their DEA registrations. When a DEA investigation reveals that a practitioner is knowingly or intentionally diverting any controlled substances (not necessarily schedule II substances), DEA may invoke its statutory authority to revoke or deny the practitioner's DEA registration, or initiate criminal proceedings. A non-exhaustive summary of some administrative and criminal actions may be found on DEA's website.

When appropriate, DEA does take administrative action against various registrants that may lead to the suspension, revocation or surrender of a DEA registration. DEA does not, however, track revocations by drug or schedule. *Operation Pill Nation*, an operation targeting rogue pain clinics in south Florida, is an example of DEA action against DEA registrations. As of February 21, 2012, Operation Pill Nation I resulted in 47 arrests, including 27 doctors; the issuance of 34 Immediate Suspension Orders against 63 DEA registrations; 92 DEA registrations being surrendered for cause; and the seizure of more than \$18.9 million in assets. DEA conducted a similar operation in the central Florida area dubbed Operation Pill Nation II. As of January 31, 2012, Operation Pill Nation II resulted in 57 arrests, including 8 doctors and 3 pharmacists; the issuance of 4 Immediate Suspension Orders; 6 DEA registrations being surrendered for cause; and the seizure of approximately \$311,995.00 in assets.

7. Should there be further restrictions on who can be licensed to prescribe opioids?

Response:

The President's 2010 National Drug Strategy recognizes that pharmaceutical drug abuse is a serious problem. One of the action items contained in the Strategy discusses educating physicians about opiate painkiller prescribing. Training and education on proper prescribing of opioids is an important element in reducing the diversion of controlled substance

pharmaceuticals. On April 19, 2011, the Administration released its action plan to address the national prescription drug abuse epidemic. This new strategy strikes the balance between cracking down on drug diversion and protecting delivery of effective pain management. The Administration's "Epidemic: Responding to America's Prescription Drug Abuse Crisis" provides a national framework for reducing prescription drug diversion and abuse by, *inter alia*, supporting the education of healthcare providers. In support of the action plan, the FDA is requiring an Opioids Risk Evaluation and Mitigation Strategy (REMS). The new program will require manufacturers of long-acting and extended-release opioids to provide educational programs to prescribers of these medications, as well as materials prescribers can use when counseling patients about the risks and benefits of opioid use.

It is important to note that pursuant to 21 U.S.C. § 823(f), state authorization to dispense controlled substances is a necessary predicate to being registered with DEA to dispense controlled substances. Accordingly, individual States are important in determining the criteria regarding who may prescribe and handle controlled substances.

8. **When you look at the stunning charts and statistics of Florida prescribing more pills than the rest of the nation, shouldn't that indicate a need to reexamine the quota system for production of the pills?**

Response:

By statute, the quota system requires DEA to determine how much of a particular controlled substance may be manufactured/produced annually for medical, scientific, research needs, exports and reserve stock. It does not permit DEA to determine the geographical distribution of any particular finished dosage forms. The charts referred to in the above question demonstrate a significant problem with the non-medical use of controlled substance pharmaceuticals. This problem is better addressed through education of the public, practitioners, and pharmacists; through treatment; and through enforcement. The large volume of dispensation being conducted in Florida is due in part to practitioners who are complicit in illegal pill mill operations and who are ignoring their ethical and legal obligations.

- a. **Should Florida be subject to a quota on par with the rest of the states on a similar metric (pills per adult, or pills prescribed per registered doctor)?**

Response:

21 U.S.C. §826 and companion regulations 21 CFR 1303.11 and 1303.12 discuss the establishment of quotas. Neither the statute nor the regulations provide for establishing quotas for individual States or any other geographical region. Quotas are issued to manufacturers of each basic class of controlled substance in schedule I and II. Furthermore, the CSA and implementing regulations do not set limits on the amount of pills a practitioner may prescribe for their patient provided that the prescription is written for a legitimate medical purpose and is done so in the usual course of professional practice.

- b. When Florida looks like it is the outlier, should they be thrown out of the equation of determining quotas and use a system based on the norm for each state?**

Response:

Again, the quota system determines how much of a particular controlled substance may be manufactured/produced; it does not determine the geographical distribution of any particular finished dosage forms.

- c. If Florida dispensed more than 41 million oxycodone pills, the second highest prescribing state dispensed 1 million pills, and large states like California have dispensed fewer than 400 thousand, doesn't that clearly indicate there are at least 40 million extra pills in the supply chain that should be discontinued?**

Response:

DEA does review and consider known diverted drug data when calculating the annual production quota for a specific drug class. Additionally, there are no statutory prohibitions on the geographical distribution of any particular finished dosage form of controlled substances.

Methods to reduce or eliminate diversion can include administrative, civil or criminal action against those involved. This is clearly the case within the State of Florida where Federal, state, and local law enforcement efforts were and continue to be directed at rogue pain clinics, their owners and complicit practitioners. Over the past year and a half, DEA has conducted a large-scale operation dubbed Operation Pill Nation which is designed to eradicate these rogue clinics. This operation has targeted wholesale distributors, practitioners and clinic owners/operators in a concerted effort to cut off the source of supply of oxycodone to the illicit market. Bringing the wholesale distributors into compliance will help reduce the diversion of oxycodone and other controlled substance pharmaceuticals. Arresting practitioners or revoking their DEA registration will also help reduce the flow of these painkillers into the illicit market.

- 9. Is there any indication that the prescription drug trade is in any way linked to the organized crime or the drug cartels?**

Response:

There are no current indications that pharmaceutical controlled substance diversion is linked to traditional organized crime syndicates or traditional foreign-based drug cartels.

- 10. Would on-dose marking for controlled drugs be a practical strategy for getting at the root of the diversion problem?**

Response:

There are certainly ancillary factors that contribute to the diversion of controlled substance pharmaceuticals; however, the root cause of diversion is an increasing demand for these

substances for non-medical purposes. On-dose marking provides a means to track and trace drugs that have left the closed system of distribution. However, the ability to track and trace these drugs down to the individual pill does not eliminate or reduce demand. Track and trace is a reactive rather than proactive solution to a complex problem. As stated above, this problem is better addressed through education of the public, practitioners, and pharmacists; through treatment; and through enforcement.

11. Why did abuse of opioid drugs become a problem so quickly?

Response:

America's problem with prescription drug abuse is not a new phenomenon. There are multiple factors that contribute to the abuse of prescription drugs. One factor that makes pharmaceutical drug abuse seem different from illicit drug abuse is the misperception that when we do not see a particular pharmaceutical drug being abused, the problem has gone away. However, previously abused pharmaceutical drugs give way to newer, more potent, quicker acting, and longer lasting pharmaceutical drugs because over the years, pharmaceutical companies have continued to develop new drugs or improve on older formulations. Some pharmaceuticals we see on the market today were not on the market 15 to 20 years ago. And pharmaceuticals we saw being abused 15 to 20 years ago are no longer being marketed.

There are many scientific studies and journal articles examining the use of opioids to treat chronic noncancer pain. The U.S. Department of Health and Human Services, National Institute on Drug Abuse (NIDA) published a Research Report titled "Prescription Drugs: Abuse and Addiction," in which NIDA explores the nonmedical use and abuse of prescription drugs, including opioids. In May, 2011, NIDA published a research update on prescription drug abuse in its "Topics in Brief" series. NIDA stated that multiple factors are driving the prescription drug abuse problem in the United States, including: misperceptions about prescription drug safety; increased environmental availability; and varied motivations for abuse such as getting high, countering anxiety, pain or sleep problems, or to enhance cognition.

12. You have cited the huge number of 1.3 million registrants under the Controlled Substances Act. Should we be considering sharp reductions in the number of registrants who can legally handle these substances? Would DEA have the ability to do that on its own or would it require action by Congress?

Response:

DEA's mandate to register persons to handle controlled substances is outlined in 21 U.S.C. §§ 822 and 823. The CSA provides DEA with specific criteria that must be considered when denying or revoking a registration (21 U.S.C. §824). The vast majority of DEA registrants adhere to their statutory and regulatory obligations under the CSA. There are, however, a limited number of registrants that forego their responsibilities and violate the statute or regulations, contributing to the diversion of controlled substance pharmaceuticals. DEA is working on several fronts to ensure that DEA registrants continue to adhere to their

responsibilities. DEA's Distributor Initiative Program is designed to educate and remind wholesale distributors of their responsibility to design effective programs that identify suspicious orders, thereby ferreting out potential sources of diversion. DEA also has reorganized its Diversion Control Program and retrained all of its Diversion Investigators with an emphasis on enhanced regulatory oversight. DEA has vastly expanded its use of TDS in an effort to effectively stop those individuals or groups that are committing criminal violations of the CSA.

- 13. You mentioned that as a result of your Distributor Initiative Program, some distributors have voluntarily stopped selling or voluntarily restricted sales of controlled substances to certain domestic pharmacies and practitioners. What is the next step? If we know enough to discourage sales to these places, can DEA take more direct action?**

Response:

In accordance with 21 U.S.C. § 827(d)(1), every distributor must report to DEA all narcotic controlled substance sales. The Automation of Reports and Consolidated Orders System, or ARCOS-2, is the DEA database that captures this controlled substance activity. Even though the reporting requirement is limited to narcotic controlled substances, DEA is overhauling its ARCOS system and developing additional IT systems to better identify potential sources of diversion and to do so more rapidly. DEA is also working to expand the number of TDS as well as hire additional Diversion Investigators over the next few years. This concerted effort will allow DEA to take additional action against registrants as warranted.

- 14. If a distributor refuses to sell because of a suspicious order, does DEA usually get timely notice of the distributor's concern?**

Response:

21 CFR 1301.74(b) requires a registrant to design and operate a system to disclose to the registrant suspicious orders of controlled substances and to inform DEA of these suspicious orders "when discovered" by the registrant. The timeliness of notifications varies. DEA, through its Distributor Initiative Program, reminds wholesale distributors of their responsibilities under the CSA and implementing regulations, which includes information regarding the above citation.

- 15. Why did the rogue pharmacies specialize in hydrocodone versus oxycodone or other controlled substances? Why do the pill mills specialize in oxycodone instead?**

Response:

Hydrocodone is a schedule II controlled substance, unless it is contained in a combination product of up to 15 milligrams per dosage unit, in which case it is a schedule III controlled substance. All oxycodone products are listed in schedule II. Pursuant to 21 CFR 1306.11(a) a pharmacist can only fill a prescription for a schedule II substance if he or she is presented with the original prescription. 21 CFR 1306.21(a) allows a pharmacist to fill a prescription issued for a schedule III substance that has been transmitted by facsimile or pursuant to an oral prescription issued by an individual practitioner. In the case of rogue Internet pharmacies, the

“patient” never saw the doctor and therefore could not obtain an original prescription. Conversely, owners of rogue pain clinics recruit practitioners who are willing to participate in the criminal scheme and “patients” come directly to these clinics. This allows a face-to-face encounter whereby the “patient” can receive the pills instantaneously at the clinic (through practitioner dispensing), or they can receive an original prescription for a schedule II controlled substance.

In the illicit market, the demand for oxycodone products is greater than the demand for hydrocodone combination products due to their potency, which drives the profit margin up for the drug dealers.

16. How much of a problem are the foreign-based Internet pharmacies? Do you have the tools you need to address them?

Response:

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 DEA continues to take steps to address it.

While internet pharmacies remain a problem, the National Survey on Drug Use and Health (NSDUH) shows that the majority of prescription drugs that are abused are not purchased on the Internet. The 2010 NSDUH survey shows among respondents aged 12 or older who used pain relievers non-medically in the 12 months preceding the survey, only 0.4% of people bought them over the internet. In contrast, 4.4 percent received them from a drug dealer or stranger, 17.3% said they received them from a doctor, and 55% said they received them from a family member or friend.

There are foreign-based websites that offer to sell both controlled and non-controlled substances. Upon further investigation, these sites are backed not by foreign-based brick and mortar pharmacies, but rather by unscrupulous criminal entrepreneurs. Persons ordering from these sites are likely to run the gamut of scenarios. For example, they may not receive any controlled substances, they may receive look-alike pills that contain other substances (controlled or non-controlled). And in some instances they may receive actual controlled substance pharmaceuticals. The latter appears to be somewhat limited. DEA works with Customs and Border Protection in an ongoing operation dubbed Operation Safeguard. Under this operation, law enforcement officials monitor inbound international packages for the illicit smuggling of controlled substance pharmaceuticals. DEA is also a participant in the Permanent Forum on International Pharmaceutical Crime (PFIPC). PFIPC consists of professionals from 15 member countries that exchange information on international pharmaceutical drug trafficking. This includes information on the trafficking of both controlled and non-controlled pharmaceuticals.

Title 21 USC § 959 provides DEA with authority to investigate members of foreign-based drug trafficking organizations that manufacture or distribute a controlled substance intending that it be unlawfully imported into the United States, or knowing that such substance will be unlawfully imported into the United States. This statute is limited to schedule I and II substances (or flunitrazepam or listed chemicals). There are, however, controlled substance pharmaceuticals that are abused in schedules III and IV that are of concern.

17. What type of “administrative action” did DEA take against the wholesale distributors who were supplying rogue pain clinics in south Florida? Are the penalties severe enough to deter criminal behavior?

Response:

Operation Pill Nation is a combined federal, state and local law enforcement effort to target rogue pain clinics operating in south Florida. As part of this operation DEA is also using its regulatory authority to pursue wholesale distributors who failed to adhere to their regulatory responsibilities. DEA has taken administrative action against four wholesale distributors. One such action has resulted in a \$6 million civil penalty paid by Harvard Drug Corporation in April 2011. Actions taken against wholesale distributors supplying south Florida pain clinics have thus far involved penalties for civil rather than criminal violations.

Florida was previously the epicenter for diversion from rogue internet pharmacies that illegally distributed millions of dosage units of hydrocodone. These schemes were not limited to just Florida but operated nationwide. These operations were supplied by wholesale distributors who failed to adhere to their regulatory responsibilities. To address that problem, DEA brought civil action against various wholesale distributors. For example, in April 2008, McKesson Drug Corporation paid \$13.5 million in civil penalties and Cardinal Health paid \$34 million in civil penalties in October 2008.

18. Other than throwing more resources at the problem, are there steps that Congress can take to assist you in combating this enormous problem?

Response:

The 2011 National Drug Control Strategy reflects a comprehensive approach to reducing drug use and its consequences. The key objectives include: strengthening efforts to prevent drug use in our communities; breaking the cycle of drug use, crime, delinquency, and incarceration; disrupting domestic drug trafficking and production; and strengthening international partnerships. On April 19, 2011, the Administration revealed an action plan to address the national prescription drug abuse epidemic. It expands upon the National Drug Control Strategy and includes four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement.

One element under the Administration’s plan is: “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.”

Additionally, DEA is striking at every level of the distribution chain to combat the growing problem of prescription drug abuse. Activities in support of the National Drug Control Strategy include:

- **NTBI and disposal regulations:** As you know, the medicine cabinet is a source of supply for teens and other family members for abuse or accidental ingestion. DEA is engaged in implementing regulations to provide the basic framework to allow Americans to dispose of their unused and unwanted medications in a secure and responsible manner. Before passage of the Secure and Responsible Drug Disposal Act, DEA sponsored a nationwide take-back initiative that resulted in the removal of 121 tons of medication from America's medicine cabinet. DEA sponsored the second nationwide take-back initiative on April 30, 2011, which resulted in the collection of more than 188 tons of unwanted or expired medications. DEA again sponsored a take-back initiative on October 29, 2011 which resulted in the collection of more than 188.5 tons of unwanted or expired medications. ONDCP, SAMHSA, the Department of Justice, the Bureau of Justice Assistance, the Office of the National Coordinator for Health Information Technology (ONC), the Indian Health Service (IHS), the Bureau of Indian Affairs (BIA), and the Bureau of Indian Education (BIE) are all working cooperatively to promote drug take back programs in all communities. DEA will continue to sponsor this take-back program until the regulations are in place.
- **Operation SOS:** South Florida is the "prescription drug ground zero." DEA is actively investigating pharmacy applications for registration in south Florida, and seeking to deny those applications that are inconsistent with the public interest.
- **Expanded TDS:** 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). As of February 2012, 46 of the TDS groups are operational, but some may not be fully staffed.
- **OPN:** Operation Pill Nation is but one example of the success of the TDS in removing the sources of diversion and preventing future diversion of even greater quantities of prescription drugs. This operation involved the mobilization of 11 TDS 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. OPN has targeted rogue pain clinics in south Florida since February 14, 2010, and culminated in a series of major takedowns in February 2011.
- **Distributor Initiative:** 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 March 28, 2011, DEA has briefed 74

DEA-registered corporations/companies comprising 212 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.

- Increased regulatory oversight: DEA has increased its Diversion Investigator ranks to provide increased regulatory oversight of the more than 1.3 million DEA registrants, a number which grows at an annual rate of approximately 2.5 percent. These Diversion Investigators carry out more frequent scheduled inspections, thereby improving our regulatory oversight and thereby reducing avenues of diversion.
- The DEA, ONDCP, SAMHSA, DOJ, BJA, ONC, IHS, BIA, and BHE are all working cooperatively to promote the use of Prescription Drug Monitoring Programs (PDMPs) in all communities.

The Honorable Bill Cassidy

- 19. A number of pharmaceutical distributors have created and implemented a system to proactively track and limit the distribution of controlled substances. The stated purpose of this initiative is to limit the amount of controlled substances that can be purchased by a specific pharmacy and report suspicious orders to DEA. How useful has this information been to the DEA in their investigation of suspicious activity? Please provide statistics from before and after implementation of the program with your response.**

Response:

21 CFR 1301.74(b) requires a registrant to design and operate a system to disclose to the registrant suspicious orders of controlled substances and to inform DEA of these suspicious orders "when discovered" by the registrant. DEA, through its Distributor Initiative Program, reminds wholesale distributors of their responsibilities under the CSA and implementing regulations which includes the requirement to notify DEA of suspicious orders when discovered. DEA uses these suspicious order reports as investigative leads and to bolster ongoing investigations.

FRED UPTON, MICHIGAN
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ONE HUNDRED TWELFTH CONGRESS
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April 29, 2011

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Dear Dr. Boyd,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on April 14, 2011, to testify at the hearing entitled "Warning: The Growing Danger of Prescription Drug Diversion."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for 10 business days to permit Members to submit additional questions to witnesses, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and then (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please email your responses, in Word or PDF format, to the legislative clerk (Alex.Yergin@mail.house.gov), by the close of business on Friday, May 13, 2011.

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

Sincerely,



Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing, and Trade

cc: The Honorable G. K. Butterfield, Ranking Member,
Subcommittee on Commerce, Manufacturing, and Trade

Attachment

The Honorable G. K. Butterfield

1. National studies implemented by the Substance Abuse and Mental Health Services Administration (SAMHSA) find that painkillers are the prescription drug category most frequently used non-medically. But surveys on drug use among young people, including the University of Michigan's Monitoring the Future dataset, suggest that prescription drug abuse by teenagers – compared to that of the population at large – is more evenly spread out across different classes of drugs, including opioid analgesics, stimulants, and tranquilizers/sedatives.

a. Please briefly summarize the conclusions of recent surveys that have examined young people's use and abuse of different categories of prescription drugs. Please outline how these findings align with or diverge from findings compiled through the National Survey on Drug Use and Health (NSDUH) or other SAMHSA studies.

Both the *National Survey of Drug Use and Health* (SAMHSA, 2010) and *Monitoring the Future* (Johnston et al., 2010) are epidemiological studies that provide descriptive data and thus, make no attempt to establish causal relationships nor to describe the nonmedical use of controlled medications in detail. However, there are additional studies that focus on adolescents and/or young adults (see Arria et al., 2008; Boyd et al. 2006a, 2006b, 2007, 2009; McCabe et al., 2004, 2007); several of these provide insights into this substance abuse problem among adolescent and/or young adults. In fact, these studies complement the NSDUH and MTF. Below are general conclusions drawn from current literature.

- Prescriptions for controlled medications have increased in adolescent and young adult populations (Fortuna et al. 2010). In a school-based sample (N=912), 36.8% of the respondents reported having a legal prescription of a controlled medication within the previous 12 months (Boyd et al., 2009). Thirty-two percent (32.5%) of 12th graders in the 2009-2010 *Monitoring the Future* (MTF) reported *nonmedically using their own* narcotic medication and 19.2% reported nonmedically using their amphetamine medications (e.g. ADHD medication). However, it is unclear whether these adolescents were using their medications to self-treat or to "get high". Neither the NSDUH nor the MTF adequately address the issue of medical use or misuse/abuse of one's own controlled medication, nor do they correlate this misuse with doctor shopping. Conclusion: Controlled medications are increasingly prescribed to adolescents and young adults and these age groups appear to use their own medications for nonmedical purposes. However, more data are needed to determine the reason for misusing one's own medication. It is unclear whether 12 to 15 year olds are engaging in the misuse of their own controlled medications for purposes of self-treatment (i.e. to treat uncontrolled pain) or for other purposes (e.g. get high, mix with other drugs, etc.).
- The highest risk groups for nonmedical use of controlled medications are young adults, followed by adolescents. The NSDUH (SAMHSA, 2010) provides these data as well as other studies (Boyd et al 2008; McCabe et al. 2006, 2007, 2008). Conclusion: Prevention efforts should be age appropriate and focus on parents and health providers as well as adolescents and young adults.
- Using annual data and in a nationally representative sample of 8th, 10th and 12th graders, MTF data show that 5.9% have engaged in the nonmedical use of Vicodin® while 4.3% have used Adderall® nonmedically. In addition, 4.5% have nonmedically used tranquilizers and 3.8% have nonmedically used OxyContin® (Johnston, et al., 2010). NSDUH data are reported differently and are difficult to compare to MTF data; however, NSDUH reveal that approximately 10% to 12% of 17 and 18 year olds have engaged in the nonmedical use of prescription pain medications (not just Vicodin®). Conclusion: Vicodin®, Adderall®, OxyContin® and tranquilizers are used by a similar proportion of 8th, 10th and 12th graders; however, when combining all of the opioid analgesics into one category (e.g. Tylenol 3®, Percocet®, etc.), the largest drug class abused is the opioid analgesics with 10-12% of older adolescents reporting annual nonmedical use.
- The NSDUH, MTF and regional studies all report that opioid analgesics are the drug category most likely to be abused by adolescents and young adults (Boyd et al., 2006b; Johnston et al., 2010; McCabe et al., 2007;

SAMSHA, 2010), however, the abuse of stimulants and tranquilizers (anti-anxiety medications) is also prevalent, especially among young adults (18-25 year olds). When considering people under the age of 20 years, more went to the emergency room for an alprazolam (Xanax®) overdose than for a hydrocodone overdose (SAMHSA, Drug Abuse Warning Network, 2010). Conclusion: It would be a mistake to only focus on the opioids analgesics, the focus should stay on the nonmedical use of all controlled medications.

- Using NSDUH data, Schepis et al (2008) found that nonmedical use of controlled medications is correlated with other forms of drug/alcohol use; smaller studies have found the same result (McCabe et al 2007; Teter, et al, 2006). Risk taking and/or sensation-seeking are highly correlated with nonmedical use of controlled medications among adolescents and young adults (Boyd, et al 2009; McCabe, et al., 2009; Schepis & Krishnan-Sarin, 2008). Conclusion: The nonmedical use of controlled medications is often (but not always) associated with a constellation of other problem behaviors, including poly-substance abuse.
- Using data from the NSDUH, several researchers have found that girls are more likely to engage in the nonmedical use of controlled medications (Schepis et al, 2008; Sung et al 2005), although the NSDUH shows that females are only more likely to abuse tranquilizers. Catalano et al (2011) found there were no sex/gender differences in the nonmedical use of opioids, although for other drugs, males were more likely to use. In a smaller, regional study, McCabe et al, 2007 also found that girls were more likely to engage in this behavior; further, African American youth are less likely to engage in nonmedical use. Conclusion: Females engage in nonmedical use at about the same rates as their male counterparts and this represents a change in the demographics since males are more likely to engage in all other forms of substance use. At this time, African American youth are less likely than their Euro-American counterparts to engage in the nonmedical use of controlled medications.
- Using 2009-2010 national data from 12th graders, MTF(Johnston, et al., 2010) reported that 55% were given amphetamine medications (e.g. ADHD medications) from a friend and 6.9% from a family member while 52.5% were given narcotic medications (i.e. opioid analgesics) from a friend and 15.9% from a family member. Only 1.1% bought narcotics on the Internet while 19.5% bought narcotics from a drug dealer. Multiple studies have found that diversion most likely occurs among family and friends (Boyd et al., 2007; Johnston, et al., 2010; SAMHSA, 2010). The nonmedical use, and diversion of controlled medications are parallel to their availability. Conclusion: Drug dealers and the Internet are NOT the main source of diverted, controlled medications. Most adolescents and young adults get controlled medications from family and friends for free.
- The nonmedical use of controlled pain medications is associated with psychiatric co-morbidities. (Huang et al., 2006; Schepis et al., 2010; Wu, et al., 2010). Conclusion: The high prevalence of psychiatric and mental health problems among nonmedical users of controlled pain medications should be considered in treatment protocols.

b. Please discuss potential reasons why statistical disparities exist between the reported drug use and abuse of young people and the reported use and abuse of all individuals age 12 and older.

The findings from the national studies differ in their conclusions because the samples differ (i.e. the age used in the samples), study designs differ (i.e. cross-sectional versus panel), the questions differ (i.e. some surveys use complex questions in contrast to a simple question) and in some situations, different statistical techniques are used.

The two largest cross-sectional, national studies that focus on adolescents and young adults and address the nonmedical use of controlled medications are the *National Survey on Drug Use and Health* (NSDUH) and *Monitoring the Future* (MTF). However, these studies rely on different sampling plans and time frames (e.g. MTF is school based and NSDUH is household based), different modes of data collection (i.e. computer

assisted versus paper-and-pencil), and different survey questions to assess the nonmedical use of controlled medications. Further, the study investigators often report on different time periods (i.e. 30 days, 12 months or lifetime); 30 day will have the lowest estimates and lifetime the highest. Each study also focuses on different age groups, with MTF reporting on 8th, 10th, and 12th graders and the NSDUH reporting on 12 to 17 and 18 to 25 year olds. Relative to the one question that determines nonmedical use: the MTF stipulates it was taken without a doctor's order, the NSDUH stipulates that the medication was “not prescribed” or it was “taken for the experience or feeling it caused”. The use of such different questions makes comparisons among the two studies very difficult and probably accounts for some of the discrepancies in the prevalence estimates generated by the studies. Further, the MTF and NSDUH fail to distinguish between people who misuse or abuse their own medications (e.g. use more medicine than prescribed, use more often than prescribed, etc.).

Another source for data on nonmedical use is the *Youth Risk Behavior Survey* (YRBS); a survey sponsored by the Centers for Disease Control (CDC). The YRBS contacts students in the 9th through 12th grades and is a school-based survey conducted every other year. In general, the YRBS produces somewhat higher prevalence rates than either the MTF or NSDUH but the trends are similar. Comparing the YRBS, NSDUH and MTF data are very difficult because they use different periods of time (i.e. YRBS is biennial and NSDUH and MTF are annual) and the ages covered by the samples are different.

In regional studies there may be different prevalence estimates because the study sample, prescription practices and nonmedical use vary by region. Further, the regional studies often use a different mode of data collection (e.g. web-based surveys, face-to-face interviews, etc.). Boyd and McCabe ask very detailed questions about medical and nonmedical use, focusing on subtypes of nonmedical users (Boyd, et al., 2006; Boyd et al., 2009; McCabe et al. 2009). Their studies distinguish among those who abuse their own medications and those that use diverted or someone else's medications.

c. To what extent do you believe these differences are attributable to current teens' and young adults' membership in a specific generational cohort with particular views on the utility and risk of each drug? Alternatively, to what extent do you believe these differences are the result of the unique physical and social characteristics of adolescence, and that as these teens and young adults age, their views and behavior will change?

This is a very important question, and one that is impossible to conclusively answer because of a lack of prospective data. It is well established that illicit drug use moves in social and behavioral patterns, with individual drugs gaining and losing popularity; the patterns may be regional or national. However, this ebb and flow is not true for alcohol, which remains a very popular substance.

Because prescription medications share social characteristics with alcohol (e.g. legal for certain groups, relatively safe in small doses, etc.), nonmedical use may be more similar to alcohol misuse/abuse. Our society promotes the legal use of both alcohol and controlled medications; we are one of a very few countries that allow the television marketing of controlled medications (for example, Lunesta®).

Like the abuse of alcohol, the nonmedical use of controlled medications is probably not cohort driven; indeed, it is increasing in several age groups, including those over 50 years of age (Blanco et al., 2007; NSDUH, 2010). This nonmedical phenomenon -- among all age groups -- is most likely a product of our social mores as well as attitudes about our bodies, medications and self-treatment. Historically young adults and adolescents (illegally) use many different substances (including controlled medications) at higher rates than their older counterparts; fortunately, most curtail these behaviors as they advance to middle adulthood. There are some young substance users who do not stop; it is for this reason that drug prevention and early intervention is so very important.

2. The National Survey on Drug Use and Health (NSDUH) is the most comprehensive federal study of drug use among those 12 years and over and the source for much of our current understanding on prescription drug abuse. Nevertheless, in the 2010 National Drug Control Strategy, the Office of National Drug Control Policy indicated that it believes there are many ways the study can be improved.

a. What do you believe are the most notable shortcomings of the National Survey on Drug Use and Health, as it currently exists, and what do you believe could be done to improve the survey in these areas?

The National Survey on Drug Use and Health (NSDUH) is a yearly, in home survey of non-institutionalized U.S. population. Households are selected for screening, with in person screening conducted to identify individuals 12 years and older. Once eligible households are identified and full interviews are conducted on a random sample. All interviews occur in the home using interviewer-assisted and computer-assisted methods. Conclusion: General limitations of the NSDUH include: 1) it is cross-sectional data so causal inferences are constrained; 2) the questions are not aligned with the needs of the treatment and prevention communities; 3) the data are self-reported and not confirmed with other data (i.e. self-report combined with drug testing); 4) the sample does not include institutionalized individuals and thus, some behaviors may be under reported; 5) the survey lacks questions regarding routes of administration and motivations for nonmedical use, 6) some of the questions have not been determined to be valid and 7) in some instances, the questions are poorly constructed.

b. Given shortcomings of the National Survey on Drug Use and Health, and how would you recommend solving them?

Compton and Volkow (2006) noted that our understanding of nonmedical use of controlled medications is limited by not having a consistent definition that is “measured” uniformly across national studies. And thus, some of the NSDUH shortcomings center on the nonmedical questions related to controlled medications. Recommendations include: 1) Revising the question that addresses the nonmedical use of controlled medications and making this question consistent with other NIDA funded studies. As the question is currently written, it has two parts and thus, it is difficult to determine the intent of the respondent. 2) Adding additional questions about the medical use of controlled medications. These questions would seek to establish the prevalence of controlled medications in households, particularly those that are stored and not currently used; 3) Adding questions to determine whether the respondent is engaging in nonmedical use with their own prescriptions as well as with someone else’s prescription and 4) asking more detailed questions about the source of the controlled medications, the attitudes toward controlled medications, the motivations to engage in nonmedical use and the beliefs about safety, and the routes of administration.

c. How would NSDUH enhance our understanding of the prescription drug abuse problem if the study were to improve in the ways you suggest?

Prevention and treatment experts need reliable and valid data in order to deliver their services. If the NSDUH questions were enhanced, experts would have a more complete picture of the risk factors and consequences associated with the nonmedical use of controlled medications.

It is well established that nonmedical use is a behavior that takes on many forms – each form is risky but some forms are riskier than others. With enhanced questions, we would learn: 1) The percentage of people (by age group) that engage in nonmedical use with their own medications in contrast to those who use someone else’s medications; 2) The extent to which people (by age group) give away “extra” pills from their own medicine bottles; 3) The reason people (by age group) save their medicines rather than dispose of them when they are no longer needed; 4) The extent to which people (by age group) ask their family and friends for “extra” pills; 5) The reasons people (by age group) engage in nonmedical use and how often they engage in the behavior and 6) The beliefs about controlled medications and the safety of using them nonmedically.

It would be very helpful if the NSDUH data provided a more complete picture of the risk factors and consequences associated with the various forms of nonmedical use in adolescent and young adult populations, the use of controlled medicines (legal use); the abuse of one's own controlled medications; the sources and diversion practices (in greater detail), and the motivations to engage in nonmedical use of each of the four drug classes (pain, sleep, stimulant and anti-anxiety). There is strong evidence that nonmedical users of controlled medications are a diverse group.

d. What can be done to improve other federal studies of drug use and abuse?

(See previous answers) Federal studies can be improved in several ways: 1) improve the questions pertaining to nonmedical use of controlled medications in large federally funded studies, work to make the questions more uniform across studies so data can be compared; 2) add questions about routes of administration, medical use (legal prescriptions) and adherence; 3) add questions about diversion, including how controlled medications are stored and finally, add questions about availability, attitudes and knowledge as these pertain to controlled medications.

3. Based on the academic research, please provide a discussion of how teens are most likely to put prescription drugs into their bodies. What is the prevalence of each route of administration for the different categories of prescription drugs taken non-medically? How does this differ by age group?

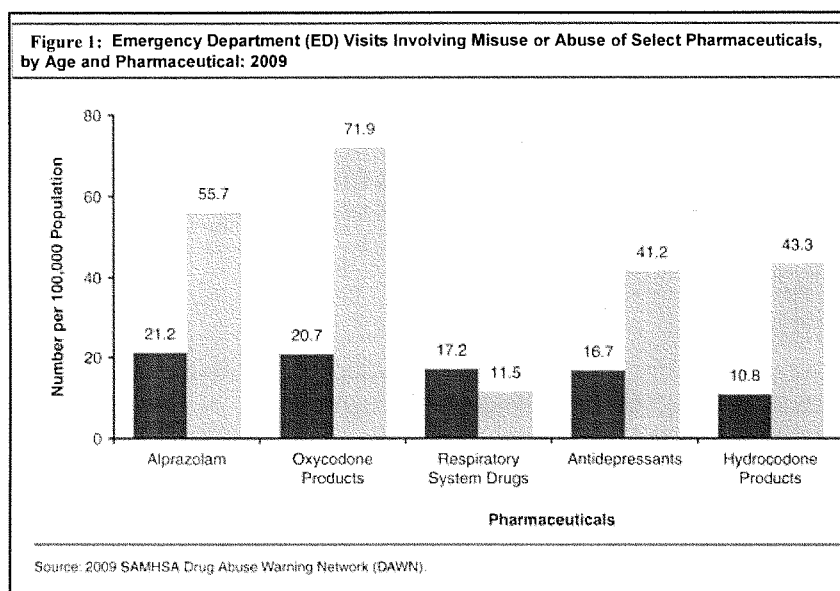
National data provide few (if any) insights into the prevalence of each route of administration (e.g. oral, injection, nasal, etc.) because no such national prevalence studies have been published. Smaller epidemiological studies show that approximately 95% of collegiate nonmedical users of controlled stimulant medication self-administer orally, 38% via intranasal (snorting), 6% via smoking, and less than 1% via inhaling, injecting or other routes of administration (McCabe & Teter, 2007; Teter et al., 2006). Similarly, another study found that approximately 97% of collegiate nonmedical users of controlled stimulant medication self-administer orally, 13% via intranasal (snorting), 4% via smoking, and less than 1% via inhaling, injecting or other routes of administration (McCabe et al., 2007). In 2005, McCabe and Boyd conducted the Student Life Survey (SLS) on one Midwest college campus; in the SLS McCabe and Boyd asked about the nonmedical use of oxycodone and hydrocodone medications in the previous year. They found that approximately 49% (n=35) of those students who nonmedically used oxycodone engaged in non-oral routes of administration, while 36% (n=125) of hydrocodone nonmedical users engaged in non-oral routes. To date, there is a lack of epidemiological research in terms of which routes of administration are being used for anti-anxiety and sleeping medications. Based on the limited research in this area, little can be confirmed regarding routes of administration and how they differ by age group.

4. Please provide a discussion of overdose deaths where prescription drugs are involved, including the relative prevalence of deaths from polydrug use.

It is difficult to find good data on overdose deaths, particularly when there is an attempt to establish that a certain medication caused the death. In a report issued by the Center for Substance Abuse Treatment (2010), it was noted that in 2006 more than one type of drug was mentioned in the majority of opioid analgesic poisoning deaths, with benzodiazepines involved in 17 percent and benzodiazepines with cocaine or heroin in an additional three percent.

Although not directly related to overdose deaths, the Drug Abuse Warning Network (DAWN) provides insights into overdose visits to our nation's emergency departments (ED). According to DAWN data, many of the most commonly misused or abused pharmaceuticals were found to have increased more than 100 percent between 2004 to 2009. The largest increases were seen for oxycodone products (242.2 percent increase), alprazolam (148.3 percent increase), and hydrocodone products (124.5 percent increase). There was also a notable increase with zolpidem, a controlled medication to induce sleep (154.9 percent increase). Using 2009

data from DAWN that involved pharmaceuticals, approximately 50% of the ED visits were for the misuse or abuse of narcotic pain relievers (129.4 visits per 100,000 population) while another third involved drugs used to treat sleep or anxiety disorders, primarily the benzodiazepines (121.6 visits per 100,000 population). However, for people under 20 years, alprazolam (i.e. Xanax®) was as likely to be implicated as either oxycodone formulations and more likely than hydrocodone formulations (see Figure 1)



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May 16, 2011

To: The Honorable Mary Bono Mack
Chairman, Subcommittee on Commerce, Manufacturing, and Trade

cc: The Honorable G. K. Butterfield
Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade

From: Amelia M. Arria, Ph.D.
Director, Center on Young Adult Health and Development
University of Maryland School of Public Health

Re: Responses to Questions from the Subcommittee on Commerce, Manufacturing, and Trade related to testimony on April 14, 2011 at the hearing entitled "Warning: The Growing Danger of Prescription Drug Diversion."

The Honorable Mary Bono Mack

1. You recommend tightening the "chain of custody" that governs the supply of prescription drugs. What specifically do you believe is necessary?

Response: Pharmaceutical drugs pass through many places and hands before reaching the user. To prevent nonmedical use, we must understand and document the variety of paths that prescription drugs take—from the manufacturer all the way down to the user. Documenting the "chain of custody" is a very complex problem. We must determine the major weak spots in the transfer of prescription drugs from place to place. There are two scenarios to consider:

1. In the case of a user who has a legitimate prescription, nonmedical use of prescription drugs involves using more of the drug than intended by the physician. At the very least, we must have a system of knowing from how many physicians an individual is obtaining the same types of potentially addictive drugs. We must have a way of alerting prescribers and/or pharmacists that multiple prescriptions are being dispensed to the same person.

2. In the case of the user who does not have a legitimate prescription, nonmedical use involves obtaining the drug from a variety of sources, including individuals who have prescriptions, strangers, family members with leftover prescriptions, drug dealers, etc. Another source could be online pharmacies, although very little information exists regarding the characteristics of purchasers who buy drugs from online pharmacies. The chain of custody for this scenario is much harder to document.

At the very least, there should be efforts to document on an ongoing basis the discrepancy between the amount of pharmaceutical drug being manufactured and the corresponding amount of drugs being dispensed through legitimate prescriptions.

2. When we know that the most typical source of pills is from family or friends, or taking from a medicine cabinet in the house, does that indicate a problem in the way information

accompanies prescriptions if parents are not more cognizant of the possibility their children may divert the drugs?

Response: Yes, it is true that more information is required to accompany the prescription to prevent diversion. This is especially true when the source of drugs obtained for nonmedical use is either family, friends or acquaintances. We have advocated for better physician-patient communication around risks of sharing and selling psychoactive medication. However, information-only approaches are likely to have limited utility. Just telling someone not to do something usually does not work. Therefore, we must develop and evaluate better strategies to reduce the likelihood of sharing and selling medication. One potential way to reduce diversion is to ensure that the number of pills dispensed matches the number of pills to treat the condition or manage pain. Dosing judiciously, as suggested by McLellan and Turner (2010) should be the rule, not only for chronic pain, but especially for many acute pain conditions (e.g., wisdom tooth extraction). Parents and other adults should be vigilant about leftover unused prescription medications in their households.

3. Do drugs affect a young adult's brain differently than an adult's?

Response: It is most likely that drugs affect a young person's brain differently than an adult's brain. A definitive research study (where adolescents and adults are exposed to various amounts of illicit drugs) would be impossible and unethical to conduct because of the inherent ethical violations. But research has illuminated that adolescents appear to be less sensitive to internal signals that help us recognize our level of alcohol intoxication (like feeling woozy). Not having a fully developed sense of how intoxicated one is can lead to more problems because these signals help us to curtail our drinking. We also know from research that adolescents seem to be more vulnerable than adults to alcohol-related impairments, especially damage in the hippocampal region of the brain which is associated with memory and learning. There are several good resources on this issue; here are just a few:

<http://teenbrain.drugfree.org/>

http://www.actforyouth.net/resources/rf/rf_brain_0502.pdf

<http://www.npr.org/templates/story/story.php?storyId=124119468>

<http://www.nimh.nih.gov/health/publications/teenage-brain-a-work-in-progress-fact-sheet/index.shtml>

http://www.thechallenge.org/challenge_14_3.pdf

The Honorable G. K. Butterfield

1. In your testimony, you discuss how prescription drug abuse by our youth cannot be viewed in isolation because those who abuse prescription drugs non-medically may also be heavy drinkers or users of illegal drugs. The data you present, involving college-age individuals, is shocking and troubling.

- a. You wrote that non-medical prescription stimulant use is a “red flag” for underlying alcohol and/or drug problems in a college student, and that this student is often someone who attempts to use Adderall or another prescription stimulant as a “shortcut” to make up for the time they have lost to their substance abuse problem. Please help us understand this a little more. What can or should the parent, professor, or roommate notice? For example, should one see poor, last-minute, rushed performance and worry about prescription drug abuse? Or should the use of prescription stimulants be noticeable in some way and then one should look for alcohol or other drug problems?

Response: Many research studies have shown that individuals who use prescription drugs nonmedically are likely to either have a history of heavy alcohol use and/or other illicit drug involvement or to be current users of other substances. Substance use in college is often associated with skipping class, and skipping class is likely to place one at risk for poor performance in school. Therefore, one of the most obvious signs of a problem would be regularly missing class. This is not to say that all students who miss class have substance use problems, but missing class regularly should alert friends or concerned instructors to the possibility that there might be an underlying problem that should be addressed. It is also possible, as you have suggested, that poor, last-minute rushed performance could be a sign of substance use. Lastly, many students will directly admit to using stimulants nonmedically to their parents or friends. When revealed to parents and friends, nonmedical use should be discouraged, rather than encouraged or seen as something benign. A comprehensive assessment of alcohol and all forms of substance use is warranted to mitigate possible escalation of both substance use problems and academic failure.

- b. With so many forms of abuse, early detection is crucial. You mention that NIH research can help us better understand risk factors for youth drug involvement. Are there certain people, because of behavior, family history, or other reasons, that counselors in middle schools, high schools, colleges should be keeping an eye on?

Response: While no person is completely immune to risk for developing substance use problems, certain children, adolescents, and adults are at high risk for initiating and sustaining habitual substance use which often leads to addiction. Detection of high risk individuals thus has paramount importance. The best example of NIH-funded work in this area has been conducted at the University of Pittsburgh’s Center for Education and Drug Abuse Research (CEDAR), directed by Dr. Ralph Tarter. During the past two decades, this program, supported by NIDA, has led to the development of three instruments for identifying high risk youths and adults: the *Drug Use Screening Inventory* (DUSI), the *Dysregulation Inventory*, and the *Transmissible Liability Index*. The DUSI has additionally been validated for use in practical settings in multiple language formats on the Web. This efficient (15-minute) screening can detect vulnerable youth with about 80% accuracy who will transition to substance use and succumb to addiction as well as predict commonly related adverse outcomes such as violence, psychiatric illness, and social maladjustment.

If the use of these sorts of screening tools could become more mainstream in educational settings, problems could be detected and resolved much earlier in life before substance use begins. The cost-effectiveness of systematic brief screening used in surveillance is well-established, thereby enabling efficient allocation of resources for prevention along with quick objective determination of the person's problems that need to be addressed. The enormous social toll and economic costs associated with substance abuse and addiction (e.g., crime, chronic health problems, family dysfunction, unemployment, etc.) tells us that a systemic prevention approach would have profound impact. The fact is that the tools for detection of susceptible youths, tactics for effective intervention, and contexts for efficient service delivery (prevention and treatment) are already in place. Now the major challenge for addressing substance abuse and related problems is primarily systems integration facilitated through appropriate extant Federal and State agencies.

2. National studies implemented by the Substance Abuse and Mental Health Services Administration (SAMHSA) find that painkillers are the prescription drug category most frequently used non-medically. But surveys on drug use among young people, including your dataset at the University of Maryland, suggest that prescription drug abuse by young adults – compared to that of the population at large – is more evenly spread out across different classes of drugs, including opioid analgesics, stimulants, and tranquilizers/sedatives.
 - a. Please briefly summarize the conclusions of recent surveys that have examined young people's use and abuse of different categories of prescription drugs. Please outline how these findings align with or diverge from findings compiled through the National Survey on Drug Use and Health (NSDUH) or other SAMHSA studies.

Response: It is very difficult to briefly summarize the findings of dozens of studies that have been conducted on this topic. Because of the different methodologies and populations utilized, comparison of results with those of epidemiologic surveillance systems the NSDUH and other SAMHSA studies would require a greater amount of time than was allowed. However, in general, it is true that studies of college students have reported higher estimates of nonmedical prescription stimulant use than estimates from the NSDUH and studies of younger adolescents. Moreover, there appears to be a greater prevalence of nonmedical stimulant use among college students relative to nonmedical use of prescription analgesics in some studies.

- b. Please discuss potential reasons why statistical disparities exist between the reported drug use and abuse of young people and the reported use and abuse of all individuals age 12 and older.

Response: Age is a very important correlate of drug use. For many drugs, use peaks during young adulthood. Therefore, studies focusing specifically on young adults will report higher estimates of drug use than surveys of the entire population 12 and older. Another reason for the difference is school attendance. Being in school can change the likelihood of exposure opportunities for various drugs. It is also important to realize the great deal of heterogeneity that exists among colleges; for example, Dr. McCabe reported estimates of nonmedical

prescription stimulant use from 0 to 25% depending upon the particular campus studied. A reason for the discrepancy between study results may be related to local availability; where there is a high availability of prescription stimulants, higher estimates of nonmedical use might be found. Yet another reason pertains to the way that the questions are asked. Studies that define nonmedical use as including overuse of one's own prescription medication will yield higher estimates than restricting the definition to not having a legitimate prescription.

- c. To what extent do you believe these differences are attributable to current teens' and young adults' membership in a specific generational cohort with particular views on the utility and risk of each drug? Alternatively, to what extent do you believe these differences are the result of the unique physical and social characteristics of adolescence, and that as these teens and young adults age, their views and behavior will change?

Response: This is a very difficult question to answer based on empirical data. One could argue that adolescents and young adults are more likely to initiate drug use than older adults simply because of the inherent characteristics of their developmental stage (e.g., young people are more likely to take risks). However, generational differences also play an important role.

3. The National Survey on Drug Use and Health (NSDUH) is the most comprehensive federal study of drug use among those age 12 and over and the source for much of our current understanding on prescription drug abuse. Nevertheless, in the 2010 National Drug Control Strategy, the Office of National Drug Control Policy indicated that it believes there are many ways the study can be improved.

- a. What do you believe are the most notable shortcomings of the National Survey on Drug Use and Health, as it currently exists, and what do you believe could be done to improve the survey in these areas?

Response: The National Survey on Drug Use and Health is an incredibly valuable tool for the nation for monitoring the magnitude of alcohol and other substance use and related problems among the population. It is an epidemiologic surveillance system that has been modeled by many other countries in the world and therefore its worth cannot be overestimated. Nonmedical prescription drug use is a complex phenomenon, involving many different types of substances that are obtained from a number of different sources and used in a variety of contexts. The NSDUH survey contains questions that allow us to measure basic statistics regarding prevalence of nonmedical drug use. One issue that is of concern relates to the purchase of prescription drugs via online pharmacies. Currently, there is a question on source of obtaining prescription drugs for nonmedical use, but this question is only asked if a person reports that they used a prescription drug nonmedically in the past year. This is a problem because we do not know anything about the characteristics of people who use online pharmacies who are not recent nonmedical users. It would be helpful to ask every respondent whether or not they have ever purchased prescription drugs online and for what purpose, regardless of their answers about nonmedical use.

- b. What do you believe are the most easily-solved shortcomings of the National Survey on Drug Use and Health, and how would you recommend solving them?

Response: The most easily-solved shortcomings of the NSDUH, in my opinion, are three things related to current restrictions that exist for researchers who wish to analyze the data:

1) ***A state code variable exists in the dataset, but this state code is not released to researchers.*** Not having the state code available to researchers prohibits state-level comparisons of the effectiveness of various policies. For example, one cannot compare the prevalence of nonmedical use in the states that have prescription drug monitoring programs with the prevalence in other states that do not have them. Even though it would be extremely difficult, if not impossible to identify a particular respondent in the data, the state code is supposedly not released because of confidentiality concerns. But all researchers already must adhere to strict confidentiality regulations with every dataset they analyze. SAMHSA could require an additional confidentiality certification for researchers who wish to use the data.

2) ***Information is collected on both parents and children within the dataset, but researchers are not allowed to analyze data that links parents and children.*** Again, this is supposedly done for confidentiality reasons. Allowing researchers to analyze the data under strict confidentiality regulations would maximize the use of the data.

- c. How would NSDUH enhance our understanding of the prescription drug abuse problem if the study were to improve in the ways you suggest?

Response: As mentioned above, release of the state level code would enable researchers to understand whether or not various state level policies are effective in reducing prescription drug abuse and its consequences (e.g., evaluating the effectiveness of prescription drug monitoring programs) . Release of linked parent-child information would help us to understand to what extent parents behavior, knowledge, or attitudes have an impact on their children's drug use.

- d. What can be done to improve other federal studies of drug use and abuse?

Response: A comprehensive review of other federal studies of drug use and abuse to understand the adequacy of how nonmedical prescription drug use is assessed, as well as the timeliness of data availability should be undertaken.

4. Please provide a discussion of overdose deaths where prescription drugs are involved, including the relative prevalence of deaths from polydrug use.

Response: As availability and abuse of opioids have increased, so have adverse events associated with their use. Half of the 1.8 million emergency department (ED) visits in 2006 associated with drugs involved pharmaceuticals (SAMHSA, 2008). The estimated number of emergency department visits involving nonmedical analgesic use rose from 144,644 in 2004 to 305,885 in 2008, an increase of 111 percent. ED visits involving oxycodone products, hydrocodone products, and methadone—the three most frequently listed narcotic pain

relievers in each year—increased 152, 123, and 73 percent, respectively, between 2004 and 2008 (SAMHSA, Office of Applied Studies, 2010).

Moreover, drug overdose death rates have increased roughly five-fold since 1990 (CDC, 2010). From 1999 to 2004, unintentional drug poisoning deaths increased by 68% (Paulozzi & Annest, 2007) and between 1999 and 2007 it increased 124% (Bohnert, et al., 2011). Unintentional poisoning is now the overall second-leading cause of unintentional injury death in the U.S. and the leading cause of unintentional injury death among Americans aged 35-54 (CDC, 2011). The majority of this increase has been attributed to deaths associated with prescription opioids (Hall, et al., 2008; Paulozzi, et al., 2006).

While time constraints prohibited consolidating other data related to the deaths due to all forms of prescription drug use, several reports were available related to opioid analgesic deaths. The Centers for Disease Control and Prevention recently released a set of slides that describe the issues related to overdose deaths:

<http://www.cdc.gov/about/grand-rounds/archives/2011/01-February.htm>

Earlier testimony by Dr. Leonard J. Paulozzi, M.D., M.P.H., Medical Epidemiologist National Center for Injury Prevention and Control, Centers for Disease Control and Prevention on Trends in Unintentional Drug Overdose Deaths before the Senate Judiciary Subcommittee on Crime and Drugs on Wednesday, March 12, 2008 can be found here:

<http://www.hhs.gov/asl/testify/2008/03/t20080312b.html>

Another report from the National Center on Health Statistics stated that “drug poisonings are the largest portion of the poisoning burden and opioid analgesic-related deaths are among the fastest increasing drug poisoning deaths. The following report highlights trends in fatal opioid analgesic-related poisonings from the years 1999–2006:

<http://www.cdc.gov/nchs/data/databriefs/db22.pdf>

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April 29, 2011

Dr. John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs
Generic Pharmaceutical Association
777 6th Street, N.W., Suite 510
Washington, D.C. 20001

Dear Dr. Coster,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on April 14, 2011, to testify at the hearing entitled "Warning: The Growing Danger of Prescription Drug Diversion."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for 10 business days to permit Members to submit additional questions to witnesses, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and then (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please email your responses, in Word or PDF format, to the legislative clerk (Alex.Yergin@mail.house.gov) by the close of business on Friday, May 13, 2011.

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

Sincerely,



Mary Bonomo Mack
Chairman
Subcommittee on Commerce, Manufacturing, and Trade

cc: The Honorable G. K. Butterfield, Ranking Member,
Subcommittee on Commerce, Manufacturing, and Trade

Attachment



Representative Mary Bono Mack
United State House of Representatives
104 Cannon House Office Building
Washington, DC 20515

Representative John Dingell
United State House of Representatives
2328 Russell House Office Building
Washington, DC 20515

GPhA would like to submit the following for your recent request for answers on the record.

The Honorable Mary Bono Mack

1. What efforts does industry now undertake to help address the problems of abuse and diversion of prescription drugs? What further steps can you take or do you plan to take?

GPhA and its member companies are committed to stemming the abuse and diversion of prescription drugs. GPhA belongs to and actively participates in a number of coalitions and programs that raise awareness to the dangers of prescription drug abuse. One such group is NCPPIE, the National Council on Patient Information and Education. GPhA is a permanent board member of NCPPIE. "NCPPIE is a coalition of over 125 diverse organizations whose mission is to stimulate and improve communication of information on appropriate medicine use to consumers and healthcare professionals. NCPPIE is the nation's leading authority for informing the general public and health care professionals on safe medicine use through better communication." Additionally, GPhA commits financial resources to Smart Rx, a groundbreaking public-private partnership that educates consumers about the proper disposal of medicines in a safe and environmentally protective manner. Educating consumers about the proper disposal of unused medicine will help reduce drug diversion and accidental poisonings.

GPhA and its members will continue to remain actively involved in these and many other organizations that promote a safe and secure supply chain, consumer awareness on the dangers of prescription drug abuse, and the correct disposal of unused medicines. Just recently, GPhA and the Pharmaceutical Research and Manufacturers of America (PhRMA) funded a public service announcement supporting the DEA's National Prescription Drug Take Back Day. Through PSAs, educational campaigns and other methods, GPhA is dedicated to addressing the problems of prescription drug abuse and diversion.

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2. **The DEA is working on regulations that would permit certain entities to recapture drugs that are controlled substances. What do you plan to do, or what can you do, to help educate patients about these new take back mechanisms – of their existence and why patients should use them?**

As we previously mentioned, GPhA and PhRMA funded a public service announcement promoting National Prescription Drug Take Back Day, which took place on April 30 of this year. Public service announcements of this nature are effective tools highlighting the existence of take back programs, but also in raising awareness to the dangers of prescription drug abuse. GPhA has also helped to fund the American Medicine Chest Challenge since its inception, a take back program that involves law enforcement in the unwanted drug disposal process—the model upon which the DEA take back program is based. GPhA and its members are supportive of DEA's efforts and will continue to work with the Agency and other stakeholders to see that consumers are made aware of the proper means for disposing of unused and unwanted medicines.

3. **When you see the statistics and graphs Governor Scott provided showing the disproportionate share of drugs dispensed in Florida, and national statistics on drug diversion, do you think the DEA and FDA quota system needs to be reevaluated in light of the high percentage of diversion – particularly Florida?**

There is no doubt that these numbers are quite alarming and that is why GPhA and its members are committed to educating providers and consumers about proper prescribing, use, and disposal of prescription drugs. Through industry programs like Smart Rx, the Partnership for Safe Medicines, and the National Council on Patient Information and Education, and government programs like Operation Medicine Cabinet we can successfully raise awareness and develop innovative policies that help combat the scourge of prescription drug diversion and abuse. We do not believe reevaluating the DEA quota system is an appropriate way to address concerns with prescription drug abuse. We are concerned that further restrictions on the quota system could hinder access to important medical therapies for patients. For example, there are drugs specifically aimed at Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder (Ritalin and Adderall), in the quota system that are on FDA's drug shortage list. The quota system cuts both ways and if Congress starts to tip the balance in the quota system, it could have unintended consequences.

4. How should healthcare professionals be educated on these issues – by their own medical associations or by someone else?

The generic pharmaceutical industry is committed to providing the best information on the product to providers and patients. However, in terms of how to prescribe medications, this is best left in the hands of the experts, which are the specific medical association or physician groups.

5. Is there any indication that there is a lack of availability or access to prescription pain killers for those who legitimately need such medication.

According to FDA's drug shortage website, there are shortages of medicines that physicians use in conjunction with cancer medications to help with pain management. One common pain medication on FDA's drug shortage list is morphine. Low supply of morphine and other drugs have led providers to use alternative medicines, which in turn have created high demands and shortages for other drugs. With respect to pain medicines, the DEA does not allow GPhA and its members to overproduce product in the off chance that there may be a shortage. Our manufacturers produce what the federal government allows them to produce.

The Honorable John Dingell

1. Do you believe that improving the safety and security of the nation's pharmaceutical supplies is in the best interest of the American people?

Yes, GPhA believes in safe and secure pharmaceutical supplies.

2. As you know, I recently introduced legislation to enhance FDA's resources and authorities to ensure the safety of our pharmaceutical supply. Do you agree that additional steps must be taken to protect the safety and security of the nation's drug supply?

Yes, GPhA believes that the nation's drug supply should be secured.

- 3. More specifically, do you agree that more must be done to ensure that foreign drug manufacturers are held to the same standards as their U.S. counterparts?**

Yes, GPhA believes that more should be done to protect the quality of pharmaceutical products in the United States.

- 4. Well, my legislation will do just that. Will you commit publicly to working with me and the Members of this Committee on my legislation moving forward?**

Yes, GPhA looks forward to working with members of the Committee on Energy and Commerce in the future.

Respectfully,

Generic Pharmaceutical Association



May 13, 2011

VIA ELECTRONIC MAIL

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Ms. Bono Mack,

Thank you for your follow-up questions sent to me by letter dated April 29, 2011. As requested, the responses of the Pharmaceutical Research and Manufacturers of America (PhRMA) appear below for inclusion in the hearing record.

The Honorable Mary Bono Mack

1. **What efforts does industry now undertake to help address the problems of abuse and diversion of prescription drugs? What further steps can you take or do you plan to take?**

When used appropriately, under the direction and care of a licensed health care professional, prescription medicines can improve and save lives. However, when used inappropriately and not as intended, devastating consequences can result. PhRMA supports efforts to bring attention to the importance of appropriate use and preventing misuse and abuse of prescription drugs. We also recognize the need for broad stakeholder engagement to reduce diversion and misuse and abuse of prescription medicines. PhRMA and our member companies are actively engaged in a range of efforts to help ensure that prescription medicines are used appropriately and to reduce prescription drug abuse. At the same time, it must be recognized that national data on the non-medical use of prescription drugs, particularly among youth, reinforces the importance of improving communications between providers and patients on secure storage of prescription medicines in the home and safe disposal of unused and expired medicines as well as the need to ensure that patients are adequately monitored by health care providers.

According to the National Institute on Drug Abuse (NIDA), the three types of prescription drugs most commonly abused are opioids, central nervous system (CNS) depressants, and stimulants.¹ While many of the medicines included in these categories are produced by brand name or innovator manufacturers, it is important to recognize that

¹ National Institute on Drug Abuse, *Prescription Drugs: Abuse and Addiction*, August 2005; 2010 NSDUHF Methodology Section.

The Honorable Mary Bono Mack
 U.S. House of Representatives
 May 13, 2011
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among these drugs, in 2010, 88.5% of prescriptions were for generic drugs with only 11.5% of the prescriptions for brand name medicines.² For opioids, 92.4% of 2010 prescriptions were for generics; for CNS depressants, 93.4%, and for stimulants, 47.4%.³ These statistics reinforce that addressing the problem of non-medical use of prescription drugs is a shared responsibility and there is no single solution. Instead, collaborative efforts must be undertaken between the federal government, PhRMA, the Generic Pharmaceutical Association, American Medical Association, and other relevant associations and stakeholder groups – including healthcare providers, law enforcement, faith-based and other community organizations, schools and colleges, parents, pharmacists, and state and local governments – to address this public health issue.

We have worked collaboratively with the medical community, drug abuse prevention organizations, and others on educational efforts to prevent the misuse and abuse of prescription drugs. Select examples of PhRMA initiatives include those described below.

Educational efforts related to the proper disposal of unused and expired prescription medicines and secure storage of prescription medicines. According to the 2009 National Survey on Drug Use and Health, 55.3 percent of those who reported non-medical use of prescription pain relievers reported that they obtained them from a friend or relative for free. If you also include the number who reported buying them from a friend or relative, or took them from a friend or relative without asking, the percentage increases to 70.2 percent in 2008.⁴ PhRMA supports educational efforts to promote prompt and responsible disposal of unused and expired prescription medicines. As a practical matter, any medicine that appears damaged, discolored, or otherwise different from when the prescription was initially filled should be disposed of promptly and properly. PhRMA partnered with the U.S. Fish and Wildlife Service and the American Pharmacists Association to create the SMARxT DISPOSAL program (see, for example, www.SMARxTDISPOSAL.net) to help educate consumers about how to properly and safely dispose of medicines in an environmentally-friendly manner. This educational program outlines how in just a few small steps, consumers can promptly, safely, quickly and easily dispose of any unused or expired medicines in their home. PhRMA also recently helped educate consumers about the option to participate in a national take back program administered by the Drug Enforcement Administration (DEA) on April 30, 2011.

Development of a school curriculum to prevent abuse of prescription and over-the-counter drugs. The curriculum is comprised of components for students (in grades 5 through 12) as well as presentations for parents (information available at

² PhRMA analysis of retail claims data for January-December 2010 for the classes of most commonly abused prescription drugs based on SDI Health's Vector One National Audit (VONA), April 8, 2011.

³ PhRMA analysis of retail claims data for January-December 2010 for the classes of most commonly abused prescription drugs based on SDI Health's Vector One National Audit (VONA), April 8, 2011.

⁴ *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, SAMHSA (2010).

⁵ Substance Abuse and Mental Health Services Administration, *Results from the 2009 National Survey on Drug Use and Health: National Findings*, September 2010, table 6.47B.

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<http://www.dare-america.com/home/features/documents/RxOTCInfoFlyer.pdf>). This curriculum was created by D.A.R.E. America (Drug Abuse Resistance Education), with the support and expertise of law enforcement officials; PhRMA; Abbott; the Consumer Healthcare Products Association (CHPA); and a number of other organizations, including the White House Office of National Drug Control Policy (ONDCP), the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), NIDA, the Substance Abuse and Mental Health Services Administrations' Center for Substance Abuse Treatment (SAMHSA/CSAT) and the Partnership at Drugfree.org.

A tool kit and brochure to raise awareness of the dangers of abusing over-the-counter cough medicines, alcohol, and prescription drugs. In collaboration with the Community Anti-Drug Coalitions of America (CADCA) and CHPA, PhRMA developed a 16-page newspaper supplement distributed nationwide as well as online, entitled "Stay Smart, Don't Start: The Truth About Drugs and Alcohol" (available at <http://www.nieteacher.org/staysmart.pdf>) to educate youth and parents about the dangers of abusing over-the-counter cough medicine and prescription drugs as well as a brochure targeting teenagers entitled "The Real Truth About Rx and OTC Medicine Abuse" (available at <http://www.otesafety.org/Media/129096000527317246.pdf>).

Study of health care provider attitudes in collaboration with Partnership for a Drug-Free America (PDFA). PhRMA and PDFA (now Partnership at Drug Free.org) assessed healthcare provider attitudes as to their need for more information on prescription drug abuse for their patients. Many specialties stated they received information through their journals or their respective professional associations but several groups expressed the need for more patient-friendly materials for use in the emergency room, dental offices, orthopedic offices, nurse practitioner locations, etc. Through these interviews, we were able to assess the need for additional materials and educational opportunities, as well as guide them to valuable resources within the prevention and treatment community.

Educational tools and guidelines to prevent the misuse and abuse of prescription medicines targeting undergraduate and graduate students. In collaboration with the Washington Health Foundation, a program to improve health for the people of Washington state, PhRMA along with a diverse group of stakeholders recently unveiled a new initiative that will help educate college students in Washington state about the proper use of medicines and provide resources to help prevent the abuse and misuse of prescription drugs and over-the-counter products. The tools and guidelines available online (available at <http://www.whf.org/my-health>) were developed by other young people and the site is exclusively maintained by current undergraduate and graduate student interns from across the state. Key elements of the Washington state initiative include the use of resident assistants in college dormitories to conduct peer-to-peer education and the use of university healthcare clinic staff to increase awareness of the misuse or abuse of prescription drugs.

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In conclusion, PhRMA has engaged in significant educational efforts surrounding the issue of prescription drug abuse. We believe, however, that addressing the issue must be a shared responsibility. PhRMA is committed to continuing to work with relevant stakeholders to help address the problem.

2. **The DEA is working on regulations that would permit certain entities to recapture drugs that are controlled substances. What do you plan to do, or what can you do, to help educate patients about these new take back mechanisms – of their existence and why patients should use them?**

PhRMA testified at the DEA's public hearing in January 2011 on the regulatory process to implement the Safe and Secure Disposal Act of 2010. In the interim, while those regulations are in process, PhRMA has worked to help publicize the availability of the national take back events as an option for consumers to help dispose of any unused medicines. The DEA stated that it is unable to partner with any stakeholders in its national take back events. PhRMA looks forward to reviewing and potentially commenting on the DEA's proposed regulations once published and will continue to work with the U.S. Fish and Wildlife Service and others to create awareness about SMAR_XT DISPOSAL, described above.

3. **When you see the statistics and graphs Governor Scott provided showing the disproportionate share of drugs dispensed in Florida, and national statistics on drug diversion, do you think the DEA and FDA quota system needs to be re-evaluated in light of the high percentage of diversion – particularly in Florida?**

When analyzing potential public policy changes targeted to reducing prescription drug diversion or misuse, we must be careful to ensure that legitimate patient access is not negatively impacted. Physicians may also prescribe any FDA-approved medicine for any legitimate medical purpose. As Congress debates policies designed to reduce the rates of prescription drug misuse and abuse, it is vitally important that any policies do not unintentionally create barriers to patient access to needed medicines.

When considering the issue of prescription drug diversion, we believe the enforcement of existing laws that can help deter abuse of prescription drugs should be a key law enforcement priority. Congress is uniquely positioned to encourage state, local, and federal law enforcement officials to use their full arsenal of existing enforcement authorities to deter prescription drug abuse. By increasing the emphasis on the enforcement of existing laws, financial incentives for illegal activities will be reduced, and the risks for those seeking to divert and profit from the illegal sale of prescription medicines will be increased. Areas of focus could include:

- Increased emphasis on enforcement of existing prohibitions on sales of prescription drugs without a doctor's prescription or without an in-person medical evaluation.

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- Limits on online sales of prescription medicines to those Internet sites operating in compliance with all state pharmacy laws, per a recent report from the Joint Strategic Plan on Intellectual Property Enforcement, which references ongoing U.S. government efforts to prohibit paid advertising for illegal on-line pharmaceutical vendors and to explore means to ensure those operating in violation of relevant laws can be subject “to the full reach of law enforcement jurisdiction.”⁵
- Increased law enforcement emphasis on pursuing investigations in this area; for example, the April 2011 Office of National Drug Control Policy (ONDCP) prescription drug abuse strategy⁶ calls for increasing the number of High Intensity Drug Trafficking Areas involved in intelligence gathering and investigation around prescription drug trafficking and increasing participation on statewide and regional prescription drug task forces.

Similarly, state prescription drug monitoring programs (PDMPs) can help prevent abusers from obtaining prescriptions from multiple doctors and help identify inappropriate prescribing patterns. According to the National Alliance for Model State Drug Laws, as of July 15, 2010, 43 states have enacted legislation enabling the establishment of a PDMP, of which, 33 states have operational programs.⁷ Recognizing that the diversion and abuse of prescription medicines is not limited to geographic boundaries, the April 2011 ONDCP prescription drug abuse strategy calls for having legislation in all 50 states establishing PDMPs within 3 years. PhRMA has also supported legislation to reauthorize the National All Schedules Prescription Electronic Reporting Act.

As part of a comprehensive strategy designed to reduce and/or prevent prescription drug abuse, the utility and effectiveness of PDMPs to assist in the identification of inappropriate prescribing practices and the identification of prescription drug abusers should be assessed. Key considerations with respect to assessing the utility of PDMPs in reducing or preventing prescription drug abuse include:

- Interoperability across state lines,
- Appropriately populated with data from prescribers,
- Adequate funding and routine updating to serve as a reliable data source,
- Operate as “real-time” databases or static data files,
- Outcome measures tracked by the state that are appropriately matched to identifiable policy goals such as increasing the number of referrals for treatment,

⁵ “2010 Joint Strategic Plan on Intellectual Property Enforcement,” (June 2010), available at: < http://www.whitehouse.gov/sites/default/files/omb/assets/intellectualproperty/intellectualproperty_strategic_plan.pdf >, at 17.
⁶ ONDCP. Epidemic: Responding To America’s Prescription Drug Abuse Crisis. April 2011.

http://www.whitehousedrugpolicy.gov/publications/pdf/rx_abuse_plan.pdf

⁷ National Alliance for Model State Drug Laws. Status of State Prescription Drug Monitoring Programs. <http://www.namsdl.org/documents/StatusofStatesJuly152010.pdf>.

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- Assessment of extent to which the use of PDMPs can be further incentivized and incorporated into health care providers' clinical practices,
- Assessments of provider perspectives on PDMP effectiveness and administrative burden,
- Detailed outcome assessments for providers using PDMPs versus those not using PDMPs, that is, how patient-level outcomes differ,⁸
- An understanding regarding whether and to what extent PDMPs have impacted fraud and related criminal investigations, and
- Understanding any gaps in PDMP data resulting from mail-order and internet purchases.

4. **How should healthcare professionals be educated on these issues – by their own medical associations or by someone else?**

Public policy discussions about the appropriate role of prescription medicines in health care often assume that medicines are widely overused. The importance of ensuring appropriate use of medicines through appropriate training of health care providers cannot be overstated. PhRMA does not have a view regarding who best to conduct this education for health care professionals; however, we do believe all prescribers should have proper education regarding all medications that they prescribe, especially medications with the potential to be abused. In addition to the importance of reinforcing to patients that they should take their medication exactly as prescribed (whether it is a blood pressure medication, asthma medication or antibiotic, for example), it is equally important to discuss the risks and benefits and potential side effects of any medication, including whether there is a potential for addiction, and how to appropriately store and dispose of unused and expired medications. In addition, Screening, Brief Intervention, Referral and Treatment (SBIRT) can help health care and other professionals determine whether someone uses alcohol and/or drugs in unhealthy ways. This is an important early intervention and research has shown that health care providers are a respected source of information for patients. ONDCP's prescription drug abuse strategy recognizes the importance of screening patients for potential prescription drug abuse problems and has set a goal of increasing by 25 percent the number of states reimbursing for SBIRT within 24 months.

5. **Is there any indication that there is a lack of availability of access to prescription pain killers for those who legitimately need such medication?**

PhRMA and its members urge that any evaluation of policies to help reduce misuse and abuse of prescription medicines must also ensure continued patient access to needed

⁸ Possible outcome measures could include, of those identified as abusing prescription medicines, what percentage are prosecuted and sentenced and do they have access to treatment, what percentage are referred to treatment, is there adequate treatment capacity in the community, do those identified have better treatment outcomes due to earlier intervention in the drug abuse cycle, do those identified have fewer emergency department visits and hospitalizations.

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prescription medicines. Potential barriers to patient access include poor or insufficient training of health care workers regarding appropriate prescribing practices, unnecessarily restrictive drug control regulations and practices which may impede good clinical care, and fear among health workers of the potential for legal sanctions for legitimate medical practice which may lead to undertreatment (see, for example, Gatchel 2010).⁹ Articles in the peer-reviewed medical literature and a number of patient and provider organizations have raised concerns about increasing prescriber hesitancy to prescribe certain medications. As just one example, a survey of physicians regarding pain management found "that concerns of potential abuse or addiction often affect how pain is pharmacologically treated" by physicians."¹⁰ The end result of such practices is that millions of Americans who suffer significant or chronic pain are likely being undertreated either due to inadequate training or concerns about the potential for prescription drug abuse.

Experts agree that appropriate use of medicines plays a central role in both the quality of health care patients receive and the quality of the lives they lead. Numerous studies have reported that appropriate prescribing of medication therapy and adherence to that therapy improves quality and outcomes, while often reducing total costs and use of other, often more expensive, health services.¹¹ One study found that non-adherence has been shown to result in \$100 billion each year in excess hospitalizations alone.¹² Stakeholders from all sectors of health care, including researchers, payers, employers, patient advocates, and health care practitioners, agree that non-adherence is a serious problem that should be solved. Supporting better communication between providers and patients is a key step to improving adherence as well as enhancing the patient's understanding about his or her disease or condition, its course, and its related target laboratory test values. Providers, when given support by the proper tools and systems, can play a central role in helping patients understand how to take their medicines properly. For instance, one main cause of preventable hospital readmissions is poor communication with patients during the discharge process, especially regarding medications.¹³

Public policy discussions about the appropriate role of prescription medicines in health care often assume that medicines are widely overused. The importance of ensuring appropriate use of medicines through appropriate training of health care providers cannot be overstated. As policies around prescription drug abuse are discussed, it is important to

⁹ Gatchel, R.J. Is fear of prescription drug abuse resulting in suffers of chronic pain being undertreated?" *Expert Rev. Neurotherap* 2010;10(5):637-39.

¹⁰ McCarberg, BH et al. "The Impact of Pain on Quality of Life and the Unmet Needs of Pain Management: Results From Pain Sufferers and Physicians Participating in an Internet Survey," *American Journal of Therapeutics* 2008;15(4): 312-20.

¹¹ Examples include, but are not limited to: W.H. Shrank, et al. "A Blueprint for Pharmacy Benefit Managers to Increase Value," *American Journal of Managed Care*, February, 2009.; D. Cutler, et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, January/February 2007.; M. Cloutier, et al., "Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity," *Pediatrics*, November 2006.; M. Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, June 2005.

¹² New England Healthcare Institute, "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," A NEHI Research Brief, August 2009.

¹³ H.W. Jack et al. "A Reengineered Hospital Discharge Program to Decrease Rehospitalization," *Annals of Internal Medicine*, February 2009.

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recognize that, while research indicating overuse of prescription drugs is limited, there is much evidence that large percentages of patients underuse needed medical care, including prescription medicines, for many serious health conditions. Efforts to stimulate better prescribing of and adherence to essential medications improves health, averting costly emergency department visits and hospitalizations, and improving quality of life and productivity.¹⁴

Long-term policy solutions to ensuring appropriate use and reducing the potential for abuse will require substantial ongoing education, training, and responsibility among a broad range of stakeholders, including patients, physicians, nurses, pharmacists, insurers and others involved in health care delivery. Any policies to prevent prescription drug abuse must recognize and ensure that patients with a legitimate need continue to receive their medicines.

The Honorable John Dingell

1. Do you believe that improving the safety and security of the nation's pharmaceutical supply is in the best interest of the American people?

America's patients trust that the medicines they and their loved ones take meet the high standards set by the Food and Drug Administration (FDA) for safety and efficacy and are not substandard or counterfeit, and they rely on our comprehensive drug regulatory system to help ensure that is the case. America's research-based biopharmaceutical companies also depend on a safe, secure prescription drug supply chain. This is why our companies take great measures to help assure the quality, safety and integrity of materials used from third party sources in our finished products.

The regulatory system that governs the development, approval, marketing, and surveillance of new drugs and biologics in the United States is the most complex and comprehensive in the world. The FDA regulates virtually every stage in the life of a prescription medicine sold in the U.S., from pre-clinical testing of investigational compounds in animals and human clinical trials before a medicine is sold, to manufacturing, labeling, packaging, and advertising, to monitoring actual experience with the drug after its approval.

In addition to the requirement to obtain FDA approval of a New Drug Application (NDA) before a new drug may be sold in the U.S., manufacturers of pharmaceuticals sold legally in the U.S. must also comply with the "gold standard" of quality manufacturing – FDA's current Good Manufacturing Practice (cGMP) regulations. These regulations apply to all

¹⁴ See, for example, M. Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, June 2005; B.W. Jack et al., "A Reengineered Hospital Discharge Program to Decrease Rehospitalization," *Annals of Internal Medicine*, February 2009; New England Healthcare Institute, "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," A NEHI Research Brief, August 2009.

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pharmaceuticals sold in the U.S., wherever they are made, and extend to all components of a finished drug product, including active pharmaceutical ingredients (APIs), without regard to where those ingredients are sourced. FDA's cGMP regulations are based on the fundamental quality assurance principle that quality, safety and effectiveness "cannot be inspected or tested into a finished product," but instead must be designed and built into a product.¹⁵ While FDA inspections are an important part of FDA's regulatory authority and oversight, cGMPs represent a comprehensive, systems-based approach that requires a company to build quality directly into the entire manufacturing operation, in order to ensure that the process itself is under control and therefore will consistently produce a drug product that meets designated specifications. As FDA has noted, "[i]mplementing comprehensive quality systems can help manufacturers to achieve compliance with" FDA's cGMP requirements.¹⁶

The Prescription Drug Marketing Act of 1987 (PDMA) is another critical piece of consumer legislation passed as a result of Congressional investigations into the integrity of the drug distribution system that existed at the time. The PDMA created the closed prescription drug distribution system in place today, and coupled with the regulatory requirements and oversight of the FDA, helps minimize the possibility of a consumer receiving a counterfeit drug.

2. **As you know, I recently introduced legislation to enhance the FDA's resources and authorities to ensure the safety of our pharmaceutical supply. Do you agree that additional steps must be taken to protect the safety and security of the nation's drug supply?**

Since September 2007, PhRMA has worked constructively with House Energy and Commerce Committee members and staff in their efforts to enhance the capability of FDA to inspect foreign facilities engaged in prescription drug manufacturing. As previously stated, the FDA regulatory system that governs the development, approval, marketing, and surveillance of new drugs and biologics in the United States is the most complex and comprehensive in the world. Even with FDA's comprehensive regulatory system; however, the increasing globalization of the pharmaceutical supply chain presents new challenges that require biopharmaceutical companies and the FDA to be more adaptive and flexible in the review and oversight of entities located around the world. When incidents of economically motivated adulteration occur, FDA should use its powerful existing enforcement authorities to take action against violative products and to promote accountability among regulated entities – enforcement authority that the FDA under the current Administration has made a priority to exercise when warranted. Moreover, supply chain security is the responsibility of all parties involved in the distribution of medicines to American patients.

¹⁵ 61 Fed. Reg. 20104, 20105 (May 3, 1996).

¹⁶ FDA, Draft "Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations," Sept. 2006, at 3.

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One basic element to help preserve the safety of our country's drug supply is maintenance of our closed distribution system, created after the passage of the PDMA. Even with our "closed" distribution system, from time to time counterfeit and tainted products can surface, and the public health could be placed at risk. Domestic challenges thus remain great. These challenges would, however, be multiplied exponentially by the added complexities and burdens of an expanded international supply of foreign drugs from various wholesalers and pharmacies. In fact, in 2009, the number of medical product counterfeit cases in the EU increased compared to 2008.¹⁷ As such, Congress should reject proposals, such as proposals to legalize prescription drug importation, which would further strain and compromise the FDA's ability to protect Americans from potentially dangerous counterfeit medicines and maintain the current "closed" distribution system.

3. **More specifically, do you agree that more must be done to ensure that foreign drug manufacturers are held to the same standards as their U.S. counterparts?**

PhRMA agrees with the notion that all foreign establishments manufacturing prescription drug products or components destined for import into the U.S. must register with FDA and list their products, to the extent they are not already required to do so under current law. By requiring such facilities to register, the FDA will be able to establish a single database that will contain information on all facilities that manufacture products or components of products that are sold in the U.S. Prior Congressional testimony and Government Accountability Office reports suggest that such information appears in several different formats and databases managed by FDA, and, therefore, it is not easily accessible or usable by Agency personnel. A single, standardized database would, among other things, allow the FDA to help ensure that foreign inspections are occurring at appropriate intervals.

H.R. 1483 provides FDA with flexibility to adjust inspection intervals based on risk. We support providing FDA with the flexibility to prioritize inspections of foreign establishments based on the risks they present, and relying on set criteria such as compliance history, time since last inspection, and type of products produced, will enhance the FDA's ability to target its inspection resources efficiently and effectively. We also recommend that FDA generally increase its current Good Manufacturing Practice (cGMP) inspections of foreign facilities, including API manufacturers, to help ensure that cGMPs are being followed.

In recognition of the fact that the Agency does not have unlimited resources and in order to help ensure that foreign inspections occur on a more regular basis, Congress should consider allowing FDA to rely on the inspection results of other foreign regulatory bodies with similarly robust drug regulatory oversight systems or to use accredited third parties

¹⁷ (European Commission, "Report on EU Customs Enforcement of Intellectual Property Rights: Results at the EU Border 2009).

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to conduct some foreign inspections (such as inspections of facilities considered moderate to low risk, based on appropriate criteria). These inspections would not take the place of FDA inspections, which are a necessary and important part of the Agency's mandate; however, they would provide FDA with the flexibility to leverage the work of foreign regulatory bodies and maximize its resources, all without foreclosing its ability to inspect any facility.

Finally, we also support the creation of a cadre of FDA inspectors who are dedicated to conducting inspections in foreign jurisdictions.

4. **Well, my legislation will do just that. Will you commit publicly to working with me and the Members of this Committee on my legislation moving forward?**

As previously stated, since September 2007, PhRMA has constructively engaged with House Energy and Commerce Committee members and staff in their efforts to enhance the capability of FDA to inspect foreign facilities engaged in prescription drug manufacturing. PhRMA testified twice before the House Energy and Commerce Health Subcommittee on these issues -- in May 2008 and in September 2007. PhRMA was also prepared to testify before the Committee in September 2010; however, that hearing was cancelled. Supply chain security is the responsibility of all parties involved in the distribution of medicines to American patients. PhRMA fully intends to continue to work with the Committee and other stakeholders on these important issues and looks forward to the opportunity.

Thank you for the opportunity to provide these responses on behalf of PhRMA. Please feel free to contact me should you have any questions or wish to discuss these issues.

Sincerely,



Kendra A. Martello
Assistant General Counsel

Cc: The Honorable G.K. Butterfield, Ranking Member
Subcommittee on Commerce, Manufacturing and Trade



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**House of Representatives Committee on Energy and Commerce Subcommittee
on Commerce, Manufacturing, and Trade
“Warning: The Growing Danger of Prescription Drug Diversion” Hearing
Oncology Nursing Society Response
Provided by Patrick Coyne, MSN, APN, FAAN**

1. **Mr. Coyne, you testified that all people of legitimate need must have access to medications that help preserve their daily lives. You also agreed that prescribers must be educated to better assess pain and that opioid diversion can wreck families and communities. Does your organization have an opinion on what a “legitimate need” is?**

Pain is a common symptom experienced by patients with cancer. Whether as a result of disease or disease-related treatment, pain causes significant physical and psychosocial burdens. A uniquely personal experience, pain markedly impacts the quality of an individual's life, increases vulnerability in an already vulnerable population, and engenders dependence on healthcare providers for access to adequate pain management. Cancer pain frequently is assessed and treated inadequately (Miaskowski et al., 2004; National Comprehensive Cancer Network [NCCN], 2009).

Effective pain management may include pharmacologic and nonpharmacologic measures. Because oncology nurses embrace holistic care and have sustained contact with patients throughout the continuum of cancer care, they are in a position to identify undertreated and untreated cancer pain and advocate for its relief. As members of interdisciplinary teams involved in practice, education, administration, and research, oncology nurses are in a pivotal position to improve cancer pain management.

NCCN (2009) reported that cancer pain can be well controlled in the vast majority of patients if evidence-based guidelines are applied, monitored, and individualized and if patients engage in informed decision making for managing their pain.

Although ONS does not define the term legitimate need, it is our position that

- “All people with cancer have a right to optimal pain relief that includes culturally relevant and sensitive pain education, assessment, and management.
- “The public, people with cancer, and significant others must be educated about the right to relief from cancer pain.”
- “Healthcare professionals, particularly nurses, pharmacists, and physicians, are accountable to manage cancer pain effectively.

- "All professionals caring for patients with cancer have an ethical responsibility to acquire and use current knowledge and skills and to implement evidence-based pain management guidelines."
- "Comprehensive cancer pain management is a multidisciplinary and collaborative effort that must include ongoing individual assessment, planning, intervention, and evaluation of pain and pain relief. Comprehensive pain management addresses physical, psychological, spiritual, and sociocultural effects of unrelieved pain."
- "Healthcare systems and clinicians providing care to patients with cancer are responsible for adopting and monitoring institutional and clinical guidelines for cancer pain management and symptoms related to its treatment. Healthcare systems must establish mechanisms for continuous evaluation of pain outcomes in patients at risk for cancer pain."
- "Healthcare facilities must establish minimum standards for clinician's pain assessment and technical skills (e.g., epidural and patient-controlled analgesia pump management). Organizations and healthcare facilities must adopt and support the use of evidence-based pharmacologic and nonpharmacologic interventions and establish minimum standards for competency in their use" (ONS, 2010).

Clearly, opioids have demonstrated the ability to relieve moderate to severe pain from various acute and chronic disease states. The majority of patients who are prescribed opioids use them as directed by their healthcare provider. While every medication has side effects, opioids in general, have fewer side effects (typically sedation, constipation) when used as prescribed. Patients are often prescribed opioids for acute and chronic pain when they can no longer tolerate other pain relievers such as nonsteroidal antiinflammatory drugs (NSAIDs) such as ibuprofen due to intolerable side effects (stomach upset, swelling) or underlying medical conditions that make them too risky to prescribe (high blood pressure, stomach ulcers, kidney disease). An example of patients who may need medical pain relief and because of underlying medical conditions cannot take NSAIDs would be our growing population of elderly. The American Geriatrics Association has released guidelines that support the use of opioids in chronic noncancer pain conditions for this reason.

As with any medication, there are risks that accompany the use of opioids and, thus, they are not the answer for every patient with acute or chronic pain. Short-term side effects, such as sedation and constipation, may be intolerable, and long-term side effects, such as hormone suppression, are concerns as well. As a result of prescription drug misuse (a societal problem), certain patients who are high risk for misuse (including psychological dependence) or diversion (illegal behavior) should not be prescribed opioids for long-term use. The medical literature has identified those at "high risk." Additionally, the medical literature is beginning to define which patients may be at risk of unintentional overdose. Prescriber education regarding these risks is critical. With education, prescribers are learning to use these medications safely by recognizing who may be at risk of side effects, unintentional overdose, and prescription drug misuse. Virginia Commonwealth University Medical Center (VCUMC) has created online education that addresses how to safely prescribe opioids for pain (<http://www.paineducation.vcu.edu/curriculum/>). Through a partnership with the Virginia Department of Health Professions, this online education is available free to all healthcare providers within our state. In addition, all medical students and residents at VCUMC have access to the course. Unpublished outcomes show that an online educational program such as this can improve knowledge, confidence, attitudes, and prescribing behaviors.

Honestly, both within and outside of cancer pain, few providers relish the role of prescribing opioids and would rather avoid it. In these cases, many patients suffer because an opioid, which may be the safest and most effective medication, is avoided. Defining "legitimate need" is challenging as there is no vital sign, blood test, or x-ray that can "prove" if pain is present, what

the pain level is, and what the impact of the pain is on the patient's life. Suffering extends beyond even the pain state, as many patients are shuffled from provider to provider in a broken healthcare system searching for someone to prescribe a medication that "works," lessening their pain, and allowing their quality of life to improve. This is even more challenging in chronic pain.

Pain management really relies on patient and provider communication, trust and ongoing assessment, and inclusion of the appropriate disciplines, such as physical therapy, occupational therapy, psychology, as well as others as needed. When opioids are used to decrease pain and it becomes moderate or mild, does one then stop the opioids because the pain is no longer severe?

The available data suggest that opioid therapy (along with a multimodal treatment regimen) represents a valuable treatment option in patients who do not respond to other analgesics and in whom the benefits of these medications outweigh the potential risks. Thus, this would be "legitimate need." Stopping opioid therapy when pain becomes mild or moderate may be possible in some situations but not all. The focus of assessment when opioids are used is the patient's function. So if the pain level is reduced with the prescribed opioid and the patient's function has improved, that would, in fact, be a reason to continue the prescribed opioid. If the function has not improved, even if the pain level has lessened, that would not necessarily be a reason to continue the prescribed opioid.

All efforts toward managing pain and minimizing prescription drug misuse need a balanced and thoughtful review by the provider, through a provider-patient relationship that is based on transparency (Pergolizzi, Böger, Budd, et al., 2010).

2. What's wrong with limiting these addictive drugs only to people who are in severe pain, who need serious medications to preserve their daily lives?

First, "these addictive drugs" is a statement that may not be quite accurate. Literature has found that opioids are addictive in patients who have a personal or family history of substance abuse but not necessarily in all patients. Those who are prescribed opioid for chronic pain will likely become physically dependent but not "addicted." Addiction is a disease and has a specific set of criteria to define it, according to the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*.

The challenge of this question is that there is no way other than discussion to determine who is in severe pain. The World Health Organization analgesic ladder, which has been used as a guide worldwide for over 20 years, educates clinicians in pain management to use opioids if pain is moderate to severe. Even with this guide, not all will achieve acceptable pain relief. As previously mentioned, there are no physical, laboratory, or radiology findings that can tell us that a patient is in severe pain. It all boils down to good physical assessment, a well-trained provider, and a level of trust.

3. Should there be a different treatment standard or protocol for cancer patients than for someone who has a broken ankle or strained back?

There should be guidelines for treating specific kinds of pain, and there are (i.e., cancer pain, acute pain, sickle cell pain, chronic opioid therapy in chronic noncancer pain as well as others available from associations such as the American Pain Society), but these guidelines are just that—they should *guide* a practice, not *dictate* a practice. Why would we not prescribe opioids for an individual with a crush injury to the ankle if the patient is suffering and if prescribing opioids can allow that patient to improve his or her function, possibly even return to work? On the contrary, a patient with prostate cancer with few bone metastases and minimal pain may not

even need opioids. Those with postoperative pain may need opioids to recover from surgery but only for a short time. There is extreme individual variability in response to opioids. While there is some pharmacogenetic information that supports this, choosing the appropriate analgesic is still the art, not the science, of managing pain. A well-informed clinician, however, can provide safe and effective pain care with opioids as one of several medications for pain. It would be naïve to assume that all prescribers will recognize every patient who is “doctor shopping” for diversion or every patient who has addiction. However, limiting the medications because of this reason will result in many patients not being able to find pain relief. Already, due to “fears” of regulatory oversight, suspicion of patients’ misusing, and a general discomfort with this class of medication, many prescribers (including pain practices) are refusing to prescribe any opioids. Additionally, the time it takes to assess, treat, and monitor patients (following the Federation of State Medical Boards’ Model Policy) is not reimbursed by insurances, and insurance limitations on type, quantity, and purpose of using opioids (resulting in time-consuming prior authorizations, mostly not approved) have been enormous barriers to appropriate pain care (Chou, Ballantyne, Fanciullo, Fine, & Miaskowski, 2009).

4. Who is in the best position to educate prescribers on how to assess pain and prescribe the appropriate treatment?

Prior to prescribing opioids, every provider needs to be aware of the medication’s benefits and risks including burdens to the patient, their family, and society. For some patients, regardless of diagnosis (cancer or not cancer), opioids will be the best treatment to improve quality-of-life and function. But, opioids are not for everyone. Pain management education that includes opioid prescribing should be included in medical and dental school training as well in nursing and pharmacy schools. Education should focus on proper pain assessment and treatment including using a multimodal approach to therapy. Residency programs for these same groups should include competencies based in pain management. Finally, current providers should have education available to them to refine their pain assessment and management skills. Nonpharmaceutical-supported and hospital-supported education would be ideal. Additionally, healthcare organizations could provide resources to their providers to support them in safe prescribing behaviors through the electronic health record.

5. Who is in the best position to educate families on safe storage and disposal of medications such as opioids?

Within a health system or office, standard education is needed when opioids are prescribed. This can be done through in-office education with handouts and electronic health records. Clinicians and prescribers certainly can support the educational principles, but standard education is necessary in order to reach each patient with a consistent message. With the growth of Patient Centered Medical Home, a team approach to medication safety is ideal. For example, a case manager may follow up patients who are prescribed controlled substances within several days via telephone or email in order to reinforce the directions, safe use, side effects, and disposal. Widespread education should come from community organizations. This is the only way to reach those who are not accessing medical services and also reach children and teens. The focus should be on safely storing and disposing of medications and about the dangers of taking medications not prescribed for you. Social media would also be a supportive avenue to relay this education.

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