

**PRESCRIPTION DRUG DIVERSION: COMBATING
THE SCOURGE**

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

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PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE

THURSDAY, MARCH 1, 2012

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

The subcommittee met, pursuant to call, at 11:10 a.m., in room 2322 of the Rayburn House Office Building, Hon. Mary Bono Mack (chairman of the subcommittee) presiding.

Members present: Representatives Bono Mack, Blackburn, Stearns, Harper, Lance, Cassidy, McKinley, and Butterfield.

Staff present: Paige Anderson, Policy Coordinator, Commerce, Manufacturing, and Trade; Charlotte Baker, Press Secretary; Kirby Howard, Legislative Clerk; Brian McCullough, Senior Professional Staff Member, Commerce, Manufacturing, and Trade; Gib Mullan, Chief Counsel, Commerce, Manufacturing, and Trade; Shannon Weinberg, Counsel, Commerce, Manufacturing, and Trade; Michelle Ash, Democratic Chief Counsel, Commerce, Manufacturing, and Trade; and Will Wallace, Democratic Policy Analyst.

Mrs. BONO MACK. Good morning. If statistics hold true, by the time this hearing is over 10 Americans will have tragically and I believe needlessly died from prescription drug overdoses. Today prescription drug abuse is a deadly, serious, and rapidly escalating problem all across our Nation. We have a solemn obligation to tackle this growing epidemic head on, and I am going to keep beating the drums until Congress, the FDA, and the DEA come up with a comprehensive plan for action.

The Chair now recognizes herself for an opening statement, and the clock is not working. That is all right for me. It won't be all right for you all, though, so don't get too comfortable.

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

As Americans we rally around efforts to fight breast cancer, childhood diseases, and other serious health threats. But for far too long there have been only hushed whispers about prescription drug abuse, now the fastest-growing drug problem in America according to the CDC.

Today as the death toll from prescription drug overdoses continues to rise sharply, it is time to move the story from the obituary page to the front page where it belongs. It is time to realize

that we can't simply wish this horrific problem away, not with nearly 30,000 people a year dying from it. See no evil, hear no evil often leads to a society's unspoken evil, indifference.

We can do better than that, and we must. Just about everyone knows someone who is affected by prescription drug abuse, which impacts an estimated 12.5 million Americans and is now considered a health epidemic by the CDC. According to a recent, "Monitoring the Future," national survey nearly one in four twelfth-graders have abused prescription drugs.

Today two classes of medicines, painkillers and insomnia and anxiety drugs, are responsible for about 70 deaths and nearly 3,000 emergency room visits a day. These are stunning numbers, but here is what is even more alarming. The death toll from overdoses of these powerfully-addictive medicines is now more than double the death toll from heroin, cocaine, and all other illegal drugs combined. As a result, for the first time ever drug deaths outnumber traffic fatalities and has become the leading cause of accidental death in America.

So what is the answer? When it comes to prescription drug abuse, where are the safety belts and the airbags that we need to deploy? First, like anyone in recovery knows we have to admit we have a serious problem. Americans today simply are prescribed too many medicines. There is a pill for just about every ache, pain, and malady.

So what is wrong with that? Well, consider this. Not long ago the DEA conducted three national drug take-back days, and I applaud them for that, and at those 3 take-back days they collected an astonishing 995,815 pounds of unused and unneeded medicines. That is 995,000 pounds, not pills, in just 3 days.

Today doctor shopping is a widespread problem which contributes to our Nation's alarming prescription drug addiction rate, increases costs to all of us through higher insurance rates, and makes it extremely difficult for the DEA to crack down on abusers. Compounding the problem is an oftentimes false sense of security. "If it is approved by the FDA and prescribed by a doctor, then it must be OK." Wrong. Too many pills taken at once or combining them with other drugs and alcohol can have a serious and even deadly consequence.

But the issue confronting us today is much more complex and involved than just what have you found lately in Grandma's medicine cabinet. The black market sale of powerful and highly-addictive narcotic painkillers such as OxyContin and Vicodin is big business, prompting the DEA to attack the problem on multiple fronts from street-level sales all the way to the top of the supply chain. Targeted first were the so-called, "pill mills" in Florida which were largely unregulated until last year, and they routinely dispensed painkillers like they were M&Ms from a gumball machine.

There is yet another, more insidious side of the story as well. After becoming addicted to prescription painkillers, law enforcement authorities say more and more people are now switching to heroin. In San Diego County, which borders my district, drug treatment experts say the use of heroin by young adults has more than tripled since 2006. Much of this growth is due to people who have switched to heroin as a cheaper alternative to OxyContin, now

going on the street for as much as \$80 for an 80-milligram tablet. By contrast, OxyContin sells for about \$6 a tablet in pharmacies.

Personally, I will never forget the very chilling phone call I received one night from a constituent of mine who told me that his son had had a gun put to his head because he couldn't pay the street price any long for his OxyContin.

So what is the answer? I believe my legislation, the Ryan Creedon Act, H.R. 2119, and the Stop Oxy Abuse Act, H.R. 1316, are good starting points. My goal is to improve prescriber education by getting doctors, dentists, nurse practitioners, and other prescribers up to speed on the dangers of addiction and to make certain that powerful and seductive narcotic prescription drug such as OxyContin are used to treat severe pain only, not moderate pain like a toothache or a sore knee. In far too many cases addiction becomes a much greater health threat than the original pain itself, and in far too many cases death is the final result of a failed rehab.

So let us not continue to blame this on Grandma and her medicine chest. She knows better, and in our hearts Americans do, too.

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

As Americans, we rally around efforts to fight breast cancer, childhood diseases and other serious health threats. But for far too long, there have only been hushed whispers about prescription drug abuse – now the fastest growing drug problem in America, according to the Centers for Disease Control and Prevention.

Today, as the death toll from prescription drug overdoses continues to rise sharply, it's time to move this story from the obituary page to the front page where it belongs. It's time to realize that we can't simply wish this horrific problem away – not with nearly 30,000 people a year dying from it. "See no evil, hear no evil" often leads to a society's unspoken evil – indifference.

We can do better than that – and we must. Just about everyone knows someone who is affected by prescription drug abuse, which impacts an estimated 12.5 million Americans and is now considered a health epidemic by the CDC. According to a recent "Monitoring the Future" national survey, nearly one in four 12th graders have abused prescription drugs.

Today, two classes of medicines – painkillers and insomnia/anxiety drugs – are responsible for about 70 deaths and nearly 3,000 emergency room visits a day. These are stunning numbers. But here's what's even more alarming: the death toll from overdoses of these powerfully-addictive medicines is now more than double the death toll from heroin, cocaine and all other illegal drugs combined. As a result – for the first time ever – drug deaths outnumber traffic fatalities and have become the leading cause of accidental death in America.

So what's the answer? When it comes to prescription drug abuse, what are the safety belts and air bags we need to deploy? First, like anyone in recovery knows, we have to admit we have a serious problem. Americans today simply are prescribed too many medicines. There's a pill for just about every ache, pain and malady. So what's wrong with that? Well, consider this: not long ago, the Drug Enforcement Administration conducted three national drug take-back days and collected an astonishing 995,815 pounds of unused and unneeded medicines. That's 995,815 pounds – not pills – in just three days.

Today, "doctor shopping" is a widespread problem which contributes to our nation's alarming prescription drug addiction rate, increases costs to all of us through higher insurance rates and makes it extremely difficult for the DEA to crack down on abusers. Compounding the problem is an often-times false sense of security: "If it's approved by the FDA and prescribed by a doctor then it must be okay." Wrong. Too many pills taken at once, or combining them with other drugs, and alcohol, can have serious and even deadly consequences.

But the issue confronting us today is much more complex and evolved than just "what have you found lately in grandma's medicine cabinet?" The black market sale of powerful and highly-

addictive narcotic painkillers, such as Oxycontin and Vicodin, is big business, prompting the DEA to attack the problem on multiple fronts – from street level sales all the way to the top of the supply chain. Targeted first were the so-called “pill mills” in Florida which were largely unregulated until last year and routinely dispensed painkillers like they were M&Ms from a gumball machine.

There’s yet another, more insidious side of this story as well. After becoming addicted to prescription painkillers, law enforcement authorities say more and more people are switching to heroin. In San Diego County – which borders my district – drug treatment experts say the use of heroin by young adults has more than tripled since 2006. Much of this growth is due to people who have switched to heroin as a cheaper alternative to OxyContin, now going on the street for as much as \$80 for an 80 milligram tablet. By contrast, OxyContin sells for about \$6 a tablet in pharmacies.

Personally, I will never forget the chilling phone call I received one night from a Palm Springs man who told me his son had a gun put to his head because he couldn’t pay the “street price” of OxyContin.

So what’s the answer? I believe my legislation, the Ryan Creedon Act (HR 2119) and the Stop Oxy Abuse Act (HR 1316) are good starting points. My goal is to improve prescriber education by getting doctors, dentists, nurse practitioners and other prescribers up to speed on the dangers of addiction and to make certain that powerful and seductive narcotic prescription drugs, such as Oxycontin, are used to treat severe pain only – not moderate pain like a tooth ache or sore knee. In far too many cases, addiction becomes a much greater health threat than the original pain itself. And in far too many cases, death is the final result of a failed rehab.

Don’t blame this on grandma. She knows better. In our hearts, Americans do too.

Mrs. BONO MACK. And I am happy to recognize the gentleman from North Carolina, the ranking member of our subcommittee, Mr. Butterfield, for his 5 minutes.

OPENING STATEMENT OF HON. G.K. BUTTERFIELD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mr. BUTTERFIELD. Thank you. Let me thank the chairman for holding today's hearing on this very important subject of prescription drug diversion, and I know that this issue is very important to you, and I admire your work on it.

Prescription drug diversion is an ever-growing problem in our country. In fact, a couple years ago in 2010, seven million people, seven million, over the age of 12 were considered current users of a prescription pain reliever; tranquilizers, stimulant, or a sedative, that was not prescribed to them. Sadly, it has become clear that as legitimate prescription drug use rises, so, too, does the number of people who abuse these drugs and so, too, does the number of people who accidentally die from prescription drug overdose. It is unconscionable that since 1990, a little over 20 years ago, the deaths resulting from an overdose of prescription drugs have risen. It has risen five-fold. Sometimes must be done, and I agree with that.

But the question is what and by whom. Some of the testimony we will hear today comes from manufacturers and distributors of prescription drugs. It seems to me that the security and safeguards these entities employ is very impressive and goes beyond what might be expected. The use, layers upon layers of—they use layers upon layers of security. They hire third parties to audit the processes and make immediate changes if a vulnerability is indentified. They track shipments with GPS precision and have built in a lot of redundancy in their security procedures.

Understandably, though, the further down the supply chain a particular drug travels the greater are the opportunities for diversion. The National Survey on Drug Use and Health reported that 76 percent, more than three-quarters of people who use prescription drugs non-medically, gain access to them from someone they know. I think this needs to be our focus as we go forward.

To that end, we need to focus on anti-diversion efforts, and I am pleased that the director from the White House Office of National Drug Control Policy is here today to tell us about their action plan.

In a perfect world the answer to this problem is personal responsibility, but in the real world it is clear the Federal Government does have a defined role to play. We need to provide greater support for education programs for young people so they can learn at an early age the dangers of misusing prescription drugs. We need to provide greater support for rehabilitation initiatives so those who are addicted to prescription drugs have access to the help they medically need, and we need to make sure DEA has access to the resources it needs to scrutinize all the players involved and the manufacturer, distribution, and dispensing of controlled substances. Most involved in this process are good and honest people. DEA needs to find the ones who are not.

And so I would like to personally on behalf of the Democrats on this committee thank all of you for coming today, and I look forward to your testimony. I stand ready to work with each of you, Madam Chair, and our colleagues and witnesses to curtail prescription drug abuse in the United States of America.

Thank you so very much. I yield back.

[The prepared statement of Mr. Butterfield follows:]

STATEMENT OF CONGRESSMAN G. K. BUTTERFIELD
DEMOCRATIC RANKING MEMBER

HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE

HEARING: "PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE"
MARCH 1, 2012

Chairman Bono Mack, thank you for holding today's hearing on prescription drug diversion. I know this issue is very important to you for many reasons and I admire your work on it.

As you know, prescription drug diversion is an ever growing problem in our country. In fact, in 2010, seven million people over the age of 12 were considered current users of a prescription pain reliever, tranquilizer, stimulant, or sedative that was not prescribed to them. Sadly it's become clear that as legitimate prescription drug use rises, so too does the

number of people who abuse these drugs and so too does the number of people who accidentally die from prescription drug overdoses. It is unconscionable that since 1990 – a little over 20 years – deaths resulting from an overdose of prescription drugs have risen fivefold. Something must be done. But the question is what? And by whom?

Some of the testimony we will hear today comes from manufacturers and distributors of prescription drugs. It seems to me that the security and safeguards these entities employ is very impressive and goes beyond what many might expect. They use layers upon layers of security. They hire third-parties to audit

the processes and make immediate changes if a vulnerability is identified. They track shipments with GPS precision and have built in a lot of redundancy in their security procedures. Understandably though, the further down the supply chain a particular drug travels, the greater are the opportunities for diversion.

The National Survey on Drug Use and Health reported that 76 percent – more than three quarters – of people who use prescription drugs non-medically gain access to them from someone they know. I think this needs to be our focus moving forward. To that end, we need to focus on anti-diversion efforts and I'm pleased that Director Kerlikowske [KER-LA-COW-SKI] from

the White House Office of National Drug Control Policy is here to tell us about their Prescription Drug Abuse Prevention Action Plan.

In a perfect world, the answer to this problem is personal responsibility. But in the real world, it's clear the federal government has a role to play. We need to provide greater support for education programs for young people so they can learn at an early age the dangers of misusing prescription drugs. We need to provide greater support for rehabilitation initiatives so those who are addicted to prescription drugs have access to the help they medically need. And we need to make sure DEA has access to the resources it needs

to scrutinize all the players involved in the manufacture, distribution, and dispensing of controlled substances. Most involved in this process are good, honest people. DEA needs to find the ones who aren't.

I'd like to thank the witnesses for being here today and look forward to their testimony. I stand ready to work with you, Madam Chair, our colleagues, and today's witnesses to curtail prescription drug abuse in the United States.

Thank you very much.

Mrs. BONO MACK. Thank you, Mr. Butterfield. Chairman Upton has yielded his 5 minutes for an opening statement to me in accordance with committee rules, and as his designee I now recognize Mr. Stearns for 2 minutes for an opening statement.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. Thank you, Madam Chair, and just wanted to compliment you for this hearing on prescription drug diversion. Very important and I am also very pleased to have and welcome our attorney general, Florida's own attorney general, Pam Bondi. She is here to testify on this important hearing. She is Florida's 37th attorney general, sworn in in January of last year. She is a native of Florida, and she graduated from the University of Florida, which I represent, so I am proud to have her as a so-called constituent. She also graduated from Stetson Law School and was a prosecutor for almost 18 years.

Among her top priorities is strengthening penalties to stop pill mills in the Sunshine State, which from our last hearing, Madam Chair, on this issue was a prevalent problem in our State, and with her dedication and leadership against prescription drug abuse, Florida went from having 98 of the top 100 dispensing physicians for oxycodone pills to have 13 dispensing physicians residing in Florida.

So frankly her success in this effort resulted in recognition from the National Association of Drug Diversion Investigators, Florida Police Chiefs Association, and from the Florida Board of Medicine. So I want to welcome her, and I thank you, Madam Chair, for the opportunity to do so.

Mrs. BONO MACK. Thank you, and I just want to point out that there is a hearing going on in the Health Subcommittee with the Cabinet Secretary. So a lot of members are bouncing in and out. If they are able to attend, I just want to thank the members who are here.

Mr. BUTTERFIELD. Madam Chairman, that is where I was until I figured out I was in the wrong place.

Mrs. BONO MACK. I am glad you figured it out. But we do have three panels before us today. Each of our witnesses has prepared an opening statement. They will be placed into the record. Each of you will have 5 minutes to summarize that statement in your remarks. The good news is the clock is working, and there is a timer in front of you now.

On our first panel we have the Honorable Gil Kerlikowske, Director of the Office of National Drug Control Policy. Good morning, Director, and once again, thank you very much for being here. I am happy to recognize you now for 5 minutes for your statement.

STATEMENT OF R. GIL KERLIKOWSKE, DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY

Mr. KERLIKOWSKE. Thank you, Chairman Bono Mack and Ranking Member Butterfield and distinguished members of the subcommittee. It is a great opportunity for us to update you on this important issue of prescription drug abuse in the United States.

Prescription drug abuse has been a major focus of the Office of National Drug Control Policy since my confirmation. I am particularly indebted to Chairman Bono Mack for calling me up to her office in the first week that I was in the office to really begin to educate me about an issue that, frankly, 3 years ago was not on the public's radar screen, but it is clearly in front of the public today.

I included prescription drug abuse as a signature initiative as part of the administration's National Drug Control Strategy. As been mentioned, it has been categorized as a public health epidemic by the Centers for Disease Control and Prevention.

The scope of non-medical use of pharmaceuticals is striking. CBC found in 2008, that the opioid pain relievers were involved in 14,800 deaths, and opioid pain relievers are now involved in more overdose deaths as has been mentioned in heroin and cocaine combined. The vast majority of abused pharmaceutical drugs originally enter into circulation through a prescription. The quantity of prescription painkillers sold to pharmacies, hospitals, and doctors' offices has quadrupled from 1999, to 2010.

When I testified last year before this subcommittee in April, the administration had just released that month its Comprehensive Prescription Drug Abuse Prevention Plan. The plan focuses on four major pillars.

The first pillar is education. Most prescription painkillers are prescribed by primary care doctors, internists, and dentists, not pain specialists. The FDA is requiring manufacturers of these opioids to develop educational materials and training for prescribers. The administration is working with Congress to amend the Federal law to require mandatory education and training for prescribers, and we are also working very hard to educate the general public about the risks and the prevalence of prescription drug abuse and about the safe use and proper storage and disposal of these medications.

The second pillar, monitoring. We focused on expanding and improving State prescription drug-monitoring programs. Forty-eight states have those laws. Despite the progress, some states lack operational programs. Many states operate PDMPs that lack interoperability with other states. But I am pleased to report the administration worked with Congress to secure legislative language to allow the Department of Veterans' Affairs to share prescription drug data with these PDMPs.

Our third pillar focuses on safe disposal of unused and expired medications and through the National Prescription Drug Take Back Days that the DEA has collected and was talked about by the chair. The administration also recognizes the significant role that pill mills and rogue prescribers play in this issue. Our surveys and research show that with chronic addiction to prescription drug they are more likely to obtain their drugs from the pill mills than the recent initiates.

And final pillar of the administration's plan focuses on improving law enforcement capabilities to address diversion. Across the country law enforcement regulatory and legislative actions are forcing doctors and shoppers and doctor shoppers and others seeking these sources of prescription drugs to be apprehended.

The problem, of course, was highlighted in the State of Florida, which was in 2010, the epicenter of the Nation's pill mill epidemic, but I have to tell you that working with the attorney general in the State of Florida has led to marked changes in that State, and I couldn't be more pleased that not only she, but Attorney General Conway are also here.

In 2011, ONDCP, our office, supported training events because we know if you are going to do the enforcement, it can't be just at the Federal level. It has to be at the State and local level also, and experts in law enforcement need that kind of training in order to investigate these complex cases.

We are undertaking a data analysis project right now to examine the ways that prescription drugs are purchased, purchasing behaviors, and whether those patterns are indicative of suspicious behavior. We held a round table with members of the pharmacy community and law enforcement to discuss pharmacy robberies and burglaries. We called in the heads of organizations that worked on the security of the manufacturers and distributors to make sure that we were knowledgeable about what they were doing to secure these very potent pharmaceuticals.

In closing just let me thank the members of Congress for their support on the ONDCP and my Executive Branch colleagues who know that without your efforts and without your support we would not make a difference in this very important area.

Thank you.

[The prepared statement of Mr. Kerlikowske follows:]



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

**“Prescription Drug Diversion:
Combating the Scourge”**

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

Thursday, March 1, 2012
10:15 a.m.
2322 Rayburn House Office Building

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

STATEMENT OF
R. GIL KERLIKOWSKIE
DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

before the

SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

MARCH 1, 2012

Chairman Bono Mack, Ranking Member Butterfield, and distinguished members of the Subcommittee, thank you for this opportunity to appear before this Subcommittee once again to address the issue of prescription drug diversion and abuse in our country. As you know, the Office of National Drug Control Policy (ONDCP) was established by Congress with the principal purpose of reducing illicit drug use, illicit manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences. Our office establishes policies, priorities, and objectives for the Federal drug control program agencies. 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 you are also aware, I am charged with producing the *National Drug Control Strategy (Strategy)*, which directs the Nation's anti-drug efforts and establishes programs, a budget, and guidelines for cooperation among Federal, state, and local entities. The Obama Administration recognizes that addiction is a disease, and that prevention, treatment, and law enforcement must all be included as part of a strategy to stop drug use, get help to those who need it, and ensure public safety. Building upon this national *Strategy*, the Administration has developed the comprehensive *Prescription Drug Abuse Prevention Plan*. As I will discuss later in further detail, this document establishes a plan to reduce diversion and abuse of prescription drugs, while continuing to ensure legitimate access to medications for patients who need them.

The Administration's inaugural *Strategy*, released in May 2010, committed to reducing drug use and its consequences through a science-based public health approach to policy. The *Strategy* established specific goals by which to measure our success. The *Strategy* included action items that comprehensively address all areas of drug control. We added a few more action items relating to special populations as part of the 2011 *Strategy*, and the 2012 *Strategy*, which will be released in the coming weeks, will provide a status update on where we are in terms of meeting these goals. We have made significant progress on many of these items. In addition, we have highlighted three signature initiatives in each year's *Strategy*—prevention, drugged driving, and most pertinent for this hearing, prescription drug abuse.

The Epidemic of Prescription Drug Abuse

Over the past decade, the Nation has witnessed alarmingly high rates of prescription drug abuse and misuse, as well as dramatic increases in the consequences that have been devastating for public health and safety. We have seen increases in substance abuse treatment admissions, emergency department visits, and most alarmingly, deaths attributable to prescription drug overdoses. These trends and the scope of the problem have led the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) to characterize prescription drug abuse as a public health epidemic, a label that draws further urgency to both policy and community-based responses.

The latest survey data show that approximately seven million Americans currently abuse psychotherapeutic drugs. In 2010, 2.4 million Americans aged 12 or older used psychotherapeutics non-medically for the first time, which equates to nearly 6,600 new users per day. The largest share of these new users started with pain relievers (approximately 2.0 million or 5,500 new users per day). This figure is second only to new users of marijuana.¹

These figures translate into very real consequences. In 2009, estimates indicate over 1.2 million emergency department visits involved the non-medical use of pharmaceuticals, double the estimate from 5 years earlier, and outnumbering visits involving all other illicit drugs combined. Much of this increase is attributable to visits involving narcotic pain relievers, a class of drugs that includes oxycodone, hydrocodone, and methadone.² Pain relievers are driving many of the negative trends in prescription drug abuse. Data indicate a six-fold increase in addiction treatment admissions for individuals primarily abusing prescription painkillers from 1999 to 2009.³ These increases span age groups, gender, race, ethnicity, education, employment level, and region. We also know that pain relievers are the most commonly involved drugs in drug-related suicide attempts.⁴

In 2008, more than 36,000 Americans died from drug overdoses, and prescription drugs—particularly opioid painkillers—were involved in a significant proportion of those deaths. The CDC found that opioid pain relievers were involved in 14,800 of these deaths.⁵ Opioid pain relievers are now involved in more overdose deaths than heroin and cocaine combined. In the

¹ Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2011]. Available: <http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm>

² Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2009: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [August 2011]. Available: <http://www.samhsa.gov/data/2k11/DAWN/2k9DAWNED/HTML/DAWN2k9ED.htm>

³ Substance Abuse and Mental Health Services Administration. *Treatment Episode Data Set (TEDS) Report*. U.S. Department of Health and Human Services. [2011]. Available: <http://www.dasis.samhsa.gov/teds09/teds2k9nweb.pdf>

⁴ Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2009: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [August 2011]. Available: <http://www.samhsa.gov/data/2k11/DAWN/2k9DAWNED/HTML/DAWN2k9ED.htm>

⁵ Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report: Vital Signs: Overdoses of Prescription Opioid Pain Relievers— United States, 1999-2008*. U.S. Department of Health and Human Services. [November 2011]. Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_vv

United States in 2009, drug-induced deaths outnumbered motor vehicle crash deaths for the first time.⁶

Substance use has also affected our military, Veterans, and their families. According to the latest Department of Defense survey, one in eight (12 percent) active duty military personnel reported past month illicit drug use, largely driven by the abuse or misuse of prescription drugs (reported by 11 percent).⁷ We also know that substance abuse affects many of the country's estimated 67,000 homeless Veterans.⁸

The human costs of prescription drug abuse are tragic and cannot be overstated for the families and friends that have experienced the loss of a loved one. Yet there is also a cost to society at large. A recent study estimated that the health care, workplace, and criminal justice costs of prescription opioid abuse amounted to over \$56 billion in 2007.⁹ Financial consequences are just part of the damage caused by prescription drug abuse.

The vast majority of abused pharmaceutical drugs originally enter into circulation through a prescription. And we know that most prescription painkillers are prescribed by primary care physicians, internists, dentists, and orthopedic surgeons, not pain management specialists.¹⁰ The quantity of prescription painkillers sold to pharmacies, hospitals, and doctors' offices approximately quadrupled between 1999 and 2010. In fact, CDC estimates that by 2010, enough opioid pain relievers were sold to medicate every American adult with a typical dose of 5 milligrams of hydrocodone every 4 hours for 1 month.¹¹

Unfortunately, once they are prescribed and dispensed, these drugs are frequently diverted to people using them without prescriptions. The latest survey shows that in 2009 and 2010 approximately 55 percent of the nonmedical users of prescription pain relievers got them "from a friend or relative for free." Another 11 percent bought them from a friend or relative, and 5 percent took them from a friend or relative without asking. This means that over 70 percent of people abusing or misusing prescription pain relievers obtained them from friends or family.¹²

⁶ National Center for Health Statistics. (2012). National vital statistics reports: Deaths: Final Data for 2009. Centers for Disease Control and Prevention: Washington, DC. Highlights/Detailed Tables available: http://www.cdc.gov/nchs/data/dvs/deaths_2009_release.pdf

⁷ 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.

⁸ Office of Community Planning and Development. *The 2011 Point-in-Time Estimates of Homelessness: Supplement to the Annual Homeless Assessment Report*. U.S. Department of Housing and Urban Development. [December 2011]. Available: http://www.hudhre.info/documents/PIT-HIC_SupplementalAHARReport.pdf

⁹ Birnbaum H.G., White, A.G., Schiller M., Waldman T., et al. (2011). Societal costs of prescription opioid abuse, dependence, and misuse in the United States. *Pain Medicine*. 12:657-667. Available: <http://www.ncbi.nlm.nih.gov/pubmed/21392250>

¹⁰ Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SRB. "Characteristics of opioid prescriptions in 2009." *JAMA* 2011;305(13):1299-1301. Available: <http://jama.ama-assn.org/content/305/13/1299.full>

¹¹ Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report: Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008*. U.S. Department of Health and Human Services. [November 2011]. Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w

¹² Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2011]. Available: <http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm>

This same survey shows that 17 percent of Americans using prescription pain relievers non-medically obtained them from one doctor, while just over 4 percent got them from a drug dealer or other stranger, and 0.4 percent bought them online.¹³

Researchers have begun to identify risk factors for overdosing on opioids. The first of these is “doctor shopping” – obtaining multiple prescriptions from different providers.^{14,15} Other predictors include taking one or more sedative/hypnotic (Benzodiazepine-like) medications, high daily dosages of prescription painkillers, and multiple overlapping prescriptions as well as prescriptions for certain drugs and visiting multiple pharmacies.^{16,17,18,19,20,21} Individuals with histories of mental illness or other substance abuse are also at increased risk.²²

Regionally, the drug overdose epidemic is most severe in the Southwest and in Appalachia, and rates vary substantially between states. The highest drug overdose death rates in 2008 were found in New Mexico and West Virginia (27.0 and 25.8 deaths per 100,000 population, respectively), which had rates nearly five times that of the state with the lowest rate, Nebraska (5.5 deaths per 100,000). The national average for drug overdose death is 11.9 deaths per 100,000, and California, at 10.4 deaths per 100,000, sits just below the national average.²³

¹³ Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2011]. Available: <http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm>

¹⁴ White AG, Birnbaum HG, Schiller M, Tang J, Katz NP. “Analytic models to identify patients at risk for prescription opioid abuse.” *Am J of Managed Care* 2009;15(12):897-906. Available: <http://www.ncbi.nlm.nih.gov/pubmed/20001171>

¹⁵ Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, et al. “Patterns of abuse among unintentional pharmaceutical overdose fatalities.” *JAMA* 2008;300(22):2613-20. Available: <http://jama.ama-assn.org/content/300/22/2613.full>

¹⁶ Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG, Harvey W, Loring LD. A history of being prescribed controlled substances and risk of drug overdose death. *Pain Med*. 2012 Jan;13(1):87-95. Available: <http://www.ncbi.nlm.nih.gov/ezproxy.nihlibrary.nih.gov/pubmed/22026451>

¹⁷ Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, et al. “Patterns of abuse among unintentional pharmaceutical overdose fatalities.” *JAMA* 2008;300(22):2613-20. Available: <http://jama.ama-assn.org/content/300/22/2613.full>

¹⁸ Green TC, Graub LE, Carver HW, Kinzly M, Heimer R. “Epidemiologic trends and geographic patterns of fatal opioid intoxications in Connecticut, USA: 1997–2007.” *Drug and Alcohol Dependence* 2011;115:221-8. Available: <http://www.ncbi.nlm.nih.gov/pubmed/21131140>

¹⁹ Paulozzi LJ, Logan JE, Hall AJ, McKinstry E, Kaplan JA, Crosby AE. “A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia.” *Addiction* 2009;104(9):1541-8. Available: <http://www.ncbi.nlm.nih.gov/pubmed/19686524>

²⁰ Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, et al. “Association between opioid prescribing patterns and opioid overdose-related deaths.” *JAMA* 2011;305(13):1315-1321. Available: <http://jama.ama-assn.org/content/305/13/1315.full>

²¹ Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, et al. “Opioid prescriptions for chronic pain and overdose: a cohort study.” *Ann Intern Med*. 2010;152(2):85-92. Available: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3000551/>

²² Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, et al. “Association between opioid prescribing patterns and opioid overdose-related deaths.” *JAMA* 2011;305(13):1315-1321. Available: <http://jama.ama-assn.org/content/305/13/1315.full>

²³ Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report: Vital Signs: Overdoses of Prescription Opioid Pain Relievers— United States, 1999–2008*. U.S. Department of Health and Human Services. [November 2011]. Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w

There are also some socioeconomic trends in these overdose deaths. According to researchers at the CDC, those living in rural areas are at higher risk for overdose,^{24,25,26} as are those in areas with higher proportions of impoverished residents.^{27,28} Among individuals on Medicaid, studies have found disproportionate patterns of painkiller use as well as significantly higher risk of overdose on prescription pain relievers.^{29,30} In addition, analysis of 31 states' poison control center calls shows that the percentages of residents living in poverty and unemployed correlate with prescription drug abuse reports, while the percentage with bachelor's degrees, and to a lesser extent high school diplomas, are related to less prescription abuse.³¹

These figures highlight the continuing health and safety dangers that prescription drug abuse, misuse, and diversion pose for the country. The ease of access to prescription drugs, combined with a low perception of risk, make reducing prescription drug abuse especially difficult, particularly among youth. When properly and safely prescribed by healthcare professionals, prescription medications can provide enormous health and quality of life benefits to patients. Medical science has successfully developed medications that can alleviate suffering, such as opioids for cancer pain and benzodiazepines for anxiety disorders, and allowed more individuals to have access to the medicines they need. However, we all now recognize that these drugs can be just as dangerous and deadly as illicit substances when misused or abused.

An Improved Response

The ongoing public health and safety consequences of prescription drug abuse underscore the need for action. When I testified before this Subcommittee last April, the Administration had just released its comprehensive *Prescription Drug Abuse Prevention Plan*, entitled "Epidemic:

²⁴ CDC grand rounds: prescription drug overdoses - a U.S. epidemic. Centers for Disease Control and Prevention (CDC). MMWR Morb Mortal Wkly Rep. 2012 Jan 13;61(1):10-3. Available: <http://www.cdc.gov.ezproxy.nihlibrary.nih.gov/mmwr/pdf/wk/mm6101.pdf>

²⁵ Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008 Dec 10;300(22):2613-20. Available: <http://www.ncbi.nlm.nih.gov.ezproxy.nihlibrary.nih.gov/pubmed/19066381>

²⁶ Wunsch MJ, Nakamoto K, Behonick G, Massello W. Opioid deaths in rural Virginia: a description of the high prevalence of accidental fatalities involving prescribed medications. Am J Addict. 2009 Jan-Feb;18(1):5-14. Available: <http://www.ncbi.nlm.nih.gov.ezproxy.nihlibrary.nih.gov/pubmed/19219660>

²⁷ Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report: Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008. U.S. Department of Health and Human Services. [November 2011]. Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w

²⁸ Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008 Dec 10;300(22):2613-20. Available: <http://www.ncbi.nlm.nih.gov.ezproxy.nihlibrary.nih.gov/pubmed/19066381>

²⁹ Centers for Disease Control and Prevention. "Overdose deaths involving prescription opioids among Medicaid enrollees—Washington, 2004-2007." MMWR. 2010;59:705-9. Available: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5842a1.htm>

³⁰ Braden JB, Fan MY, Edlund MJ, Martin BC, DeVries A, Sullivan MD. "Trends in use of opioids by noncancer pain type 2000-2005 among Arkansas Medicaid and HealthCore enrollees: results from the TROUP study." J Pain 2008;9(11):1026-1035. Available: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2661263/>

³¹ Spiller H, Lorenz DJ, Bailey EJ, Dart RC. Epidemiological trends in abuse and misuse of prescription opioids. J Addict Dis. 2009;28(2):130-6. Available: <http://www.ncbi.nlm.nih.gov/pubmed/19340675>

Responding to America's Prescription Drug Abuse Crisis." This plan builds upon the Obama Administration's *National Drug Control Strategy*, and brings together Federal, state, local, and tribal leaders to reduce diversion and abuse of prescription drugs. It strikes a balance between our need to prevent diversion and abuse of pharmaceuticals with the need to ensure legitimate access, focusing on four major pillars, each designed to intervene at a critical juncture in the process of diversion and abuse. These pillars include education for prescribers and the public; prescription monitoring; safe drug disposal; and effective enforcement. I am pleased to report that we are making significant progress in each of the four major pillars outlined in the plan.

The first pillar of our response plan is education. As stated earlier, most prescription painkillers are prescribed by primary care physicians, internists, dentists, and orthopedic surgeons, not pain specialists. Despite this reality, surveys of health care professionals and schools reveal significant gaps in education and training on pain management, substance abuse, and safe prescribing practices. For these reasons, the Administration continues to support mandatory prescriber education. The urgency of this epidemic and the fundamental need for safe prescribing practices in modern medical care demand effective curricula for prescribers. The HHS Substance Abuse and Mental Health Services Administration (SAMHSA) is providing critical training on prescription drug abuse for physicians both online, and since 2007, in 40 sites in 29 states with particularly high rates of opioid dispensing.

These training programs are providing important knowledge and tools for medical professionals responsible for safely prescribing these medications. In addition, the HHS Food and Drug Administration have developed a Risk Evaluation and Mitigation Strategy (REMS) for long-acting and extended-release opioids. This REMS requires all manufacturers of long-acting and extended-release opioids to develop educational materials and training for prescribers of these medications. The manufacturers must also develop information that prescribers can use when counseling patients about the risks and benefits of opioid use.

Another aspect of this education effort involves the general public, especially people using prescription medications, as well as parents and caregivers. We are working to educate Americans about the risks and prevalence of prescription drug abuse and about the safe use and proper storage and disposal of these medications. Through our National Youth Anti-Drug Media Campaign, ONDCP has developed materials for use by community anti-drug coalitions to educate youth about the dangers of prescription drug abuse. However, we also know that the average age of first non-medical use of pain relievers is 21 years old.³² Americans start abusing prescription drugs later in life than with other illicit drugs, so we need to ensure that prevention messaging targets adults as well. With these issues in mind, the Administration is producing educational materials, holding public events, and working with other government and private sector stakeholders to provide the right information to Americans who most need it.

The second pillar of the Administration's plan focuses on expanding and improving state Prescription Drug Monitoring Programs (PDMPs). As you know, these state-wide databases

³² Substance Abuse and Mental Health Services Administration. *Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2011]. Available: <http://oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.htm>

monitor the prescribing and dispensing of controlled substances, and serve a multitude of functions. PDMPs can and should serve as a tool for patient care, a drug epidemic early warning system (especially when combined with other data), and a drug diversion and insurance fraud investigative tool. Information contained in the PDMP can be used by prescribers and pharmacists to detect drug-drug interactions and identify patients who may be doctor shopping or in need of substance abuse treatment. 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.

In 2006, only 20 states had PDMPs. Today, 48 states have laws authorizing PDMPs, and 40 states have operational programs. Despite this progress and the demonstrated benefits of PDMPs, some states lack operational programs, and many states that do operate PDMPs lack interoperability with other states. All states should have operational PDMPs with mechanisms in place for sharing between states. Additionally, health care providers must use these databases regularly and consistently, incorporating PDMP checks as a standard part of patient care. We are working with other Federal and state health care and law enforcement officials to expand and improve the operations of these PDMPs, as well as resolve issues concerning implementation and interoperability among State databases, as permitted by law. I am also pleased to report that the Administration worked with Congress to secure language in the Consolidated Appropriations Act, 2012, to allow the Department of Veterans Affairs (VA) to share prescription drug data with state PDMPs. VA will soon begin the necessary rulemaking process that ultimately will provide state monitoring programs with critical data from VA prescribers.

ONDCP continues to work with the Office of the National Coordinator for Health Information Technology at HHS to explore connecting PDMPs with health information technology systems and state Health Information Exchanges. We are also exploring ways to incorporate real-time PDMP data at the point of care and dispensing. These advances will maximize the public health and public safety benefits of PDMPs.

The third pillar of our plan focuses on safe disposal of unused and expired medications. As I mentioned earlier, over 70 percent of people misusing prescription pain relievers report getting their painkillers from a friend or relative. Unused medications sitting in our medicine cabinets are falling into the wrong hands. Safe medication disposal programs provide a clear mechanism through which to ensure unused or expired medications are disposed of in a timely, safe, and environmentally responsible manner. The Drug Enforcement Administration (DEA), in partnership with hundreds of state and local entities, is providing more opportunities for safe disposal of unused or expired medications. Through coordinated, nationwide *National Prescription Drug Take Back Days*, DEA has collected more than 498 tons of unused medications to date. The next “Take Back Day” is scheduled for April 28, and we are looking forward to safely collecting, disposing, and preventing diversion of unwanted medications.

The passage of the Secure and Responsible Drug Disposal Act in October 2010 was a critical step forward in expanding prescription drug disposal nationwide. We anticipate the DEA rulemaking process to be completed later this year, making safe disposal of prescription drugs more convenient and accessible for all Americans. If we want to ensure a reduction in the

amount of prescription drugs available for diversion and abuse, a drug disposal program needs to be easily accessible to the public, environmentally friendly, and cost-effective, and the cost burden must not be placed on consumers. ONDCP is working with Federal, state, local, and tribal stakeholders to identify ways to establish take back programs in their communities upon completion of the rulemaking process.

The Administration also recognizes the significant role that “pill mills” and rogue prescribers play in this issue. For this reason, the fourth and final pillar of the Administration’s plan focuses on improving law enforcement capabilities to address diversion as the source of prescription drugs. ONDCP has worked with congressional partners and law enforcement and prosecutor groups to raise awareness of the scope of the prescription drug epidemic. The National Methamphetamine and Pharmaceutical Initiative (NMPI), which is funded through ONDCP’s High Intensity Drug Trafficking Area (HIDTA) program, is providing critical training on pharmaceutical crime investigations to law enforcement agencies across the country.

This enforcement and prosecution training is an important start to what requires a coordinated, long-term focus. One example of the ongoing challenges comes from Florida, which in 2010 was the epicenter of the nation’s pill mill epidemic.³³ At the time, DEA reported that 90 of the top 100 oxycodone purchasing physicians in the nation were located in the state. However, new state laws have stripped doctors of their ability to dispense controlled substances, including opioid based pain relievers, at rogue pain clinics. These state actions, combined with DEA’s significant enforcement actions, have resulted in a decreased number of rogue pain clinics. As a result, oxycodone purchases by doctors in Florida have dropped dramatically. In fact, there was a 97 percent decrease in 2011 compared to 2010, and the number of Florida doctors appearing on the list of the top 100 oxycodone purchasing physicians dropped from 90 in 2010 to only 13 in 2011.³⁴

The combination of law enforcement, regulatory, and legislative actions are forcing doctor shoppers and others seeking sources for prescription drugs for abuse to turn from Florida to other states in the region. There have been notable increases in doctors purchasing oxycodone in Georgia, Tennessee, and Kentucky. Among oxycodone purchasing doctors, 21 doctors located in Georgia and 11 in Tennessee are now among the top 100.³⁵ In order to prevent pill mill operators and rogue prescribers from simply popping up in other areas of the country, the Administration is working with state and local leaders to learn from Florida’s experience and explore enforcement, regulatory, and legislative options to prevent diversion and its consequences for public health and safety.

There remain other challenges, including data limitations that inhibit our ability to construct a more detailed picture of the prescription drug diversion and abuse problem. In order to address

³³ Rigg KK, March SJ, Inciardi JA. Prescription Drug Abuse & Diversion: Role of the Pain Clinic. *J Drug Issues*. 2010;40(3):681-702. [January 2011] Available: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3030470/?tool=pmcentrez>

³⁴ See DEA Press Release, “Florida Law Enforcement Prescription Drug Efforts Produce Positive Results,” January 30, 2012 Available: <http://www.justice.gov/dea/pubs/states/newsrel/2012/mia013012.html>

³⁵ *Ibid.*

these gaps, ONDCP is undertaking an analysis project that uses other data sources to fill in major information gaps. This project will examine methods by which prescription drugs are purchased, patterns in those purchasing behaviors, and whether those patterns are indicative of suspicious behavior. Examples of suspicious acquisition patterns that the project will examine include disproportionate numbers of cash-based purchases or the filling of multiple prescriptions for the same drug in an unusually short period of time. Identification and analysis of behaviors such as these will then be used to develop a complete profile of prescription drug diversion. Having first identified the ways in which the most commonly diverted prescription drugs are acquired, this project will then estimate the proportion of prescription drugs that are likely diverted from the legitimate market either for illicit resale or abuse. This is a crucial effort in developing a fuller understanding of the size and scope of prescription drug diversion in the U.S., and will provide valuable information to policymakers seeking to reduce diversion and its consequences.

Conclusion

As discussed above, we have seen extensive strides in efforts to address the prescription drug abuse problem. The public at large is better aware of the epidemic, and monitoring and disposal efforts have produced results. Unfortunately, however, these efforts have not yet translated into a reduction in prescription drug abuse. This means that we must redouble our efforts to achieve the as-yet unmet goals of the plan, such as mandatory prescriber education and improving PMDP utilization, and make needed enhancements to existing activities. The Administration is committed to maintaining its focus on prescription drug abuse as a signature initiative as part of the *National Drug Control Strategy*.

In closing, I recognize that none of the things ONDCP and my Executive Branch colleagues want to accomplish for the Nation are possible without the active support of Congress. Thank you for your continued support of ONDCP's efforts. I appreciate the opportunity to testify here today on this public health epidemic, and I look forward to continuing to work with you to reduce prescription drug abuse.

Mrs. BONO MACK. Thank you very much, Director. I will recognize myself now for 5 minutes for questioning.

And just ask you with everything that your office is doing together, the DEA and the FDA, why are we losing this battle against the prescription drug epidemic, and you have mentioned a lot of progress we have made, but you do live in Florida, but prescription drug abuse has not decreased. What is the next step?

Mr. KERLIKOWSKIE. I think the fact that all of these things are coming together, that we actually are starting to see some fruition to all of the work that has been going on. For instance, in the most recent Monitoring the Future Survey, eighth, tenth, and twelfth graders have actually reduced their level of use of prescription drugs, but I couldn't agree with the chair more that it is an epidemic, that it is so wide spread and that people still don't get it. They don't understand that these are dangerous, they can be deadly, and they can certainly be addictive.

I think that one of the greatest hopes will be in the next step forward, and that is mandatory prescriber education. Physicians must be told and must have unequivocal information about the dangers of addiction, pain management, tolerance, dependence, and they really don't get that in medical school. The second part I know you will hear from the Drug Enforcement administration as non-enforcement. The laws have to be enforced, and people have to be prosecuted.

Mrs. BONO MACK. I appreciate that and especially your viewpoint on prescriber education, but a problem for me, too, is we examined this problem. There are clearly gaps in the data, and we don't really know the extent of the problem.

What are the gaps, and how can they be filled?

Mr. KERLIKOWSKIE. Well, quite often we rely, for instance, on fatality data to come from the individual states, and we know that depending on the particular State, whether it is a medical examiner system or others, those states can often be delayed.

We also know that at times, whether it is from fatalities from driving accidents or others, that the level of examinations to determine what the cause and whether or not that person had the drugs in their system is not always as thorough as it can and should be. There are data gaps, but I will be happy at another time to tell you about this new initiative to take some of the data and really identify and drill down into it.

Mrs. BONO MACK. I would be happy to work with you on that. I think they are critical even for policymakers. We need that data critically.

The DEA is going to testify that there are 1.4 million DEA registrants. That seems awfully high. Do you think that 1.4 million registrants is about right for America, or is that kind of a crazy number?

Mr. KERLIKOWSKIE. Chairman, I actually wouldn't know what the right number would be, but I think when you look at nurse practitioners, physicians, and all of the other people that hold those DEA registration licenses across the country in the healthcare field, that the number doesn't seem completely out of line to me. I think more importantly is how they are policed.

Mrs. BONO MACK. Thank you, and lastly, should we be thinking about creating new classification schedules under the Controlled Substance Act with stricter regimes for the drugs that are clearly the biggest problems?

Mr. KERLIKOWSKE. I know that issue has come up before to put those into the higher schedule. I think the more important part is to try and keep them out of the hands of the abusers but not at the same time they get so restrictive that the issues that led us to where we are today 15 years ago, which was the clear indication that pain was not being adequately treated in the United States, I think the pendulum was too far over there. Clearly today the pendulum is too far over here when it comes to the availability of these.

I am not sure scheduling would be the right answer, but we have to bring this back to some equilibrium.

Mrs. BONO MACK. Are you working with the physicians who are saying that pain shouldn't always be treated solely with opioids and that there have to be other ways of treating pain, that this is creating an epidemic that is hurting more people than it is saving?

Mr. KERLIKOWSKE. I have. I have heard from a number of physicians that want to be much more flexible and understanding and treating pain rather than writing prescriptions for 30, 60, or 90 days worth of very powerful painkillers. They also want to make sure that there are systems in place where they can be adequately reimbursed for treatments other than what right now seems to be a very simple and quick method but not always particularly effective in treating pain by writing a script.

Mrs. BONO MACK. In the last 22 more seconds that I do have something Attorney General Bondi cares deeply about are the opiate babies. Can you speak briefly to what you have learned about opiate babies?

Mr. KERLIKOWSKE. I can. I can tell you that in the past and having visited in one of the centers for newborns in Seattle the issue always centered around newborns and the addiction through heroin. Today when I met and saw all of those infants and actually held one of those infants, the issue was all about prescription drugs, and there was very little discussion about mothers using heroin.

And so we are building some tremendous healthcare costs as a result of not treating this adequately.

Mrs. BONO MACK. Thank you very much, Director, and happy to recognize Mr. Butterfield for 5 minutes.

Mr. BUTTERFIELD. Thank you. Again, thank you very much for coming forward today with your testimony. We have heard your testimony, and we appreciate so much what you do.

I have a question that I would like to ask, and I may even ask it of the other panels as well, but I believe it is very critical, and it is central to the problem that we are dealing with.

Efforts in one state may yield declines in the number of pills dispensed, hospitalizations, or deaths, any of which are very commendable achievements within that state's border, but how can we be sure that addicted individuals simply don't go to another state?

Mr. KERLIKOWSKE. I think the key would be on the example would be the fact that Florida had become such as has been talked

about, so publicly an epicenter for not only the use of these very powerful, misuse and abuse of these very powerful prescription drugs for people within the State of Florida but for people traveling all the way through Appalachia and actually New York, Connecticut, and other places.

The regulation of medicine is done at the state level. It is not done at the Federal level, and we have to provide the training, the technical assistance, the start-up money for the computer systems, and the assistance to law enforcement, particularly state and local law enforcement to understand how to investigate these complex cases.

I would tell you that greater use of the PDMPs is necessary. Not as many physicians or people in the healthcare industry utilize them as should and that they need to be real time and that they need to be interoperable across states.

When those things come together and I think we are seeing some of this in the number of states that are sharing the information, I think that that way we can stop that balloon effect that you were talking about, Congressman.

Mr. BUTTERFIELD. We have been looking at the data in our office, and the data seems to suggest that the total number of illicit drug users was constant for 2 years, even though we have seen great strides in states like Kentucky and Florida and even Ohio.

Are we on the right path with this?

Mr. KERLIKOWSKA. I think we are on the right path with this with what I believe is a very balanced way and a very comprehensive way of looking at this. I think that if I go back and look at where we were, and believe me, I am the first one to tell you that a lot more has to be done, particularly in redoubling our efforts in some of these areas, but I look at where we were 3 years ago. As a chief of police of a city of almost 700,000 people, I was really unaware of this prescription drug problem. I think that my colleagues who were sworn to protect people in the city and learn about what are the dangers when you don't realize it, when we didn't realize it and prosecutors and judges and many others did not realize it, we weren't paying attention to it because after all, it is a prescription, it is coming out of the medicine cabinet. It was a huge mistake.

This is on the front page of every major newspaper on a regular basis. It is on television. We are moving in the right direction.

Mr. BUTTERFIELD. Let me talk about tribal communities for a minute, and I only have a minute 50 left. As the National Drug Control Strategy points out, tribal communities have been particularly hard hit by unemployment and combined with problems accessing healthcare, education, and other services, tribal communities can be disproportionately vulnerable to prescription drug abuse.

A 2009, study by the Substance Abuse and Mental Health Administration found that American Indians are more than twice as likely as whites to abuse prescription drugs. What is the administration doing to help tribal communities address these unique challenges?

Mr. KERLIKOWSKA. We started looking at that almost immediately and a couple things that are done. First Assistant Secretary

Echo Hawk from the Department of Interior has been a great partner, along with the Indian Health Service and along with the Bureau of Indian Affairs. We have made trips to a number of the tribal lands, for example, the Tohono O'odham Nation in Arizona, and the issues around dietary issues, alcohol issues, and illegal drugs was significant, but the growing problem that was pointed out to us is exactly as you said, and that is around the prescription drug issues.

Mr. BUTTERFIELD. But are you working with them to set up databases?

Mr. KERLIKOWSKE. Education, so the education and prevention and working through the Indian Health Service and the Treatment Service, and let me just mention on the enforcement side for the first time one of our high-intensity drug trafficking groups, HIDTA, in Portland includes a member of—a tribal chief to help direct those needed enforcement resources back onto tribal lands.

Mr. BUTTERFIELD. That includes databases and other resources?

Mr. KERLIKOWSKE. I don't know about the database in particular. I would think that the health service would probably be more knowledgeable about that.

Mr. BUTTERFIELD. All right. Thank you. You have been very kind.

Mr. KERLIKOWSKE. Thank you.

Mrs. BONO MACK. Thank you, Mr. Butterfield.

The Chair recognizes Mr. Stearns for 5 minutes.

Mr. STEARNS. Thank you, Madam Chair.

Is it true that prescription drug overdose deaths now surpass our car-related fatalities?

Mr. KERLIKOWSKE. It is true that all overdose deaths are now the leading, from drugs, misuse and abuse, not accidental, are the number one cause of accidental death in this country, ahead of gunshot wounds and ahead of car crash deaths, driven by prescription drugs.

Mr. STEARNS. That is a startling fact, don't you think?

Mr. KERLIKOWSKE. Yes.

Mr. STEARNS. Do you think based upon that that we should have a radical change in our approach?

Mr. KERLIKOWSKE. I think that we haven't gotten anywhere near the attention or near the traction to something that is killing more people in this country than car—

Mr. STEARNS. And, in fact, 10 or 20 years ago I wouldn't find the statistics like it is today?

Mr. KERLIKOWSKE. Not at all.

Mr. STEARNS. And why do you think that occurred?

Mr. KERLIKOWSKE. One, I think that the driver of the prescription drugs as we have been, as has been mentioned a little bit, people don't see them as addictive, they don't see them as dangerous, and they don't see them as deadly, because they are, after all, a prescription.

Mr. STEARNS. I think in your opening statement you were talking about opiates were sold in 2010, to medicate every American adult six times a day for a month. That was in your statement.

Mr. KERLIKOWSKE. Yes.

Mr. STEARNS. Doesn't that put a line to the claim that we are just getting better at pain management?

Mr. KERLIKOWSKE. When I have spoken with the physicians who looked at and were instrumental in the early days of under-treating and the recognition of under-treating pain, I think that a clear recognition, and as I mentioned a minute ago I think that the pendulum was there and that in very good faith ways they worked very hard to make sure that people actually were adequately treated for pain.

A few things were missing. One is the amount of education that a physician would need to clearly understand and recognize some of the dangers of these. The other is that as many people have mentioned, we have become kind of an overmedicated society.

Mr. STEARNS. How would we educate Americans to not be an overly medicated society?

Mr. KERLIKOWSKE. It is a pretty tough issue. It is kind of like dealing with the obesity issue.

Mr. STEARNS. Do you think it is something to do with our culture today that—

Mr. KERLIKOWSKE. I think that the more important part is to educate the physicians around this, as physicians are so much more knowledgeable about dietary issues and the causes, I don't see the same level of knowledge among them and among healthcare practitioners when it comes to the addictive properties of these drugs.

Mr. STEARNS. Could you from your department make it more difficult for the doctors to provide prescription drugs in the areas that are causing the overdoses? Is there something that you could do?

Mr. KERLIKOWSKE. I—we are kind of a small policy shop that—

Mr. STEARNS. You couldn't make any recommendations?

Mr. KERLIKOWSKE [continuing]. We bring all of these folks together. I think the key will be education and then making sure that they follow the rules, and I think that we are well on the way to hopefully getting that done.

Mr. STEARNS. You mentioned in your opening statement the actual cost to society is estimated at \$56 billion in 2007, and maybe likely higher today. Do you have any idea what the cost in terms of devastating affects on families and communities—so if it is \$56 million [sic] in 2007, what do you think it is today?

Mr. KERLIKOWSKE. Well, and I think that the most recent study on the costs to the United States taxpayer on drug abuse is well around \$190 billion that—

Mr. STEARNS. One hundred and ninety billion.

Mr. KERLIKOWSKE. For—and that includes all types of heroin, cocaine, marijuana issues, et cetera, but I think that you couldn't be more correct in putting forward the fact that it is not only a huge cost in our healthcare system, it is a huge personal cost and a huge personal tragedy the child that doesn't graduate from high school, the employer that wants to start a new business and can't find people that are drug free so that they will have less accidents and be more productive. All of these things play a huge part, and so the dollar cost is one thing. The tragedy to this country is another important part.

Mr. STEARNS. Lots of times all of us talk about the legal war on drugs, but we are also—I think we have to consider a war on prescription drugs, and so I guess the question is where does the current prescription drug war rank compared to our war on illegal drugs?

Mr. KERLIKOWSKA. I think my colleagues, particularly in the Drug Enforcement Administration, when they set their goals and they move forward each year in recognizing what the drug threat is, several years ago they recognized this issue much more quickly and actually changed their direction and focus. I think you will hear about the number of what are called tactical diversion squads, the number of investigations, the number of local law enforcement and prosecutors that have been trained in how to investigate these complex cases, because these are actually legal drugs that are manufactured and often through prescriptions or pill mills. So those are important steps forward.

Mr. STEARNS. Are we winning or losing?

Mr. KERLIKOWSKA. We are moving ahead. I am encouraged by a couple of things. One, the number of dispensed opioid prescriptions has flattened, and if you looked at the charts in a number of years, it looked like the space shuttle taking off. The amount of opioids manufactured has flattened, and the fact that in this most recent monitor in the future, eighth, tenth, and twelfth graders actually decreased in their use of one of the very powerful painkillers, Vicodin.

I think we are moving there, but as the chair and others know so well, it is not enough, and it is not fast enough.

Mrs. BONO MACK. Thank you very much, Mr. Stearns, and I am pleased to recognize Mr. McKinley for 5 minutes for his questions.

Mr. MCKINLEY. Thank you, Madam Chairman.

Briefly, I think you and I had a little conversation beforehand, before we began, and we were concerned about privacy. I still would, I would like you to expand a little bit about that. What—to me from an engineering for small business perspective, I am a little concerned about, very concerned about the privacy, but I know and I think you would recognize that if there were a national registry of all the prescription drug used in America, the pharmacies would be held responsible to check that registry to find out that they just got OxyContin just one day earlier for a 3-months' supply, and they would be able to say no.

Isn't there something, some form, I know we don't want to have FDA, because as we have had other hearings here, someone being able to hack into that information.

Mr. KERLIKOWSKA. Right.

Mr. MCKINLEY. There were penalties according—that are related to that, but we all know if we had a list, if someone had a list, we could go hold those people responsible more so than the distributors that are doing the best they can to curtail that.

Tell me a little bit about what efforts we can do in security privatizing those names so that individuals can't be identified but yet we—a pharmacy would be able to know that they have now, this is their third prescription for the same medicine in the last 2 weeks. Isn't there something you are doing on that?

Mr. KERLIKOWSKA. I think—

Mr. MCKINLEY. I saw this the other night. I just think that is just great, education. It works so well with teenage pregnancies and everything else, hasn't it? Sanctions against governments that they continue to—so I really want something with more substance to it that is going to solve the problem.

Mr. KERLIKOWSKE. Sure. I think the answer is the prescription drug monitoring plans that are done by the state. Since the Federal Government doesn't regulate the practice of medicine and the state does, having the PDMP, that electronic database that would be used by all physicians and healthcare professionals that would be real time and that in states, particularly neighboring states, that information could be shared across the states.

When it is led and directed and the start-up money comes from the Federal Government but led and directed by the state government, they can put in the protections about patient confidentiality and privacy. I think in the best of all worlds that national database would be a wonderful thing. I think it would be difficult to implement because of the protections that would be needed to prevent exactly as you said hacking, and I think that part of that national database would be the fact that it would be 5 or 6 or 7 years in the making. Right now we have all but two states that have PDMPs, and as they become more well used and more well robust, it will actually make a difference with their use.

Mr. MCKINLEY. So are you suggesting, and I think I understand, something that would not work with mail orders because they are ordered someplace else other than just in the state, but tell me again, you think that if pharmacists knew by looking at computer screen that that person got—would he or she still fill that prescription if he knew it was being violated?

Mr. KERLIKOWSKE. When I speak with all of the different groups and the individual pharmacists, and you look at their ethical standards and their patient safety practices and the number of pharmacists that have picked up the phone and either said, either called the physician saying something isn't right or the ones that have told that patient, you know what, I am not going to fill that because I have that information, I am pretty heartened by where the pharmacists are.

But I think going upstream a little bit, that doctor that realizes that that patient that has come into his or her office has been to two or three other physicians or that patient that walks in on Friday evening to an emergency department and says, gee, I am traveling or I have lost my prescription or I need something like that, when that frontline, upstream person can take a look at that system and say, well, this is the third hospital you have been to this weekend or you are seeing two other doctors with a similar complaint, I am not going to be dealing with this, I think that is a help also.

Mr. MCKINLEY. So what do we do with that individual when they come in? Are they held?

Mr. KERLIKOWSKE. They are not held because I think that unless they actually get, unless there is a law violation, they are not going to be charged or they are not going to be held, but I think the other important part of this education piece is that they need to get into the treatment. I have met so many people now across this country

on these travels that have become addicted to prescription drugs, have received proper quality treatment, and they are back. I mean, they are back taking care of their families, they are back paying taxes, they are back working, and I think that this is the entry point to get them the help that they are needed, because we are talking about a disease. We are talking about addiction.

Mr. MCKINLEY. OK. I guess we have run out of time. Thank you very much.

Mr. KERLIKOWSKE. Thank you, Congressman.

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

Mr. HARPER. Thank you, Madam Chair.

Director Kerlikowske, thank you for your time here and all that you are trying to do in a very serious situation. You know, with regard to the PDMPs, what do you think the biggest barrier is in the implementation of a drug-monitoring program for states whose programs have yet to go online?

Mr. KERLIKOWSKE. One of the barriers is the fact that it needs to be real time, and it needs to be ease of use. Physicians have about, as I have been told, about 16 minutes with a new patient to assess everything. These are busy practices and busy offices, and they need to be given a tool that is easy, that is accessible in order to use it and of course, once they do and they become schooled in it and rely on it, the physicians that I have spoken with tell me that it is a patient safety tool.

Mr. HARPER. OK. Now, we have 48 states that have authorized programs, 40, I understand, have operational programs. Are all of these state PDMPs created equal?

Mr. KERLIKOWSKE. No.

Mr. HARPER. OK.

Mr. KERLIKOWSKE. They are not, but we are fortunate at Rice University to have a center of excellence that takes the best practices that helps those that are—and of course, the heads of each of these agencies come together several times a year for us to be able to speak with them. We want to be able to make them as robust and helpful as possible, but I would be the first to tell you that some are better than others.

Mr. HARPER. Well, are there some that you would hold out as a role model for the other states or for those that have yet to go operational?

Mr. KERLIKOWSKE. I think you will hear from Attorney General Conway, and I think Kentucky is clearly one of those states that has addressed this not just with a very robust and smart PDMP and some pending changes that they have planned in their laws to make it an even better system. I would tell you that from what I have looked at in California, the CURES System, is another one. The Center for Excellence, they have done a very good job of putting in the hands of the people that use these, develop these systems, information that is necessary.

Mr. HARPER. What are you seeing as strengths and weaknesses as communication between the various states with their monitoring programs? Is that a weak link? Do you feel like that the communication between those states can be improved, and if so, what would you suggest?

Mr. KERLIKOWSKA. Now, you ask the million-dollar question, and I think you are exactly right. Some states are easier to get along with amongst each other on this particular issue and to work together. Some states when you look at these systems and it is not a huge amount of money but every state is facing difficult budget times, how much of a priority is it. But when I talked to these physicians or listen to these physicians in all these states, I said, look. If I am in eastern Kentucky, I really don't want to spend the time to check Ohio, West Virginia. I need to get to a system that is already linked to those neighboring states.

Mr. HARPER. Uh-huh. Do you—are the PDMPs the only option out there for states to implement the sharing of this information?

Mr. KERLIKOWSKA. Right now on the prescription drug abuse issue, those are the options. I think the healthcare technology in the future, e-prescribing, all of these other things will play a big role in the future and make it easier and more helpful.

Mr. HARPER. We want to thank you for your work on this very important topic, and with that I yield back, Madam Chair.

Mrs. BONO MACK. Thank you, Mr. Harper.

Director Kerlikowski, thank you so much for being here today and all of your hard work. You have been generous not only today but every day in working with me on these issues. I applaud you for raising the profile for many years and especially coming from somebody who said you didn't know 3 years ago, you certainly know now. I don't know that we have all the answers, but at least we are finally starting to confront it, and I look forward to working with you.

Thank you, again, very much for being here today. Is there anything you would like to close—rather than a second round of questions, something you just need to say that you didn't get to say?

Mr. KERLIKOWSKA. Madam Chair, one—I am indebted to the committee and the members of Congress that take this issue on. You have so many issues in front of you, and yet as I mentioned to the President on the drug issue, when we think about keeping our kids in school and we think about who is going to be the workforce that we are all going to depend on in the future, I think about healthcare costs, I think about law enforcement issues.

The more that we can do on the drug prevention side and the more that we can do to get people adequate treatment and get them back into the—into being productive members of society, none of that could happen without the will and the support and the help of members like you all.

Thank you.

Mrs. BONO MACK. Thank you very much.

And with that we are going to take a very, very brief recess just while we seat the second panel. Hopefully it is 30 seconds or so, and we ask the second panel to join the table.

[Recess]

Mrs. BONO MACK. All right. On our second panel we have four very distinguished witnesses who are very deeply involved in the issues of prescription drug abuse and prescription drug diversion, which clearly go hand in hand. We are honored today to have with us the Honorable Pamela Jo Bondi, attorney general for the State of Florida, the Honorable Jack Conway, attorney general for the

State of Kentucky. Also joining us are Aaron Haslam, Senior Assistant attorney general for the State of Ohio, and Joseph Rannazzisi, Deputy Administrator for the Drug Enforcement Administration.

Thank you all, again, for being with us this morning. To help you keep track of time there is a timer light on your table. When it turns yellow, you have a minute to wrap up. So, again, you don't have to come to a screeching halt when it turns red, but if you can wrap up your comments, we would appreciate it.

So with that we are happy to recognize Attorney General Bondi for her 5 minutes, and please just remember to turn your microphones on, and you may begin.

STATEMENTS OF PAMELA JO BONDI, ATTORNEY GENERAL, STATE OF FLORIDA; JACK CONWAY, ATTORNEY GENERAL, COMMONWEALTH OF KENTUCKY; AARON E. HASLAM, SENIOR ASSISTANT ATTORNEY GENERAL, STATE OF OHIO; AND JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION

STATEMENT OF PAMELA JO BONDI

Ms. BONDI. Thank you, Congresswoman Bono Mack, and thank you for championing this cause on behalf of our country, and thank you as well, Ranking Member Butterfield, for having us here today and also to Congressman Stearns from Florida and to all the committee members. We truly appreciate this.

I am here to tell you about what Florida is doing to try to stop prescription drug abuse. As Congressman Stearns told you, just to put it in perspective, of the top 100 oxycodone dealers in the entire country, 98 of them were in Florida. Now we have 13, and that is with legislation that has been in effect barely a year. So last year we had over 900 pain management clinics registered within our state. Today we have 580, and I guarantee you that number is going to continue to plummet.

I want to outline now briefly our comprehensive legislation and what we have done in our state. As you know, we have become the Oxy Express, and that is why I worked so closely with General Conway, with General DeWine in Ohio because what was happening, people were buying their drugs in Florida, taking them to Kentucky. I had to hug a mother in Kentucky when I was with General Conway who lost her daughter 2 years ago to prescription drugs that were bought in Florida, and that had to stop.

So we passed, with that we passed tough new legislation in our state, and we are very proud of that legislation. Long, long overdue, let me tell you that.

The common characteristics of a pill mill in Florida were cash business, \$200 to \$300 cash, armed guards at the door, little to no medical equipment at all. Just shelves and shelves of pills. These doctors who we call drug dealers wearing white coats are sitting in a back room just signing prescription pads, and it was legal, and it was killing our kids.

So we had very weak regulatory oversight of the pain management clinics. We had limited oversights of the physicians who were

dispensing, which was very important, and we had a non-operational prescription drug monitoring program.

So with that we have now passed some very tough legislation, and we are very proud of that. One of the most important things to me was that we banned doctors from dispensing most abused narcotics, and we made that a violation of the ban, both a third degree felony and how do you hurt a bad doctor? Take their license away. So with that dispensing ban we feel that we have been very successful as well.

We also have—we created a standard of care for physicians prescribing controlled substances. We require these doctors to either electronically prescribe or to use counterfeit-proof prescription pads, none of which had been done in our state. We also added, as I said, enhanced criminal penalties, which were very important and required all of these pharmacies to be re-permitted by the State of Florida.

We did great things. We now have the PDMP up and running, which if you have any questions, I can discuss that with you as well, and with that, you know, we can always create tough new laws and onto something else, but what we did in Florida with Governor Scott's help, we started a strike force, and that is joint with Federal, state, and local officials all working together. You can pass these laws and move on, and it is not going to work. We are targeting these guys, and we are putting them out of business.

And with that just—we have seven strike forces throughout our state, and if you have questions about the strike force, I can explain that in greater detail, but what we have done, since we have had the strike force is we have truly gone in and started putting these guys out of business. We are targeting them, and we are not letting up on them.

We also have an educational component of this legislation, and that involves narcotics overdose prevention education, NOPE, and this task force, these remarkable people have done an amazing job of going into our schools and educating our children about this.

We have also instituted along with DEA state drug take back days. I have participated personally in as many of those as I could. You would not believe the drugs that are being turned in, and it has gotten so successful that we plan on putting permanent drop boxes up at our police stations and our sheriff's offices as well. At two drug take back days alone we seized over five tons of prescription drugs. Unbelievable.

So and we are very pleased to announce that as of February, 2012, our strike force efforts have resulted in 2,040 arrests, 34 of those are doctors. We have seized 390 weapons, almost \$5 million, but there is one other problem. I have run out of time, but that is the babies being born addicted to prescription drugs, and that is our newest fight this session, and we are not going to give up on that as well.

Thank you for all of your efforts, and we do know we have a long way to go, but I don't think any of us in this room are going to stop.

Thank you.

[The prepared statement of Ms. Bondi follows:]

**Testimony to House Energy and Commerce Committee
Subcommittee on Commerce, Manufacturing & Trade
Chairman Mary Bono Mack (R-CA)
Ranking Member G.K. Butterfield (D-NC)**

“Florida’s Roadmap to End its Prescription Drug Abuse Epidemic”

**By
Pamela Jo Bondi
Florida Attorney General**

**Presented
Thursday March 1, 2012**

Introduction

Chairman Bono Mack, Ranking Member Butterfield, and Members of the Committee, thank you for inviting me to testify. Today, I would like to outline the number one public safety threat confronting Floridians – prescription drug abuse - and what Florida is doing to stop it. Prescription drug abuse is killing more than seven Floridians each day, and this death toll has been on a relentlessly upward trend for the past eight years.

Florida became the epicenter of prescription drug diversion because – until recently – my state had weak regulatory oversight of pain management practices, limited oversight of physician dispensing habits, and no statewide Prescription Drug Monitoring Program (PDMP). I therefore made shutting down “pill mills” and stopping prescription drug abuse my number one priority in my first year as Florida’s Attorney General.

The prescription drug epidemic is certainly not confined to Florida. Many other states have been getting good results fighting pharmaceutical drug diversion by pairing multi-agency and multi-jurisdictional law enforcement operations with the routine use of some form of a Prescription Drug Monitoring Program, while fostering cooperative engagement with the

pharmaceutical industry to jointly work in tandem with the public health community to change cultural norms regarding pharmaceutical drug use.

Florida has looked to other states' successes to help craft its own campaign. An immediate challenge in attacking this epidemic has been stopping the proliferation of so-called medical clinics operating under the guise of providing "pain management," but whose real activities fall outside the scope of legitimate medical practice. As a first step, Florida defined these "pill mills" as doctor's offices, clinics, or health care facilities that routinely conspire in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice or violates the laws regarding the prescribing of prescription drugs. Armed with this new working definition, Florida's law enforcement and regulatory agencies could better identify targets for investigation. The next step was to then bring all of the state's resources to bear on closing these pill mills.

Florida's Drug Enforcement Strike Forces

A critical step forward in organizing Florida's balanced attack on pill mills began in March 2011, when Governor Rick Scott and I created Florida's *Drug Enforcement Strike Forces*. Using Florida's seven current domestic security regions to organize this statewide effort, each of the seven Strike Forces is co-led by a Sheriff and a Police Chief from within each respective region.

Strike Force operations seek to reduce the supply of diverted prescription drugs through intelligence driven multi-jurisdictional operations against the whole spectrum of the pill mill phenomenon: corrupt wholesalers, unscrupulous "physicians", rogue pharmacies and the "doctor-shopping" "patients" supporting their addiction.

The seven regional Strike Forces also support demand reduction policies being implemented by local community coalitions. The end-state of these policies must be to shift people's perceptions and attitudes regarding the harm that comes from misusing prescription drugs, and foster a community climate capable of providing effective drug treatment to prescription drug addicts. Florida's prevention efforts focus on dispelling the deadly myth that misusing prescription drugs is somehow safer for the user than using "traditional" illegal street drugs, while greatly increasing overall public awareness of the negative health consequences of prescription drug diversion and abuse.

Thanks to outstanding cooperation between Florida's law enforcement and public health care communities, our state is now bringing to bear a comprehensive strategy for fighting prescription drug trafficking and abuse, particularly pill mill driven drug diversion. By drawing on the hard earned lessons from fighting previous drug epidemics, we note that only a balanced approach - attacking both the supply side, driven by a flood of diverted pharmaceuticals, and the demand side, driven by pharmaceutical drug abuse and addiction - will ultimately reduce what is still a growing prescription drug diversion epidemic in Florida because it is, at its roots, an intertwined public health and law enforcement problem.

In Florida, the Narcotics Overdose Prevention Education (NOPE) Task Forces do an amazing job of getting this prevention message out by going into our middle and high schools and educating young people about the perils of prescription drug misuse and prolonged abuse. In addition, my office is also working with local law enforcement, prevention coalitions and pharmacies to host drug "take back" events where citizens can safely dispose of dangerous, expired, unused, and unwanted prescription drugs. Last year more than five tons of prescription

drugs were collected at two “take back” events, and this is just one illustration of how various government and private entities can cooperate to lower the availability of diverted drugs.

Comprehensive Legislation

In the Spring of 2011 I worked closely with the Florida Legislature in creating a tough new law on prescription drug diversion that:

- Banned dispensing of Schedule II and Schedule III controlled substances by physicians and made a violation of the ban both a third degree felony and grounds for licensure discipline.
- Created a standard of care for all physicians prescribing controlled substances to treat chronic pain.
- Required physicians to either electronically prescribe controlled substances or use counterfeit-proof prescription pads.
- Added new criminal penalties.
- Improved reporting to the state’s PDMP from 15 to 7 days.
- Required wholesale distributors to credential customers and report on distribution of controlled substances.
- Required pharmacies dispensing Schedule IIs and IIIs to be re-permitted with the state
- Provided \$3 million to fund state Strike Force.

While any one of these legislative enhancements on their own would have helped fight prescription drug diversion and abuse, all of these statutory changes - working in tandem with Strike Force operations, stricter regulatory oversight and drug prevention messaging - is creating dramatic early results just now being tallied.

Measures of Success

I am pleased to report that as of February 2012, Regional Drug Enforcement Strike Forces efforts statewide have resulted in 2,040 arrests (including 34 doctors), and the seizure of 445,690 pharmaceutical pills, 56 vehicles, 390 weapons, and \$4,648,621. Additionally, 27 clinics have been closed as a direct result of strike force action.

At one point in 2011 we had over 900 pain management clinics registered within the state – but today there are less than 580, and that number continues to decline. Thanks to the Florida

Legislature's dispensing ban coupled with aggressive regulatory efforts to close pill mills, I can report to you today that there has been an absolutely dramatic decline in the number of Florida doctors dispensing the most oxycodone within a given year. In 2010, 98 of the top 100 dispensing physicians of oxycodone pills nationally resided in Florida but today, as of last count, I can report that only 13 of the top 100 now reside in Florida.

The result of Florida's leadership, teamwork, and structural reforms has been a rapid turn-around in my state's ability to turn-off the prescription drug diversion spigot that had stayed open for far too long and which contributed so much to the problems we are all now fighting. While such a dramatic turn-around in some key metrics is encouraging, much remains to be done however to lower the most important metric of all – the number of Floridians dying each and every day from prescription drug-related overdose.

Prescription Drug Abuse & Newborns

I also want to report to you about another sad and disturbing development from the prescription drug abuse epidemic in Florida. Over the past year, as I spoke out about "pill mills" and the lives that were being lost to prescription drug abuse, doctors and nurses began reaching out to me, to make me aware of another growing problem. Today, in hospitals across Florida, growing numbers of babies are being born addicted to prescription drugs, suffering terribly from withdrawal symptoms such as tremors, abdominal pain, incessant crying, and rapid breathing.

I personally visited the NICU at St. Joseph's Hospital in Tampa and saw firsthand the smallest victims of prescription drug abuse. At St. Joseph's, 15-20 percent of the babies born are addicted to prescription drugs and experience neonatal withdrawal syndrome. That's just one hospital in Florida. Since Florida leads the nation in prescription drug diversion, I think we will see similar numbers at hospitals across the state.

Part of the problem may be that expectant mothers understand the dangers of using cocaine or heroin –thanks to years of “traditional” drug prevention efforts - but do not yet understand the harm of using or abusing prescription drugs while pregnant.

Right now, I am working with the Florida Legislature to create a *Prescription Drug Abuse and Newborns* task force that will seek to determine the scope of this problem in Florida, the long-term effects and costs associated with caring for these babies, and what the prevention and intervention strategies should be for expectant mothers. The task force will then report its findings and policy recommendations to the Legislature.

Conclusion

Finally, I want to take a moment in closing to stress a very important point – though often overlooked - to our national and state drug control efforts, which is very salient for this Congressional Subcommittee.

The prescription drug abuse epidemic jeopardizes our workforce’s productivity. To rise to the challenges posed by a dynamic, intensely competitive 21st Century global market place, we must ensure a drug-free environment for all our citizens, starting with our youth. We must have a critical mass of educated, productive and healthy citizens because a healthy and drug-free Florida is the cornerstone to any effort to spur economic rejuvenation and free enterprise. Indeed, the very success of our society will be determined in large part by the productive nature and quality of the people that constitute our work force.

Thanks to the leadership of Florida’s law enforcement and public health care communities, the “Welcome” sign for pill mills to set-up and operate in Florida has been permanently turned off. My state is now bringing to bear a broad based anti-prescription drug

diversion and abuse strategy, focused on both the supply and demand sides of the equation to fight an epidemic of prescription drug trafficking and abuse.

Thank you Chairman Bono Mack and Ranking Member Butterfield for holding this hearing and focusing on solving this epidemic. I look forward to working with members of this Subcommittee to develop proactive, and effective ways to reduce prescription drug diversion and abuse that is negatively impacting so many of our communities.

Mrs. BONO MACK. Thank you very much.
And General Conway, you are recognized for 5 minutes.

STATEMENT OF JACK CONWAY

Mr. CONWAY. Well, thank you, Chairwoman Bono Mack and Representative Butterfield for your commitment to this issue. I also want to recognize Congressman Guthrie, who is not here, but who is a fellow Kentuckian who works with our drug task forces on this very important issue.

Prescription pill abuse is a reality that has touched the lives of just about every Kentucky family. It has touch my family's life in a very personal way. It has ravaged our communities, it has shattered families, and it has fueled crime.

Depending on which study you believe, Kentucky is either the most third- or fourth-most medicated State in the entire country, and the four you always hear at the top of the list are Kentucky, West Virginia, Tennessee, and Oklahoma. Last year in Kentucky we had over 1,000 people that we documented died from prescription painkiller overdoses. That is more than we lost to auto accidents.

And Madam Chairman, we actually think that is underreported, because our estimates are that only about half the people that actually die from overdoses autopsied by a medical examiner's offices. And when you take a look at the unnatural deaths in the Commonwealth of Kentucky, what you see over and over is not heroin or not cocaine, not even alcohol as much as you see Xanax, oxycodone, Methadone, and hydrocodone. Last year, Kentucky hospitals treated over 5,000 overdose patients.

Now, this is an epidemic we first started to see in the 1990s in eastern Kentucky. Eastern Kentucky is a region of heavy industry, of laborers, of coal mines. We have more injury-prone jobs, but it is also an area of economic depression, and we have too many doctors who overprescribed and too many people became hooked. And because of the economic depression, people figured out they could sell their pills on the street, and a black market was born. And today when you go through eastern Kentucky, which I do on a regular basis, you will find that about 80 percent of the crime according to law enforcement and prosecutors is fueled by the abuse and the insidious addiction to prescription painkillers.

The problem has spread across the Commonwealth. It is not just in eastern Kentucky. According to a "Lexington Herald" leader study not too long ago in 120 of our counties which we have total, 118 were up in the number of schedule two and three narcotics prescribed, and I am sad to report that estimates from law enforcement and those in the healthcare community say that we have only about 10 percent of the treatment beds that we actually need in the Commonwealth of Kentucky.

You know, I am sick and tired of hearing about losing an entire generation to prescription pill abuse in the Commonwealth of Kentucky, so we have started a public education program for doctors and also for school children in Kentucky. I actually travel across the Commonwealth with two mothers from Morehead, Kentucky, who lost their daughters to prescription pill abuse, and it is really important to get people like that who look like the mothers of these

kids to tell them their story, because they will listen to an elected official for 5 minutes or so, but when the mothers talk, they really listen.

And here is what is disheartening. You can look at these kids, middle schoolers, high schoolers, and say, OK, you know, tell the truth. Just because I am the attorney general, tell the truth. How many of you have used a prescription pill or your best friend has used it for an off-label purpose. I am sad to report 70 or 80 percent of the hands go up. I ask them how many think that prescription pills are easy to get. Seventy or 80 percent of the hands will stay up. Then I will ask them how many of their parents lock up their medicine cabinets. All the hands will go down. I realize it is not a problem that starts with Grandma, but in some instances, particularly in Kentucky, it is an addiction that is starting in our homes.

I have tried to do all I can. I have created the State's first prescription pill task force. That is my drug investigators working with local law enforcement. We are trying to collaborate and share resources in a time of dwindling law enforcement resources. We participated in Operation Flamingo Road, where we partnered with the DEA and the Kentucky State Police to round up 500 individuals who were vanning pills up from Florida in 2009.

At that point we thought about 60 percent of our pills in our streets were coming from Florida. Pam Bondi told me a story one time that they executed a search warrant on a pain management clinic in Broward County, Florida, and they seized 1,700 patient records. Of those 1,700 individuals they seized the records 1,100 of them are from the Commonwealth of Kentucky. That is what we in law enforcement call "a clue." We had people by the vanload going to Kentucky to bring pills back.

And that is why I am not only happy to a friendship with Pam or General Bondi I should say, I am grateful that she came along at this time. She has done a tremendous job of taking on these pill pushers in her State. As she said, Florida was home to 97 or 98 of the Nation's top 100 prescribers of oxycodone. Now they are down to 13.

This issue knows no party. It is an American tragedy. We are doing all we can. We have new legislation in the Commonwealth of Kentucky to reregulate our pill mills. We have entrepreneurs getting in the pill mill business. We need to stop them. We have the issue of the mail order forms cease shipping 90-day supplies of schedule two and three narcotics. I understand the issue of efficiency in our healthcare system, but that needs to be 30 days, and we need to make certain that we get doctors using these systems. Yes, we have KASPER, our PDMP. It is a good system, but only about 25 percent of our doctors are using it, and on top of that those of us in law enforcement can't see the data to do the investigations that we need to do, and I would be happy to talk with you a little bit more about that.

I have heard the questioning here today, and I am out of time, so I am going to wrap up, but if you want to know what you can do to help, help us get all 50 states up with PDMPs and with systems that talk to one another. We can do our jobs if we can get

those systems up and running and if we can get the doctors to use them.

Thank you very much for the opportunity to appear.

[The prepared statement of Mr. Conway follows:]

Kentucky Attorney General Jack Conway

Testimony for the Committee on Energy and Commerce/Subcommittee
on Commerce, Manufacturing, and Trade

March 1, 2012 - 10 a.m. EDT

"Prescription Drug Diversion: Combating the Scourge"

Attorney General Jack Conway will testify before the subcommittee regarding prescription drug abuse in the Commonwealth of Kentucky. He will outline the history of the abuse, how pervasive abuse is in the Commonwealth and his efforts to crackdown on prescription drug abuse.

Attorney General Conway will discuss his public education initiative, his prescription drug task force (the first of its kind in Kentucky) and his partnership with Florida Attorney General Pam Bondi.

Attorney General Conway will address the need for prescription drug monitoring programs in all 50 states and additional federal grants for states to ensure that all of the programs can share data. He will outline pending legislation in Kentucky that would help crackdown on rogue pain clinics.

Attorney General Conway's Testimony

Chairwoman Bono Mack and Rep. Butterfield, thank you for inviting me to testify before your subcommittee today. I would also like to thank Rep. Brett Guthrie from Kentucky who serves on this subcommittee. I appreciate his attention to this issue.

Prescription pill abuse is a reality that has touched the lives of almost every Kentucky family - including my own.

Prescription pill abuse has ravaged communities, shattered families and fueled crime.

A recent analysis by *Forbes Magazine* comparing the number of filled prescriptions for schedule II and III narcotics to the number of residents in the state, finds Kentucky is the fourth most-medicated state in the country. Our neighbors, West Virginia and Tennessee, are one and two respectively.

Last year in Kentucky, more people died from drug overdoses than car accidents. And we believe the number of overdoses is grossly underreported because only 55 percent of total statewide overdose deaths were autopsied. In those autopsies, the most common drugs found weren't heroin or cocaine; they were Xanax, Oxycodone and Methadone. Last year, Kentucky hospitals treated 5,000 overdose patients.

Law enforcement officers first started seeing the diversion of prescription painkillers in Eastern Kentucky. Residents in this part of our state generally work in the coal mines or with heavy machinery related to construction or mining. These are injury-prone jobs. Some people who were prescribed these pills by a doctor became hooked. Eastern Kentucky is also an economically depressed area. People who were hooked found they could sell their pills for cash on the streets - creating new addicts. Law enforcement officers now estimate that 80 percent of the crime committed in Eastern Kentucky stems from the abuse of prescription painkillers.

The problem has spread across the Commonwealth like wildfire.

I travel across Kentucky teaching kids about the dangers of prescription pill abuse because I refuse to lose another generation of Kentuckians to this insipid addiction. I am blessed to be joined in my efforts by two amazing mothers who lost their daughters, childhood friends, to prescription drug abuse. Dr. Karen Shay and Lyn Kissick are committed to trying to save other families from experiencing the pain of losing a child.

In every high school or middle school we visit, I ask the question, "How many of you think prescription drugs are easy to get?" About 70 to 80 percent of the hands go up. I then ask, "How many of you have ever taken prescription drugs for a purpose not listed on the bottle?" About 70 to 80 percent of the hands go up. I conclude by asking, "How many of your parents lock up their medicine cabinets?" All of the hands in the room go down. This is an addiction that is starting in our homes.

As Kentucky's Attorney General, I am on the front lines of this battle against prescription drug abuse. I created Kentucky's first statewide prescription drug task force. This isn't just a task force that sits around talking about the issue - our task force is made up of sworn law enforcement officers that coordinate our investigations with state, local and federal agencies. We participated in the largest drug bust in Kentucky history - Operation Flamingo Road - which resulted in more than 500 indictments. This was a coordinated law enforcement effort to help shutdown the pipeline of pills flowing into our state from Florida.

At one point, our officers believed 60 percent of the pills on the streets of Kentucky were coming from Florida. In fact, my

good friend, Florida Attorney General Pam Bondi, told me she raided a clinic in Broward County and seized 1,700 medical records - 1,100 were patients from Kentucky. That's what we in law enforcement call "a clue."

General Bondi and I have worked tirelessly in a bipartisan effort on this issue. She's done a tremendous job taking on these pill pushers dressed in white lab coats. She created a strike force that's cracked down on pill mills. Florida was home to 97 of the nation's top 100 prescribers of oxycodone. That number is now down to 13. I applaud her for working to ensure her state implemented electronic prescription drug monitoring.

This issue knows no party. We are both committed to fighting the scourge of prescription drug abuse and we agree that EVERY state must have prescription monitoring in place. Thirty seven states have prescription drug monitoring programs and another 11 have legislation authorizing their creation, but they are not yet online or fully operational.

I appreciate Mr. Kerlikowske's commitment to reducing prescription drug abuse across the country by 15 percent, but I know that in order to reach this goal, there must be an

investment by the federal government. I urge this committee and the National Office of Drug Control Policy to create a grant program that would bring all states online with electronic monitoring and upgrade software for existing states so that all of our systems can communicate with each other.

My state is not an island. Kentucky borders seven states. If people will drive or fly to Florida to get their hands on prescriptions, you can bet they are driving to Missouri, Tennessee, Indiana, Ohio, West Virginia, and Illinois.

Right now our state legislature is working to strengthen laws to help shut down rogue pain clinics. I worked with our Governor and House Speaker to craft legislation that would keep entrepreneurs out of the pill mill business by requiring that all pain management centers be owned by a licensed medical professional or hospital. The bill requires our Kentucky Board of Medical Licensure to stop granting licenses to doctors who've been charged for overprescribing in other states and to immediately yank doctors' licenses when they are indicted. It also would move the state's electronic prescription monitoring system into my office to afford law enforcement increased access to data.

Let me be clear, prescription drug abuse is killing our people. Three people will die today of prescription drug overdoses in Kentucky. One hundred people in this country will die today from prescription drug overdoses.

I promise you, we are fighting the good fight in Kentucky, but we can't do it alone. We need your help.

Madam Chair, I appreciate your attention to this issue and will be happy to answer any questions you many have now or in the future.

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Mrs. BONO MACK. Thank you very much, General Conway.
Mr. Haslam, you are recognized for 5 minutes.

STATEMENT OF AARON E. HASLAM

Mr. HASLAM. Thank you Chairman Bono Mack, Ranking Member Butterfield, and distinguished members of this committee. I thank you on behalf of Ohio attorney general Mike DeWine and all of Ohio for the opportunity to address you today.

As the Chief Assistant Prosecutor and later the elected Prosecutor in Adams County, Ohio, I had a front row seat for the devastation that this scourge can cause on a community. In February, 2011, Ohio attorney general Mike DeWine recruited me to lead his prescription drug task force. Attorney General DeWine has been committed to using every resource Ohio has to fight this scourge.

In Ohio we have taken nationwide—a nationwide stance in fighting back through changes in legislation, proactive law enforcement actions, partnering with prescribers and dispensers and being proactive with awareness, education, and treatment.

Through this effort Ohio has raised public awareness, increased public education, and improved Ohio's investigations and prosecutions in both criminal and regulatory cases.

However, to make a real difference we must limit the availability of prescription drugs to those individuals in actual need and in the proper quantities. In Ohio unintentional fatal and non-fatal drug poisoning has cost Ohioans \$3.6 billion annually. Between the years of 1999, and 2007, Ohio's rate of opioid distribution increased 325 percent. During that same time period Ohio's unintentional drug overdose death rate increased 305 percent. If you will look to my left, you can see this remarkable correlation on the graph located closest to the back of the room.

In 1997, Ohio averaged seven doses of opioids per capita. In 2010, our average dose of opioid per capita increased to 67. In less than 15 years Ohio watched that average dose of opioids per capita increase almost 900 percent.

The chart to my left, the closest to the front of the room, will illustrate that the death rates during the current prescription drug scourge is much higher in Ohio than the death rates in Ohio during the heroin epidemic in the '70s and the crack cocaine epidemic in the 1990s.

Ohio's leaders recognize the seriousness of Ohio's prescription drug problem. On February 8, 2011, Representatives Terry Johnson and Dave Burke, a physician and a pharmacist, introduced what is known as House Bill 93 in Ohio. The bill passed through the House and the Senate unanimously. With the support of the attorney general, Governor John Kasich signed the bill into effect on May 20, 2011, and it became law.

Much like Florida, our pain clinics, our pill mills were not regulated. House Bill 93 for the first time regulated pain clinics in Ohio. It required physician ownership of pain clinics. It required prescribers to review our PMDP—sorry, our Prescription Drug Monitoring Program, which is known as OARRS in Ohio, and they had to do that when they were treating chronic pain patients.

Attorney General DeWine has worked tirelessly to create a multidisciplinary approach to the investigation and prosecution of pre-

scription drug cases. Attorney General DeWine has worked with law enforcement at the local, State, and Federal levels in Ohio to investigate prescription drug cases. We are currently working with county prosecutors and Federal prosecutors all across Ohio to prosecute these cases. He is proud to be a part of the State-wide team in an effort to protect Ohio's families.

Our next step the attorney general believes is to build a bridge with State and Federal officials across the Nation. To have a true impact we must collaborate on a multi-State approach to combat this scourge. Ohio and the Nation must be proactive working with all the stakeholders to tackle this epidemic. When this happens you will see success.

For example, in Scioto County, one of Ohio's hardest hit counties, also a border county to Kentucky, the last pill mill was closed this past December. Scioto County has a population of approximately 78,000 residents. At one time it housed 12 pill mills prior to Ohio's efforts. Today it houses zero pill mills. Just last week Scioto County learned that accidental overdoses decreased 17 percent and drug-related deaths decreased 42 percent in 2011. This was the first decrease Scioto County had seen in the past decade in these numbers. It had been a steady increase prior to 2011.

I will end with a quote from Reverend Martin Luther King Jr., who said, "We may have all come on different ships, but we are in the same boat now." Each of us may have arrived at the prescription drug scourge on a different ship, but today we are all in the same boat, and more importantly, people will die if we continue to ignore the scourge.

Thank you.

[The prepared statement of Mr. Haslam follows:]



MIKE DEWINE
★ OHIO ATTORNEY GENERAL ★

**Statement for the Record of
Aaron E. Haslam
Senior Assistant Attorney General
Office of the Ohio Attorney General, Mike DeWine
Special Prosecutions Unit**

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

"Prescription Drug Diversion: Combating the Scourge"

Presented on
March 1, 2012

Chairwoman Bono-Mack, Vice Chair Blackburn, Ranking Member Butterfield and distinguished members of the Subcommittee, I thank you on behalf of Ohio Attorney General, Mike DeWine and all of Ohio for the opportunity to address you on the Prescription Drug problem plaguing Ohio and our great nation. As you are aware it is no understatement to say that the Prescription Drug Epidemic is the most serious law enforcement and public health problem facing our state and nation today.

As the Chief Assistant Prosecutor and later as the Elected Prosecutor in Adams County Ohio, I had a front row seat for the devastation that prescription drug diversion created in Southern Ohio. In one year I saw the number of felony criminal cases increase two hundred and seventy-five percent in Adams County directly related to prescription drug diversion and abuse. Adams County, Ohio has approximately twenty eight thousand residents and in one year we had more than twenty overdose deaths directly linked to prescription painkillers. I watched first-hand the community I grew up in devastated by this silent killer. As a community, we came together to fight this silent killer by bringing the community's stakeholders to the table. The community rallied around the cause and had truly had an impact. Unfortunately, Adams County was plagued by many other factors out of its control. We had prescription painkillers coming in from other counties and other states. We lacked resources for raising awareness, for educating our youth, parents and other community members, and for treatment. We had an impact locally but we knew to make a real difference others had to join the cause. At first we were naïve that this was an isolated problem to our community and later learned that it was a state-wide and nation-wide epidemic.

In February 2011, Ohio Attorney General Mike DeWine recruited me to lead his Prescription Drug Task Force because of my experiences and successes in Adams County. I knew the problem was much greater than just Adams County and the only way to truly help Adams County out was to help Ohio. Now as an Assistant Attorney General, I have had the opportunity to have a front row seat and help lead the charge in Ohio to combat prescription drug diversion and abuse. Attorney General DeWine had made this issue one of his top priorities.

Attorney General DeWine is committed to using every resource his office has to fight this epidemic. Some of those resources include: The Ohio Bureau of Criminal Investigation (BCI); The Ohio Organized Crime Commission (OOCIC); the Special Prosecutions Unit; The Medicare/ Medicaid Fraud Section; and the Health and Human Services Section of the Ohio Attorney General's Office. Because this problem cannot be solved by one person or one office we are working with law enforcement entities around Ohio to attack this problem. Those entities include members of The Buckeye State Sheriffs Association, The Ohio Association of Chiefs of Police, The Ohio Prosecuting Attorneys Association, The Ohio State Highway Patrol, The Ohio State Pharmacy Board, The Ohio State Medical Board, The DEA, the FBI, and the US Attorney's Offices for the Northern and Southern Districts of Ohio.

While Ohio has been hit hard by Prescription Drug Diversion, Ohio has also taken a nationwide stance in fighting back through changes in legislation, proactive law enforcement actions, partnering with prescribers and dispensers and being proactive with awareness, education, and treatment. Because this problem is bigger than law enforcement, Attorney General DeWine has been on the front lines of this battle with

other state leaders like Governor John Kasich, Senators Rob Portman and Sherrod Brown, and federal leaders like our US Attorneys for the Northern and Southern District, Steve Dettelbach and Carter Stewart, to fight this epidemic. Ohio's leaders recognize that the severity of this epidemic and understand that no one person can solve it. Attorney General DeWine, Governor Kasich and the rest have broken down traditional barriers that have led to an unprecedented effort in Ohio surrounding the prescription drug epidemic. In a short time, Ohio has raised public awareness, increased public education, amplified both criminal and regulatory investigations and prosecutions, and made great strides in making Ohio's treatment more prevalent.

The single biggest action that can be done is to restrict the availability of prescription drugs to only those who need them and only in the amount needed. In addition, no one agency or one organization has all the answers or all the expertise to fight this problem. Therefore, a holistic approach has been spearheaded in Ohio that is cooperative, collaborative and breaks down traditional barriers.

The Problem

While we all know the problem, I think that it is useful to remember, that in the State of Ohio the cost of unintentional fatal and nonfatal drug poisonings cost Ohioans at least \$3.6 billion.¹ Ohio's overdose death rate tripled from 1999-2006. In the same time frame, the U.S. death rate (only) doubled.² Ohio's death rate increased 350% from 1999 to 2008 because of unintentional Rx overdoses.³ Prescription opioids were

¹ Ohio Department of Health, citing Ohio Hospital Association. "Hospital discharge data, 2002-2007."

² Ohio Department of Alcohol and Drug Addiction Services, citing Ohio Department of Health, "Burden of Poisoning in Ohio, 1999-2008"

³ Ohio Department of Alcohol and Drug Addiction Services, citing Ohio Department of Health, "Burden of Poisoning in Ohio, 1999-2008"

involved in at least 4 out of 10 (39 percent) fatal drug overdoses in Ohio in 2009, which is more than heroin and cocaine combined (36 percent).⁴ From 1999 to 2007, Ohio's rate of opioid distribution increased 325 percent and during that same time period the unintentional drug overdose death rate increased 305 percent, which is a remarkable correlation. (Figure 1).

In 2010, there was an average of 67 doses of opioids dispensed for every Ohio resident. When you consider that in 1997, Ohio's per capita dosage averaged 7 doses of opioids, that is an almost 900% increase.⁵ Use in southern Ohio has been even higher. For example, in Scioto County, this ratio was nearly twice as much as the State average, with 123 doses for every Scioto County resident.⁶ Jackson County, Ohio which neighbors Scioto but has received far less media attention is the highest at 130 doses.⁷ It should also be kept in mind that the death rates as a result of prescription drug abuse are much higher than the death rates during the heroin epidemic in the mid-1970s and during the peak years of the crack cocaine epidemic in the early 1990s (Figure 2). Many hospitals throughout Ohio are reporting that more than twenty percent of babies being born have prescription painkillers in their systems. There are no exact studies or statistics that I am aware of to confirm the numbers of babies being born with these drugs in their system as many hospitals are just beginning to collect such data in Ohio and around the country. Southern Ohio Medical Center (SOMC) reported to Attorney General DeWine more than twenty percent of its babies born in November and December 2011 had prescription pain killers in his or her system. These results were

⁴ *Ohio Department of Health Office of Vital Statistics*

⁵ *OARRS, Ohio Board of Pharmacy*

⁶ *OARRS, Ohio Board of Pharmacy*

⁷ *Id.*

part of an SOMC study where every baby born in the hospital will have his or her cord drug test after birth. In 2007, more than 1 out of 4 teenagers reported using a prescription drug without a prescription one or more times during his or her lifetime.⁸

Sources of prescription Drugs

In order to combat diversion it should be understood that Prescription drugs in Ohio, and nationwide, are diverted primarily through the following means:⁹

- “Bad” prescribers/dispensers “pill mills”

“Pill Mills” and bad prescribers are the most offensive and dangerous of these trends. These are drug traffickers and drug trafficking organizations (DTO), and they should be treated no differently than DTO’s who push methamphetamines, heroin and other traditional street drugs. Although a minority of prescribers make up this population the amount of damage they do is unbelievable. The profits they make are equally unbelievable. For example, a low volume relatively cheap pill mill that sees “only” 30 patients a day at \$200 per visit, every 30 days, will gross over 2 million dollars a year.

- Forged/Altered Prescriptions

With the rise of prescription monitoring programs (PMP) this method of diversion is becoming more difficult, but remains an issue. This crime is accomplished in many low tech ways, including pure theft of prescription pads, color photo copying of a prescription, or simply adding a zero or a 1 to increase the amount of pills in an otherwise legitimate prescription.

⁸ Ohio Dept. of Health, 2007 Ohio Youth Risk Behavior Survey

⁹ Ohio Attorney General’s Office, Rx Abuse: The Scope of the Problem

- Doctor Shopping (seeing multiple doctors to obtain multiple prescriptions)

This likewise is becoming more difficult due to PMP's, however it is still a concern in trans-border areas where PMP information is not shared across state lines. An important subset of Doctor Shopping is the "prescription drug tourist". Prescription drug tourists are individuals and DTO's that take and transport individuals from one state to another state where they will obtain prescription drugs from rouge prescribers. The tourist then returns to their State of origin and turns over all or a large portion of the prescription drugs to a third party for re-sell on the streets. These tourists have their expenses paid or "sponsored" by the organizer and receive either a kickback or a portion of pills to feed their addiction. Several of the advantages for DTO's of prescription tourists are that: these people have prescriptions and thus can transport large amounts of prescription drugs back into their state of origin with low risk; these prescription tourists are unknown to local law enforcement in the source state and thus are difficult to identify for investigation and prosecutorial purposes; these groups by design help to defeat Prescription Monitoring Programs (PMP), this is because of the lack of sharing among PMP when these groups bounce from state to state or even have the prescription filled in a third state, the PMP's effectiveness is minimalized or even canceled.

- Theft from home/family sharing

This is the biggest source of prescription drug diversion. The simplest and most effective solution is to reduce the number of prescription drugs in a home by

implementing drug take back days along with education of prescriber's and the public. A great suggestion on how to reduce the number of unneeded prescription drugs going into a home was given to me by Dr. Jack Amato, MD, an OB/GYN and a supervising member of the Ohio Medical Board. Dr. Amato suggested that instead of a doctor writing a 30-day supply of prescription drugs for post-surgery (so that a patient only has one co-pay), introduce legislation that requires the physician to break down a 30-day supply into smaller- as needed amounts. That way, only one co-pay is required but it would reduce the number of situations most have experienced where only a 2-3 day supply is actually used and the remainder of the prescription is left in the medicine cabinet.

- Robbery/Burglary of Pharmacies/Cargo Thefts

From 2003-2011, Ohio was third in the nation in pharmacy related robberies.¹⁰ The robbery and burglary of pharmacies is of great concern because of the inherent violent nature of these acts. The theft of cargo shipments of prescription drugs is also of great concern and we are starting to come to the understanding that many of these thefts go unreported.

- Internet Pharmacies

While recent federal legislation has helped to regulate internet pharmacies it should always be remembered that in 2006, 34 "rouge" internet pharmacies dispensed 98 million doses of hydrocodone. That is the same amount it would

¹⁰ RxPatrol, <http://rxpatrol.org>

take 1,118 legitimate average pharmacies to fill.¹¹ Recently scheduled Carisoprodol (Soma) was also frequently sought by drug seekers who would obtain a prescription from an out-of-state internet doctor working in conjunction with an internet pharmacy. It would be used by addicts as part of a “cocktail” that no legitimate doctor would prescribe to them.

Legislative response

Recognizing the seriousness of Ohio’s prescription drug diversion problems, House Bill 93 was introduced into the Ohio House on February, 8 2011. House Bill 93 was introduced by Rep. Dr. Terry Johnson, who is the former coroner of Scioto County and then Representative now Senator David Burke, a Pharmacist from Union County. House Bill 93 was passed by both the House and Senate unanimously. House Bill 93 was signed into law by the Governor on May 20, 2011 with an emergency clause and became effective immediately.

The main things that House Bill 93 did to help combat prescription drug diversion included the following:

- Defines what a pain management clinic is and what it is not.¹²
- Requires physician ownership of pain management clinics.¹³
- Prohibits employment in a pain management clinic of any person who is a convicted drug felon or has been convicted of felony theft.¹⁴

¹¹ ONDCP; Ohio Attorney General’s Office, Rx Abuse: The Scope of the Problem

¹² R.C. 4731.054

¹³ R.C. 4729.552

-Requires the Medical Board to establish administrative rules for pain management clinics operations.¹⁵

-Requires the Pharmacy Board to review clinic operations while mandating that all pain management clinics be licensed as category III terminal distributors of dangerous drugs.¹⁶

-Places limits on the amount of controlled substances that may be “personally furnished” by the prescriber to the patient.¹⁷ This step is critical, because many times local pharmacists refused to fill the prescriptions from pill mills and rouge prescribers, but these bad actors exploited a loophole in Ohio law, and one that exists in many states, that allowed them to personally furnish drugs to their clients. This loophole prevented the checks and balances of having a pharmacist review a prescription and allowed for additional profit sources to these rouge prescribers. For example, one pill mill that I am prosecuting had significant price mark ups on most drugs, versus the local drug stores which refused to fill that “clinics” prescription. This led to an additional profit over a four month period of over \$400,000 in that case.

-Requires two state wide drug take back days per year to be administered by the Ohio Attorney General’s Office, the Ohio Alcohol and Drug Addiction Services

¹⁴ R.C. 4729.552

¹⁵ R.C. 4731.054

¹⁶ R.C. 4729.552

¹⁷ R.C. 4729.29, 4729.291

(ODADAS) and the Pharmacy Board.¹⁸ This is critical because it helps to reduce the supply of unwanted and unneeded prescription drugs in our medicine cabinets. Nationally, among persons aged 12 or older in 2009-2010 who used pain relievers non-medically, a full 55% received their drugs for free from a friend or relative and another 17% stole drugs from a friend or relative.¹⁹ The first drug take back day under house Bill 93 was held in October 2011 in conjunction with the DEA and local law enforcement and netted 18,672 pounds of unwanted and unneeded pharmaceuticals.

-Requires that a doctor review a patients profile in Ohio's prescription Drug Monitoring Program²⁰ (OARRS) before deciding upon a course of treatment.

-Allows the Medical Board to issue a summary suspension of a medical license when there is clear and convincing evidence that a violation of medical board rules and regulations has occurred and the continued practice of that person presents an immediate and serious harm to the public.²¹

House Bill 93 was the first shot fired in attacking Ohio's "pill mills." The most significant role it played was eliminating the criminal element from "pill mills." Prior to House Bill 93's passage, pain management clinics in Ohio were unlicensed and unregulated. The physicians working in these clinics were regulated by the Ohio State

¹⁸ R.C. 109.90; 3793.22 and 4729.69

¹⁹ Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings

²⁰ 4729.79

²¹ R.C. 4731/054(D) and 4731.22(G)

Medical Board but the clinics were unregulated. As you know, we regulate in this country to avoid greed and corruption. Because pain management clinics were not required to be licensed and were not under any regulation requirements, many clinics throughout Ohio were owned and/or operated by convicted felons. House Bill 93 eliminated the criminal element from involvement with these facilities. House Bill 93 gave Ohio's regulatory boards the tools necessary to police these pain management facilities and those owning and operating them. House Bill 93 has had such an impact on Ohio's "pill mills" that other states are modeling legislation after House Bill 93.

Law Enforcement Response

While prior to 2011 Ohio's law enforcement response to prescription drug diversion was unsystematic and often haphazard, it was driven by great individual officers and great prosecutors that cared and were committed to the issue. It should be noted that in a number of jurisdictions individual officers and prosecutors took the initiative and educated themselves on how to investigate and prosecute prescription drug diversion. Law enforcement often worked together informally to trade insight and tips.

As I have stated and this cannot be over emphasized, the only way that law enforcement can attack this problem is via a collaborative effort. Attorney General DeWine has worked tirelessly to create a multi-disciplinary approach to the investigation and prosecution of these "pill mill" cases. Attorney General DeWine has also made it a top priority to provide law enforcement with the necessary resources and training for investigating and prosecuting drug diversion cases across Ohio. Law enforcement across Ohio including local, state, and federal agencies have come together

to fight this epidemic affecting Ohio's citizens. The result has been an unprecedented collaboration among Ohio's law enforcement and prosecutors to attack this epidemic.

Attorney General DeWine's Bureau of Criminal Investigation through its narcotics unit is working with law enforcement across the state at the local, state, and federal levels to investigate drug diversion and abuse. Attorney General DeWine's special prosecutions prescription drug unit works with local law enforcement, county prosecutors and federal prosecutors across the state to prosecute drug diversion and abuse cases. In addition to working with local law enforcement, there has been great collaboration between not only local law enforcement throughout the state but also with the Bureau of Criminal Investigation, Ohio State Highway Patrol, Ohio's Organized Crime Commission, The Board of Pharmacy, The Ohio Medical Board, DEA, FBI and the IRS. The special prosecutions team is working with local prosecutors as well as the US Attorney's Office to make sure these cases are prosecuted to the fullest extent. Attorney General DeWine has been a driving force in breaking down traditional barriers in law enforcement that prevented collaboration to this extent in the past. He is proud to be a part of this statewide team in an effort to protect Ohio's families.

Attorney General DeWine believes the next step, which he has already begun, is building a bridge with state officials across the nation to collaborate on a multi-state approach to apprehending these criminals. In 2011, Attorney General's DeWine and his Bureau of Criminal Investigation, local law enforcement, and federal law enforcement united in a coordinated effort to go after and disrupt "pill mills" in Ohio and where appropriate assist in the prosecution of these cases. Because of the number of prescription painkillers coming into Ohio from other states, Attorney General DeWine

knew more needed to be done. In order to help coordinate and facilitate the interdisciplinary model used in Ohio, Attorney General DeWine held an Interstate Prescription Drug Abuse Summit at his annual Law Enforcement Conference in October, 2011 with representatives from Ohio, Florida Georgia, Indiana, Kentucky, Michigan, Pennsylvania and West Virginia. At that conference local law enforcement, state law enforcement officials and federal government officials shared best practices in an effort to help break down traditional law enforcement silos that have too often prevented successful prosecutions in Ohio and nationwide. Since that time, the group has held quarterly phone conferences to discuss best practices, work on interstate cases, and discuss public awareness, education, and treatment issues.

Law Enforcement Success

Some examples of the success that has come from these coordinated efforts resulted in 2011 when Bureau of Criminal Investigation (BCI), working to support local law enforcement, increased seizures of prescription drugs via covert operations by over 400% from 2010. Another example of this success comes from the Crime Lab at the BCI which accepts submissions from all Ohio law enforcement agencies. In 2011, this lab generated 14,324 forensic drug cases of which 50% involved prescription drugs.

The Ohio State Highway Patrol has increased their criminal interdiction efforts as well. Ohio is a main nexus for prescription drug tourists and smugglers because of the large number of East-West and North-South highway routes that transverse the State. We are also working with our law enforcement colleagues in other states to choke the distribution points for prescription drug trafficking across state lines.

The Ohio State Medical Board with assistance from Attorney General DeWine as part of this multi-disciplinary approach has permanently taken the licenses of doctors – 14 in all so far - who illegally dispensed prescription pills. In 2011, more than 30 doctors were disciplined in one form or another by the Medical Board for prescribing and dispensing habits.

On the criminal prosecution side, because these matters are time consuming and often highly complex, Attorneys General DeWine hired three prosecutors to work in his special prosecutions unit to assist local law enforcement and prosecutors with pill mills and prescription related Drug Trafficking Organizations (DTO).

One recent success story occurred this past fall when Attorney General DeWine and his special prosecutions unit teamed up with Clark County Prosecutor Andy Wilson, Clark County Sheriff Gene Kelly and Montgomery County Sheriff Phil Plummer and the RANGE task force²². This collaboration was an example of Ohio's multi-disciplinary approach, which included not only local law enforcement mentioned above but also the Ohio State Medical and Pharmacy Boards, the Ohio Bureau of Worker's Compensation, Attorney General DeWine's Medicaid Fraud Section, and others. This collaborative effort led to a doctor from the Dayton/Springfield area being convicted of multiple counts of Drug trafficking, Medicare fraud and Engaging in a Pattern of Corrupt Activity

²² RANGE (Regional Agencies Narcotics & Gun Enforcement Task Force) is made up of law enforcement from Montgomery County Sheriff's Office, ATF, BCI, Clayton Police Department, Germantown Police, Five River Metro Parks, Miami Township Police, New Lebanon Police, Perry Township Police, Riverside Police

(state version of RICO). That doctor was sent to prison where he can think about the people he poisoned in multiple counties over multiple years. ²³

In a similar type effort, our Federal partners at the US Attorney's Office for the Southern District of Ohio led by US Attorney Carter Stewart recently convicted a prominent pill mill physician who practiced in Portsmouth, Ohio. That doctor received four life sentences in Federal District Court for the lives he took as part of his criminal drug trafficking²⁴.

In addition to assisting in the investigation and prosecution of bad prescribers we have teamed with local, state, and federal law enforcement and local, state, and federal local prosecutors to assist in the investigation and prosecution of "prescriptions tourists". An example is a recent case prosecuted by the special prosecutions unit with the local prosecutor of a "prescriptions tourists" DTO operating out of Jackson County, Ohio. That ring on one out-of-state- trip alone (which took less around 72hrs) obtained prescription drugs with a local street value of approximately \$50,000. They were caught in an undercover sting operation by several law enforcement agencies pulling together, manpower, money, intelligence and resources. One member of the ring, at trial, tried to use the traditional "drug tourists" defense, which is "my pills were prescribed by a Doctor and I am not responsible for the fact that the people who paid for my trip are trafficking drugs". The jury was out for less than 30 minutes and that defendant sits in prison today. ²⁵

²³ State v. Yang 2012CR0016, Clark County Common Pleas Court

²⁴ USA v. Volkman Case No. 1:07-CR-060-03, S.D. Ohio

²⁵ State v. Harris 201CR061; State v. Arryo 2011CR0060; State v. Sherrian 2011CR0059; State v. Sherrian 2011CR00146.

In 2011, Attorney General DeWine through his Ohio Peace Officer's Training Academy helped train more than 650 law enforcement officers throughout the State of Ohio on the scope of prescription drug diversion and is considering adding more types of instruction on the issue in the future.

However as we squeeze the neck of the beast that is prescription drugs we are starting to see a rise in the number of prescription addicts who are switching to heroin because it is much cheaper and in some areas of Ohio much easier to obtain on the streets. No rational law enforcement discussion can be had about prescription drug diversion without acknowledging the role that heroin plays, in this epidemic. The re-rise of heroin is the next step in this issue.

Public Private Partnerships

In addition to legislation, regulation and the law enforcement efforts we have increased community involvement by partnering with local groups, businesses and religious organizations to increase awareness and educate Ohio citizens about the dangers of prescription drug diversion and abuse.

Because we recognized the need to spread the awareness on a local grass roots level, in November of 2011, Attorney General DeWine began sponsoring a pilot project modeled on a drug abuse awareness video entitled REACT (I am Responsible, I am Educated, I am Aware, I am Clean, I am True to Myself). That video included interviews with four recovering addicts and three mothers whose lives have been forever altered. Rather than a one size fits all approach, all videos will be locally sponsored with local participants to emphasize the individual needs and character of a community. The umbrella program is called, "Speak Up...U R Better than Drugs". The first video that

will be complete was created in partnership with the group, Tyler's Light, out of Pickerington Ohio. Tyler's Light was created by Wayne and Christy Campbell. Tyler Campbell passed away from a heroin overdose which was started by an addiction to prescription pain killers from a football injury.

To increase the public awareness of the dangers of prescription drug diversion the Ohio Attorney General's Office has partnered with the Ohio State Medical Association, Ohio Hospitals Association, Ohio Retail Merchants, Ohio Grocers Association and the Ohio Children's Hospital Association to distribute a statewide poster initiative informing the public regarding the Bureau of Criminal Investigation's anonymous tip line.

Attorney General DeWine has convened an Advisory Council on Prescription Drug Abuse comprised of stakeholders from all areas of Ohio including many different professions that meets quarterly. This group includes local law enforcement, judges, prosecutors, members of the prevention and treatment community, physicians, pharmacists, nurses, educators, and members of the business community along with many others. The purpose was to better understand and gain a perspective from all of Ohio of how this prescription drug epidemic is affecting all of Ohio. In addition we vet ideas through this group and they propose ideas for us to develop and implement.

We worked with Senator Rob Portman to establish a HIDTA task force in two counties in Southern Ohio including my home county of Adams and neighboring Scioto County. HIDTA, as you are probably familiar with is, stands for High Intensity Drug Trafficking Area. HIDTA will assist local law enforcement with much needed resources in combating the drug trafficking that is occurring in that part of Ohio.

Attorney General DeWine has worked closely with Governor Kasich on the prescription drug epidemic. Governor Kasich has been instrumental through many of his agencies in helping to curb this epidemic. We have had the opportunity to partner many of the Governor's agencies on awareness campaigns, education and prevention, and treatment. These agencies include The Ohio Department of Alcohol and Drug Addiction Services (ODADAS), The Ohio Department of Health (ODH), The Office of Medicaid, and The Ohio Bureau of Worker's Compensation (BWC).

The Ohio Department of Alcohol and Drug Addiction Services is working to establish fifteen new support and family engagement models throughout Ohio modeled after a group titled SOLACE (Surviving Our Loss and Continuing Everyday.) The original group was created in Portsmouth, Ohio by local citizens that had lost loved ones to the prescription drug epidemic. ODADAS plans to open a new treatment facility in Southern Ohio where treatment is largely unavailable because of a lack of resources and the treatment available has long waiting lists. ODADAS has assisted in funding and creating 24 new Opiate Task Force community coalitions focusing on prevention, treatment, and assisting law enforcement efforts throughout Ohio. ODH has funded ten new community based Prescription Drug Task Forces throughout Ohio. They will continue to promote their prevention campaign called "Prescription for Prevention" throughout Ohio. Office of Medicaid will establish its lock-in rule to help prevent pharmacy shopping and comply with House Bill 93. BWC will establish its lock-in rule to prevent pharmacy shopping and comply with House Bill 93. Both entities will accomplish this by Spring 2012.

Conclusion

In summation, we can win this battle. The prescription drug scourge can be successfully curbed. The answer is a holistic approach that Ohio and the nation must take to be successful in combating this scourge. Law Enforcement alone cannot successfully fight this problem from a reactive position. Ohio and the nation must be proactive working with all the stakeholders to tackle this epidemic. The only answer is a multi-disciplinary approach not only within law enforcement but within all agencies and across all agencies. All the stakeholders must come together at the local, state and federal levels to fight this epidemic.

When this happens you will see success. For example, in Scioto County (one of Ohio's hardest hit Counties) the last pill mill was shut in December 2011. Scioto County, population of approximately 78,000, housed twelve pill mills prior to Ohio's efforts and now it has no pill mills. After a decade of increasing deaths, Scioto County learned last week of its first decrease in accidental overdoses and drug-related deaths in over a decade. It had a 17% decrease in accidental overdose and a 42% decrease in drug-related deaths from 2010 to 2011.²⁶ I will end with a quote from the famous Martin Luther King, Jr., "We may have all come on different ships, but we're in the same boat now." Each of us may have arrived at the prescription drug epidemic on a different ship, but today we are all in the same boat and our countrymen are dying.

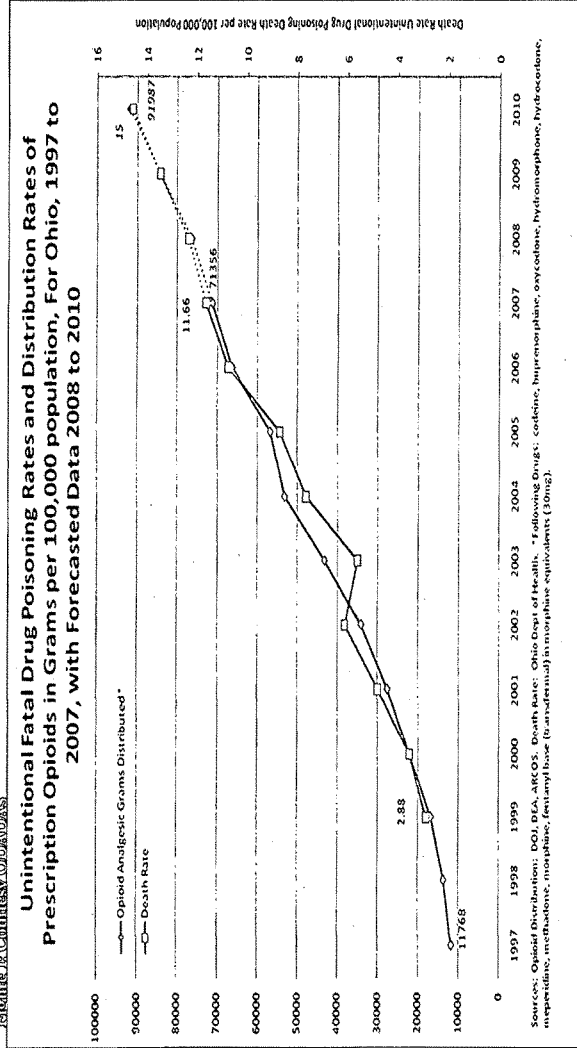
I thank you for your time.

²⁶ Portsmouth City Health Department

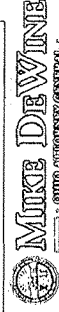
Prescription Drug Diversion: Combating the Scourge

FIGURE 14 CHRISTOPHER ODADAS

Unintentional Fatal Drug Poisoning Rates and Distribution Rates of Prescription Opioids in Grams per 100,000 population, For Ohio, 1997 to 2007, with Forecasted Data 2008 to 2010



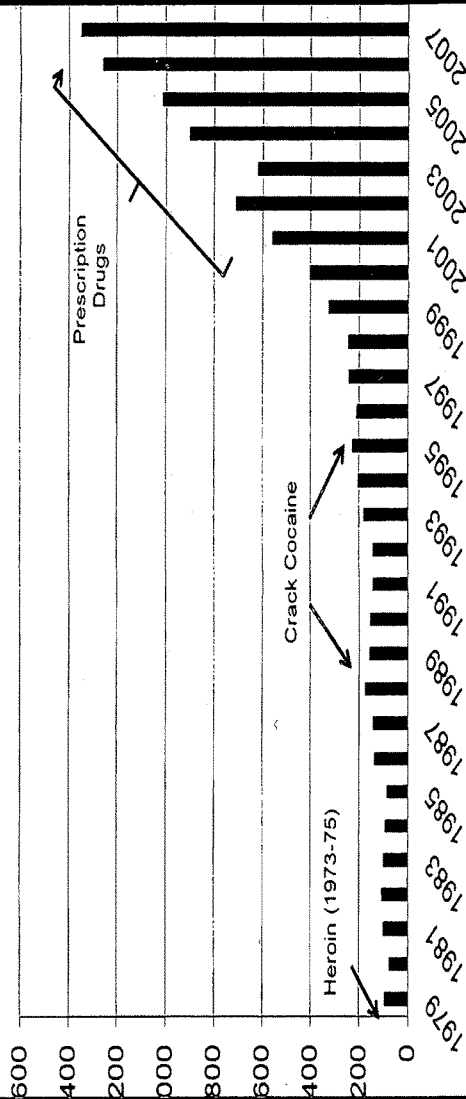
Sources: Opioid Distribution: DOJ, DEA, NCSOS. Death Rate: Ohio Dept. of Health. *Following Drugs: codeine, buprenorphine, oxycodone, hydromorphone, hydrocodone, meperidine, morphine, tramadol, fentanyl base (as anhydrous) in morphine equivalents (10mg).



Prescription Drug Diversion: Combating the Scourge

Figure 2. Courtesy ODADAS

Epidemics of unintentional drug overdoses in Ohio, 1979-2008^{1,2,3}



Source: WONDER (NCHS Compressed Mortality File, 1979-1998 & 1999-2005) ²2006-2008 ODH Office of Vital Statistics, ³change from ICD-9 to ICD-10 coding in 1999 (caution in comparing before and after 1998 and 1999)



Mrs. BONO MACK. Thank you very much.
Mr. Rannazzisi, you are recognized for 5 minutes.

STATEMENT OF JOSEPH T. RANNAZZISI

Mr. RANNAZZISI. Thank you. Chairman Bono Mack, Ranking Member Butterfield, distinguished members, on behalf of Administrator Michele Leonhart and the men and women of the Drug Enforcement Administration, I would like to thank you for the opportunity to appear today to discuss prescription drug diversion and the critical role the DEA plays in securing the integrity of the controlled substance supply chain and delivery system.

Before I get going I would just like to thank the chairman and this committee for their leadership on this problem, and I also want to thank you for promoting the National Take Back Program. If I may throw in a plug, we will do it again April 28, Saturday, State, Federal, local agencies with community groups working together to collect those drugs, and I want to thank you again for that.

Also, I would like to thank the leadership of Director Kerlikowske, who has gone out of his way to ensure that we get the—all of the resources that we need to do our job.

The abuse of pharmaceuticals continues to be a significant problem in the United States, and it is based on pharmaceutical diversion from the supply chain and the medication delivery system, and we believe that is the major reason. There is just holes in the system. Over the last few years individuals and organizations have created schemes within the healthcare delivery system that appear legitimate but are nothing more than illegal operations to facilitate the illegal distribution of pharmaceuticals. Pharmaceutical diversion facilitated by these operations can be prevented if DEA registrants would just fulfill their obligations under the Controlled Substances Act.

The act was designed so that each DEA registrant is a link in the closed system of distribution. Each registrant, manufacturers, wholesalers, distributors, practitioners, and pharmacies have a critical role to play in keeping the distribution chain closed.

Two major schemes have emerged to divert millions of dosigents, powerful addictive drugs. The first one a few years back was the internet pharmacy scheme. You could go online, and you could purchase pretty much any schedule three, four, or five controlled substance you would like. hydrocodone was the drug of choice, and it came out of the distribution chain, and really no one fulfilled their obligations to the chain. You had distributors that weren't doing due diligence on pharmacies that were ordering huge amounts of hydrocodone. The pharmacists weren't checking those prescriptions to ensure they were valid, that is they were issued for legitimate medical purposes in the usual course of professional practice, and the doctors weren't doing the same thing. They were just prescribing without a legitimate reason for prescribing. There was no medical determination made. It was a major breach in the system.

But because of law enforcement's focus on that problem and then Congress coming in and passing the Ryan Haight Act, we basically shut down that system. Unfortunately, that system moved back to Florida and turned into pain clinics, and pain clinics grew.

Now, these pain clinics, besides the fact that they are operating illegally, they were doing the same thing that the internet pharmacies did. The only difference is on the internet pharmacies there was no face-to-face visit. In pain clinics they actually see patients, but, again, the doctors are moving huge amounts of prescriptions out the door. Pharmacists are not checking the validity of those prescriptions. They are not ensuring they are valid prescriptions, and the wholesalers and distributors just continue to ship large amounts of drugs to those pharmacies without doing due diligence, without knowing their customer, without saying, well, why are you ordering? Why are you ordering this amount of drug when every other average pharmacy in the U.S. only orders this, and you are ten, 12, 14 times more than that? They have a responsibility under the act. They choose not to comply with that obligation.

We are fighting this problem through education and regulatory control and enforcement. Since 2005, we have a distributor initiative that has educated distributors of their obligations under the act. When distributors fail to adhere to their obligations, DEA takes administrative or civil action against their registration. From mid 2010, through the end of 2011, we took action against five wholesaler distributors for unlawfully supplying Florida-based pain clinics or associated pharmacies with controlled substances. These actions included the issuance of immediate suspension orders and result in the restriction and loss of DEA registrations.

We also focus our resources on practitioners that issue those prescriptions not for legitimate medical purpose. These practitioners feed the addiction of drug seekers and allow drugs to enter the illicit market and facilitate overdose and death. Rogue practitioner activity is not limited to Florida. In fact, rogue pain clinics are moving northward, and they operate in Georgia, Tennessee, Kentucky, and southern Ohio now in addition to out west. A DEA investigation with State and local and Federal agencies of a pain clinic doctor operating in Portsmouth, Ohio, culminated this February with the doctor being sentenced to four life terms for overdose deaths of four individuals.

I have to wrap it up here, but we are making progress. DEA is using its regulatory authority to ensure compliance with the CSA and its implementing regulations. These measures that we are taking are beginning to show promise. We are strengthening the integrity of the system through registrant compliance.

In closing I want to assure you that DEA is working closely with all of our counterparts; Federal, State, and local, and our regulatory counterparts as part of the Administrator's comprehensive approach to combating prescription drug abuse. We are committed to balancing the need for diversion control enforcement with the need for access to these important medications by legitimate users.

Thank you for this opportunity to appear, and I look forward to answering any questions.

[The prepared statement of Mr. Rannazzisi follows:]



Department of Justice

STATEMENT FOR THE RECORD OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

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

ENTITLED

"PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE"

PRESENTED ON

MARCH 1, 2012

**Statement for the Record of
Joseph T. Rannazzisi
Deputy Assistant Administrator
Drug Enforcement Administration
United States Department of Justice**

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

**“Prescription Drug Diversion: Combating the Scourge”
March 1, 2012**

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 Drug Enforcement Administration’s efforts in combating prescription drug abuse.

Overview

Every day prescription drugs are abused in the United States at an alarming rate. Leading indicators show substantially high levels in the abuse and misuse (non-medical use) of these drugs and the adverse 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 Association of Poison Control Centers’ National Poison Data System, CDC’s National Vital Statistics System, and the National Forensic Laboratory Information System (NFLIS).

- According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2010 National Survey on Drug Use and Health (NSDUH), 7 million Americans were current (past month) non-medical users of psychotherapeutic drugs, significantly higher (by 12 percent) compared to 6.2 million in 2008. Over three-quarters of that number, 5.1 million Americans, reported non-medical use of 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 6,600 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 4030 in 1999 to 14,800 in 2008, more than tripling in 8 years.¹
- SAMHSA's Treatment Episode Data Set shows that between 1999 and 2009 the number of admissions to substance abuse treatment that reported any pain reliever abuse increased more than sixfold.
- According to DAWN data, the number of emergency department visits involving the misuse or abuse of pharmaceuticals increased by 98.4 percent between 2004 and 2009. The prescription drugs most implicated were opiate/opioid pain relievers, oxycodone products increased 242 percent, and hydrocodone products increased 124 percent.
- The approximate number of cases submitted by state and local law enforcement to forensic labs between 2001 and 2010 increased significantly (331 percent for oxycodone, 253 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 The number of new initiates for narcotic pain relievers 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 2011 Monitoring the Future (MTF) study reported use rates for two narcotic drugs, OxyContin (oxycodone) and Vicodin (hydrocodone and acetaminophen). According to the MTF

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

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

³ Ibid, p. 49.

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.

study annual prevalence for OxyContin in 2011 was 1.8%, 3.9% and 4.9% in grades 8, 10, and 12 respectively and annual prevalence for Vicodin was 2.1%, 5.9% and 8.1% in grades 8, 10, and 12.⁷ The MTF study stated, “One group of drugs that is not down much from peak levels is *narcotics other than heroin*; their continued high rate of use is a disturbing finding.”⁸ On average, every day 2,046, 12-17 year olds abuse a prescription pain reliever for the first time.⁹

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).¹⁰

The Growing Pain Pill Epidemic in Florida

Over the past several years, the DEA has seen two major schemes used to divert powerful and addictive controlled substance pharmaceuticals. Circa 2005-2009, hydrocodone combination products (e.g. Vicodin), which are schedule III controlled substances, were illegally diverted through unscrupulous prescribers as well as rogue internet pharmacies. Florida was the epicenter for many of the illegal operations whereby tens of millions of dosage units of hydrocodone were diverted into the illicit marketplace across the United States.

Congress addressed the problem of rogue internet pharmacies with the passage of the Ryan Haight Online Pharmacy Consumer Protection Act that took effect in April 2009. This action, combined with intensified law enforcement actions, virtually eliminated domestic-based rogue internet pharmacies.

As the number of domestic-based rogue, internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics, particularly in Florida. Instead of hydrocodone, the practitioners in these clinics dispensed millions of dosage units of oxycodone, a schedule II controlled substance that is more potent than hydrocodone. Again, Florida was and remains the epicenter for these illegal pain clinic operations. DEA, State and local law enforcement investigations reveal that thousands of drug seekers flock to these Florida-based rogue pain clinics to obtain a supply of oxycodone, which is in turn illegally redistributed in states along the entire East Coast and the Midwest.

The State of Florida has attempted to address this problem through a patchwork of legislation. Current state legislation restricts a physician’s ability to dispense oxycodone from a pain clinic. These rogue operations adapted by issuing illegitimate prescriptions for oxycodone rather than dispensing directly to the “patient,” and DEA and other law enforcement agencies saw an increase in the volume of oxycodone dispensed from various pharmacies across the state. DEA also saw a sharp increase in the number of new pharmacy applications in the State of

⁷ 2011 Monitoring the Future Study: *Overview of Key Findings 2011*, p. 33. University of Michigan, Ann Arbor.

⁸ *Ibid.*, p. 11.

⁹ Substance Abuse and Mental Health Services Administration, 2010 National Survey on Drug Use and Health.

¹⁰ *Clinical Journal of Pain*, Hansen, RN; Oster, G; Edelberg, J; Woody, GE; and Sullivan, SD. “Economic costs of nonmedical use of prescription opioids. *Clinical Journal of Pain*, 2011 Mar-Apr; 27(3):194-202.

Florida. Further investigation of pharmacy applicants revealed “straw purchases” of pharmacies that showed ties to established rogue pain clinics. The purchase of pharmacies is part of the scheme by rogue pain clinic owners to circumvent Florida laws: if a pain clinic cannot lawfully dispense drugs directly to a “patient,” then the pain clinic will issue illegitimate prescriptions to “patients,” and the pain clinic pharmacy will dispense drugs based on those illegitimate prescriptions. DEA has instituted a program to investigate Florida-based pharmacy applicants prior to issuing a DEA registration, a regulatory step normally reserved for the State Board of Pharmacy.

DEA registered pharmacies are generally supplied by DEA registered wholesale distributors. Rogue pain clinics, pharmacies that fill illegitimate prescriptions for pain clinic “patients”, and the wholesale distributors who supply these pharmacies have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted. Consequently, the registrants involved-- practitioners, pharmacies, and wholesale distributors that do not comply with the Controlled Substances Act (CSA) and its implementing regulations-- are allowing millions of dosage units of controlled substances to pour into the illicit market, posing an imminent danger to the public health and safety. The damage to society from these drugs flooding into the illicit market is evident by the number of deaths associated with pharmaceutical abuse.

According to the Florida Medical Examiner’s Office, they have seen a 345.9% increase in the number of overdose deaths associated with oxycodone between 2005 and 2010. For 2010, their data showed that approximately 4,091 persons died in Florida alone from an overdose caused by just one of five drugs or drug classes: methadone, oxycodone, hydrocodone, all benzodiazepines, or morphine. This is an average of 11.2 persons dying in the State of Florida every day. Since many of the drug seekers who frequent the rogue Florida pain clinics return to their state of residency, there are surely more deaths and injuries caused from the drugs that are diverted from these clinics than just those reported by the Florida Medical Examiner’s Office.

The Closed-System of Distribution and the Regulatory Scheme

The Food and Drug Administration, through the Federal Food, Drug and Cosmetic Act, generally regulates pharmaceutical drugs. However, due to their potential for abuse and danger to public health and safety, Congress recognized the need for greater scrutiny over controlled substances. As such, they established a separate and distinct framework under the CSA and implementing regulations that creates a closed-system of distribution for all controlled substances and listed chemicals. See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) (“[I]t cannot be overemphasized that the ...[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.”). Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA. Congress acted to halt “the widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” H.R. Rep. No. 91-1444, 1979 U.S.C.C.A.N. at 4572.

This closed-system is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted. For example, registrants must adhere to

many security, recordkeeping and reporting requirements. Also, a practitioner can only dispense/prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. 21 CFR § 1306.04. In order to obtain and maintain a distributor registration, a distributor must be able to “maintain ... effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels...” 21 USC § 823(b)(1). With respect to the wholesale distributors who supply pharmacies with controlled substances, “*The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.*” 21 CFR § 1301.74. When all registrants are complicit in diversion schemes, similar to the pain clinic scheme in Florida, these necessary checks and balances collapse.

The Drug Enforcement Administration & the Diversion Control Program

Restructuring

The increase in the abuse of prescription drugs is fueled by many factors, including the development and marketing of new pharmaceutical controlled substances, and ever-changing methods of diversion such as rogue Internet pharmacy schemes or rogue pain clinics. Just as illicit drug traffickers and organizations adapt to law enforcement methods, pharmaceutical traffickers adapt to and circumvent laws that attempt to stop the flow of controlled substance pharmaceuticals into the illicit market. 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 1.4 million DEA registrants.

Expansion of Tactical Diversion Squads

Tactical Diversion Squads (TDS) investigate suspected violations of the CSA 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). Tactical Diversion Squads develop sources of information and disseminate intelligence to appropriate elements for the development of leads and subjects of investigations. As of February 17, 2012, 46 operational TDS groups are located throughout the United States; however, several are not yet fully staffed. DEA plans to add

several more TDS groups over the next few years. With the expansion of TDS groups across the U.S., the number of diversion-related criminal and administrative cases has increased. These TDS groups 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.

The restructuring of the Diversion Control Program has allowed investigative efforts to focus on specific problem areas. For example, DEA, working with its State and local partners, has put forth a substantial investigative effort towards rogue clinics which has been dubbed *Operation Pill Nation I*. 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, DEA as part of *Operation Pill Nation I*, conducted a coordinated effort with more than 500 state and local law enforcement officers in a massive takedown. 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.

Enhanced Regulatory Oversight

DEA is also using its regulatory authority to ensure that DEA registrants maintain effective controls against diversion by complying with all aspects of the CSA and its implementing regulations. One way DEA attempts to accomplish this is through our Distributor Initiative Program. This program was implemented in late 2005 and was designed to educate wholesale distributors who were supplying diversion schemes such as rogue Internet pharmacies and more recently rogue pain clinics and rogue pharmacies. The goal of the program is to cut off the source of supply to these or other schemes through effective due diligence and suspicious order reporting. As stated above, wholesale distributors are required to design and operate a system that would detect suspicious orders to the registrant and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA provides registrants with information such as "red flags", trending information, and data analysis that they should be aware of prior to distributing controlled substances. These warning signs include, but are not limited to, type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, location of the customer, and the percent of controlled versus non-controlled substances ordered.

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 action. These investigations resulted in record-breaking civil fines (McKesson Drug

Corporation paid \$13.25 million in April 2008 and Cardinal Health paid \$34 million in October 2008).

DEA has and will continue to vigorously pursue criminal, administrative and civil actions against registrants who fail to comply with all aspect of the CSA and its implementing regulations as required. More recent examples include, but are not limited to, actions against wholesale distributors such as Harvard Drugs, Keysource, and Sunrise

Due to the recent rise in the number of new pharmacy applications in the State of Florida, DEA is also using its regulatory oversight authority to conduct in-depth investigations of pharmacy applicants in order to determine whether to issue a DEA registration to handle controlled substances. These efforts have thwarted a significant number of attempts by individuals associated with rogue pain clinics to open a new pharmacy and thereby circumvent newly established laws within the state.

Scheduling Actions

The abuse of prescription drugs is not isolated to just one drug. Abusers and addicts routinely abuse prescription drugs in combination with one another to enhance the effects. This activity significantly increases the risk of potential harm to the individual. This combination is often referred to as the “trinity” or “holy trinity”, and is typically hydrocodone or oxycodone used in combination with alprazolam and carisoprodol.

To address this problem, DEA published a Final Rule in the Federal Register on December 12, 2011, scheduling carisoprodol as a schedule IV controlled substance, effective January 11, 2012.¹¹

DEA has also been working with the Food and Drug Administration to determine whether hydrocodone-combination products should be moved from schedule III to schedule II of the Controlled Substances Act.

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 treatment. 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

¹¹ See: Federal Register Notice 76 FR 77330, December 12, 2011.

most teens get prescription drugs from their own family's medicine cabinets.¹² The Administration recognizes the issue of prescription drug abuse as described in the 2011 Prescription Drug Abuse Prevention Plan. One of the items set forth in the Plan is to increase prescription return/take-back and disposal programs.¹³

On September 25, 2010, DEA coordinated the first-ever National Take-Back Initiative. Working with more than 3,000 state and local law enforcement partners, take-back sites were established at more than 4,000 locations across the United States. Since then DEA, in conjunction with its state, local and tribal law enforcement partners, along with numerous other governmental and private groups,¹⁴ have conducted two other Take-Back Days. This massive undertaking has resulted in the collection of more than 498 tons of unwanted or expired medications.

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. As part of this effort, DEA conducted a public meeting on January 19 and 20, 2011, to receive information regarding 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 coordinating another National Take-Back Initiative on April 28, 2012.

Conclusion

Prescription drug abuse is a serious problem. Reducing prescription drug abuse is vital to the health and welfare of the American people and is a priority for this Administration. 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

¹² Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATS) Teens 2010 Report.

¹³ 2011 Prescription Drug Abuse Prevention Plan: *Epidemic: Responding to America's Prescription Drug Crisis*, pp. 7 & 8.

¹⁴ Other governmental and private groups include: the Office of National Drug Control Policy, the Department of Justice, Indian Health Services, Bureau of Indian Affairs, Substance Abuse and Mental Health Administration, Department of Education, Environmental Protection Agency, National Institute of Drug Abuse, Department of Transportation, Health Resources and Services Administration, National Association of Attorneys General, National District Attorneys Association, National Association of Chiefs of Police, National Sheriff's Association, National Association of Drug Court Professionals, Fraternal Order of Police, National Organization of Black Law Enforcement Executives, Partnership at Drugfree.org, Federation of State Medical Boards, National Association of Boards of Pharmacy, American Association of Poison Control Centers, Community Anti-drug Coalitions of America, D.A.R.E. America, Senior Corps, Veterans and Military Families, Home Instead Senior Care, Law Enforcement Explorer's Association, Save Our Society from Drugs, School Nurses Association, and the National Family Partnership.

distribution. Despite the many hurdles outlined herein we are making progress. DEA is identifying and investigating threats of diversion at all levels of the distribution chain. DEA's enhanced criminal and regulatory oversight is forcing all levels of the pharmaceutical industry to comply with the CSA. When necessary, DEA takes action to revoke the registration of the affected registrant. Manufacturers are now sending letters to their wholesale distributor customers warning them of their due diligence obligations and that their lack of customer monitoring will result in a discontinuation of business. States have also stepped up their focus on preventing the diversion of pharmaceuticals. Forty-eight states have now enacted legislation to implement a Prescription Drug Monitoring Program within their state which will ultimately identify and limit medications dispensed to drug seekers and doctor shoppers. Federal, State and local officials, law enforcement, professional organizations and community groups continue to work together to fight this epidemic. Progress is being made, but we have a long way to go.

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. Thank you very much.

I am going to recognize myself for 5 minutes of questioning, and I would like to begin with General, Attorney General Bondi, and I know you care passionately and you and I have spoken about the opiate babies, and it is my belief that when people dabble with heroin or cocaine, they understand they are dabbling with a potential addiction. They don't necessarily think that when they start playing around with pharmaceuticals.

Can you speak to why you are so focused on the opiate babies? I mean, you really are passionate about it. I would love for you to— you ran out of time, so please talk about it for a little bit if you could.

Ms. BONDI. Absolutely. You know, right after we passed our legislation last session I started getting calls from neonatal intensive care nurses, neonatologists, and said there is another problem, and you have got to come see this. I went to Saint Joseph's Hospital in Tampa. Twenty percent of the babies going through the neonatal intensive care unit are born addicted to prescription drugs.

Now, imagine the worst addict you can see on TV going through those withdrawals, that is how these babies are born into this world. Their incubators have to be covered with blankets. They are sensitive to light, to sound, to touch. Instead of milk, they are getting morphine or methadone. That is how these kids are coming into this world.

All Children's Hospital in St. Petersburg, that is a premiere hospital for children, 30 percent of the babies going through the neonatal intensive care unit born addicted to prescription drugs, and it has to stop. Take it from a cost perspective. I take it from a life, babies' lives, but if you look at it from a cost perspective, Saint Joe's had to expand their NICU just to accommodate these babies. So it is costing taxpayers a fortune, and I think a lot of it really has to do with education, and that is why we have legislation proposed this session. I have talked to adoption lawyers, I have talked to nurses, we brought in the Board of Health, we brought in the Board of Medicine. It is all about working together to educate these women, because unfortunately, I think some of these women will say I have stopped drinking alcohol, I have stopped smoking marijuana, but because it is the word prescription drugs, they don't realize the harm that it is doing to their unborn child.

What scared me to death, Chairman Bono Mack, was when I asked a doctor, I said, we can't let this become the next crack baby epidemic, and he said, we have already surpassed it.

Mrs. BONO MACK. Thank you. I just wanted to say we don't even know the long-term consequences for these opiate babies, and I just want to turn with my limited time to Mr.—and hopefully we will have a second round of questioning, but Mr. Rannazzisi, you and I have had multiple discussions, and we are not always on the same page, but I applaud some of your efforts recently.

You and I have talked about quotas. If Florida is having success at shutting down their pill mills, wouldn't the quotas show a correlating reduction in the quotas that you do allow the manufacturing of these drugs? Are you seeing that?

Mr. RANNAZZISI. Actually, we are seeing a decrease somewhat in Florida, but we are seeing the expansion of these pill mills

throughout the country. If you go to Tennessee, Kentucky, southern Ohio, and most of those in southern Ohio were shut down, but we still continue to see those flow out, and I just right now, even though Florida is on the going downhill, states north of Florida are starting on the rise. This problem is just, again, just moving north and west.

Mrs. BONO MACK. Well, I am just glad you hear you admit that and to say that. That is encouraging to me, but can you speak briefly about the Cardinal Case? Now that the district court has dissolved the temporary restraining order, what are the next steps in the Cardinal Case, and apparently Cardinal plans to appeal. If the district court's order is upheld, what is the next step?

Mr. RANNAZZISI. Because that case is in active litigation, I am not allowed to answer questions, however, I can tell you we have had cases similar to Cardinal in the case in the last 2 or 3 years. They are exercising their appeal rights, and we respect that. We will continue on with this program. Looking at our distributors, making sure that they meet their obligations under the act, and if they don't meet their obligations under the act, we will take the same action that we have taken.

Mrs. BONO MACK. I am just encouraged because long ago you and I argued that it was all coming out of Grandma's medicine chest. Correct?

Mr. RANNAZZISI. Yes, ma'am, and not that I don't still believe it is coming out of the medicine chest, but I believe that we are handling it upstream now to prevent it from getting down to that level.

Mrs. BONO MACK. Thank you for that.

Mr. Haslam, you talk about shipments, whole cargo containers that go missing but they are unreported. Do you want to speak to that?

Mr. HASLAM. Anecdotally, law enforcement throughout Ohio has told us that they, that cargo shipments are falling off the trucks. We have heard—

Mrs. BONO MACK. Just magically.

Mr. HASLAM. Just magically. We have heard—

Mrs. BONO MACK. Yes.

Mr. HASLAM [continuing]. Through conversations with manufacturers about their security measures, and they do seem to be very good security measures as Director Kerlikowske alluded to earlier.

However, there seems to be a point as it gets further down the chain that the security measures either weaken or are not as efficient, and once it gets to the distributors and then they send it to their distributors who send it out, there appear to be security measures that aren't in place that allow shipments to fall off of trucks.

Mrs. BONO MACK. Thank you very much. My time is up, and I would like to recognize Mr. Butterfield for 5 minutes.

Mr. BUTTERFIELD. Thank you. Let me go to the gentleman from the DEA. How do you pronounce your name? Is it Rannazzisi?

Mr. RANNAZZISI. Rannazzisi. Yes.

Mr. BUTTERFIELD. Yes. All right. Thank you. Let me talk with you about the security procedures followed by the prescription drug manufacturers, specifically how the drug moves from raw materials to usable medicine, then to distributors, and then down to the

wholesalers. Are you comfortable, sir, with the security mechanisms employed by these companies?

Mr. RANNAZZISI. The physical securities for the most, the physical security systems for the most part I am. We do onsite inspections every 3 years or so for manufacturers, importers, exporters, any other raw material holders, and if there is problems in physical security, we handle it onsite. We make suggestions, and generally it is corrected.

Mr. BUTTERFIELD. All right. What kind of relationship does the DEA have with the prescription drug industry? Specifically, what programs does DEA employ to educate DEA manufacturers and distributors? How closely, if at all, does DEA audit or approve security measures employed by the manufacturers and distributors, and is there a difference in procedure for authorized distributors versus secondary distributors?

Mr. RANNAZZISI. Well, first of all, we are on site for these distribution and manufacturing facilities every 3 years. In addition, for instance, the wholesalers and the distributors, we have a program called the Distributor Initiative where we sit down, not as a group, but individually with each company, and we go over their distributions, and we talk to them about what to look for when they are sending their drugs downstream. We offer them assistance to help them identify what diversion is and where it is, and that is done individually by company.

The manufacturers, we have an open door as far as the manufacturers go. I don't think we have ever had a problem with the manufacturers where we haven't rectified that problem.

So we are regulators. We have a relationship between regulators and the industry, and we oversee them and make sure that they are operating under the act, in compliance with the act.

Mr. BUTTERFIELD. All right. Technology advances have enabled new abuse deterrent drugs to take the place of conventional pills. I am encouraged by the addition of abuse-deterrent drugs into the marketplace, and while it is not a silver or magic bullet in completely stopping prescription drug abuse, it seems to be a tool that can greatly help.

Some medications have been reformulated to be extremely difficult to crush and dissolve. These are what we call abuse deterrent drugs and new additions to the prescription drug marketplace and have not yet been widely adopted. But things are moving in the right direction.

Question. How do you think abuse-deterrent formulations will have an impact on reducing opiate abuse, and how do we ensure that those who are addicted do not just switch to a new drug such as Fentanyl or heroin?

Mr. RANNAZZISI. I think that the abuse, well, first of all, we are very supportive of these assistance formulations. We think that is the future that will curb drug abuse.

However, we also know that abuse-resistance formulations tend to stop drug abusers from ingesting the drug in certain manners, for instance, injection or snorting the drug. When they need to, they take it orally, and abuse-resistant medication generally does not affect how you take it orally.

What we are seeing in the field is they are taking the drug orally with an agent that will give it a synergistic property to enhance the, for instance, for a drug like oxycodone, they will take it with an Alprazolam product or Carisoprodol, which is a muscle relaxant to enhance the product, the effects of the product.

Mr. BUTTERFIELD. Thank you. I yield back.

Mrs. BONO MACK. Thank you, Mr. Butterfield.

Mr. Harper, you are recognized for 5 minutes.

Mr. HARPER. Thank you, Madam Chair, and if I could, Mr. Rannazzisi, if you I could ask you a few questions.

First, what regulation does DEA have that specifically outlined the legal requirements that pharmacies, distributors, and manufacturers are required to take to avoid drug diversion?

Mr. RANNAZZISI. Well, for starters, pharmacists are held pretty much to the same standard that doctors are under 1306.04, 1306.04 says a prescription is not valid unless it is issued for legitimate medical purpose and use, of course, a professional practice. It also goes on to say that a corresponding responsibility exists with the pharmacist to ensure that the prescription is valid.

Mr. HARPER. OK.

Mr. RANNAZZISI. The manufacturers under 1301.71 and 1301.74 have to maintain a system that stops diversion or the diversion of controlled substances into other than a legitimate marketplace. And it also goes on to say that you also have to maintain a system of suspicious ordering monitoring, and they leave it up to the manufacturers and distributors to determine how to set up that system of suspicious ordering and monitoring.

Mr. HARPER. You know, I know the DEA has the ability to see unusual ordering patterns. Are there certain thresholds or levels that you pass on to the distributors to look for? Are you giving them guidelines to—that you pass off?

Mr. RANNAZZISI. No. I think what distributors have to do is look at their customers. They know their customers. I don't know all of their customers. They do. If they went onsite and looked at their customers, they could make a determination of what thresholds should be maintained for those individual registrant customers.

The problem is is I don't believe that the distributors and the wholesalers are actually looking at their customers as closely as they should. If you have customers that on the average purchase, I don't know, 70,000 oxycodone tablets a year and you have customers purchasing well in excess of a million a year, I think that would trigger something where you should go onsite and find out why that is the issue.

Mr. HARPER. Does the DEA have those volume parameters that it uses but are not shared with manufacturers or distributors?

Mr. RANNAZZISI. No. We—no, we don't share, we don't give them volume parameters. That is up to them. It is their system that they are setting up.

Mr. HARPER. All right. Well, what guidance has DEA provided to the manufacturers, distributors, pharmacies, or whatever on the specific steps that they should be taking to identify fraudulent prescriptions? What advice are you giving them to look for or suggestions?

Mr. RANNAZZISI. Well, there are certain red flags.

Mr. HARPER. OK.

Mr. RANNAZZISI. For instance, a pharmacy. If you have, if you are sitting in we will say Portsmouth, Ohio, and all of your customers are coming from, I don't know, 80 or 100 miles away, and the doctor you are filling for is 100 miles the opposite way, and it is all cash transactions, and you are seeing this over and over again, you know, I am not the smartest guy, but red flags pop up in my mind when that happens.

Mr. HARPER. Yes.

Mr. RANNAZZISI. And I think those are typical red flags, and Attorney General Bondi I am sure, or any one of these distinguished gentlemen could tell they are seeing the same thing that I am seeing. So over and over again we see these red flags. The pharmacists should see them, too.

Mr. HARPER. Would you favor under the Controlled Substance Act to create a stricter requirement, legal requirement for the most problematic drugs?

Mr. RANNAZZISI. I think the requirements that are in place right now for these drugs are fine if the individuals within the supply chain and healthcare delivery system would follow them. The problem is that the doctors continue, not all doctors, 99 percent of the doctors are perfect. It is that small percentage of doctors that just don't want to fulfill their obligation. What they do is prescribe for illegitimate purposes, or they don't make a medical determination. They just go with patient-directed prescribing, which is just wrong. I think that if everybody within that supply chain would just police each other, we wouldn't have the problem that we have right now.

Mr. HARPER. I thank each of the witnesses for being here today and for your insight, and with that I yield back.

Mrs. BONO MACK. Thank you, Mr. Harper.

Mr. McKinley, you are recognized for 5 minutes.

Mr. MCKINLEY. Thank you again.

Let us go back to Florida or maybe Kentucky, but let us start with Florida. When you have your program, your PDMP, do you have an identification system? Is that how—is that included in it?

Ms. BONDI. We, as I am sure you are aware, we had some very difficult problems getting our PDMP in place, our Prescription Drug Monitoring Program. It was, you know, 48 states have a PDMP but many weren't up and running, and ours was one of them.

We received some resistance. What we have done now is that it is up and running. We had some issues with getting it funded. Do you know who came forward?

Mr. MCKINLEY. Wait a minute. Do you have an identification so when someone comes in, is this—do they enter their name or something into—

Ms. BONDI. Yes.

Mr. MCKINLEY [continuing]. A file?

Ms. BONDI. Yes, and it used—

Mr. MCKINLEY. It is available for everyone in the State of Florida?

Ms. BONDI. Absolutely, and it used to be 15-day reporting, and now we have limited that down to 7-day reporting.

Mr. MCKINLEY. OK. So—

Ms. BONDI. So we have shortened the reporting period.

Mr. MCKINLEY [continuing]. If it works in your State, why wouldn't that work nationally?

Ms. BONDI. Well, and this is, like I said, brand new in our State because it had never been funded. So now it is funded by forfeiture funds from our sheriff for the next few years.

Mr. MCKINLEY. What about Kentucky? What are you doing in Kentucky? Do you have the database or names?

Mr. CONWAY. We have the database, and what happens in Kentucky, we were one of the first states to bring a PDMP online, Congressman, but our doctors will go in and enter a patient name to see if that particular patient is doctor shopping. The problem we have in Kentucky is, it is a pretty good system, but only about 25 percent of our doctors are using it. It is not mandatory. It is not mandatory that ER docs, for example—

Mr. MCKINLEY. OK. Thank you.

What concerns me some is you have done a great job in Florida. You just chased them to another State. That is what I am hearing from the other testimony here, and what we are hearing from around the country is that you did a great job. It happens in law enforcement when you start performing your duties, they go someplace else because they are not going to change their behavior. They just transfer to another State.

I am looking to see how we can capture them nationally.

Ms. BONDI. And we still have a long way to go in Florida, but I think what we are doing is we are working together, and as long as I can tell you the two of us are still alive, we are going to put this, we are going to put these guys out of business. I mean, we work together constantly, we share ideas, we share thoughts, and we frankly in Florida we work great with the DEA. We—you have to work as a team, and I don't know if you were here earlier for that part of it, but you have to bring State, local, and Federal authorities and now wrap all of our states into this, because this is a national crisis, and I mean, we are in a war with drugs, and just the drug has changed.

Mr. CONWAY. If I may address that point, Congressman, not to take up too much of your time, but Kentucky borders seven states, and the pharmacists when they fill a script, enter the data that goes into the system that doctors later check.

The problem for us has been that the docs feel like it is too time consuming. The docs don't want to be forced to do this, and they don't have a system that they think is user friendly that they can type in, takes 30 seconds or less, and tells you if you are in eastern Kentucky whether or not this patient has been to West Virginia, Ohio, or Virginia or Tennessee.

And that is what we don't have, and really a State like Kentucky can't get to where we need to be. We can't get 50 states with a good system that is interoperable unless we have the help of the Federal Government.

Mr. MCKINLEY. And Ohio, do you have the names up on—do you have with your program, do you have the names, the individual, so they know, we know what prescription drug they are acquiring?

Mr. HASLAM. We do, Congressman, and our program has been up and running for many years as well just as Kentucky's has.

Mr. MCKINLEY. Do you see a problem with that going nationally?

Mr. HASLAM. I don't. I think it is one of the necessary tools that we are going to need to fight this epidemic.

Mr. MCKINLEY. How do you deal with the privacy matter, because that seems to be the hang up, the confidentiality of people to access. What—how did you get around that for the State of Ohio?

Mr. HASLAM. Well, it is very protected by—our Ohio State Pharmacy Board houses that program, and they are very protective over the information and who it goes to and how it is distributed, and that is how they get around it. They make sure that it is protected, but it is, it is a necessary tool in this battle as we move forward.

Mr. MCKINLEY. So you are saying some states, in your three states, you all have that. You are doing something along that line.

Mr. CONWAY. The information is protected. Only the doctor is going to see it, and if we have a designated case open on a specific target, we can ask to see the KASPER data, but one of the problems we have seen is that the Board of Medical Licensure when they see disturbing trends are not forwarding onto law enforcement. We have that problem in Kentucky.

Mr. HASLAM. That is the same issue in Ohio, Congressman. It is a great tool. It is under-utilized by our physicians. House Bill 93 required physicians that are treating pain management to utilize it, but as, exactly as you have alluded to, as we have success in law enforcement, we are squeezing the balloon and people are just moving to other states.

And what has happened, the three states represented here today have all worked wonderfully together to tackle this issue and to share that information and investigations.

Mr. MCKINLEY. I know the time. I think you are great models. I just want to see it replicated in all 50 states so we can protect this thing. We can't have you operating in the middle. So thank you. I yield back my time.

Mrs. BONO MACK. Thank you, and Dr. Cassidy, you are recognized for 5 minutes.

Mr. CASSIDY. Thank you, Madam Chair. First I will say that we are introducing Mike Ross and I from the other side of the aisle, H.R. 4095, which is the Stop Online Pharmacy Safety Act, which attempts to close down or at least prevent the publicizing of these rogue pharmacies. So hopefully we will get some cosponsors on this.

Secondly, Mr. Rannazzisi, man, I keep on thinking with the databases you all have, if we gave them to Google, I have no doubt that Google knows what color dress my daughter has on today. And so it seems like data mining could really go a long way to pinpointing these problems for a specific intervention. I am told by industry that you all have lots of data forwarded to you regularly.

My question is why not?

Mr. RANNAZZISI. I think the data they are referring to is our ARCOS System.

Mr. CASSIDY. Yes.

Mr. RANNAZZISI. Yes. Under 827(D) they are required to send all narcotic control substance transactions to us to be put in a data-

base, and we do have that information, and quite frankly, we use that information to assist us in investigations.

However, that information is proprietary. It is protected information. I can't release that information to industry, and they have asked—

Mr. CASSIDY. But you could release it to local law enforcement.

Mr. RANNAZZISI. If local law enforcement is involved in investigation and they request the information, yes, we can.

Mr. CASSIDY. Let me ask because as I go through the testimony you have rank ordered states in which there is the highest prescriptions per capita of controlled substances, you have related it to over 65 how many people on Medicare Part D are getting X amount per, in a certain region. I also see other statistics where you speak about three or four physicians moving from one State to another, so you have physician level, and I am sure you also have a pharmacy level. It just seems, again, if Google had that or some other data miner had that, we could have a specific intervention here. Boom. And then there and then there. I seems like there is missed opportunities. What am I missing on this?

Mr. RANNAZZISI. I don't believe there is missed opportunities. The data that we have is very narrow. It is for the narcotic controlled substances. For instance, I am dealing with a pharmacy or a group of pharmacies and manufacturers or distributors that are selling Fentermine or Alprazolam or drugs like that. I have no way of tracking because it is not entered into the system.

Mr. CASSIDY. But if we just took those which are narcotics, I mean, probably there is going to be a correlation between somebody getting an illegal prescription for Ativan as well as an illegal prescription for OxyContin. So I am not saying you have to do the breath, but, again, if you have reported to you the narcotics for OxyContin—

Mr. RANNAZZISI. Uh-huh.

Mr. CASSIDY [continuing]. Again, knowing that you just from here have a heck of a lot of data—

Mr. RANNAZZISI. Uh-huh.

Mr. CASSIDY [continuing]. Why aren't we doing every week another intervention at another pharmacy, because it seems like it is a target-rich environment.

Mr. RANNAZZISI. We are. We have active investigations across the country based on complaints and our ARCOS data. Now, sometimes the ARCOS data might show up with a pharmacy that is, indeed, a legitimate pharmacy that does have a high volume, and the reason they have a high volume is because they are next to a hospital or oncology—

Mr. CASSIDY. And that is a fair statement. I can imagine a cross tab which would say, OK, here are the variables that we find associated with, you know, again, I can see Google with an algorithm that you give them.

Mr. RANNAZZISI. Right.

Mr. CASSIDY. Which would data mine. Are you all data mining on that, formally data mining?

Mr. RANNAZZISI. Yes. We look at that, we look at ARCOS data on a regular basis. We look at the top 50, top 100 in different areas of the country. We make sure that, you know, we do background

and make sure those pharmacies and wholesalers are operating within the confines of the law, and if we have further information on it, we open investigations. Yes. That is what ARCOS is for. ARCOS is a targeting tool.

Mr. CASSIDY. How many active investigations do you all have right now?

Mr. RANNAZZISI. I would have to get back. I don't want to throw out a number.

Mr. CASSIDY. Ballpark, 50, 100, or 1,000?

Mr. RANNAZZISI. Oh, we have a lot. Many more than 1,000.

Mr. CASSIDY. Now, kind of a recurring theme from these folks is that people go from one State, they go to another. I live in Louisiana, my pain doc is legitimate and tell me that illegitimate patients, if you will, go to Mississippi or Houston and then back again.

So is Federal, in your mind is Federal legislation required that would almost mandate some sort of standard so that Texas, Louisiana, Mississippi, Arkansas, or Kentucky with every State bordering it would be in some sort of interchangeable information?

Mr. RANNAZZISI. I think—my personal opinion is, yes, I would love to see that because I think doctors need that additional tool. I think there as a practitioner you would agree that I want to know what my patient is doing and who my patient is seeing, whether it is in Kentucky, Ohio, or, you know, four states over.

The problem is interconnectivity, and the problem is is a lot of these states have different State laws and different laws regarding the information and how it could be distributed. So I don't think it is—I think the problem lies within the states. They have to work it out. This is not a Federal Government system, and while we support the states and we want the states to get that interconnectivity, that is a question better asked to the states. It is their decisions.

Mr. CASSIDY. Just if I may have a few more seconds, I will say that after Hurricane Katrina and all my patients were displaced to other states, I found that those, there is something that happened, a switch was turned, and a doctor in Oklahoma could find out the drugs I was prescribing for my patients in Louisiana, and so it does seem as if that interoperability could occur in a fairly straightforward fashion if we had, you know, a little direction.

Mr. RANNAZZISI. I remember that, and that State boards were working extremely well together, and I don't know how that information was passed because we don't have dispensing information, but I do know that we were working with the—

Mr. CASSIDY. I think it was through E-scripts. I think that there was something like that.

Mr. RANNAZZISI. But the State boards really came together, and they did a fine job getting everybody in line.

Mr. CASSIDY. So there is a chance we just need those folks to talk to their State boards.

Thank you. I yield back.

Mrs. BONO MACK. Thank you, Dr. Cassidy.

The chair recognizes Ms. Blackburn for 5 minutes.

Mrs. BLACKBURN. Thank you so much, and I want to thank you all for your patience today. As you know, we have had other hearings downstairs. We had Secretary Sebelius and looking at the

budget that is there, and I know that those of you at the State level are quite concerned about the Obama Care impact that is coming to a State near you very quickly.

Mr. RANNAZZISI, am I saying your name correctly?

Mr. RANNAZZISI. Yes, ma'am.

Mrs. BLACKBURN. I am close enough.

Mr. RANNAZZISI. Perfect.

Mrs. BLACKBURN. OK. On the Ryan Haight Act how many online pharmacies have registered under that act? What is—how is that being built out?

Mr. RANNAZZISI. Currently I—we have no registered pharmacies under the act. We have I think four or five applications pending but no pharmacies have been registered. Now, remember there are a lot of provisions in the act that allow you to do certain things online that is not, that you don't—the Act was written so it would prevent the rogue pharmacies from jumping online and continuing practice, and it has done that. There is no domestic pharmacies currently there operational that are under—

Mrs. BLACKBURN. OK. Then let me ask you this another way. How many enforcement actions has DEA taken against online pharmacies or rogue pharmacies under the act?

Mr. RANNAZZISI. I would have to get back to you, ma'am. Very few because the act pretty much shut down the domestic online pharmacy problem, and the problem moved overseas.

Mrs. BLACKBURN. OK. Are you having difficulty in sorting and finding out which are the rouge foreign-based pharmacies or—I would like to visit with you more about that. I think that it is an issue that is of concern to us and being able to see where we have these online pharmacies, find out who is registering or not. That would be helpful and instructive to us.

So let us look at that a little bit and then if you could quantify the kind of actions that have been taken against some of these rogue pharmacies, just—it allows us to do a little bit of due diligence and see if decisions we are making are working or having an impact or not. So I would appreciate having that time with you.

I want to talk with you for just a little bit, if you can answer this within the allotted time, that is great, and if you need to get back to me, that would be great. I am no cheerleader for the FDA, but I understand their philosophy and approach that, in that an agency as it applies to controlled substances seems much more measured than that of the DEA at times, and my understanding is I want to talk about this post-inspection feedback in the form of what is known as the FDA form 483, Inspection Report.

And my understanding on this FDA form 83 [sic] is that it sets out with specificity the agency's concerns and the parties have the opportunity to meet with the FDA and discuss any issues that may be before them, that companies are given the opportunity to address issues and solve problems in a collaborative dialogue.

And if the company were to choose not to address the issues, the agency then typically takes further action in the form of a warning letter and proceeds with prosecution and consent decrees as appropriate. And I think that that FDA-type approach is different from the DEA approach when there are problems, which is just enforcement and not the opportunity to address concerns.

So it seems like DEA there is no post-inspection give and take or dialogue that may be there and no information sharing or the opportunity to address issues or—that are out there. So my question to you is this, and you mentioned Tennessee as one of the states with the pill mills, and you know, we all are concerned about patients that are in pain that need medication, companies that are trying to meet those needs, and here, again, want companies to do the right thing, want them to spend the money wisely, want individuals to be safe, want there to be protections that are in place.

So my question is is there a more surgical approach? Should we be thinking of a more surgical approach to addressing the issue of prescription drug abuse rather than just looking at suspension of licenses? You know, where is the right balance in a vetting process? Is there a more proportional approach to take rather than just going to an immediate suspension?

Mr. RANNAZZISI. Yes. I would love to answer that question. First of all, the FDA deals mostly with legend drugs, and they do have manufacturing processes they do with controlled substances, but the vast majority of their authority is over legend drugs and prescription drugs, making sure they have good manufacturing processes, maybe making sure that labeling is correct, putting the drug through the appropriate validation process.

My responsibility under the act is to ensure that there is no diversion of highly-addictive medications into an illicit marketplace. We do give chances to companies. If you look at our history, we went onsite on many of these companies that we have taken action against and pharmacies and explained to them what their obligations were. We sat down with them and talked to them of what their obligations were. They just—

Mrs. BLACKBURN. OK. So your response then would be that you all are carrying out that dialogue?

Mr. RANNAZZISI. Yes.

Mrs. BLACKBURN. OK. All right.

Mr. RANNAZZISI. Yes. I look at Florida and the millions of tablets that are going into the illicit marketplace in Florida, not only from the pharmacies but also from the distributors and the doctors. And I think we have to hold the line somewhere. These are drugs that are killing people. It is not Amoxicillin, and you know, we have to take a stand.

Mrs. BLACKBURN. OK. Do any of the others of you want to make a response to that? No? OK.

Madam Chairman, I will yield back.

Mrs. BONO MACK. Thank you, and I am going to recognize myself for 5 minutes for a second round and any other member who wants to ask a second round, I will yield to you for your own 5, and then we will move to the third panel.

My, first of all, my comment on what Dr. Cassidy had to say, I think he brought up a good point, and I think it is fair to ask if the DEA data mining capabilities are as robust and clever as you would suspect. Googles are and perhaps we can visit that in the days ahead, but this is a, sort of a general question to each of you, and thank you, Mr. Rannazzisi, for mentioning my support of your take back days, but 995,000 pounds of drugs in 3 days.

The question I want to ask each of you if you would care to comment or weigh in is who is paying for those pills? Are we paying for them in the form of healthcare premiums? Are we paying for them through diversion out of Medicare Part D and Medicaid? Who is paying for all of those pills? Why are there 995,000 pounds of extra pills being turned back in? What is the overall toll in healthcare in our country just from this problem?

Anybody?

Ms. BONDI. I can tell you from our local take back days these are good, solid citizens who are coming in with brown paper bags filled with prescriptions that they have had and that they are concerned because they know you cannot flush prescription drugs down your toilet, and they don't know what to do with them, and they don't want their grandkids to get a hold of them, and you know, when I speak to people, I say, no one ever wants to believe it is their kids, so I say, your kid's friends can get into your medicine cabinet.

So people—it is our citizens, and I think a lot of them are getting them from their doctors, their dentists for legitimate purposes. They are taking one or two of them, and they are just stockpiling them because they don't know what to do with them, but we have had remarkable results with good citizens turning them in to have them properly disposed of.

Mrs. BONO MACK. But the question is why is there so many left over in the medicine chest to turn back in? Who is paying for—what is the cost, and General Conway, you mentioned this is an American tragedy, and I couldn't agree with you more. There is no question our doctors are working too hard, and ultimately this comes out of their patient visit, they are scrambling because healthcare is squeezed more and more and more, and this is a part of the problem. But \$148 million diverted out of Medicare Part D in 2008, alone.

So are we really, I mean, General Conway, do you want to weigh in on—

Mr. CONWAY. Well, I don't know that I can quantify the cost. I mean, sitting here as the attorney general of Kentucky I can't quantify the cost, but my experience is similar to General Bondi's. When I go to one of our drug take back days and sit there with my plastic gloves on, it is the concerned mother who doesn't want her kids and realized she saw something on TV and her hydrocodone she got for a broken arm is expired.

The cost comes in crime. People are committing thefts to get access to resources to buy pills. The cost comes in cash. A lot of these pill mills deal on a purely cash basis. When you have healthcare companies that are trying to get more efficient in mandating 90-day supplies of some of these mail order pills, a 90-day supply in Kentucky of hydrocodone or oxycodone, chances are about 50 percent of that is hitting the streets. That is what my law enforcement officials are telling me. That is something that we need to quantify.

And certainly Medicare and Medicaid are paying some of that.

Ms. BONDI. And Chair Bono Mack, I think what you are saying is if you go in for a routine dental surgery, why do you need 60 oxycodone pills.

Mrs. BONO MACK. Exactly.

Ms. BONDI. You don't.

Mrs. BONO MACK. Thank you. Thank you, and Mr. Haslam, you speak on this, to this in your testimony, too. You suggest that maybe they have sort of a tiered approach into needing the drugs. Do you want to speak a little bit about your beliefs on this, too?

Mr. HASLAM. Absolutely, Madam Chairman. The—what we see in Ohio we see—to answer your original question, the taxpayers at some level is paying for the problem. No matter how you look at it when you boil it down to the common denominator, it is the taxpayer that is paying for it, whether it is Medicaid costs in Ohio, especially in southern Ohio, which is economically depressed, it borders eastern Kentucky as we have heard Attorney General Conway elude to is an economically-depressed area. That—it is a huge burden on the Medicaid System there, and as you move across the State of Ohio, though, it is not limited to that socio-economic class. It goes all through all the way to the middle class up to the upper class, and whether it is a company that has to pay increased healthcare premiums that is I providing for its employees because of the number of pills their employees are receiving as part of a prescription or the insurance companies, the cost to those folks. The insurance companies in Ohio have recently reached out to the attorney general's office to talk with us and say what role do we play in this? This is a huge cost to our bottom line. It touches everybody.

So at the end of the day it is the taxpayer that is footing the bill for this prescription drug problem and for those large amounts of pills that are on the street.

Mrs. BONO MACK. Thank you. So when we win the day with the arguments of the human suffering of the budgetary tolls, there is no rhyme or reason why we wouldn't be tackling this head on as a Nation, and again, Mr. Rannazzisi, one last question to you.

This committee has been investigating nano encryption, intagence, and other technologies coming out. Can you speak briefly about future technologies that you might be exploring like this on tracking drugs?

Mr. RANNAZZISI. Ma'am, I can't take that question for the record. I am not an expert on—

Mrs. BONO MACK. OK.

Mr. RANNAZZISI. But I do have experts on staff.

Mrs. BONO MACK. That is fair. You know we will be submitting plenty of questions to each of you for the record.

Mr. Butterfield, did you have—

Mr. BUTTERFIELD. I have one.

Mrs. BONO MACK. All right. I will yield to you—

Mr. BUTTERFIELD. Thank you.

Mrs. BONO MACK [continuing]. For 5 minutes.

Mr. BUTTERFIELD. Thank you. Under the careful supervision of a doctor, prescription drugs can alleviate severe pain or help those suffering from mental disorders like psychosis or depression or anxiety or insomnia or attention deficit disorder. Unfortunately, there are true stories of these drugs being prescribed inappropriately or not for their intended use.

Only 54 percent of physicians ask about prescription drug abuse when taking a patient's medical history, and only 55 percent regu-

larly contact their patients' previous doctor before prescribing controlled pain medication.

Question. State entities certify and regulate both doctors and pharmacies. Through this role, General Conway, what do you think State authorities can do to educate medical practitioners?

Mr. CONWAY. Well, the thing about the medical community, Congressman, is that it is not a one-size-fits-all approach, and we have a piece of legislation we are considering right now in the general assembly that I am supportive of that would require anyone who wants to prescribe a schedule two or three narcotic to mandatorily register with our PDMP.

But I think that the education component for the medical community is important. The Chairwoman talked about what needs to happen with short-term prescriptions. Our ER docs need to have standards for how much should they prescribe if someone shows up at the ER. They ought to do mandatory PDMP checks.

The problem for us in law enforcement and in Kentucky, and I can't speak to it in other states, but in Kentucky we have a little bit of a battle with our medical community in that the KASPER System, our PDMP, is housed over in a cabinet of Health and Family Services. They have the data. They observe the trends that are problematic. They are supposed to take actions against licenses if they spot problematic trends and then refer them to law enforcement if necessary.

Until this issue received increased scrutiny here in the last couple of months, in my first 4 years as attorney general, I didn't have a single law enforcement referral from the Board of Medical Licensure.

So the doctors, if they are going to be prescribing, you know, there are different standards for an oncologist or pain management doctor from a podiatrist and an allergist. But the doctors that are going to be prescribing have an obligation to use the system, to check their patients, and to help us police their profession, because they are under-utilizing the system right now, and they need to work with us so that we can see the data.

I cannot ask who are the two largest prescribers of schedule two and three narcotics in Pike County. I would love to, but the law prohibits me from doing it, and the Board of Medical Licensure is not sending me the data. So I am using old-fashioned surveillance and talking to people about where are they getting the pills in order to figure it out, and we have a great system, and all the data is right there. We are just under-utilizing it, and we are under-utilizing it because we don't have the partnership we need with the medical community to make certain that that is getting addressed in Kentucky.

Mr. BUTTERFIELD. Would it be helpful to work with some of the medical schools, the dental schools to develop a curricula in this area?

Mr. CONWAY. Oh, absolutely. I speak to the pharmacy students, and I speak to a lot of medical students on an annual basis to tell them how big the problem is and to look out for this. You know, it is a balance here. The medical community gets nervous whenever an attorney general or a lawmaker gets in the middle of the doctor, patient relationship, and I respect that. I respect that, but there

ought to be some way for us to see the disturbing trends so that we can do our job in law enforcement, and right now in Kentucky our data monitoring law says I have to have a designated case, a bona fide case open on a designated target. I can't look at trends. I can't see where the problems are. I have to ask about Mr. Smith, and the data is all there, and I can't use it, and I can't tell you how incredibly frustrating that is.

Mr. BUTTERFIELD. Do you believe the Federal Government should consider certain minimum standards for doctors, for doctor education or training in the area of addiction medications?

Mr. CONWAY. I don't think it is a bad idea. Traditionally the regulation of the practice in medicine has been left to the states. I respect that. I think we are doing all we can in the Commonwealth of Kentucky to educate doctor. A lot of the healthcare organizations are starting to set up—some of our larger hospital companies are starting to set up standards for their ER docs. I think that is great. I think it is something probably best left to the states, but I would welcome some Federal guidance on that.

Mr. BUTTERFIELD. All right. Thank you. I understand you may have spent some time at Duke University.

Mr. CONWAY. I did, sir. I did, sir, and I don't know your allegiance. One of the toughest things I have to do is get elected statewide in the Commonwealth of Kentucky being a graduate of Duke University. It is—basketball passions being what they are.

Mr. BUTTERFIELD. The State legislature has just added Duke University to my district.

Mr. CONWAY. Well, Roy Cooper and I have a running argument every time we see each other, and I am going to see him this weekend. I am sure we will be arguing over that little game this weekend.

Mr. BUTTERFIELD. All right. Thank you.

Mrs. BONO MACK. Thank you. Mr. McKinley? No?

OK. Well, we—the next panel. OK. We want to thank you all very, very much for your expertise and your hard work on this. We look forward to working with you. Please anticipate further questions in writing. We look forward to getting your responses.

Again, thank you for fighting this battle, and we look forward to partnering with you in the future. Safe travels home.

Ms. BONDI. Thank you, Chair.

Mr. CONWAY. Thank you.

Mrs. BONO MACK. We will take quick 30-second break while we seat the next panel.

[Recess]

Mrs. BONO MACK. On our third panel we have five witnesses. First is John Gray, President and CEO of Healthcare Distribution Management Association. Our next witness is Joseph Harmison, a Pharmacist and Owner of DFW, it sounds like Dallas Fort Worth Airport—oh, it is. OK. Of DFW Prescriptions, who is testifying on behalf of the National Community Pharmacists Association. Hopefully I will be flying through DFW later today.

We also have another pharmacist joining us, Kevin Nicholson, Vice President of the National Association of Chain Drug Stores. Next is Kendra Martello, Assistant General Counsel, Pharmaceutical Research and Manufacturers of America, and our final wit-

ness is David Gaugh, Vice President for Regulatory Science of the Generic Pharmaceuticals Association.

Welcome everyone. I think you know the drill. The 5 minutes. There is the timer, and with that we will be happy to turn to you, Mr. Gray, for your 5 minutes. Please make sure your microphone is on.

STATEMENTS OF JOHN M. GRAY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION; JOSEPH H. HARMISON, OWNER, DFW PRESCRIPTIONS, ON BEHALF OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION; KEVIN N. NICHOLSON, VICE PRESIDENT, NATIONAL ASSOCIATION OF CHAIN DRUG STORES; KENDRA A. MARTELLO, ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; AND DAVID R. GAUGH, VICE PRESIDENT FOR REGULATORY SCIENCES, GENERIC PHARMACEUTICALS ASSOCIATION

STATEMENT OF JOHN M. GRAY

Mr. GRAY. Now it is greener. Thank you. Good afternoon, Chairman Bono Mack and Ranking Member Butterfield and members of the Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade. I am John Gray, President and CEO of the Healthcare Distribution Management Association, and I want to thank you all for the opportunity to come here today and talk about this critically important problem of prescription drug abuse and diversion, and most importantly, what my members are doing to combat that problem.

The pharmaceutical distribution industry's primary mission is operate the safest, most secure, and efficient supply chain in the world. As part of this mission HDMA and its members are committed to addressing the serious national problem of prescription drug abuse and to being a part of the solution.

HDMA members have not only statutory and regulatory responsibilities to detect and prevent diversion and control prescription drugs, but to undertake such efforts as responsible members of our society.

To address the issue of prescription drug abuse, distributors have developed complex systems to help prevent diversion of medicines and to comply with the DEA's expanded expectation for suspicious order in monitoring and reporting.

To aid in the development and implementation of these systems, in 2008, HDMA and its member companies developed the Industry Compliance Guidelines to support the distribution industry practices on the evaluation of customer orders for controlled substances and the reporting of so-called suspicious orders to the DEA. The ICGs, as we call them, were vetted with the DEA in advance to their publication.

These guidelines emphasize the concept of "know your customer." That is obtaining and reviewing thorough background information about a perspective healthcare provider prior to doing business with them. Therefore, in many cases potential problems can be avoided even before an order is placed.

Because the advanced systems now in place and the industry's proactive efforts, the DEA reported last year that since 2006, and 2011, distributors in this country stopped shipping controlled substances to more than 1,500 customers that could have posed an unreasonable risk of diversion.

Let me add it is critical that the anti-diversion efforts of our industry, as well as the enforcement actions of DEA, should always carefully balance the need to cut off supply to any customer engaged in diversion while not limiting access to appropriately-prescribed and legally-dispensed medicines for seriously ill patients or potentially putting legitimate pharmacies out of the business.

Despite the best efforts of our industry, we find ourselves today in a conundrum. Pharmaceutical distributors do not manufacture legal controlled substances. We do not license pharmacies or healthcare providers. We do not write prescriptions for patients. We do not dispense these products to patients. We do not see the prescription a patient presents for filling at a pharmacy. A single pharmaceutical distributor does not know and has no way of knowing if a pharmacy customer is purchasing prescription drugs from other distributors.

Furthermore, we do not determine or set prescription drug fill rates.

However, the DEA receives information from each distributor that sells controlled substances to a particular pharmacy or prescriber. The agency also sets annual allowable production quotas for manufacturers of these controlled substances. Distributors are often held accountable with incomplete information for diversion from parts of the supply chain they simply do not control.

To comply with DEA's expectations, distributors are being asked to judge the diagnosis, intent, medical knowledge, experience of doctors and pharmacists.

Furthermore, the DEA's emphasis on volumes and national averages to determine suspicious orders may simply oversimplify the problem for schedule two controlled prescription drugs. Our members have found the analysis of a single pharmacy's controlled substance ordering pattern is simply far more complex and includes critical factors such as the size of the pharmacy, the patient demographics, the geographic proximity to the hospitals or surgery centers, nursing homes, cancer clinics, hospice providers, and other major urban areas.

Now, as was stated earlier today, I need to correct that. We do not choose not to comply with these laws of suspicious ordering. The fact is our members have many questions about the compliance. You have heard this is a relatively new process, a new procedure, and unfortunately, today with the questions we have remaining each distributor essentially operates in an information silo. We are unaware if a new pharmacy customer may have been cut off by another distributor who had concern about potential diversion at the pharmacy, or we are unaware that an existing pharmacy customer is ordering controlled substances from multiple distributors. Or we are also unaware that specific pharmacies may be dispensing controlled substances for physicians who are writing prescriptions for patients when there is no legitimate medical need.

So in an effort to break down these walls and get this new program going, HDMA has asked DEA in face-to-face meetings over the last several years as well as in written communications to provide some clarification and guidance on the agency's expanded expectations of an anti-diversion program for wholesale distributors, and we have sought greater information sharing in the process between the agency and our industry.

Throughout these communications HDMA and its members have also asked DEA to provide aggregated and critically-important blinded data from the ARCOS System that could be used to further assess product orders and provide supportive information for the agency and for the members.

A distributor does not have the independent ability to determine whether a pharmacy or a physician customer is ordering from multiple distributors. Only the DEA possesses that information.

In closing, we strongly believe that all stakeholders, doctors, pharmacists, distributors, manufacturers, and indeed, the government must work together to achieve this shared goal to ensure a sufficient, safe supply of medicines for legitimate patients while keeping those same drugs out of the hands of individuals who will abuse them.

Ms. Chairman, thank you for your time.

[The prepared statement of Mr. Gray follows:]



Statement from
John M. Gray, President and CEO
Healthcare Distribution Management Association

For the U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Commerce,
Manufacturing, and Trade

March 1, 2012

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Good morning Chairwoman Bono Mack, Ranking Member Butterfield and Members of the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade. I am John Gray, President and CEO of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to inform the Subcommittee's efforts regarding the critically important issue of prescription drug abuse and diversion.

HDMA is the national association representing America's primary pharmaceutical distributors – the vital link between manufacturers, pharmacies and healthcare providers.

Our industry's primary mission is to operate the safest and most secure and efficient supply chain in the world. As part of this mission, the pharmaceutical distribution industry is committed to addressing the serious national problem of prescription drug abuse and to being part of the solution.

HDMA's members have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.

The remedies for prescription drug abuse are not the same as those involving illegal drugs handled by criminals. Prescription drugs are

approved by the government (many of which are manufactured under stringent controls and pursuant to active ingredient quotas set by DEA), intended to improve the lives of patients and are distributed by fully licensed distribution companies.

To address the issue of prescription drug abuse, distributors have developed complex systems to help prevent the diversion of medicines and to comply with the Drug Enforcement Administration's (DEA) expanded expectations for suspicious order monitoring and reporting.

To aid in the development and implementation of these systems, in 2008 HDMA and its member companies developed Industry Compliance Guidelines (ICGs) to support distribution industry practices on the evaluation of customer orders for controlled substances and the reporting of "suspicious" orders to the DEA. The ICGs were vetted with the DEA in advance of their publication.

The guidelines emphasize the concept of "Know Your Customer" – that is, obtaining and reviewing thorough background information about a prospective healthcare provider prior to doing business. Therefore, in many cases, potential problems can be avoided even before an order is placed.

Obviously, because of antitrust concerns, individual distributors must make their own decisions regarding their business practices. Individual

distributors take proactive steps to prevent controlled substances from entering into the wrong hands. An individual distributor may place limits on the amount of controlled substances that a provider may purchase, and may cease to do business with a provider who has engaged in what appears to be suspicious ordering.

Because of the advanced systems now in place and the industry's proactive efforts, the DEA reported last year that between 2006 and 2011 distributors stopped shipping controlled substances to more than 1,500 customers that could have posed an unreasonable risk of diversion.

Let me add, it is critical that the anti-diversion efforts of our industry as well as the enforcement actions of the DEA always carefully balance the need to cut off supply to any customer engaged in diversion while not limiting access to appropriately prescribed and dispensed medicines for seriously ill patients or potentially putting legitimate pharmacies out of business.

Despite the efforts of our industry, we find ourselves in a conundrum. Pharmaceutical distributors do not manufacture controlled substances. We do not license pharmacies or healthcare providers. We do not write prescriptions for patients. We do not "dispense" products to patients. We do not see the prescription a patient presents at a pharmacy for filling. A single

pharmaceutical distributor does not know, and has no way of knowing, if a pharmacy customer is purchasing prescription drugs from other distributors.

However, the DEA receives information from each distributor that sells controlled substances to a particular pharmacy or prescriber. The agency also sets annual allowable production quotas for manufacturers of controlled substances.

Distributors are often held accountable, with incomplete information, for diversion from parts of the supply chain they do not control. To comply with DEA's expectations, distributors are being asked to judge the diagnosis, intent, medical knowledge and experience of doctors and pharmacists. Furthermore, the DEA's emphasis on volumes and national averages to determine suspicious orders oversimplifies the problem for Schedule II controlled prescription drugs. The analysis of a single pharmacy's controlled substance ordering patterns is far more complex and includes critical factors such as pharmacy size; patient demographics; and proximity to hospital and surgery centers, nursing homes, cancer clinics and hospice providers.

Today, each distributor essentially must operate in an information silo:

- Unaware that a new pharmacy customer may have been cut off by another distributor who had concern about potential diversion at that pharmacy; or,
- Unaware that an existing pharmacy customer is ordering controlled substances from multiple distributors; or,
- Unaware that a specific pharmacy may be dispensing controlled substances for a physician who is writing prescriptions for patients when there is no legitimate medical need.

In an effort to break down the silo walls, HDMA has asked the DEA to provide clarification and guidance on the agency's expanded expectations of an anti-diversion program for wholesale distributors, and sought greater information sharing between the agency and our industry. In face-to-face meetings as well as in written communications with the agency, our questions have ranged from seeking a better understanding of distributors' responsibilities for controlled substances suspicious orders monitoring and reporting, to improved understanding of DEA's perspective on the relationships between prescribers, pharmacies and distributors.

Throughout these communications, HDMA and its members also have asked DEA to provide aggregated and blinded data from the Automation of Reports and Consolidated Orders System (ARCOS) that could be used to further assess product orders or to provide other supportive information. A distributor does not have the independent ability to determine whether a pharmacy or physician customer is ordering from multiple distributors – only DEA possesses that information. Our members report orders for controlled substances to DEA but do not have access to the aggregated data.

To conclude, there are three themes that I would like for the Subcommittee to take away from my testimony today.

First, there is a need for the DEA to acknowledge that prescription drugs are different from illegal drugs and, therefore, a completely different mindset is required to fix the problem.

Second, anti-diversion efforts led by our industry and the DEA need to balance the responsibility to take action to prevent the diversion of prescription drugs to illegitimate use while avoiding disruptions and shortages for patients with real medical needs. We ask for proportionate enforcement by the DEA for distributors who have implemented necessary anti-diversion controls.

Third, the more information that is shared between DEA and distributors, and across the supply chain, the more effective our anti-diversion efforts will be.

HDMA strongly believes that the healthcare industry as a whole, the government and all supply chain stakeholders – doctors, pharmacists, distributors, and manufacturers – must work collaboratively to effectively detect and fight prescription drug abuse and diversion. We all share the same goal: to ensure a sufficient, safe supply of medicines for legitimate patients while keeping these same drugs out of the hands of individuals who will abuse them.

I thank you again for the invitation to participate in this hearing and hope this overview was valuable to the Subcommittee as it explores this important topic.

Mrs. BONO MACK. Thank you, Mr. Gray.
Mr. Harmison, you are recognized for 5 minutes.

STATEMENT OF JOSEPH H. HARMISON

Mr. HARMISON. Thank you, Madam Chairwoman.

Mrs. BONO MACK. Turn the mic on and pull it close to you, please.

Mr. HARMISON. Does it help if I get it closer?

Mrs. BONO MACK. Yes. Thank you.

Mr. HARMISON. I am sorry. I have a hearing deficit, and people say I talk too softly. Sorry. Good afternoon, Madam Chairwoman Bono Mack, Ranking Member Butterfield, and Members of the subcommittee. I am Joe Harmison. I am a practicing pharmacist. I am a pharmacy owner and past President of the National Community Pharmacists Association. NCPA is a national organization representing the owners and pharmacists of the non-publically traded community pharmacies.

Everyone here today is in agreement that the United States has a problem with drugs abuse, misuse, and diversion. I hope we will also acknowledge that the drugs we are discussing today when used appropriately are extremely beneficial. When they are not used as intended, they are destructive in many ways.

As has been stated over and over, the majority of people that abuse prescription drugs get them from the family medicine cabinet or friends. This shines a very bright light on how we need to destroy these drugs. The community pharmacists in the United States have been excited, willing participants in the Drug Take Back Program for Destruction.

The problem we have, we are not allowed to take back the controlled substances of what—those are the drugs we really want to get off the street. We can't handle that. We are anxiously awaiting the rules we have been told with DEA they are promulgating to allow us to participate in this process.

The pharmacists of America interact with millions of patients every day and advises them on how to use their medicine correctly and what can happen if they don't. We cannot cure the problem we are addressing today by ourselves. We use the tools we have, but we need more tools.

There have been many suggestions on how you can get more or people can get more information to us. I am very much in agreement that the most readily-implementable procedure we have out now is the PDMPs. Every pharmacist in I believe it has been stated 48 states has to submit on a regular basis the information on the controlled substances they dispense. This goes into some giant computer somewhere.

The problem the pharmacists have with it is most of us don't have access to that information. It is certainly not in real time, and it is not able to be incorporated into our workflow systems. If you can find a way to get that to us, we will be your greatest advocates in using it. We do not want to be the drug police. We would be very willing to work with all parties to prevent abuse, misuse, and diversion.

Another thing with this computer database, it must not be the deciding factor on whether a patient gets their medicine. That deci-

sion must be left to the responsible parties, the prescribers and the pharmacists. We are the ones that know the patients best. We know their conditions.

Another very important part of this equation is pharmacy burglaries and robberies. In 2010, there were 686 armed robberies of pharmacies in the United States, and unfortunately, some of these end up with murders involved with them. Unfortunately, I have way too much experience first hand with pharmacy burglaries. One of my pharmacies has been burglarized three times since December 1, 2011. This is one small pharmacy, and from what I can determine the street value of the drugs taken from my pharmacy is in excess of \$575,000. And more onerous than that, there were almost 10,000 doses of controlled substances potentially put on the street.

I would like to make a few recommendations for your consideration. One, require mandatory minimum sentences for robberies and burglaries involving controlled substances. Find some way to give Federal, State, and local law enforcement and prosecutors the ability to better communicate and coordinate their efforts to do their work.

Third, shut down the pill mills. Get the back actors out of the process. Leave those of us that are trying to do the best we know how, what we are trained to do, care for patients, to do our job. Another is consider a change to the tax code to allow those of us that have put out the money to have different security systems, to depreciate those in 1 year. Don't make us depreciate it over 7, 10, or more years.

And also we would hope that you might reconsider allocating some of the money taken from forfeiture from crimes related to controlled substance, put that in a pot somewhere and let pharmacists apply for some of that money. If they can't afford security systems, let them apply to use some of that forfeiture money.

NCPA and the Community Pharmacists of the United States will—are committed to working with Congress and law enforcement to combat drug use, abuse, and diversion, but we need your help.

Thank you for the ability to be here today and your attention.
[The prepared statement of Mr. Harmison follows:]

Joe Harmison, R. Ph.
National Community Pharmacists Association
Summary of Statement
Before the
House Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade
Hearing on “Prescription Drug Diversion: Combating the Scourge”
March 1, 2012

NCPA appreciates the opportunity to share the community pharmacy perspective regarding issues relating to the dangers of prescription drug diversion and crime against pharmacies. NCPA represents America’s community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains.

Importance of access to effective pain treatments for appropriate patients

Community pharmacists recognize the importance of addressing prescription drug diversion and abuse. According to the DEA, more than 6 million Americans are currently abusing prescription drugs, but community pharmacists also play an integral role in assuring that patients in need of pain medication have timely access to controlled substances. In the process, pharmacists provide vital counseling to ensure that these medications are not misused, abused or diverted.

Role of the community pharmacist, prescribers and others in efforts to prevent drug diversion

Community pharmacists hold in high regard their responsibility to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Most community pharmacists have personal relationships with their patients, and this serves as a deterrent to abuse because we know our patients, making it easier for us to detect a doctor shopper just looking for more controlled substances. We believe the the most effective means to controlling abuse and diversion is a systems-based approach that involves the patient, pharmacist, wholesaler, manufacturer, and prescriber. Efforts that NCPA supports include appropriately structured FDA Risk Evaluation and Mitigation Strategies (REMS), prescription drug monitoring programs, and electronic prescribing, which can help to alleviate some of the problems with drug diversion once systems are in compliance with DEA requirements. In addition, pharmacy benefit managers (PBMs) should be more accountable for monitoring patient use of controlled substances and preventing drug diversion, and they should provide information that can help health care professionals make better decisions and prevent abuse.

Preventing Pharmacy Crime

Equally important to these are efforts are stronger measures to crack down on pharmacy crime. There were 686 armed robberies of pharmacies in 2010 and over 1800 pharmacies nationwide have been robbed in recent years. Small, independent community pharmacies often do not have the resources to cover the extraordinary cost of needed preventive measures such as security personnel, expensive security systems or safes. NCPA recommends the following legislative initiatives to address the scourge of pharmacy crime: increased funding to promote federal and state prosecution of pharmacy crimes; tax incentives for pharmacies to adopt safety and crime prevention measures; measures to shut down pill mills, which create a thriving black market for narcotics; require mandatory minimum sentences for robberies and burglaries involving controlled substances; and allowing pharmacies to have access to forfeiture money from prescription drug crimes and to use such funds to enhance pharmacy security systems and invest in deterrence measures.

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. We need a systems approach to address this issue.

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**United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing and Trade
Hearing on "Prescription Drug Diversion: Combating the Scourge"
March 1, 2012**

Chairwoman Bono Mack, Vice-Chairwoman Blackburn, Ranking Member Butterfield and Members of the Subcommittee, my name is Joe Harmison and I am a pharmacist, owner of DFW Prescriptions and past president of the National Community Pharmacists Association (NCPA). NCPA appreciates the opportunity to share the community pharmacy perspective regarding issues relating to the dangers of prescription drug diversion and crime against pharmacies. NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains. Together, they employ over 300,000 individuals including 62,400 pharmacists, and dispense nearly half of the nation's retail prescription medications.

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. According to the Drug Enforcement Administration (DEA), more than 6 million Americans are currently abusing prescription drugs, which is more than the number of Americans abusing cocaine, heroin, hallucinogens and inhalants combined. 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.

THE VOICE OF THE COMMUNITY PHARMACIST

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According to statistics from the Centers for Disease Control and Prevention, pain is a serious and costly public health issue, impacting 76.5 million Americans. Community pharmacists play an integral role in assuring that these patients have timely access to controlled substances 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 unused prescription drugs from the family medicine cabinet or friends, should serve as a vital reminder that efforts to curb abuse and diversion must be focused in part on proper disposal of these products. NCPA eagerly awaits regulations from the DEA that will pave the pathway for increased opportunities for patients to dispose of unused controlled substances. Many of our pharmacies serve as drop off points for patients for unused or unwanted medications – however, we cannot by law take back controlled substances.

Role of the community pharmacist and prescribers in efforts to prevent drug diversion

Community pharmacists hold in high regard their corresponding responsibility, per the Controlled Substances Act, to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. We are proud of the fact that most independent community pharmacies have strong, long-lasting, face-to-face, personal relationships with their patients. This in fact serves as a deterrent to abuse because we know our patients, making it easier for us to detect a doctor shopper just looking for more controlled substances. Accordingly, we support efforts to educate pharmacists regarding how to effectively fulfill their role in decreasing prescription drug misuse, abuse and diversion.

At the same we time, we support a more systems-based approach to controlling abuse and diversion. Everyone needs to be involved: patient, pharmacist, wholesaler, manufacturer, and prescriber.

For example, there are proposals that would require prescribers to obtain additional education or certification on understanding addiction to and abuse of controlled substances and their appropriate and safe use. In addition, we think that fewer large quantities of pain medications should be prescribed and dispensed in the first place. Patients should be encouraged to take advantage of periodic programs that allow them to return controlled substances to law enforcement.

We support efforts to decrease prescription drug misuse, abuse and diversion include appropriately structured FDA Risk Evaluation and Mitigation Strategies (REMS), prescription drug monitoring programs (PDMPs), and electronic prescribing, which can help to alleviate some of the problems with drug diversion once systems are in compliance with DEA requirements. In fact, NCPA is playing an active role in the “Enhancing Access to PDMPs Project”, managed by the Office of the National Coordinator, and supports the goal of using health information technology to increase timely access to PDMP data.

Pharmacies believe that PDMPs can be more effective as they move toward real-time reporting systems and integration into pharmacy workflow processes. However, today’s PDMP systems are not able to detect doctor shopping because of lags in data reporting. Having said this, community pharmacies are concerned that they would be put in the position of serving as “police man” once they check the database and see that a person has in fact had multiple prescriptions filled for controlled substances. There are cases where legitimate prescriptions would otherwise be blocked from dispensing based on PDMP data alone. The pharmacists’ judgment in these situations must be protected.

Proper PBM Edits Needed to Assist with Prevention of Diversion and Abuse

In addition to efforts to better educate prescribers, pharmacy benefit managers (PBMs) should be more accountable for monitoring patient use of controlled substances and preventing drug diversion.

Even though many prescriptions that may be associated with efforts to divert are paid for in cash, there are many that go through the third party insurance adjudication process. From the time the prescriber chooses a medication to the time that it is dispensed, PBMs should provide more information to health care professionals that can help us make better decisions, such as providing the complete patient medication profile, and when or where other prescriptions for these products have been filled. There might even be a way to connect PBM systems into PDMP systems to allow such information to be available to the prescriber and the pharmacist in real time.

PBMs should also be held accountable for the fact that they dispense large quantities of controlled substances through the mail. Oftentimes, certain medications that are prescribed will not work for a patient, a patient only needs a few doses, or the patient expires, which can mean these large quantities can go to waste. Having these large quantities of controlled substances sitting around patients' homes does not serve the public interest.

In fact, a recent report from the U.S. Government Accountability Office found evidence of significant "doctor shopping" in Medicare Part D, with 170,000 beneficiaries receiving prescription drugs prescribed by five or more medical practitioners for frequently abused classes of drugs. PBMs, through their claim processing role, are potentially in a better position to detect and prevent doctor shopping through claim level edits.

NCPA members are very aware of controls currently in place to address overutilization of drug therapies, as pharmacists address a multitude of these edits in their daily practice. Regarding these claim-level edits, NCPA encourages efforts to ensure that existing PBM edits in place are improved.

For example, refill-too-soon edit logic should be expanded to include review of claims for multiple prescribers and pharmacies, as this will give the pharmacist a better picture of where patients may be filling other prescriptions.

In sum, PBM's should provide more robust information to both pharmacists as well as prescribers, which is made more possible with the expanded use of electronic prescribing, but should not be the deciding factor in whether a prescription is ultimately dispensed or not.

Preventing Pharmacy Crime

Equally important to preventing doctor shopping and drug diversion fueled by prescription drug abuse are stronger efforts to crack down on pharmacy crime. There were 686 armed robberies of pharmacies in 2010 and over 1,800 pharmacies nationwide have been robbed in recent years. In fact, armed robberies of pharmacies rose 81% between 2006 and 2010. Unfortunately, some of these incidents resulted in senseless deaths. The Committee is probably already all too aware of the number of high profile pharmacy murders in the last two years, including two highly publicized pharmacy murders in New York.

Pharmacies, particularly, small, independent community pharmacies are sitting ducks for burglaries and armed robberies. Unlike chain drug stores, small, independent community pharmacies do not have the resources to hire security personnel or purchase expensive security systems or safes. Pharmacy crime has become such an epidemic that extraordinary preventive measures are now required, but such preventative measures are also extraordinarily expensive. For my pharmacy alone I have spent over twenty-thousand dollars to install security measures that are in response to three burglaries of my store.

The hearing today is a good first step to address increasing prevention and prosecution of pharmacy crime. However, more action is needed now. Accordingly, NCPA recommends the following legislative initiatives to address the scourge of pharmacy crime across the United States:

- Increase federal funding to be set aside to promote more federal prosecution of pharmacy crime. All too often, prosecution of pharmacy crime is left to thin and overstretched local law enforcement.
- Provide funding to federal and state law enforcement to better communicate and coordinate prosecution of pharmacy crime. NCPA is concerned that all too often the respective federal, state and local law enforcement agencies are unaware of what the other is doing.
- Provide tax incentives for pharmacies to adopt safety and crime prevention measures. More specifically, allow pharmacies to take an upfront deduction for purchases of security measures instead of spreading out the tax deduction over a period of years, as is now required.
- Pass legislation to shut down pill mills, which are encouraging addiction, creating a thriving black market for narcotic drugs and fueling desperate criminals to rob pharmacies. NCPA was pleased to note that DEA data illustrates a 97% decrease in oxycodone purchases by doctors in Florida from 2010 to 2011, following implementation of new state laws in 2011.
- Amend the law to require mandatory minimum sentences for robberies and burglaries involving controlled substances.
- Allow pharmacies to have access to forfeiture money from prescription drug crimes and to use such funds to enhance pharmacy security systems and invest in deterrence measures.

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. We need a system-wide approach to address this issue. Thank you for your time and for the opportunity for us to share the viewpoints of independent community pharmacy.

Mrs. BONO MACK. Thank you, and Mr. Nicholson, you are recognized for 5 minutes.

STATEMENT OF KEVIN N. NICHOLSON

Mr. NICHOLSON. Chairman Bono Mack, Ranking Member Butterfield, and subcommittee members, thank you for the opportunity to testify. My name is Kevin Nicholson. I am a pharmacist and Vice President of Government Affairs and Public Policy for the National Association of Chain Drug Stores. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Our members operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists.

Our members are deeply committed to serving the healthcare needs of Americans. We are serious about the trust our patients impart upon us and about our responsibilities to provide the highest quality care. We are keenly aware of the scourge of prescription drug diversion, and our members actively work on numerous solutions. We also support a number of new and Federal-State policy initiatives.

DEA has implemented comprehensive regulations for a closed system to minimize the diversion of controlled drugs. Our members have developed extensive policies and procedures to comply with DEA's regulatory regime and similar requirements from State agencies such as board's pharmacy and narcotic drug agencies. A complex regulatory and policy matrix of checks and balances protects Americans.

Chain pharmacies have zero tolerance for prescription drug diversion. We have implemented a variety of extensive and robust loss prevention and internal security systems from our prescription drug distribution centers to the point of dispensing to patients. Examples include that we conduct background checks and random drug testing, extensive DEA training within 30 days of hire, maintaining electronic inventories of controlled substances with random auditing, use of camera surveillance closer to television, heavy-duty safes, and complete alarm systems, training employees on how to handle suspicious prescriptions, and internally investigating unusually large drug orders.

Chain pharmacies support and comply with State prescription drug monitoring programs. We support policies to prevent illegitimate internet drug sellers from illegally selling prescription drugs to consumers, and we support efforts to provide consumers with the means for proper disposal of unwanted medications in ways authorized by law enforcement.

NACDS is pleased to offer our support for the Online Pharmacy Safety Act, which would take important steps to shut down the illegitimate internet sellers that prey on consumers. We applaud subcommittee members Bill Cassidy and Mike Ross for their strong commitment to protecting the American public. Approximately 36 million Americans have purchased prescription medications online without a prescription. Americans are being harmed by these rouge internet sites daily.

We also look forward to DEA's upcoming regulations to allow consumers to safely dispose their unwanted controlled prescription

drugs. DEA recognizes that consumers' inability to safely dispose of controlled prescription drugs contributes to prescription drug diversion.

NACDS routinely meets with DEA officials to learn about diversion trends and to develop strategies to mitigate and reduce problems, and although we support the mission and objectives of DEA, we do have concerns with DEA's recent policies surrounding the volumes of controlled substances ordered by pharmacies.

Every pharmacy environment is different, and enforcement action should not be brought against a pharmacy merely based on the number of controlled substances ordered or dispensed. Certain pharmacy locations will have higher-than-average volumes of controlled substances. For the ultimate good of patients who rely on access to controlled substances for legitimate purposes such as pain management, we urge DEA to take a holistic approach when developing policies to pursue enforcement actions.

We have worked over the past few years to develop prescription drug risk management programs with FDA called REMS to reduce the potential for addiction and abuse of prescription drugs, and we will continue to work with FDA on future similar risk management programs. We also meet routinely with the White House Office of National Drug Control Policy on trends and solutions.

We are proud of the comprehensive approach that our chain pharmacies have taken and look forward to continuing our work with Federal and State policymakers to implement solutions, including expanding prescription drug monitoring programs, shutting down illegitimate internet sites, and providing consumers with the ability to safely dispose unwanted prescription drugs.

I thank you for the opportunity to appear and welcome your questions.

[The prepared statement of Mr. Nicholson follows:]



Statement

Of

The National Association
of Chain Drug Stores

For

U.S. House of Representatives
Energy and Commerce Committee

Subcommittee on Commerce,
Manufacturing, and Trade

Hearing on

Prescription Drug Diversion:
Combating the Scourge

March 1, 2012

10:15 a.m.

2322 Rayburn House Office Building

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Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Committee for the opportunity to submit a statement for the hearing on “Prescription Drug Diversion: Combating the Scourge.” NACDS and the chain pharmacy industry are committed to partnering with law enforcement agencies, 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. In our testimony, we wish to highlight the following areas:

- The extensive federal and state regulatory regime with which pharmacies comply
- Federal regulation of pharmacies under the federal Controlled Substances Act and DEA’s regulations to implement it
- Chain pharmacies’ extensive initiatives to protect Americans from the dangers of prescription drug abuse and diversion
- Chain pharmacies’ support for the mission and efforts of DEA
- Chain pharmacies’ support for the mission and efforts of FDA
- Chain pharmacies’ support for other regulatory bodies
- Chain pharmacies’ support for Controlled Substance Monitoring Programs
- Our goal of shutting down illegitimate Internet drug sellers
- The need for proper disposal of unwanted prescription drugs

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains

operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 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 \$900 billion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.76 trillion, equal to 12 percent of GDP. 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.

Background

Chain pharmacies extensively train their personnel and have strict policies and procedures to prevent prescription drug diversion. Our members vigorously comply with state and federal laws and regulations. Pharmacies and pharmacy personnel are among the most highly regulated industries and professions.

To qualify as a pharmacist, an individual must successfully complete a rigorous six-year doctorate program. Upon successful completion, the Doctor of Pharmacy (Pharm.D.) degree is conferred. To then practice as a pharmacist, he or she must successfully pass a national board exam and a state exam for each state in which he or she wishes to practice.

Each pharmacist is licensed by the state board of pharmacy in which he or she practices and must complete mandatory continuing education in order to maintain that state license. The vast majority of states have mandatory training requirements for other pharmacy personnel that have access to prescription medications, and these pharmacy technicians are also registered or licensed by state pharmacy boards in almost every state. Each pharmacy location is individually licensed by the state board of pharmacy in which it is located and routinely inspected by board inspectors to ensure compliance with laws and regulations. Other state agencies have jurisdictional authority over pharmacies and pharmacy personnel depending on how the state executive branch is structured. These additional agencies include those that have specific authority over prescription drugs that are subject to diversion and abuse. These agencies also issue registrations and licenses and inspect pharmacies.

At the federal level, each individual pharmacy location is licensed by the federal Drug Enforcement Administration (DEA) and is subject to DEA inspection at any time. Pharmacies must also follow federal Food and Drug Administration (FDA) regulations for the prescription drugs they maintain and dispense.

The Federal Controlled Substances Act

First enacted in 1970, the federal Controlled Substances Act (CSA) regulates the manufacture, importation, possession, use, and distribution of prescription drugs that have a potential for diversion, addiction and abuse, known as “controlled substances.” The CSA creates a closed system of distribution for controlled substances; DEA often

refers to this as “cradle-to-grave” control over controlled substances. DEA has implemented a very tight and comprehensive regulatory regime pursuant to the CSA. States have followed this lead and have implemented similar, sometimes duplicative regimes. This matrix of regulation has created a multi-layered system of checks and balances to protect Americans from the dangers of prescription drug diversion and abuse. Pharmacists and other pharmacy personnel all are trained to understand and comply with this complex regulatory matrix.

Chain Pharmacy Initiatives

To comply with DEA’s “cradle to grave” regulatory regime, chain pharmacies have created a variety of extensive and robust loss prevention and internal security systems that are in place from our prescription drug distribution centers right down to the point of dispensing to the patient. We undertake initiatives to ensure that prescription drugs are accounted for in every step along the way. Some of those initiatives could include conducting background checks before hiring personnel who have access to prescription drugs, extensively training about controlled substance laws and regulations within 30 days of hire, and maintaining electronic inventories of controlled substances and conducting random audits. The tools we utilize to secure our facilities and operations can include camera surveillance, heavy duty safes, secure cages, and complex alarm systems. We work closely with law enforcement to see that perpetrators are brought to justice.

Specifically, at the pharmacy level, examples of the initiatives our members have undertaken include training pharmacy personnel on how to handle suspect prescription

drug orders, and exception reporting, in which exceptionally large or unusual orders of controlled substances will trigger an internal investigation. Chain pharmacies also may maintain perpetual inventories of controlled substances that are randomly audited by internal security personnel. Pursuant to DEA and state regulations, every pharmacy is highly secured with physical barriers and complex alarm systems. Some pharmacies also utilize cameras and closed-circuit television to ensure compliance with policies and procedures. Some pharmacies require employees to read and sign “codes of conduct,” which commits them to compliance. Some member pharmacies will conduct drug testing, including random, for cause, and pre-employment.

Chain pharmacies have zero tolerance for prescription drug diversion. Other steps pharmacies may take to minimize internal losses include: ensuring that invoices and bills are reconciled against actual inventory records, reviewing and mining system data to identify trends and potential suspicious activities, and providing toll-free anonymous tip phone lines for employees to report suspicious activities.

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

efforts to provide patients with means for disposal of their unwanted medications in ways are authorized by law enforcement.

NACDS Supports DEA

DEA holds the primary authority to implement and enforce the CSA. NACDS and our members vigorously support the mission and efforts of DEA. We seek to work with DEA and other law enforcement bodies on a routine basis. NACDS and our members frequently dialogue with DEA officials about efforts to stem prescription drug diversion, both at DEA headquarters in Arlington, Virginia and throughout the nation, working with the officials at DEA's numerous field offices. We routinely schedule industry meetings a number of times every year to meet with both officials at DEA headquarters and field offices. NACDS staff and our chain pharmacy member representatives have personally met with officials from almost every domestic DEA field office within the past few years. In these meetings, which can last from one hour to almost a full day, we discuss prescription drug diversion trends and strategies to mitigate and reduce problems. We believe these meetings are essential to supporting DEA's mission to enforce the CSA and our responsibilities to protect the health and welfare of our patients.

NACDS Supports FDA

Almost five years ago, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided the FDA the authority to impose risk management plans on prescription drugs, known as Risk Evaluation and Mitigation Strategies (REMS). A REMS will be imposed if FDA finds that a REMS is necessary to

ensure that the benefits of a drug product outweigh the risks of the drug product. Among the numerous REMS that FDA has implemented, the agency announced that a REMS will be required for long-acting and extended release opioid products (“LA/ER opioid drugs”). These are pain relieving medications that have an elevated potential for abuse. The central component of this “Opioid REMS” is an education program for prescribers (e.g., physicians, nurse practitioners, physician assistants) so that LA/ER opioid drugs can be prescribed and used safely. NACDS agrees that prescribers should be properly educated about the risks and benefits of prescription drugs, including those that have elevated abuse potential like LA/ER opioid drugs. It is critical that all prescribers understand the nature of addiction and abuse before issuing prescriptions for these medications. NACDS supports FDA’s Opioid REMS.

Beyond LA/ER Opioids, FDA recently announced a REMS for another class of drugs with elevated abuse potential, transmucosal immediate-release fentanyl (TIRF) products. The TIRF REMS is scheduled to become effective in just over a week, on March 12. NACDS and other industry stakeholders have worked closely with FDA over the past few years to design and implement this REMS. We are appreciative of this collaborative effort spearheaded by FDA. If this REMS proves successful, we are hopeful that it could serve as a model for future REMS for products similar to the TIRF products.

As we pursue solutions to the problem of prescription drug diversion, it is critical that we do not place undue burdens on legitimate patients who require prescription medications. As FDA has recognized through the REMS program, the risks of medications must be

mitigated relative to their benefits. However, we cannot mitigate risks to the point that legitimate patients cannot receive medications' benefits. We believe that FDA has struck a proper balance thus far.

Additional Chain Pharmacy Support

In addition to our support of DEA and FDA, NACDS and our member pharmacies support the mission and activities of other, numerous federal and state agencies and law enforcement bodies. NACDS interacts routinely with other state and federal officials to devise strategies to protect Americans from the dangers of prescription drug diversion and abuse. We frequently meet and interact with the White House Office of National Drug Control Policy (ONDCP) to learn about national drug abuse trends and to collaborate on solutions. NACDS recently met with officials from the High Intensity Drug Trafficking Areas (HIDTA) program to develop potential solutions to stem armed robberies of pharmacies, a problem that recently spiked in a few areas of the country. HIDTA was created by Congress with the Anti-Drug Abuse Act of 1988 to provide assistance to federal, state, local, and tribal law enforcement agencies operating in areas determined to be critical drug-trafficking regions of the United States. Other examples include our work with state legislators and policymakers on controlled substance monitoring programs, described in more detail below. We support the work of the National Association of State Controlled Substance Authorities (NASCSA) as their members develop, implement and maintain these programs. We support the mission and objectives of the National Association of Boards of Pharmacy (NABP), and have worked with them on a number of initiatives over the years, including federal legislation to

combat illegal Internet sites that lure consumers into purchasing controlled substances without a prescription, also described below.

Controlled Prescription Monitoring Programs

NACDS and chain pharmacies support controlled substance prescription monitoring programs to help combat prescription drug diversion. Currently, about 40 states have operational monitoring programs and another seven 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 encourage appropriate intervention to determine if a person may have a drug addiction, so that treatment may be facilitated. The programs also provide public information on trends in drug abuse and diversion.

NACDS and chain pharmacies support these programs as one of many strategies to help curb prescription drug abuse and diversion. We believe that these programs have proven

useful in preventing drug abuse and diversion at the prescriber, pharmacy and patient levels.

Target Illegitimate Internet Drug Sellers with the Chokepoint Approach

NACDS believes that an important strategy 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

Another important strategy to curb drug diversion and abuse is to provide consumers with appropriate means to return unwanted prescription drugs for disposal.

Finding a workable law enforcement authorized means for consumer disposal of unused and expired drug products is critical to reducing drug 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 DEA provide for such separation and avoid the potential for returned medications to re-enter the drug distribution supply chain. In addition, we support policies where consumers have a reliable and readily available means to return their unwanted medications such as mail-back envelope programs that are sanctioned by law enforcement or the DEA. The state of Maine has operated a DEA authorized drug mail-back program, funded through federal grants, where consumers are provided with pre-

paid mail back envelopes distributed at pharmacies and other locations, to mail in their unwanted medications. In addition, at various locations across the U.S. law enforcement partners with pharmacies to provide drug take-back events to give consumers means to return their unwanted medications. These programs help prevent teens and others from accessing and using prescription drugs in dangerous and potentially deadly ways. We look forward to DEA's upcoming regulations to allow consumers to properly dispose of unused, unwanted prescription drugs.

Conclusion

NACDS thanks the Committee for consideration of our comments on efforts to address the problem of drug diversion. We are committed to the health and welfare of our patients, as well as all Americans, including ensuring that they do not fall victim to prescription drug diversion and abuse.

Mrs. BONO MACK. Thank you, Mr. Nicholson.
Ms. Martello, you are recognized.

STATEMENT OF KENDRA A. MARTELLO

Ms. MARTELLO. Thank you. Chairman Bono Mack, Ranking Member Butterfield, and distinguished members of the subcommittee, 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. Our members represent America's leading pharmaceutical research and biotechnology companies.

Our prescription drug distribution system is a closed system. This means that all entities engaged in the manufacture, distribution, and dispensing of pharmaceutical products, including controlled substances, must be licensed, registered, or approved by FDA, DEA, or the states. Thus, each entity has a shared responsibility to prevent diversion of pharmaceutical products.

When an authentic product is diverted, it could be mishandled and potentially cause patient harm if reintroduced into the legitimate supply chain. Additionally, the diverted medicine can be misused or abused.

The Controlled Substances Act and DEA regulations require entities handling these products to register and to have in place effective controls and security measures to protect against theft, loss, or diversion of controlled substances. The DEA also has authority over Web sites dispensing controlled substances and recent additional authority to supervise return of unused controlled substances for disposal.

PhRMA member companies engage in a variety of activities to help prevent diversion of their products from the regulated supply chain. Our companies take these efforts seriously because fundamentally patient safety and the public health demand no less. Our members employ a range of measures to prevent diversion from facility security including uniformed guards, fences, and extensive access control and video surveillance systems to strict controls over in-process manufacturing operations to in-transit security measures such as the use of GPS tracking devices on 18 wheelers that carry medicines across the country to enhancing enforcement by information sharing with law enforcement officials and to helping educate other on best practices. Our companies work to help secure the products we manufacture in the regulated supply chain.

Because of the number of independent actors in the drug distribution chain, preventing diversion of medicines from the regulated supply chain is a shared responsibility. Recognizing this PhRMA members participate in broad-based coalitions to help address specific aspects of prescription drug diversion. These include coalitions to increase penalties for cargo theft, groups to facilitate information sharing and best practices, and participation in stakeholder coalitions that are pursuing new authorities in a variety of related and significant areas. These activities are detailed further in my written testimony submitted for the record.

We do believe that there are additional authorities that could also have a significant impact on reducing diversion as well as re-

ducing the non-medical use of prescription drugs. These include, first, increase the use of and improvements to State prescription drug monitoring programs, which can be an important tool to prevent and detect abusers and refer them for treatment.

Second, reauthorize NASPER, which provides grants for these State's monitoring tools and which is legislation we have supported. Third, increase penalties for and enforcement against criminal cargo theft, Rogan mine drug sellers, and criminal counterfeiters. Fourth, fully implement DEA authorities over online sales of controlled substances and responsible secure disposal of unused controlled substances. And finally, increase licensure requirements for wholesale distributors to prevent unscrupulous actors from moving their operations across State lines.

In conclusion, PhRMA and its member companies are dedicated to improving the lives of patients. This emphasis on the patient extends throughout the product life cycle, from researching and developing new medicines, including abuse-resistant formulations, to helping ensure medicines are used appropriately, to helping prevent diversion from the regulated supply chain.

At the same time addressing the growing problem of prescription drug abuse is also a shared responsibility, and patients need continued access to the medicines they need to allow them to live longer, healthier lives. We remain committed to addressing the issues surrounding prescription drug diversion and inappropriate use of prescription medicines, and we look forward to continuing to work with the subcommittee, members of Congress, and other stakeholders on these important issues. Thank you.

[The prepared statement of Ms. Martello follows.]

TESTIMONY SUMMARY OF KENDRA A. MARTELLO, ASSISTANT GENERAL COUNSEL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
BEFORE THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY & COMMERCE,
SUBCOMMITTEE ON COMMERCE, MANUFACTURING & TRADE
HEARING OF MARCH 1, 2012

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help patients live longer, healthier, and more productive lives.

The U.S. ensures prescription drug safety in part by maintaining a closed system for the distribution of prescription medicines. This closed U.S. prescription drug distribution system: (1) helps provide assurances regarding the quality, safety and integrity of the products lawfully sold in the U.S.; (2) helps reduce the potential for diversion from the regulated supply chain; and (3) minimizes the risks that a consumer receives a counterfeit medicine. This means that all entities engaged in the manufacture, distribution, and dispensing of pharmaceutical products, including controlled substances, must be licensed, registered, or approved by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), or the states. Further, the Controlled Substances Act and DEA regulations require entities handling these products to register, and to have in place effective controls and security measures to protect against the theft, loss, or diversion of controlled substances. The DEA also has authority over websites dispensing controlled substances and to supervise return of unused controlled substances for disposal.

Each entity in the regulated prescription drug supply must do their part to help prevent the diversion of medicines to help prevent inappropriate use or misuse.

PhRMA member companies engage in a variety of activities to help prevent the diversion of their products from the regulated supply chain. Our companies take these efforts seriously because, fundamentally and unequivocally, patient safety demands no less. A legitimate product could be compromised by diversion – resulting potentially in patient harm. Further, when a medicine is diverted, that product could be abused, potentially with devastating consequences. Efforts to prevent diversion by PhRMA members, both individually and through coalitions, include: (1) developing abuse-resistant products, (2) extensive facility and in-transit security measures; and (3) education, information sharing and consideration of best practices to help prevent and detect diversion from the regulated supply chain.

Finally, PhRMA supports increased use of and improvements to state prescription drug monitoring programs, the reauthorization of the National All Schedules Electronic Prescription Reporting Act, increased penalties for and enforcement against criminal cargo theft and rogue online drug sellers, implementation and enforcement of existing DEA authorities over online sales of controlled substances and responsible secure disposal of unused controlled substances, and increased licensure requirements for wholesale distributors, to prevent unscrupulous actors from moving their operations across state lines.

TESTIMONY OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
BEFORE THE HOUSE ENERGY & COMMERCE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

March 1, 2012

Chairman Bono Mack, my name is Kendra Martello, Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am pleased to appear before you again to provide information regarding the extensive efforts PhRMA member companies take to prevent diversion of their products from the domestic prescription drug supply chain. As you know, PhRMA 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. PhRMA applauds your continued commitment to the issue of misuse and abuse of prescription drugs. Our members take seriously the importance of preventing diversion of prescription drugs, including controlled substances, to help prevent the patient safety and public health risks that could result if an authentic medicine is diverted and re-entered into the legitimate supply chain.

I. Introduction: Appropriate Use of Medicines and Role of Education in Helping to Reduce Misuse and Abuse of Prescription Drugs

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, including developing new medicines to treat addiction and new formulations with reduced abuse potential. Our companies are 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 continuing to work with Congress, the Administration and other stakeholders on efforts to help reduce and prevent prescription drug misuse and abuse.

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

¹ Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings, SAMHSA (2010).

As highlighted in my testimony before this Subcommittee on April 14, 2011, we believe preventing and responding to prescription drug misuse and abuse is a shared responsibility, and that education – of health care providers, pharmacists, patients, and the public -- is critical to helping stem the growing tide of prescription drug misuse and abuse. The importance of education is highlighted by the Food and Drug Administration's (FDA's) recently released draft blueprint for prescriber education for long-acting opioid products.² Additionally, and consistent with the Administration's strategy to reduce prescription drug abuse, PhRMA supports a range of efforts to help educate health care providers, including revising educational curricula in health professional schools (e.g., medical nursing, pharmacy, and dental) and continuing medical education (CME) units to help ensure health care providers have specific knowledge and skills associated with appropriate prescribing while minimizing the risk of addiction. CME courses such as those developed by the Center for Substance Abuse Treatment (CSAT) provide valuable training to physicians and other health care professionals as they face the challenge of minimizing the potential for misuse of medications without impeding patients' access to needed medical care.³

One critical aspect of any educational effort is to assess their impact and effectiveness. As the Government Accountability Office (GAO) found in a December 2011 report, only two of the nine federal agencies conducting prescription drug misuse educational campaigns measure effectiveness outcomes.⁴ We believe that these federal educational efforts, which include federally-funded CME programs, would be enhanced by the incorporation of specific outcomes metrics and assessments, as GAO recommended, assessing the impact of the educational messages on behavior.

As highlighted in my testimony last April, PhRMA's educational efforts have focused on four simple messages: (1) patients should take their medicines exactly as prescribed; (2) all prescription medicines, including controlled substances, are intended only for the person named in the physician's prescription, and thus, should not be shared with anyone, including family members or friends; (3) all prescription medicines, including controlled substances, should be stored out of the sight and reach of others; and (4) any unused, unwanted, or expired medicines should be disposed of properly, either immediately through the household trash or through an organized, secure disposal program with law enforcement supervision.

With respect to disposal programs, PhRMA supports the American Medicine Chest Challenge, a national, periodic collection event and also looks forward to continuing to work with the Drug Enforcement Administration (DEA) as it develops regulations to allow ultimate users and long-term care facilities to

² FDA, "Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide REMS," Nov. 4, 2011, available at: <<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>>. In 2010, 92.4% of the opioid prescriptions dispensed were for generic medicines. (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 Office of National Drug Control Policy, "The Administration's Response to the Prescription Drug Epidemic: Action Items," available at: <http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/action_items_response_to_the_prescription_drug_epidemic.pdf>.

⁴ Government Accountability Office, "Prescription Pain Reliever Abuse, Agencies Have Begun Coordinating Education Efforts, but Need to Assess Effectiveness," GAO-12-115, Dec 22, 2011, available at: <<http://www.gao.gov/assets/590/587301.pdf>>.

return controlled substances for disposal under the Secure and Responsible Drug Disposal Act of 2010. It is important to note, however, that for a very limited set of products, including most opioids, current FDA recommendations are to flush such products.

II. The Domestic Prescription Drug Supply Chain and DEA Regulation of the Distribution of Controlled Substances

A. FDA Oversight and the U.S. Closed Distribution System Helps Prevent Against Diversion of Prescription Drugs Generally

The U.S. ensures prescription drug safety in part by maintaining a closed system for the distribution of prescription medicines. In addition to the existing standards that require FDA approval of a New Drug Approval (NDA) application for new drugs, an Abbreviated New Drug Application (ANDA) for generic drugs, or a Biologics License Application (BLA) for biologic medicines and maintenance of current Good Manufacturing Practices (cGMPs) for biopharmaceutical manufacturing, the closed U.S. prescription drug distribution system: (1) helps provide assurances regarding the quality, safety and integrity of the products lawfully sold in the U.S.; (2) helps reduce the potential for diversion from the regulated supply chain; and (3) minimizes the risks that a consumer receives a counterfeit medicine. Our prescription drug supply system was closed in 1987 after the passage of the Prescription Drug Marketing Act (PDMA), championed by Reps. John Dingell and Henry Waxman.

A drug is restricted by FDA to prescription use only after it concludes that the medicine may only be used safely under the professional supervision of a practitioner licensed by law to administer such drug.⁵ In the U.S., prescription medicines, including controlled substances, typically are sold by a manufacturer to a wholesale distributor, who may in turn sell the product to one or more wholesale distributors, or to an independent or chain pharmacy, at which point the medicine may be dispensed to a patient upon the pharmacy's receipt of a physician prescription for an individual patient. Each of these actors in the supply chain are separate legal entities who take ownership of the medicine as it travels through the supply chain until it is dispensed to a patient, and they are licensed and overseen by the relevant state licensing authority. Further, a patient may not legally obtain a prescription medicine, including a controlled substance, without a prescription from a health care practitioner authorized to write a prescription. Thus, each entity in the prescription drug supply chain – from primary and secondary wholesalers, to licensed pharmacists working in licensed independent and chain pharmacies, to physicians and other licensed health care prescribers – must do their part to help prevent the diversion of medicines to help prevent inappropriate use or misuse. The responsibility to prevent diversion must be equally shared.

⁵ 21 U.S.C. § 353(b).

B. The Role of DEA Registration, Effective Controls, and Security Requirements to Prevent Controlled Substances Diversion

Entities handling controlled substances – whether they are manufacturers, distributors, or dispensers -- must register with the DEA to handle controlled substances.⁶ Through its Diversion Control Program, DEA regulates more than 1.3 million registrants.⁷ All DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances.⁸ During manufacturing activities involving controlled substances, all substances must be stored in a secure area at the end of the workday unless manufacturing operations are continuous and must occur in an area with limited employee access.⁹ Before distributing a controlled substance, DEA registrants are expected to determine if the person ordering a controlled substance from them is appropriately registered with DEA.¹⁰ Registrants must also have in place a system to disclose suspicious orders of controlled substances to the relevant DEA Field Office.¹¹ Suspicious orders can include orders of unusual size, unusual frequency, or orders that deviate substantially from a normal pattern.¹² Further, as a condition of registration, DEA registrants must report thefts or losses of controlled substances within one business day of such theft or loss.¹³ DEA registrants are also responsible, when shipping controlled substances, to select contract carriers that provide adequate security to guard against losses in storage and in transit.¹⁴ The requirement to maintain adequate security for controlled substances in storage and transit also extends to agents of a DEA registrant.¹⁵ As will be described more fully below, PhRMA, along with many of its member companies, is part of a Coalition effort to modernize our nation's criminal laws to increase penalties for criminal networks targeting large scale shipments of medical products for theft and reintroduction into the supply chain.

As the GAO highlighted in an August 2011 report, the DEA recently expanded its resources and targeted its diversion control investigations to collaborate more with state and local law enforcement agencies and to enhance the effectiveness of the diversion control investigations it conducts. GAO also recommended that DEA should determine the extent to which these efforts have reduced prescription drug diversion.¹⁶ Most recently, the Administration's FY 2013 budget request would increase funding

⁶ 21 U.S.C. § 822. Controlled substances are placed into one of five schedules by DEA, based on the substance's abuse potential. Schedule I controlled substances have no legitimate medical use. See generally 21 U.S.C. § 812.

⁷ DEA FY 2013 Budget Summary, available at: <<http://www.justice.gov/jmd/2013summary/pdf/fy13-dea-budget-summary.pdf>>.

⁸ 21 U.S.C. § 823 and 21 C.F.R. § 1301.71.

⁹ 21 C.F.R. § 1301.73.

¹⁰ 21 C.F.R. § 1301.74(a).

¹¹ 21 C.F.R. § 1301.74(b).

¹² *Id.*

¹³ 21 C.F.R. § 1301.74(c).

¹⁴ 21 C.F.R. § 1301.74(e).

¹⁵ 21 C.F.R. § 1301.74(f).

¹⁶ Government Accountability Office, "Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results," available at: <<http://www.gao.gov/new.items/d11744.pdf>>.

for DEA's Office of Diversion Control by more than \$30 million over FY 2012 levels.¹⁷ We support these efforts to enhance the operations and effectiveness of the DEA's diversion control investigations, and agree with the GAO recommendation regarding the need for enhanced efforts to assess the effectiveness of these investigations in reducing prescription drug diversion.

C. DEA Authority Over Internet Sites Distributing Controlled Substances Can Help Prevent Diversion

In 2008, Congress recognized the need for additional oversight of Internet sites distributing controlled substances, and DEA received additional statutory authority to regulate online sales of these products. The Ryan Haight Online Pharmacy Act of 2008 contained new provisions to prevent the illegal distribution of controlled substances by means of the Internet, including:

- New definitions, such as "online pharmacy" and "deliver, distribute, or dispense by means of the Internet";
- A requirement of at least one face-to-face patient medical evaluation prior to issuance of a controlled substance prescription;
- Registration requirements for online pharmacies;
- Internet pharmacy website disclosure information requirements; and
- Prescription reporting requirements for online pharmacies.¹⁸

An update on DEA's registration and enforcement activities would help assess the effectiveness of these recent measures in combatting illegal online sales of controlled substances.

D. DEA Authority Relating to Disposal of Controlled Substances, When Fully Implemented, Can Help Prevent Diversion

As stated above, in 2010, DEA received new authorities to establish secure disposal programs that would enable ultimate users and long-term care facilities to return controlled substances for disposal.¹⁹ Since a public meeting with widespread participation in January 2011, no proposed regulations have been issued to date regarding secure disposal.

All of these measures, once fully implemented by DEA to the extent they have not been to date, will further reinforce the "closed system" in place to help prevent the diversion of prescription drugs that are also controlled substances.

¹⁷ DEA FY 2013 Budget Summary, available at: <<http://www.justice.gov/jmd/2013summary/pdf/fy13-dea-budget-summary.pdf>>.

¹⁸ Pub. L. 110-425, 122 Stat. 4820, Oct. 15, 2008.

¹⁹ Secure and Responsible Drug Disposal Act of 2010, Public Law 111-273, Oct. 12, 2010.

III. PhRMA and Member Company Efforts to Prevent Diversion of Prescription Drugs From the Regulated Supply Chain

PhRMA member companies place a high priority on their responsibility for helping ensure that the medicines patients receive are authentic and meet the established quality specifications set out in the FDA-approved application. These activities focus on working to help prevent diversion of legitimate products from the regulated supply chain, as well as to help prevent counterfeiting of prescription medicines. The patient safety risks presented by both criminal acts require nothing less. The resulting risks to patients are equally unacceptable – a legitimate product could be compromised by diversion, resulting potentially in patient harm -- or, a counterfeit could contain a deadly ingredient or no active ingredient at all – again resulting potentially in patient harm. When medicines are diverted, a second real risk exists, that the product could be misused or abused, potentially with devastating consequences. Member companies routinely assess information about issues and trends related to both diversion from the regulated supply chain and counterfeiting, because the lessons learned from one setting often helps inform the other.

Because of the number of independent actors that make up the regulated prescription drug supply chain, it is clear that preventing pharmaceutical product diversion is a shared responsibility. And PhRMA member companies are committed to doing our part. Through individual member company efforts and participation in a variety of third-party organizations and coalitions, PhRMA and its member companies are extremely proactive in helping to protect the security of their manufacturing facilities, warehouses, and the shipment of their prescription medicines in transit. At the same time, PhRMA member companies engage in robust activities to prevent the counterfeiting of their medicines, whether they are controlled or non-controlled substances. Relevant member company and coalition activities are summarized below.

A. Anti-Diversion Activities

Anti-diversion activities by PhRMA member companies are ongoing, but can best be categorized as occurring at four key points: (1) during a product's research and development lifecycle; (2) during manufacturing and storage; (3) during transit to a customer, typically a wholesale distributor; and (4) after a product has been dispensed to patients.

1. Research & Development of Abuse-Resistant Formulations: PhRMA member companies are committed to continuing to research and develop abuse-resistant formulations to reduce the potential that even if they are diverted, it will be much more difficult to extract the active ingredient for the purposes of misuse. Additional guidance from FDA to sponsors on the clinical trial and approval requirements for products with abuse-resistant formulations/dosing regimens could help facilitate the continued research and development of these products.
2. Manufacturing and Warehousing Operations: PhRMA member companies routinely employ technologically advanced measures to protect the security of both their facilities and their operations. Manufacturing sites and warehouses are commonly secured by guards, fences

and extensive electronic access control and video surveillance systems. Pharmaceutical products, and their active ingredients, are securely stored in locked cages and/or vaults. Many companies utilize background checks to qualify employees, as well as third-party vendor services. Employee access to in-process manufacturing areas, as well as those used for storage and distribution, is limited to those with the requisite education, experience and necessary security training to carry out required tasks. Visitors, and in many cases contractors, are always accompanied when travelling through or working in sensitive areas.

3. In-Transit: PhRMA member companies conduct vulnerability assessments on third party carriers, freight-forwarders, warehousemen and third party logistic providers, striving to utilize only trusted and proven vendors. As with the security of facilities, in-transit security also can involve the use of advanced electronic security measures such as GPS tracking systems to monitor carrier shipments. Actual shipper cases are commonly sealed with tamper-evident tape. A "layered" security approach is applied to the trip itself, which includes: avoiding weekend and holiday deliveries; the use of two person driver teams, secreting proprietary, portable GPS devices within the shipment itself; sealing the trailer with hardened, tamper evident devices; and never leaving the shipment unattended during a trip.
4. After Dispensing: Once products have been dispensed to patients, PhRMA and its member companies help educate on the need to use medicines exactly as prescribed, the dangers of sharing medicines with anyone, the need to store medicines where they cannot be accessed by others, and how to immediately and properly dispose of any unwanted or expired medicines in the household trash or through a secure disposal program with law enforcement oversight. Along with U.S. Fish and Wildlife and the American Pharmacists Association, PhRMA established 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 safely, quickly and easily dispose of any unused, unwanted, or expired medicines in their home. We also note that the FDA requires, for a limited set of products, including many opioids, that the products be disposed of by flushing.

B. Anti-Counterfeiting Measures

PhRMA member companies also employ a variety of overt and covert anti-counterfeiting technologies to help prevent counterfeiters who intentionally copy our products and packaging for their own financial gain to the detriment of patients. These anti-counterfeiting measures can also help deter those who may seek to divert our products from the regulated supply chain. In addition to the use of tamper-evident features on prescription product packaging, PhRMA member companies use holograms, color-shifting inks, and other mechanisms to help protect their products. These anti-counterfeiting measures are frequently updated, sometimes as often as every 12-18 months, to stay one step ahead of increasingly sophisticated criminals. PhRMA member companies engage in these activities because the consequences of a patient receiving a counterfeit medicine can also be potentially devastating. As

stated, the use of these overt and covert anti-counterfeiting measures can also help deter those who may be seeking to divert our products from the regulated supply chain.

C. Pedigree/Track and Trace Systems

Many stakeholders focus on the use of electronic technologies such as pedigree or track and trace systems to help secure our finished product supply chain and to electronically track products from the manufacturer through each change of ownership to the final point at which a medicine is dispensed to patients. We are concerned about the possibility of a patchwork of potentially conflicting state laws addressing pedigree systems. Thus, we believe that a uniform national approach to any electronic system to track finished prescription drugs in the regulated pharmaceutical distribution chain is of primary importance. As described more fully below, we currently are actively engaged in a coalition effort that includes every sector in the finished product distribution chain – manufacturers (brand and generic), wholesalers (primary and secondary), and pharmacies (chain and independent) – and we remain committed to working with that group to help develop a potential solution to a complex technological and operational issue for the prescription drug supply chain overall. While electronic systems or technologies may serve a deterrent effect, there is no one single technology or electronic system that would be a “silver bullet” to prevent diversion from the regulated supply chain.

D. Coalition Activities

Pharmaceutical Security Institute: Established in 2002, the Pharmaceutical Security Institute (PSI) is a non-profit membership organization composed of the corporate security directors from 25 global pharmaceutical manufacturers. PSI maintains the Counterfeiting Incident System (CIS), which is used to record incidents of counterfeiting, theft and illegal diversion of pharmaceutical products worldwide. CIS incidents come from a variety of sources, including open media reports, PSI member company submissions, and public-private sector partnerships. PSI and its members also help educate and train federal, state, local and international law enforcement personnel on both counterfeit and drug diversion incidents, using information in the CIS, and counterfeit and drug diversion investigation techniques. PSI members have most recently developed and distributed to all PSI members a set of best practices for pharmaceutical warehouse security.

Coalition for Patient Safety and Medicine Integrity: PhRMA and several of its members are part of this coalition of pharmaceutical, medical device and medical products companies focused on patient safety. The Coalition’s purpose is to protect patients from the risks posed by stolen and inappropriately handled medical products re-entering the legitimate supply chain. The Coalition is asking Congress to modernize the U.S. criminal code to increase criminal penalties for medical product cargo theft in order to deter this criminal behavior and prosecute the organizations that perpetrate it.

Pharmaceutical Cargo Security Coalition (PCSC): PCSC is an organization comprised of pharmaceutical industry professionals, law enforcement and government entities, cargo insurers, carriers and risk management advocates dedicated to preventing theft of pharmaceutical products in transit. Created and managed daily by a PhRMA member company, the PCSC regularly shares information about law

enforcement investigations, trends, and best practices related to securing pharmaceutical and other medical products in distribution, along with offering training, intelligence and relevant information.

Pharmaceutical Distribution Security Alliance (PDSA): PhRMA and 10 of its member companies are active participants in this informal coalition of more than 27 member organizations representing all sectors of the regulated domestic finished prescription drug supply chain, including 6 trade associations. The PDSA is developing legislative specifications addressing increasing licensure requirements for wholesale distributors, increasing criminal penalties for counterfeit drugs, enacting controls over online drug sellers, and establishing the building blocks for an electronic tracking system for finished prescription drugs, all of which could help enhance patient safety by minimizing the risk of a patient receiving a counterfeit or diverted prescription drug product.

Partnership for Safe Medicines (PSM): The Partnership for Safe Medicines is a group of not-for-profit organizations and individuals that have policies, procedures, or programs to protect consumers from counterfeit or contraband medicines. PSM regularly engages in consumer and stakeholder outreach and education designed to help educate about the dangers of counterfeit medicines, purchasing medicines online, and drug diversion. PhRMA and its member companies actively support PSM.

IV. Recommendations for Additional Finished Product Supply Chain Security and Prescription Drug Misuse/Abuse Measures

PhRMA and its member companies support a variety of additional measures that could help strengthen the domestic prescription drug supply chain against diversion and counterfeiting and that could help prevent inappropriate use or misuse of prescription drugs. Several of these efforts are summarized below.

Increased Licensure Requirements for Wholesale Distributors: We support increasing the federal licensure requirements for wholesale distributors, who are currently licensed by the states, under minimum guidelines created under the PDMA. Weaknesses or gaps in state licensing requirements can facilitate individuals obtaining wholesaler licenses for operations that could potentially deal in diverted and counterfeit drug products. As an example, H.R. 3026 sponsored by Reps. Bilbray and Matheson would prohibit persons with felony convictions related to wholesale distribution from being licensed as wholesale distributors, and would also require additional security measures such as payment of substantial performance bonds and background checks and fingerprinting for key facility managers.

Internet Drug Sellers: The prevalence of online drug sellers offering frequently counterfeit medicines, including controlled substances, without a valid prescription, is a gap that must be closed. We note that the passage of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 gave DEA new authorities over online sales of prescription drugs that are also controlled substances, and we encourage DEA to continue to exercise that authority to help protect the public and prevent diversion of controlled substances.²⁰ Additionally, in many instances, consumers face a very real risk of receiving a counterfeit drug from an online drug seller. Several PhRMA member companies are also active in the Alliance for

²⁰ Pub. L. 110-425, 122 Stat. 4820, Oct. 15, 2008.

Safe Online Pharmacies, an informal international alliance of stakeholders dedicated to protecting patient safety globally and to helping ensure patient access to safe and legitimate online pharmacies in accordance with applicable laws.

Increased Oversight of Repackaging Operations: Repackaging has been an identified weak spot in the drug distribution system that can be used as an entry point and distribution center for diverted and counterfeit drug products. Repackagers remove drug products from their original packaging and labeling, thereby destroying any counterfeit resistant technologies employed by the original manufacturer. Consequently, additional oversight is necessary to ensure that repackaged drug products are authentic and are not compromised by repackaging operations. PhRMA believes FDA could better regulate the authenticity and quality of repackaged drug products if it had authority to require prior approval of repackaging operations. At a minimum, FDA should increase its inspections of repackagers and, where appropriate, initiate enforcement action. In addition, repackagers should be subject to the same requirements regarding overt and covert counterfeit resistant technologies as original manufacturers.

Increased Criminal Penalties for Counterfeit Drugs: We support increased criminal penalties for those who counterfeit our drugs. The current criminal penalties for counterfeiting a prescription drug are less than selling illicit drugs or counterfeiting U.S. currency, and must be increased to reflect the significant negative public health impact of the crime of pharmaceutical counterfeiting.

Support Increased Funding for DEA's Office of Diversion Control: As stated above, we support the Administration's proposed FY 2013 increased funding requests for the DEA's Office of Diversion Control.

Continue to Work with DEA to Implement Regulations for Secure Disposal of Prescription Drugs: As stated above, we look forward to continuing to work with the DEA as it implements regulations under the Secure and Responsible Drug Disposal Act of 2010 to allow ultimate users and long-term care facilities to safely return for disposal controlled substances without increased risks of diversion.

Support for NASPER reauthorization: PhRMA continues to support reauthorization of the National All Schedules Prescription Electronic Reporting Act, or NASPER, which would provide and improve patient access with quality care, and protect patients and physicians from deleterious effects of controlled substance misuse, abuse and trafficking.

Support for Prescription Drug Monitoring Programs: 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. 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. PhRMA continues to believe that PDMPs can play a vital role in identifying inappropriate prescribing patterns, help identify signals of prescription drug misuse or abuse and prompt enhanced referral of patients for treatment for prescription drug abuse. A key component of effective PDMP programs is to establish interoperability across state lines, and

PhRMA has supported the PDMP Interconnect program, which facilitates the transfer of PDMP data across state laws for access by authorized users.²¹

V. Conclusion

In conclusion, PhRMA and its member companies are dedicated to improving the lives of patients. This emphasis on the patient extends throughout the life cycle of the product -- from researching and developing new medicines, to helping ensure medicines are used appropriately, to helping prevent the diversion of pharmaceutical products from the regulated supply chain. At the same time, addressing the growing problem of prescription drug abuse is a shared responsibility, and patients need continued, uninterrupted access to the prescription medicines that allow them to live longer, healthier lives. PhRMA remains committed to the issues of prescription drug diversion and inappropriate use of prescription medicines. We look forward to continuing to work with the Subcommittee, members of Congress, and other stakeholders on these important issues.

²¹ See <<http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect/index.php>>.

Mrs. BONO MACK. Thank you, Ms. Martello.
Mr. Gaugh, you are recognized.

STATEMENT OF DAVID R. GAUGH

Mr. GAUGH. Thank you. Good afternoon, Chairman Bono Mack, Ranking Member Butterfield, and members of the Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade. I am David Gaugh, Vice President of Regulatory Sciences at the Generic Pharmaceutical Association and a licensed pharmacist.

GPhA represents the manufacturers, distributors, the finished dose generic pharmaceuticals bulk chemicals, and also suppliers of other goods and services to the generic pharmaceutical industry. Generic pharmaceuticals now fill about 80 percent of all prescriptions dispensed in the United States but consume just 25 percent of the total drugs spent for the prescriptions. GPhA's member companies manufacture FDA-approved generic versions of brand-name drugs in all therapeutic classes, including prescription painkillers. We share the concern of the members of the committee when medications that are made to improve the quality of life and alleviate pain are abused. We believe that addressing this issue will require continued coordination among Federal agencies, State, local, and Federal law enforcement, healthcare professionals, drug manufacturers, patients, and even the caregivers. And we will work together to shape policy.

To control the misuse of pain medications we must recognize that the overwhelming majority of individuals, including millions of senior and cancer patients, rely on these important medications to help treat their pain. In our collective efforts to curb drug diversion, we must carefully but not inadvertently punish the patients who need these medications. Rather we should punish the criminals who illegally acquire and sell these products outside the normal chains of distribution.

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 in technologies and delivery systems to help assure that our products reach their destinations safely and securely.

For example, our industry works with the DEA through the closed system that you have heard about before of distribution to prevent a diversion and also to assure that these products do not fall in the hands of abusers.

The DEA also administers drug allotment and accountability systems to ensure against lost and diversion of controlled substances. While some have questioned whether the quota system needs to be reevaluated, we do not believe that doing so is an appropriate way to address concerns with prescription drug abuse. Further restrictions of the quota system could actually hinder access to important medical therapies for the patients who rely on them.

For example, there are drugs specifically designed for attention deficit disorder and attention deficit hyperactive disorder in the quota system that are currently on the FDA's drug shortage list. Thus we are concerned that if Congress starts to tip the balance in the quota system, it could actually have unintended consequences on the patients who need these medications.

GPhA has also been participating in the Pharmaceutical Distribution Security Alliance or the PDSA to develop a consensus technology model for increasing the security of the drug supply chain in the United States. As part of this model manufacturers have committed to maintaining a database that would associate unit level data and lot number association. GPhA believes this model will deliver greater safety to the patients and help to achieve FDA's stated goals of enhancing the identification of suspect products.

But no matter how secure we make the supply chain for prescription drugs, ensuring safe use of these drugs is a responsibility that rests on all of us. In fact, recent studies suggest that the problem with prescription drug abuse in the United States today primarily stems not from drugs that are outside the legitimate supply chain or have been obtained illegally through the black market, but instead from those who legally prescribe and are available in the homes.

According to a 2010, national survey of health more than 70 percent of people abusing prescription drugs are doing so with products that were obtained either from friends or relatives.

The general drug industry has been a leader in addressing the problem on drug diversion. We believe that education is the key component to addressing this issue and as such support efforts such as the American Medicine Chest Challenge, Smart Rx, and the National Council on Prescription Information and Education.

In addition, our industry has focused its efforts in the area by joining the brand industry, patient groups, and the FDA to develop the REMS Program, which addresses long-acting and extended-release opioid medications. REMS, which is short for Risk Evaluation and Medication Strategies, are special programs that are used by the FDA to help prevent adverse outcomes for the patients and through the education of key participants about the risks that are associated with the medications and the proper and legitimate use of these medications.

Madam Chairman, thank you for the tireless efforts to combat the problems of the prescription drug abuse in this country. You know more than anyone that this is very much a multi-faceted issue that will require multi-stakeholders to solution.

Thank you, and I will be happy to answer any questions.

[The prepared statement of Mr. Gaugh follows:]

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TESTIMONY OF

DAVID R. GAUGH., R.PH.

VICE PRESIDENT FOR REGULATORY SCIENCES

GENERIC PHARMACEUTICAL ASSOCIATION

**HEARING ON “PRESCRIPTION DRUG DIVERSION: COMBATING THE
SCOURGE”**

BEFORE THE
ENERGY AND COMMERCE SUBCOMMITTEE ON COMMERCE,
MANUFACTURING AND TRADE

U.S. HOUSE OF REPRESENTATIVES
MARCH 1, 2012

Good morning Chairman Bono Mack, Ranking Member Butterfield, and members of the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade. I am David Gaugh, Vice President for Regulatory Sciences at the Generic Pharmaceutical Association and a licensed pharmacist. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals and suppliers of other goods and services to the generic industry.

Prior to joining GPhA, I was Vice President and General Manager for Bedford Laboratories, the generic injectable division of Ben Venue Laboratories. I have also served as Senior Director, Pharmacy Contracting and Marketing, for VHA/Novation, one of the largest Group Purchasing Organizations in the U.S., and was System Director of Pharmacy for a regional referral tertiary-care healthcare system in the Midwest.

Background

Let me begin by giving some background on the role of the generic drug industry in the United States. Generic pharmaceuticals now fill 80 percent of all prescriptions dispensed in the U.S., but consume just 25 percent of the total drug spending for prescription medicines.

According to a 2011 analysis by IMS Health, the world's leading data source for pharmaceutical sales, the use of FDA-approved generic drugs in place of their brand counterparts has saved U.S. consumers, patients and the health care system more than \$931 billion over the past decade — \$158 billion in 2010 alone — which equates to \$3 billion in savings every week.

GPhA's member companies manufacture FDA-approved generic versions of brand name drugs in all therapeutic categories, including prescription pain killers. We share the concern of the members of this committee when medications that are made to improve the quality of lives or alleviate pain are abused.

We believe that addressing this issue will require continued coordination among Federal agencies, state, local, and Federal law enforcement, health professionals, drug manufacturers, patients and caregivers. And as we work together to shape public policy to control 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 to treat pain. In our collective efforts to curb drug diversion, we must be careful not to inadvertently punish the patients who need these medicines. Rather, we should punish the criminals who illegally acquire and sell these products outside the normal chain of distribution.

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 in 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, and our industry works with the agency to assure that these products do not fall into the hands of abusers. 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 ceilings 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; and
- Develop a system to identify suspicious orders of controlled substances to guard against them falling into the wrong hands.

Like other manufacturers, our members employ systems such as GPS tracking to monitor the delivery of these controlled substances once they leave the manufacturing facilities.

The DEA also administers drug allotment and accountability systems to ensure against the loss and diversion of controlled substances.

While some have questioned whether this quota system needs to be reevaluated, we do not believe that doing so is an appropriate way to address concerns with prescription drug abuse. Further restrictions on the quota system could hinder access to important medical therapies for the patients who rely on them. For example, there are drugs specifically designed to treat 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 we are concerned that if Congress starts to tip the balance in the quota system, it could have unintended consequences.

GPhA has also been participating with the Pharmaceutical Distribution Security Alliance, or PDSA, to develop a consensus technological model for increasing the security of the drug supply chain in the U.S. As part of this model, manufacturers have committed to maintaining a database that would associate unit-level data with lot numbers of products.

GPhA believes this model will deliver greater patient safety and help to achieve FDA's stated goals of enhancing the identification of suspect product.

Having said this, it is also important to understand that the diversion of prescription drugs away from the intended user or the intended use could occur at various points within the normal supply chain as products make their way from manufacturer to the patient and beyond.

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 by health care professionals to patients and consumers. The cooperation of all these parties will be required if we are to truly address the issue of drug diversion and abuse.

Main Source of Prescription Diversion

But no matter how secure we make the supply chain for prescription drugs, ensuring the safe use of these products is a responsibility that rests with all of us inside of our own homes. In fact, 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 2010 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 11 percent bought their drugs from a friend or relative and 5 percent took them from a friend or relative without asking. That means that more than 70 percent of people abusing prescription drugs were doing so with products they obtained from a friend or relative.

Medication non-compliance represents an additional and significant problem. When medications go unused, it can cost the health care system billions of dollars in other medical treatments 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 allergies, 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 are unable to return unused controlled substances to pharmacies or other non law enforcement entities at this time.

This is already changing 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

The generic drug industry has been a leader in addressing the problem of drug diversion. We believe that education is a key component to addressing this issue and, as such, support efforts such as the *American Medicine Chest Challenge*, which is a community-based public health initiative, partnering with law enforcement, 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, and the National Council

on Prescription Information and Education – known as NCPiE - which is a coalition focused on addressing and raising awareness about prescription drug abuse.

In addition, over the last few years, our industry has focused its efforts in this area by joining with the brand-name industry, patient groups and the FDA to develop 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.

The intended goal of this effort was to help reduce the potential for abuse, misuse, overdose and addiction, through the education of key participants about the risks associated with these medicines and the proper, legitimate medical use of these drugs. Participants in this collaboration included physicians, nurses, pharmacists and patients. However, the group was also committed — as we believe was FDA — to assure that any REMS program did not impede access to these medications for patients in pain, which, again, are the overwhelming majority of patients who take these 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 the REMS program could be enhanced by e-prescribing, which would give physicians more information about these medications at the point of prescribing.

Conclusion

Madame Chairman, thanks to your tireless efforts to combat the problem of prescription drug abuse in this country, you know more than anyone that this 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 more than 70 percent of people abusing prescription drugs in this country are getting those products directly from a friend or relative, it is clearly going to require the hard work and dedication of all of us to truly make a difference.

Thank you, Madame Chairman, for holding this important hearing and I would be happy to answer any questions you may have.

¹ <http://www.oas.samhsa.gov/NSDUH/2k10NSDUH/2k10Results.pdf>.

Mrs. BONO MACK. Thank you, Mr. Gaugh, and I recognize myself for 5 minutes for questioning, and I just want to say I get very frustrated anytime I hear denial from anybody in front of this committee, as if they don't have a role in this. I think that there is plenty of blame to go around. There is no doubt, and in the private sector if anybody was analyzing statistics and looking at the number of overdose deaths screaming upward, I mean, Donald Trump would say, "You are fired."

These statistics are staggering. The attorney general pointed that out. They did a fantastic job. I, you know, something that really struck me to the pharmacy, the two pharmacy representatives, the murders of the four people in New York, how the bad guy, the assailant, whatever you want to call him, was an addict, too. Correct? And it seems that—are these robberies, are these crimes on the uptick because of the prescription drug epidemic? Are they addicts themselves, and are they actually—which is worse? Are they, you know, I have seen people trying to go through withdrawal. They will do anything to get the drug, anything at all. So are you seeing it because they are addicts or just people who are trying to divert it to the black market?

Mr. HARMISON. I can't speak with a great deal of authority here. I think that it is a combination. To the best of my knowledge I have never seen a patient come in that I could say this person is in withdrawal. I think that there is so much money involved with the black market of this, I think there are so many people that enjoy the euphoria. There is a demand, and somebody is going to meet that demand. Some of them are evil enough they will do whatever it takes to get it.

Mrs. BONO MACK. But it is not the euphoria. They need a basic level to sustain themselves, so let us make it clear that it is not to sustain the euphoria. At any point in time it becomes so that they can live. Correct?

Mr. HARMISON. Yes, ma'am, but what I mean by euphoria, it has been proven over and over people in true organic pain do not get euphoria from the pain-relieving drugs. If they are an addict, they do—the threshold to keep down the withdrawal syndromes does keep rising. They do have to have more and more, probably more often and more often.

Mrs. BONO MACK. Right.

Mr. HARMISON. But I don't know the people committing the crimes are addicts or salespeople.

Mrs. BONO MACK. Mr. Nicholson, do you want to weigh in on that?

Mr. NICHOLSON. Thank you, Madam Chairwoman. First I would add that I start off by saying that nothing is more important to our members than the safety of their patients and their employees, and I would also add that the incidents that you are talking about with respect to deaths from pharmacy robberies, the pharmacy robbery problem is, in fact, not, from what we are hearing is not at a nationwide spike, but it is spiking in certain geographic areas such as in the greater, in the northeast and in the New York metropolitan area.

To help address these issues, you know, we work on a number of initiatives. We have been recently meeting with the officials at

the HIDTA Office in that area to develop solutions that would help pharmacies to prevent these types of circumstances in the future.

Mrs. BONO MACK. Do you all flag and identify willingly if an addict is willing to disclose to you he is addicted to opiates and I just want to know in my record that I am asking for these, I know it presents a whole host of other problems, but there are these sorts of things that pharmacies are not addressing right now currently. Correct? Are you able to say, I know you can say you have an allergy to iodine, and you can put that on a patient's record. Correct? But can you say none addiction to a substance with a patient's willingness to provide that kind of information? Do you track that data?

Mr. NICHOLSON. Well, we, I mean, the information that goes to a patient profile is provided either by the patient themselves—

Mrs. BONO MACK. That is what I am asking you. Do you, but do you specifically if a patient says to you, I am in recovery for an opiate addiction, if I come to you with a prescription for Opana, Opana, whatever—

Mr. NICHOLSON. Right.

Mrs. BONO MACK [continuing]. Or Vicodin, whatever opiates—

Mr. NICHOLSON. I mean—

Mrs. BONO MACK [continuing]. Please talk to me, counsel me first, call my doctor and say, "Doc, I want you to know." Do you do that now? I mean, that is a basic, simple step.

Mr. NICHOLSON. The basic practice would be in a situation where a patient comes to you and says they are an addict, you would—the ultimate goal would be to refer them to treatment.

Mrs. BONO MACK. Do you keep it on their record? It is a yes or no question.

Mr. NICHOLSON. I can't answer. I mean—

Mrs. BONO MACK. Yes, because the answer is no, but let me just move on because my time is limited. I just want to go down the line if I might and get a yes or no answer out of each of you.

Do you agree with me that there is, is there an epidemic on prescription drug abuse?

Mr. GRAY. Yes.

Mr. HARMISON. Absolutely yes.

Mr. NICHOLSON. Yes.

Ms. MARTELLO. Yes.

Mr. GAUGH. Yes.

Mrs. BONO MACK. Do you agree each of you have a responsibility in finding a solution to this problem?

Mr. HARMISON. Yes.

Mr. NICHOLSON. Yes.

Ms. MARTELLO. Yes.

Mr. GAUGH. Yes.

Mrs. BONO MACK. Thank you. Lastly I am just going to close with this one thought that I am a little bit frustrated by the notion that a prescription drug monitoring program is punitive. It shouldn't be. My daughter was a professor of, I mean, excuse me, my father was a professor of medicine, and I really hold in very high regard doctors and understand their limited time. Same with pharmacists.

But when we are thinking this is a cumulative measure rather than a holistic approach, the ability for each of you to see a patient in their entirety, perhaps if we changed the language, it is not punitive but it is supposed to be an added tool that will actually help you provide better healthcare to your patients, your consumers, your customers. I think that that would help if we could change the feeling and the language, and I am happy to work with all of you on that.

My time has expired. I am happy to yield to Mr. Butterfield for 5 minutes.

Mr. BUTTERFIELD. Thank you. I am happy that the chairman went a little bit over time because that kept me from having to ask each of you the question about whether or not you feel some shared responsibility in curbing the abuse of drugs, and each one of you answered the question as I thought you would. I don't get the sense for 1 minute that any of you are not sensitive to what we are talking about today, and so I thank you for coming. I thank you for what you do in your industry and just encourage you to—let us work together to try to solve this huge problem that we are facing.

I asked this question of the first panel, and I am going to try it again, and then I will close it out and head to the airport. Law enforcement efforts in one State may certainly yield reductions in the number of pills dispensed or hospitalizations or deaths. All of this is commendable if it happens within the State's border, but how can we be sure that addicted individuals simply don't go to another State and continue to commit the crime? We have asked other panels about that, and it is the elephant in the room. I mean, that is the big problem. If we fix the problem in one State, it is very simple for the addict to go to a neighboring State.

Now, help us with some of your ideas on that very quickly. Mr. Gray.

Mrs. BONO MACK. Please make sure your microphone is on.

Mr. GRAY. All they have to do is get in a car and go, and I think ultimately the solution is going to be the ability to link up these PDMP Systems and what other health IT record systems can be done across the country, and where doctors in Florida or doctors in Michigan can look at, you know, can go online and see what each individual patient is doing, I mean, that is the only way to kind of link up the information flow so a pharmacist in Tennessee can look up and understand that this patient was also just recently at a pharmacy in Florida, and now they are up here.

But right now as you heard the earlier panel, these systems are discreet by their states. They are not connected, so the information flow isn't there.

Mr. BUTTERFIELD. Thank you.

Mr. HARMISON. Is it on?

Mr. BUTTERFIELD. Yes.

Mr. HARMISON. I don't know why they can't be connected. There are nationwide systems right now that we deal with every day with insurance that will feed back to us in a matter of seconds. There is drug allergy on record to this. They have had it refilled too soon. It is not on our formulary. There is all sorts of information that comes back in seconds. I don't know why something like this—but

I am the most technologically illiterate person in this room, but I don't know why it can't be done.

Mr. NICHOLSON. I would agree with, you know, my—Mr. Gray and Mr. Harmison that, yes, I mean, we definitely need, you know, the mater solution is to connect the prescription drug monitoring programs. At NACDS we support appropriations for NASPER and for the Harold Rogers Prescription Drug Monitoring Program to provide funding to the states so that they can upgrade and better maintain their prescription drug monitoring programs and work on programs to interconnect them with each other.

I also would add that we are hopeful that as the healthcare delivery system becomes more interoperable that pharmacies and prescribers and hospitals and you know, other entities will have better access to patient's full, the patient's full record so that there won't be gaps that would allow a patient to go from prescriber to prescriber or from State to State.

Mr. BUTTERFIELD. OK. Counsel.

Ms. MARTELLO. Similarly prescription drug monitoring programs, we think that they can be an efficient and effective tool in helping to identify folks for treatment as well, and some of the solutions that have been talked about today include making sure that information is provided to these State prescription drug-monitoring programs in real time but also enhancing their interoperability across State lines so that you can utilize this data to its maximum effect.

Mr. BUTTERFIELD. All right. Fifty seconds.

Mr. GAUGH. I would concur with my colleagues on the panel that PDMP is a system that is in place, but it does not cross borders at this point in time, and as Mr. Harmison said, the reimbursements are instantaneously, why can't this be instantaneously.

Mr. BUTTERFIELD. Very well. Thank you.

Mrs. BONO MACK. Thank you.

Mr. McKinley, you are recognized for 5 minutes.

Mr. MCKINLEY. Thank you. Mr. Gray, I think you started in a direction, and I want to follow back up again. Maybe—but then you stopped short of going that direction.

Question. When we have spoken with the DEA, they claim for the distribution groups they give you very specific suggestions for improvements or otherwise how to—I have a feeling that there is a breakdown from what they say they are doing and what you in the distribution business—are the distributors getting good advice, good direction when they go to the DEA and ask for improvements to their delivery system before they pull the registration?

Mr. GRAY. That is the big debate, and if you talk to my members, they would tell you that those meetings, particularly at the regional level, tend to be deficient in solid advice at the end of the day as to whether or not a particular pharmacy should be—have a stop order as far as delivery.

You know, our members started in this process with the DEA 4 years ago as they said. This is a relatively new program. It was certainly a novel idea to consider the distributor as a choke point. I think that is kind of a pejorative term for what we are trying to do as a team as Attorney General Bondi said. We should be working in cooperation and collaboration with the DEA, and we

shouldn't be in an adversarial posture, which these things, when you issue an ISO, that is where you end up as was stated earlier.

So what happens then, and I have heard, I have talked to most of my members about this, and a common situation that will occur is that there will be a discussion, the distributor will sit down and say, we have reason to believe, we see some spikes, something is wrong with the ordering of this particular pharmacy. We think maybe they should be cut off. What do you think? And the common refrain, I have heard this more than once so there has got to be some element of truth to it, the common refrain is, that is a business decision for the distributor to make.

Well, sure it is, but then that business decision can be used against you if you decide not to, and the questions that we submitted to the DEA last June 1 to Administrator Leonhart attempted to get to answer some of those specific questions within the confines of these meetings. A question the distributor would obviously have about a pharmacy practice, and this all stems to the data discussion earlier.

They have data we cannot see. We cannot see that a pharmacy may be delivering, may be receiving deliveries from more than one wholesaler. All we see is our numbers, and it—that has been a source of frustration. I am hoping today we can turn the dialogue into a constructive one. It is not us versus them, but how can we work together. I think we can make a lot of progress working together.

Mr. MCKINLEY. Let me stay on that question. If the—there are two other issues with it. First, are the pharmaceuticals that distributors, are they compensated for doing this police work for the DEA?

Mr. GRAY. Oh, no. This is all out of the distributor's pocketbook. We have—our companies have invested tens of millions of dollars in doing this.

Mr. MCKINLEY. Thank you. So a smaller distribution firm, how do they do that?

Mr. GRAY. Very expensive. If you want to talk to some of them, I can make that happen.

Mr. MCKINLEY. Well, I just wonder—

Mr. GRAY. Yes.

Mr. MCKINLEY [continuing]. Is the long and the short of this with the DEA trying to put the smaller distributors out of business?

Mr. GRAY. I wouldn't want to speculate on that. I can't imagine that that would be the case. I think the DEA is absolutely, you know, fervent and correctly so in attempting to stop this problem, but I think like any new initiative, we are in our dating period trying to figure out how to get along.

Mr. MCKINLEY. Is this an—is this one of those unfunded mandates that we are passing onto the companies to do, and we are not going to compensate them. Then we are going to turn around and criticize them for the cost of pharmaceuticals?

Mr. GRAY. Well, that is an interesting way to put it, but, well, I mean, as I say, the hardcore fact is when we put in these monitoring systems, it is at the company's expense to do so.

Mr. MCKINLEY. I want to see this in a most robust way to try to correct the problem, but I just have, I have this nagging feeling here that there are parts of the chain that are not being treated equally, and I hope that the DEA will revisit how they work with each—

Mr. GRAY. Well, we do, too, because we have a long history since I have been onboard in '04, we have worked more than—we were the first responders in Katrina, our companies are the ones that got in there and got—we were the only ones that got in and got medicines to the people stranded in New Orleans. We were the ones that set up the vaccine tracking system with the CDC in a cooperative effort. We worked cooperatively with the Secretary of HHS to develop the system for bird flu maintenance and stockpiling around the country. We have a long track record in the last 5 years of working hugely cooperatively with Federal agencies and the government. I would love to see that same level of participation and cooperation with the DEA, because I believe they are correct. Together we can solve a lot of this problem. If they help us help them, we can make a lot of strides to solving this problem, but we are working in a vacuum.

Mrs. BONO MACK. Thank you very much, and I would like to begin wrapping things up, and I thank all of our panelists very much for being here today, for your time, and for your 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. For that matter, if 30,000 dolphins died and washed up on our beaches every year, Congress would take action.

So why are the victims of prescription drug abuse treated any differently? But working together as we have all said I know that we can come up with some good answers, and we can save lives.

So I again thank you all very much for being here and especially for weathering the delay that we had this morning. I would like to remind members they have 10 business days to submit questions for the record. I know we will have one specifically about undosed marking, and so we will submit questions to you, and I would ask the witnesses to please respond promptly to any questions you might receive.

Again, thank you, and the hearing is now adjourned.

[Whereupon, at 1:50 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Statement of Rep. Ed Towns (NY-10)
Before the US House of Representatives
Energy and Commerce Committee
Sub Committee on Commerce

Thank you chairwoman Chairman Bono-Mack and Ranking member Butterfield for holding this hearing today on “Prescription Drug Diversion”, an issue that has been in the news recently due to the DEA raid of two CVS pharmacies in Florida. The excess of prescription drugs on the market can have devastating consequences for families if congress does not act to curb this growing epidemic. I’m particularly concerned with the affects that the prescription drug epidemic has had on our nation’s youth. In a recent study produced by the department of Health and Human Services it indicated that in 2009 approximately 2.2 million people over the age of 12 tried prescription pain killers for the first time. This study also indicated that young adults ages 18 to 25 recorded an increase in the rate of nonmedical use of prescription-type drugs. These trends are very alarming not only because of the harm that has come to families, but also because prescription drug abuse results in higher costs to our health care system.

I am very pleased however that a number of provisions in the Patient Protection and Affordable Care Act could yield some very positive results in our efforts to curb this growing problem. We must do more to 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 safe guard against prescription drug diversion.

Some of these safeguards include recently approved Risk Evaluation and Mitigation Strategies for OxyContin and Oxycodone. These strategies if implemented properly by the FDA would train healthcare professionals about the potential for abuse and addiction associated with the use of prescription pain killers. Other safeguards would involve improving the communications abilities of our law enforcement officials, doctors and pharmaceutical dispensaries so that frequent abusers can be brought to justice.

Tackling the growing danger of prescription drug abuse will require bipartisan support because there is no single solution to this problem. This public health issue requires the input and resources of all relevant stakeholders to ensure this problem is fully addressed. 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 drug abuse.

Thanks you Chairman Bono-Mack, I yield back my time.



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

August 15, 2012

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Madam Chairman:

Enclosed please find my responses to the Questions for the Record pertaining to the March 1, 2012, hearing before your Subcommittee entitled, "Prescription Drug Diversion: Combating the Scourge."

I appreciated the opportunity to testify before the Subcommittee 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 Rob Reed, Director of ONDCP's Office of Legislative Affairs, at (202) 395-6912.

Respectfully,

A handwritten signature in black ink that reads "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, House Committee on Energy and Commerce

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

FOLLOWING MARCH 1, 2012, HEARING ENTITLED,
“PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE”
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Edolphus Towns

- 1. Prescription drug monitoring databases are one tool that can help address the problem of prescription drug abuse. Please discuss a few examples of best practices in state databases. In particular, what can and should be done so that these databases are as robust as possible and as meaningful for all purposes as possible?**

Answer: As you point out, prescription drug monitoring databases, also known as prescription drug monitoring programs (PDMPs), are promising tools for addressing prescription drug abuse problems. PDMPs perform at least three vital purposes. First, health care practitioners can consider PDMP-generated prescription histories about their individual patients to alert them to behavior patterns that may suggest potential prescription drug misuse, and in some cases, prescribers may elect to alter prescribing decisions. PDMPs can also help practitioners spot potentially dangerous drug-drug interactions. As such, PDMPs support clinical decision-making and risk mitigation by practitioners. Second, when properly structured, PDMPs can aid in understanding a given state’s problems with prescription drugs and also assist with understanding and monitoring the phenomenon of prescription drug abuse in response to policy and regulatory changes. Thus, PDMP databases are an integral component of our Nation’s drug surveillance and research infrastructure. Finally, in some states, law enforcement can use the information in PDMPs to investigate deaths, pill mills, or other drug trafficking and fraud.¹

The Administration’s action plan to address prescription drug abuse includes monitoring as an essential element. Although some states’ PDMPs have been in existence for many years, many

¹ Although we focus here on the use of PDMPs as a public health tool, many states allow PDMP data to be used by law enforcement, including through PDMP reporting to law enforcement of some data pertaining to the prescribing and dispensing activities of some practitioners and clinics.

are early in the establishment/initiation process, so there is a paucity of research on them. A review of PDMP studies published this year shows that in the past 10 years, only 11 peer-reviewed research articles on PDMPs have been published,² and most of these used PDMP data to draw conclusions about the extent of the prescription drug abuse epidemic rather than to examine PDMP practices. Frequently, when a research base is sparse, clinicians and policy makers convene expert groups to develop consensus statements concerning best practice recommendations. However, to our knowledge, no expert group has issued a list of practices for making PDMPs “as robust as possible.”³ The following list represents what the Office of National Drug Control Policy (ONDCP) believes are promising practices, which, if enacted, would improve the utility of PDMPs as public health tools. The ensuing discussion includes examples of state databases that illustrate these practices:

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

Access by researchers and medical examiners to individual-level PDMP data for surveillance/research

Researchers in Utah were among the first to call attention to PDMPs’ usefulness as a surveillance tool.⁴ Epidemiologists working with new bioinformatics approaches used Utah’s PDMP content in combination with traditional surveillance information, such as medical examiner data and poison center data, to address a range of issues including the source of medication in deaths (likely diverted or likely prescription).⁵ This was possible because PDMP

² Worley J. Prescription drug monitoring programs, a response to doctor shopping: purpose, effectiveness, and directions for future research. *Issues Ment Health Nurs.* 2012 May;33(5):319-28.

³ ONDCP is collaborating with the Department of Health and Human Services (Office of the National Coordinator for Health Information Technology, Substance Abuse and Mental Health Services Administration, and Centers for Disease Control and Prevention) and community stakeholders to develop recommendations for integrating and modernizing PDMPs with health information technology, including architecture, data elements, workflow, policies, and business agreements with intermediaries. The workgroups anticipate issuing a white paper resulting from this effort in summer 2012.

⁴ Sims SA, Snow LA, Poracznik CA. Surveillance of methadone-related adverse drug events using multiple public health data sources. *J Biomed Inform.* 2007 Aug;40(4):382-9.

⁵ *Ibid*

laws permitted researchers to match individual patient death records to patient prescription records. PDMP data in Utah also indicated that the increase in methadone being prescribed for pain (rather than for addiction treatment) was likely responsible for the increase in methadone deaths from 1997 to 2004.

PDMP data also can inform the debate concerning risks of specific medications. For example, researchers used PDMP data from the New Mexico database to show that some types of prescription drugs are more likely to be associated with deaths than others and that people receiving prescriptions for highest doses are at greatest risk.⁶

As research groups have seen how valuable PDMP data can be for surveillance, the scientific literature has grown, and numerous studies have specifically identified PDMPs as worthwhile surveillance instruments. Access to individual-level data, consistent with applicable privacy safeguards, would permit a fuller understanding of the extent of the prescription drug abuse problem. For example, a Virginia Medical Examiner has found PDMP data to be invaluable, for example, using them to guide toxicology testing postmortem.⁷

Access to and consultation of PDMPs by prescribers and other healthcare professionals

While most states allow prescribers to access PDMPs; state laws vary with respect to the provider groups permitted to access these records. This is important to note since a large minority of addiction treatment programs (23-38%, depending on funding source) do not have access to a prescribing physician and therefore do not prescribe medication in the course of treating addiction.⁸ Maryland, Indiana, North Dakota, Utah, and Colorado permit PDMP access to providers other than prescribers.^{9,10,11,12,13} Access to a PDMP may help counseling staff

⁶ Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG, Harvey W, Loring LD. A history of being prescribed controlled substances and risk of drug overdose death. *Pain Med.* 2012 Jan;13(1): 87-95.

⁷ Prescription Monitoring Program Center of Excellence at Brandeis Notes from the Field 2.6 Drug-Related Deaths in Virginia: Medical Examiner Use of PMP Data http://www.pmpexcellence.org/sites/all/pdfs/va_med_examiner_NFF_12_9_11_rev.pdf.

⁸ Roman PM, Abraham AJ, Knudsen HK. Using medication-assisted treatment for substance use disorders: evidence of barriers and facilitators of implementation *Addict Behav.* 2011 Jun;36(6):584-9. (page 587).

⁹ Maryland (Title 21, Subtitle 2A) § 21-2A-06: "(b) The Program shall disclose prescription monitoring data, in accordance with regulations adopted by the Secretary, to: . . . (5) A rehabilitation program under a health occupations board, on issuance of an administrative subpoena Maryland Senate Bill Page 13 line 30 linked to May 24, 2012 <http://mlis.state.md.us/2011rs/bills/sb/sb0883t.pdf>

¹⁰ Indiana (Title 35, Article 48, Chapter 7) § 35-48-7-11.1: "(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons: . . . (8) A substance abuse assistance program for a licensed health care provider who: (A) has prescriptive authority under IC 25; and (B) is participating in the assistance program

¹¹ North Dakota (Title 19, Chapter 19-03.5) § 19-03.5.03: "3. Unless disclosure is prohibited by law, the board may provide data in the central repository to: . . . j. A licensed addiction counselor for the purpose of providing services for a licensed treatment program in this state

¹² Utah CONTROLLED SUBSTANCE DATABASE ACT 58-376-301. 2. Access to database (i) a mental health therapist, if: (i) the information relates to a patient who is: (A) enrolled in a licensed substance abuse treatment program; and (B) receiving treatment from, or under the direction

identify patients who have ongoing prescription drug access through doctor shopping behavior, which would be valuable clinically whether or not the treatment provider was able to prescribe medications. In the state of Pennsylvania for instance, prescribers are not allowed to access the database at all.¹⁴

Additionally, state laws vary in the extent to which they suggest, mandate, or incentivize consultation with their database. Delaware, which recently established its PDMP, requires prescribers to consult the PDMP report when they suspect a patient is seeking prescription drugs for reasons other than treatment of a medical condition and to consider the report in deciding whether the prescription is necessary.¹⁵ However, in Illinois, the law specifically relieves providers from having to consult the database (“Nothing in this Act or Illinois law shall be construed to require a prescriber or dispenser to make use of this inquiry system.”),¹⁶ and Georgia gives prescribers immunity from prosecution regardless of whether they consult the database.¹⁷

Ultimately, all prescribers, including doctors, dentists, physicians assistants, and nurse practitioners, must increase their use of PDMPs in order for the healthcare system to fully take advantage of their capabilities.

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

¹³ Colorado (Title 12, Article 22, Part 7) § 12-22-705: “(3) The program is available for query only to the following persons or groups of persons: ... (c) Practitioners engaged in a legitimate program to monitor a patient’s controlled substance abuse

¹⁴ Title 28 PA Consolidated Statute, Chapter 25, Subchapter A, Section 25.131 available at <http://www.pacode.com/secure/data/028/chapter25/chap25use.htm#25.131>. See also <http://www.attorneygeneral.gov/drugs.aspx?id=5946>

¹⁵ § 4798. The Delaware Prescription Monitoring Program [Effective upon provision of funding, see 77 Del. Laws, c. 396, § 3] <http://delcode.delaware.gov/title16/c047/sc07/index.shtml>

¹⁶ CRIMINAL OFFENSES (720 ILCS 570/) Illinois Controlled Substances Act <http://www.ilga.gov/legislation/ilcs/ilcs5.asp?ActID=1941&ChapterID=53>

¹⁷ Chapter 13. Controlled Substances Article 2. Regulation of Controlled Substances Part 2. Controlled Substances Prescription Monitoring O.C.G.A. § 16-13-63 ***TITLE 16. CRIMES AND OFFENSES CHAPTER 13. CONTROLLED SUBSTANCES ARTICLE 2. REGULATION OF CONTROLLED SUBSTANCES

PART 2. ELECTRONIC DATA BASE OF PRESCRIPTION INFORMATION O.C.G.A. § 16-13-63 (2012) § 16-13-63. Liability Nothing in this part shall require a dispenser or prescriber to obtain information about a patient from the program established pursuant to this part. A dispenser or prescriber shall not have a duty and shall not be held civilly liable for damages to any person in any civil or administrative action or criminally responsible for injury, death, or loss to person or property on the basis that the dispenser or prescriber did or did not seek or obtain information from the electronic data base established pursuant to Code Section 16-13-57. HISTORY: Code 1981, § 16-13-63, enacted by Ga. L. 2011, p. 659, § 2/SB 36

Real- or near-real-time collection and reporting of prescription drug data

Prescriptions are expected to be reported to Oklahoma's PDMP in real time (defined as within 5 minutes of being delivered to the ultimate user or his designee).¹⁸ It is too soon to tell what effect the real-time availability will have on prescription drug abuse, but it may reduce a barrier to access for health care providers who may have been reluctant to use the PDMP in the past because of concerns that the data were not current. Additionally, in trying to identify patients with recent or current doctor and pharmacy shopping behavior (both of which are important), having real-time data enhances the likelihood that a physician can identify a pattern of behavior. Thus, real-time data have the potential to reduce doctor shopping, and Oklahoma may provide an example for other states to follow.

Unsolicited reporting of patients' prescription drug use information to prescribers and pharmacists

Generally, in order to access the content in a PDMP, most systems require practitioners to request information from the database. However, PDMPs can help a prescriber identify an individual who may be "doctor shopping" or visiting multiple prescribers in order to feed a prescription drug problem by sending out an "unsolicited report" on patients identified as "at risk" based on automated algorithms that evaluate their prescription history. From its inception, the Nevada PDMP instituted unsolicited reporting, and that approach has become a model for states interested in implementing this method.¹⁹ Nevada's PDMP sends an unsolicited report to a prescriber when a patient exceeds the pre-established threshold for the number of providers and pharmacies visited within a given time period.

When unsolicited reporting is used, prescriber behavior changes. For example, the PMP Center of Excellence at Brandeis University, a Bureau of Justice Assistance (BJA)-funded program, conducted an analysis of Wyoming's PDMP, in which prescribers and pharmacists received unsolicited reports concerning potential doctor shopping behavior. The analysis found that receipt of unsolicited reports increased the frequency with which practitioners solicited reports from the PDMP, suggesting that unsolicited reporting raises awareness about the database and its usefulness to providers. Over time, fewer unsolicited reports were generated, because fewer

¹⁸ Prescription Monitoring Program Center of Excellence at Brandeis Notes from the Field 3.1 Real Time Reporting: Oklahoma's Pioneering PMP http://www.pmpexcellence.org/sites/all/pdfs/ok_real_time_data_nff_11912.pdf

¹⁹ Prescription Monitoring Program Center of Excellence at Brandeis, Notes from the Field 2.5 Nevada's Proactive PMP: The Impact of Unsolicited Reports http://www.pmpexcellence.org/sites/all/pdfs/nevada_nff_10_26_11.pdf.

patients triggered the alert algorithm, suggesting that unsolicited reports activate PDMP use and functionality for providers.²⁰

Interstate data sharing/harmonization and interoperability of data across states

Data from Kentucky suggest the utility of interstate data sharing by PDMPs. Of the out-of-state prescriptions filled in Kentucky in 2005, Ohio had 23 percent of its prescriptions filled in Kentucky; Tennessee, Indiana, and West Virginia each had between 10 and 16 percent filled in Kentucky; and Florida had 5 percent.²¹ By 2009, prescriptions from Indiana rose to over 20 percent; 2.3 percent of prescriptions from Florida were still being filled; and the other states had roughly maintained their percentages. These figures suggest it would be useful for practitioners to be aware of the extent their residents obtain and fill prescriptions in other states. Without the ability for states to exchange information, patients in areas bordering other states easily can cross state lines to avoid detection by algorithms for doctor shopping.

Common metrics are needed for such exchanges. BJA, the Office of the National Coordinator for Health Information Technology (ONC) at the Department of Health and Human Services (HHS), and private entities such as the National Association of Boards of Pharmacy (NABP) and the Alliance of States with Prescription Monitoring Programs have been working on architecture and standards to allow the interoperability needed for interstate data sharing. Recommendations of a PDMP workgroup involving representatives from ONC, HHS's Substance Abuse and Mental Health Services Administration and Centers for Disease Control and Prevention, ONDCP, NABP, state PDMP administrators, vendors, pharmacy chains, providers, and electronic health record keepers, which will address a number of these interoperability issues including interstate data sharing, are expected later this year.

In addition to the data being shareable, it is essential that practitioners be able to access the prescription information from states in which they are not licensed. At least one research group acknowledges a problem with patients leaving states with PDMPs to acquire prescriptions in states lacking PDMPs.²² Although great strides have been made at the state level in establishing authority for PDMPs, more states need to engage in interoperability and data sharing.

Although the practices discussed above point to the promise and, in some cases, the utility of PDMPs, it must be noted that some evaluations of PDMP effectiveness have suggested that

²⁰ PMP Center of Excellence, "Trends in Wyoming PMP prescription history reporting: evidence for a decrease in doctor shopping?" 2010. http://www.pmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf

²¹ Kentucky Cabinet for Health and Family Services' Independent Evaluation of the Impact and Effectiveness of the Kentucky All Schedule Prescription Electronic Reporting Program (KASPER) <http://www.chfs.ky.gov/NR/rdonlyres/24493B2F-B1A1-4399-89AD-1625953BA1D43/0/KASPEREvaluationFinalReport10152010.pdf>

²² David F. Baehren, MD, Catherine A. Marco, MD, Dana E. Droz, RPh, JD, Sameer Sinha, BS, E. Megan Callan, BA, Peter Akpunonu, BS A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors *Annals of Emergency Medicine* Volume 56, July, 2012.

PDMPs do not affect critical outcomes; for example, one study comparing states with and without PDMPs saw changes in Schedule II medicine prescribing but not overdoses.²³ It is imperative to note that many factors can affect the outcomes of this type of naturalistic policy study, and without a randomized controlled trial comparing states matched on major variables, any PDMP study must be viewed as adding to the research base but not definitive. New research shows that relative to states without PDMPs, states with PDMPs mitigate the prevalence of prescription opioid abuse and misuse in both the general population and among those in opioid treatment programs.²⁴ Given the limitations discussed above, conflicting evidence concerning the efficacy of PDMPs is expected. Improving PDMP quality, harmonization, and interoperability and, in some cases, establishing PDMPs authorized by newly-passed state laws will ensure they provide maximal utility as surveillance and public health clinical decision support tools, augmenting their original use as enforcement tools.

- 2. As we have learned, 70% of non-medical prescription drug users get those drugs from family or friends. I understand that a number of communities have created “take-back” days in which medicines are safely collected by law enforcement. Can you explain what entities (for example long term care facilities) can currently take these drugs back and dispose of them?**

Passage of the Secure and Responsible Drug Disposal Act in 2010 requires the Drug Enforcement Administration (DEA) to develop regulations to facilitate the safe and effective disposal of prescription drugs. Until the DEA issues these regulations, which are in development, the only people who legally can receive leftover prescription medicines from patients are DEA agents and law enforcement officers who are engaged in the performance of state or local law relating to controlled substances and are duly authorized to possess controlled substances in the course of their official duties.

In its advance notice of proposed rulemaking, DEA stated that long-term care facilities, which provide ongoing care, including mental health care, to individuals who sometimes require large amounts of controlled medications, often end up with large amounts of unused medicines (for example, if a patient dies). The Act authorizes long-term care facilities to dispose of controlled substances on behalf of a person who resides or has resided at a long-term facility in accordance with regulations to be promulgated by the DEA.

²³ Paulozzi LJ, Kilbourne EM, Desai HA. Prescription monitoring programs and death rates from drug overdose. *Pain Med.* 2011 May;12(5):747-54.

²⁴ Reifler LM, Droz D, Bailey JE, Schnoll SH, Fant R, Dart RC, Bucher Bartelson B. Do prescription monitoring programs impact state trends in opioid abuse/misuse? *Pain Medicine* 2012; 13: 434-442.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
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Majority (202) 225-2927
Minority (202) 226-3641

March 26, 2012

The Honorable Pam Bondi
Attorney General
State of Florida
The Capitol PL-01
Tallahassee, FL 32399-1050

Dear Attorney General Bondi,

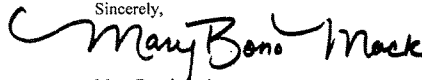
Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Thursday, March 1, 2012, to testify at the hearing entitled "Prescription Drug Diversion: Combating the Scourge."

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 respond to these questions by the close of business on Monday, April 9, 2012. Your responses should be e-mailed to the Legislative Clerk, in Word or PDF format, at Kirby.Howard@mail.house.gov.

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: G.K. Butterfield, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade

Attachment

The Honorable Mary Bono Mack

1. What lessons can the Federal government learn from Florida's recently passed laws that have so quickly yielded results in identifying prescription drug diversion and consequent enforcement efforts?

Florida finally began to turn the corner on this epidemic by the emergence of broad, bi-partisan support in the legislature, combined with Cabinet-level leadership, and a broad spectrum of grassroots support that worked together to spur adoption over a three year period (2009-2011) of important new anti-diversion tools and programs such as administrative oversight of pain management clinics, a prohibition of doctors dispensing the most abused narcotics, tough new criminal penalties for overprescribing doctors, rogue pharmacies, and pill mill operators, and the creation of Regional Strike Forces. These new initiatives were developed based on informed input from subject matter experts in various fields (health care, drug prevention and treatment, and law enforcement) coping with prescription drug abuse and diversion.

2. Florida has seen incredible success in a short time period reducing drug diversion, particularly evident in the statistic of the number of the top 100 oxycodone dispensing physicians residing in Florida, a number that fell from 98 to 13. While this drop is tremendous, 13 of the top dispensing physicians in one state still appears disproportionate. How do you scrutinize those who are the largest prescribers?

According to the DEA, in 2011, 13 of the top oxycodone purchasers were physicians in Florida. As a result of HB 7095, physicians can no longer dispense the most abused narcotics. The only exceptions for dispensing are: FDA-approved clinical trials, 14-day supply following surgery, licensed methadone clinics, hospice, and the Florida Department of Corrections. Any physicians who dispense Schedule I and II drugs and do not fall under these exceptions are in violation of the law and will be subject to penalties. If physicians are practicing in a pain clinic, the facility will be inspected and at such times his/her medical records will be reviewed to determine whether controlled substances have been prescribed in such a manner that complies with the standard of care. If the drugs were not prescribed within the standard care, the physician will be prosecuted by the Florida Department of Health and the Board of Medicine. Criminal action may also be brought against the physician and the clinic owners.

Is there a logical explanation why so many of the top dispensing physicians remain in Florida?

Until recently, there has been little regulatory oversight of pain clinics in Florida. That combined with a transient population made Florida a destination for "drug tourists." We expect that number to continue to decline going forward.

3. Are you concerned that your success in preventing drug diversion could create new problems by moving the problem users from on drug to another? For instance, have you seen any uptick in the use of street drugs? If so, has Florida undertaken concurrent efforts to combat that front?

Yes, we are concerned that our successes in preventing prescription drug diversion could create new problems by moving users to illicit drugs. The Florida Department of Law Enforcement's Office of Statewide Intelligence continues to track heroin seizures as well as arrests for meth and methamphetamine clandestine lab seizures. This statistical data is collected and maintained in response to the success of the strike forces' pill mill and opioid crack down. The creation of Regional Drug Enforcement Strike Forces aids in our efforts by not solely focusing of prescription drug diversion, but on all forms of illicit drugs, to include heroin and meth.

It is also important to note that Florida's Strike Forces are also reinforcing the importance of having prevention as the linchpin of a comprehensive state-wide anti-prescription drug diversion strategy. The seven regional Strike Forces are supporting demand reduction policies being implemented by local community coalitions. Each of the locally led Strike Forces must decide how to best combat the problem of drug diversion and abuse. Since each region in Florida has its own drug threat profile, each Strike Force will adapt the tenets of our statewide *Roadmap* to the unique needs of their area.

4. You described Florida's balance approach of attacking both the supply side and the demand side of the oxycodone epidemic. You describe the supply side being driven by "a flood of diverted pharmaceuticals." What is the primary source of diversion in the supply chain?

We believe the greatest source of diversion is from the "doctor shopping" patient. The further removed from the manufacturer, the less integrity there is in the pharmaceutical supply chain, and there is a much greater chance for diversion. The next greatest source is between the doctor and patient and between patient and pharmacist.

5. You described how Florida defined pill mills in a manner that includes those conspiring to prescribe and dispense controlled substances "outside the scope of prevailing standards of medical practice". Can you describe what those standards are and what is considered "outside the scope of prevailing standards of medical practice?"

Florida's standard of care for prescribing controlled substance for the treatment of chronic non-malignant pain can be found in Section 456.42(3), Florida Statutes. There are also standards, such as requiring urine drug testing under certain circumstances that are required by the standard of care as set forth in general law but not codified in statute or rule.

Are State medical boards empowered to suspend licenses upon discovering such standards violations?

The Florida Department of Health may issue emergency suspension or restriction orders on an expedited basis against physicians who violate the standards of care when prescribing controlled substance for the treatment of chronic non-malignant pain if the Department can demonstrate to a court that such actions constitute an immediate threat or danger to the health, safety and welfare of the public. After an emergency suspension or restriction order has been issued by the Department of Health, the Boards of Medicine and Osteopathic Medicine may suspend the physician's license for an extended period of time or permanently revoke the license in accordance with due process of law.

Do you recommend other States consider similar definitions? Yes.

6. As part of its recent efforts, Florida required all pharmacies dispensing schedule II and schedule III drugs to be re-permitted with the State. Were any pharmacies denied a permit after the review?

No, Florida's re-permitting process will not begin until July 1, 2012. The legislation passed last year (HB 7095) provided the Florida Department of Health a year to prepare for the new permitting process. HB 7095 strengthens the community pharmacy permitting process by requiring more disclosure and transparency throughout the process. The new requirements include:

- Mandatory on-site inspections
- An applicant must disclose financial interests they have had in other pharmacies within the last 5 years
 - If the pharmacy or pharmacies have closed
 - If the permit has been relinquished, suspended or revoked and;
 - Applicant must explain the reasons for those actions

DOH investigators will conduct these mandatory on-site inspections. As of January 2012, the Department of Health had 113 field investigators working out of 12 field offices throughout the state. Of these 113 investigators, 19 are now assigned to regularly perform pharmacy inspections.

In order to dispense controlled substances listed in Schedule II or Schedule III, on or after July 1, 2012, a community pharmacy applicant must be permitted pursuant to chapter 465, Florida Statutes. An application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The Board of Pharmacy will then review the applicant's policies and procedures, and may deny a permit if those policies and procedures are deemed insufficient by the Board to reasonably prevent such dispensing.

HB 7095 also improves the grounds by which the Board of Pharmacy can deny a permit, to include criminal history checks and whether the applicant has previously complied with pharmacy regulations. The following circumstances will compel the Board of Pharmacy to deny an applicant their community pharmacy permit:

- Has the applicant been convicted of or entered a guilty or no contest plea to a felony under certain federal Medicare and Medicaid laws, Florida Statutes, Chapters 409, 817, or 893, or for a similar offense in any other jurisdiction since July 1, 2009
- Has the applicant been terminated from the Florida Medicaid program; this presumption is overcome however if the applicant has been in good standing with the Florida Medicaid program for the past 5 years;
- Has the applicant been terminated from any other state's Medicaid program; this presumption is overcome however if the applicant has been in good standing for the past 5 years and their termination occurred at least 20 years prior;
- Is the applicant listed on the federal Health and Human Services list of excluded individuals and entities; or

- Has the applicant violated any provision of Florida Statutes, Chapters 465, 499, or certain federal drug laws.

HB 7095 creates a new requirement for maintaining a community pharmacy permit: the designated prescription department manager - which each pharmacy must have – must now maintain all pharmacy drug records required by state or federal law, and the manager must also ensure compliance with pharmacy practice laws and rules. The department manager must also “ensure the security of the prescription department, and must notify the Board of Pharmacy of any theft or significant loss of a controlled substance within one business day.” Furthermore a designated prescription department manager can only manage one pharmacy location, unless pre-approved by the Board of Pharmacy.

Under HB 7095, an already established pharmacy must go through the re-permitting process on or before January 1, 2012, if the owner seeks to continue to dispense Schedule II and III substances. This re-permitting process includes the same factors and steps as the permitting process.

7. A March 7, 2012, Wall Street Journal article (“New Front Opens in Florida Poll War”) indicated the demand for oxycodone and other painkiller drugs previously supplied by the pill mills has shifted to pharmacies. How is your State working with pharmacies to identify illegitimate prescriptions and drug-seeking consumers? How do you conduct oversight of Florida pharmacies to ensure only legitimate patients are able to fill their prescriptions for opioids?

Yes, DEA and Florida Department of Health (DOH) investigators are now analyzing a range of information pertaining to prospective pharmacy owners, including – starting 1 July 2012 - instituting corporate background checks on both current licensees and applicants. In short, the full implementation of HB 7095 will prevent a repetition of criminals and their pill mill conspirators establishing illegitimate community pharmacy operations throughout Florida. Furthermore, Florida’s newly operational Prescription Drug Monitoring Program (PDMP) will greatly aid Florida’s pharmacies fill only legitimate prescriptions.

But while queries to the PDMP help fight “doctor-shopper” users, vigilance regarding Florida’s pharmacy operators also remains of great importance. We recognize that pill mill operators are an agile and adaptive foe motivated by intense greed; indeed, there is growing concern here that pill mill operators are now attempting to set-up “rogue pharmacies” to by-pass HB 7095 rules. Indeed, this fear seems to be justified given that the Drug Enforcement Administration (DEA) recently reported that half of the nation’s new pharmacy applications were in Florida. Fortunately, a rise in permit applications does not directly correlate with an increase in new permits being issued.

A rogue pharmacy does not follow federal and state laws and regulations, contains a pharmacist and/or staff who knowingly engage in fraud by dispensing controlled substances they should reasonably believe to have no legitimate medical purpose based on a totality of circumstances to include, but not be limited to: the frequency of visits by a particular patient, the source and nature of the script, and the medically unbelievable amounts of drugs in scripts routinely provided. A rogue pharmacy will often feature direct collusion between a pharmacist and prescribing doctor, going so far as to attempt to share the same location or to be located within the same strip mall.

8. You concluded your testimony with a description of the risk of Florida's citizens and its economy. Has the economic cost of the epidemic been calculated?

There are currently no specific cost estimates on the impact of the prescription drug abuse epidemic in Florida. However, numerous studies have been published in the U.S regarding the negative economic costs exacted by prescription drug abuse. For e.g., see: <http://mbcc.mt.gov/PlanProj/Projects/PDMP/Prescription%20Drug%20Abuse%2020110629.pdf> and <http://www.justice.gov/ndic/pubs44/44731/44731p.pdf>.

Given the size of Florida's population, the scope of its drug abuse problems and the attendant public safety and health costs associated with dealing with the negative consequences of drug abuse, as well as the loss in economic productivity, it is not an exaggeration to assert that prescription drug abuse alone costs Florida hundreds of millions of dollars per year.

The Honorable Edolphus Towns

1. Do you believe the Florida model for combating prescription drug diversion can be a model for the country?

Yes. Out of necessity Florida forged a broad consensus across a diverse spectrum of groups that understands the urgent need for rigorous drug control, prevention and treatment efforts. This consensus in Florida supports and is driven by a science-based approach that seeks to leverage widely accepted best practices in each respective field, such as in community policing, prevention programs, and drug court based treatment programs in order to significantly cut prescription drug diversion and abuse.

2. As of June 2011, 48 states have implemented prescription drug monitoring programs (PDMP) but many of them are underfunded or poorly funded. What is being done in Florida to make sure this program has the resources it needs to succeed?

Given the importance of ensuring that Florida's Prescription Drug Monitoring Program (PDMP) is adequately funded, Florida's law enforcement community volunteered to contribute portions of their forfeiture funds to help subsidize the PDMP. However, it will be the responsibility of the legislatively established PDMP Foundation, a 501(c)(3), non-profit organization incorporated with the Department of State, that will have to raise private funding in order to sustain its operations.

KENTUCKY ATTORNEY GENERAL JACK CONWAY

March 1, 2012

“Prescription Drug Diversion: Combating the Scourge”

Additional Questions for the Record

The Honorable Mary Bono Mack -

1. **You testified the number of overdose deaths is likely underreported because not all the overdose victims were autopsied. Do you have an estimate of how large the number of overdose deaths in Kentucky could have been last year?**

In 2009, there were 978 prescription overdose deaths in Kentucky; however, only 55 percent of the total statewide accidental death cases were autopsied that year. We believe the number of overdose cases is nearly double the reported figure, and that Kentucky loses well more than 1,000 people a year to prescription overdose.

Kentucky lawmakers are currently considering legislation that I drafted with Governor Steve Beshear and House Speaker Greg Stumbo that includes a provision requiring coroners to report all suspected overdose deaths. This would provide the State Medical Examiner’s Office and Kentucky Office of Drug Control Policy a more accurate assessment of the overdose deaths in the Commonwealth.

2. **Can you estimate the economic cost to Kentucky resulting from prescription drug diversion and subsequent prescription drug misuse?**

There have been no studies in Kentucky that identify the overall economic impact of prescription drug diversion and misuse. While prescription drug abuse and overdoses have skyrocketed in the Commonwealth, funding to fight this scourge has remained stagnant. According to an analysis by *The Courier-Journal*, the roughly \$32 million Kentucky spends on drug treatment hasn’t changed in a decade.

Crimes fueled by prescription pill addiction have also strained the resources of law enforcement, prosecutors and jails. Substance abuse expenditures by the Kentucky Department of Corrections increased seven-fold from 2005 to 2011, rising from approximately \$880,000 to more than \$6.4 million last year.

Nationally, a 2006 study by the University of Washington puts the economic cost of nonmedical use of prescription opioids in the U.S. at more than \$53 billion annually. The study finds that 79 percent of the cost, or \$42 billion, was attributable to lost productivity, \$8.2 billion to criminal justice costs, \$2.2 billion to drug abuse treatment and \$944 million to medical complications.

Some believe the cost is even higher. A study by the Coalition Against Insurance Fraud puts the economic toll to health insurers alone at up to \$72.5 billion a year. This includes up to \$24.9 billion annually for private insurers and for the cost of treating patients who develop serious medical problems from abusing addictive narcotics.

3. You described your State's law enforcement efforts and the legislation you are still working to enact. How have you engaged the supply chain participants, such as pharmacies, clinics and doctors in your efforts? How would their involvement in the anti-diversion effort assist you?

In 2011, I hosted a series of roundtable discussions with physicians across Kentucky to discuss the use of our prescription drug monitoring program, the Kentucky All Schedule Prescription Electronic Reporting system (KASPER). Input from the medical community is vital as we work to improve KASPER and increase the number of physicians who utilize this important tool. Currently, only about 25 percent of prescribers in Kentucky use the KASPER system. We continue to encourage doctors to be part of the solution, instead of being part of the problem.

In legislation we have proposed to combat prescription drug diversion and abuse, KASPER will be moved to the Office of the Attorney General giving law enforcement greater access to the data.

The legislation will expand the reach of Kentucky's prescription monitoring program by requiring all prescription providers to register and use the system under circumstances outlined by their licensure boards. This will allow better information sharing among licensure boards and investigators, as well as regular data review of KASPER reports to root out unusually high prescribing rates for further investigation.

Additionally, we are trying to set parameters for the Kentucky Board of Medical Licensure's issuance of licenses to doctors who overprescribe in other states. Overprescribing physicians from other states should be prohibited from obtaining a medical license in Kentucky.

The legislation includes a prohibition on a practitioner dispensing greater than a 48-hour supply of a Schedule II controlled substance, a Schedule III controlled substance containing Hydrocodone, or a controlled substance containing Alprazolam, clonazepam

or diazepam, unless the dispensing is done as part of a narcotic treatment program licensed by the Kentucky Cabinet for Health and Family Services.

It will require pain management clinics to be owned by a licensed medical practitioner. This would eliminate the growing problem of unaccountable operators of 'pill mills' who have little or no medical proficiency but are dispensing controlled substances.

The legislation will also require medical licensure boards to investigate prescribing complaints immediately and issue a report within 120 days determining whether appropriate medical practices have been followed.

Additionally, I sit on the KASPER Advisory Board created by Governor Beshear, which discusses ways to improve the KASPER system. This task force includes physicians, dentists, pharmacists, and members of the law enforcement community.

One of our key partners in the statewide public education and awareness campaign I launched in 2010 is the Kentucky Pharmacists Association (KPhA). Pharmacists often participate in our Keep Kentucky Kids Safe assemblies and KPhA is a key sponsor in our annual student prescription drug abuse prevention PSA contest. Additionally, KPhA has made printable posters available to pharmacies statewide to alert the public to the importance of monitoring and securing prescriptions in the home.

4. **Have you seen patients with legitimate medical needs in Kentucky find it difficult to obtain pharmaceuticals as a result of the State's efforts to crack down on prescription drug diversion?**

Not to my knowledge.

5. **A physician in Los Angeles wrote more than 27,000 prescriptions over a 3-year period from 2007 to 2010. The DEA revoked her DEA license and the doctor surrendered her medical license to the California State Medical Board in 2010. In March 2012, this physician was charged with murder in the drug deaths of three of her patients. How can States and the Federal government ensure that unscrupulous physicians like this one, who prescribe drugs with no medical purpose, are charged and prosecuted for their actions?**

One of the most important ways to combat unscrupulous physicians like this one is to share information with law enforcement agencies and communicate effectively with the licensure boards. It is also important for states to be able to share prescription monitoring data with each other. Kentucky borders seven states and it is very easy for

addicts to drive across the state line to get a prescription from an unscrupulous physician in an adjoining state. Therefore, our law enforcement agents need to have access to data from other states. Adequate funding for aggressive law enforcement investigations is also essential.

Legislation we have proposed requests that law enforcement have increased access to electronic monitoring data so that we can spot trends and unscrupulous physicians.

The Honorable Edolphus Towns –

- 1. Would you mind telling us a little bit about the prescription drug abuse awareness and prevention program that you are coordinating? What progress have you made and what challenges have you faced?**

After launching the state's first and only statewide Prescription Drug Diversion Task Force, I partnered with state and local law enforcement agencies and two mothers from Morehead, Kentucky, who had lost daughters to prescription drug overdoses to create a program to educate Kentucky kids about the dangers of prescription drug abuse. We launched the Keep Kentucky Kids Safe program in partnership with the Kentucky Office of Drug Control Policy, Kentucky Pharmacists Association, National Association of Drug Diversion Investigators, Operation UNITE and concerned parents, Dr. Karen Shay and Lynn Kissick, in September of 2010.

Through school assemblies, an annual student PSA competition, informational website, printable posters and an upcoming billboard campaign, the Keep Kentucky Kids Safe program is opening students' eyes to the deadly consequences of abusing prescription pills. To date, we've spoken to more than 10,000 students in 20 different middle and high schools across Kentucky.

I am proud to say that we launched this important initiative despite unprecedented budget cuts. With the help of our partners and the courageous parents who share their stories of how prescription drug abuse has shattered their families, we are making a difference.

I am moved by the letters, emails and phone calls we have received from parents, students and concerned citizens applauding our efforts and asking if they can join our effort. Students in Boyd County, Kentucky, even launched a letter writing campaign to Florida newspapers to urge the state to implement a prescription drug monitoring program.

After reading about our efforts, North Carolina resident Frankie Andrews, who lost two nephews to prescription drug overdoses, called my office to find out how he could start a similar program in his state. On March 24, 2012, North Carolina Attorney General Roy Cooper launched a program modeled after Keep Kentucky Kids Safe and is sponsoring a statewide video PSA contest for students in his state.

2. Do you believe that promoting effective treatment for drug abusers is an important part of the equation for states that are fighting prescription drug abuse?

Promoting and providing effective treatment for drug abusers is a very important tool in fighting prescription drug abuse. I sit on the Recovery Kentucky Task Force, which partners with the Kentucky Housing Corporation and the Kentucky Department of Corrections to find funding for adequate drug treatment programs for drug addicts. These and other efforts are essential to assisting people in overcoming their addictions.

The University of Kentucky Center on Drug and Alcohol Research recently released its first-ever Recovery Center Outcome Study which finds for every dollar spent on recovery services, there was a \$2.92 return in avoided costs. Additionally, there was a 93 percent reduction in victim cost of crimes and 94 percent reduction in incarceration for individuals involved in the study.

3. What has the Commonwealth of Kentucky done to prevent “doctor shopping,” and has it sought to work at all with private insurers?

The most important tool the Commonwealth has implemented to prevent doctor shopping is the effective use of its prescription drug monitoring program, KASPER. Law enforcement agents throughout the Commonwealth have the ability to search the system when they have a bona fide specific investigation to determine if an individual has engaged in this illegal conduct.

We are also increasing investigations of overprescribing physicians and those who engage in doctor shopping through my statewide Prescription Drug Diversion Task Force.

As for working with private insurers, the majority of the so-called “pill mills” we encounter are cash-only operations and therefore private insurers are not involved.

In proposed legislation, we have requested that law enforcement have greater access to KASPER data to spot trends and unscrupulous physicians.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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March 26, 2012

Mr. Aaron E. Haslam
Senior Assistant Attorney General
State of Ohio Attorney General
30 E. Broad St., 14th Floor
Columbus, OH 43215

Dear Mr. Haslam,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Thursday, March 1, 2012, to testify at the hearing entitled "Prescription Drug Diversion: Combating the Scourge."

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 respond to these questions by the close of business on Monday, April 9, 2012. Your responses should be e-mailed to the Legislative Clerk, in Word or PDF format, at Kirby.Howard@mail.house.gov.

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: G.K. Butterfield, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade

Response to Additional Questions for the Record

Answers to the **Honorable Chairman Mary Bono Mack's** questions:

- 1. What lessons can the Federal government learn from Ohio's recently passed laws that have so quickly yielded results in identifying prescription drug diversion and consequent enforcement efforts?**

Answer:

Ohio's House Bill 93 provides a consistent and uniform set of rules and regulations for law enforcement, regulators, and legitimate providers. What the federal government can learn from Ohio's House Bill 93 is that common sense rules and regulations will assist legitimate prescribers and will curtail the abuse and trafficking of prescription drugs by bad prescribers. Some examples of the regulations under House Bill 93 which have been effective include: a requirement that pain clinics be physician or hospital owned; persons convicted of drug crimes and theft cannot be employees or owners of a pain clinic; Ohio's PDMP must be accessed in order to begin prescribing pain narcotics and annually thereafter; limits the amount of pain medication that can be personally furnished by a prescriber in most circumstances; requires that both the medical and pharmacy board issue licenses and regulate the pain management clinic. It is also worth mentioning that House Bill 93 now mandates physicians to review the PDMP in certain circumstances and strongly suggests its review in others.

- 2. In your testimony, you stated the single biggest action that can be taken to restrict the availability of prescription drugs is to restrict prescriptions to only those who need them (which suggests the definition of "need" be revisited) and only in the amount needed. The graph you included with your testimony demonstrated the tremendous increase in the amount of painkillers produced and dispensed; it also indicated that doctors now prescribe multiple times more painkillers today than just a decade ago. How are you working with the medical community regarding the use of opioids to treat pain?**

Answer:

Ohio Attorney General Mike DeWine is working with Ohio Governor John Kasich and members of the medical community including the Ohio State Pharmacy Board, the Ohio State Medical Board, the Ohio State Medical Association, the Ohio State Pharmacy Association, and Ohio's Institutions of Medical Education to provide training and education opportunities for prescribers and dispensers. The training and education outreach is accomplished through continuing medical education, seminars, and partnerships between professional organizations and regulatory agencies. In addition, Ohio Attorney General along with the aforementioned agencies and entities are re-evaluating the guidelines and standards including the research around the use of opioids for the long term treatment of chronic pain. In short, Ohio is re-evaluating how it treats long term chronic pain.

- 3. You described pill mills and bad prescribers as a minority of all prescribers but attributed to them the responsibility for the majority of the prescription drug abuse problem. How difficult is it to detect and shut down these operations, particularly if they are a low volume pill mill?**

Answer:

It is difficult to detect pill mills and extremely difficult to detect low volume pill mills. Detection grows more difficult as the bad prescribers learn from their predecessor's mistakes and law enforcement techniques are revealed during prosecutions. However, technology allows us to bridge the gap along with new techniques. In addition, education, training and outreach has Ohio's citizens a partner to law enforcement in detecting these bad prescribers to assist us in protecting Ohio's families.

- 4. You describe the difficulties posed to State PDMP programs where prescription tourism exists because boarder States do not currently share prescription information. What are the obstacles to States sharing PDMP information?**

Answer:

Some of the primary obstacles include concerns over privacy. States have different rules and regulations about who may access the information. In addition, states have rules and regulations about how and when that information can be accessed. States will face technological integration issues as well as funding challenges.

- 5. Have you seen patients with legitimate medical needs in Ohio find it difficult to obtain pharmaceuticals as a result of the State's efforts to crack down on prescription drug diversion?**

Answer:

Even after Ohio's crackdown on pharmaceutical diversion, I do not believe it is any more difficult to obtain legitimate pain medications than what it was before Ohio's crackdown. Law enforcement across Ohio has heard anecdotal stories claiming that legitimate patients are having difficulty obtaining legitimate pain medications. We have been unable to confirm any of these anecdotal stories. The difficult reality is that in rural Ohio it has always been difficult to find legitimate pain management physicians. Unless you live in a metropolitan area of Ohio it is difficult to find any legitimate pain management treatment. Since much of Ohio is still very rural it is very difficult to obtain legitimate pain treatment in those areas of Ohio. Finally, most of rural Ohio has been hit hard by the illegitimate pharmaceutical diversion problem.

- 6. A physician in Los Angeles wrote more than 27,000 prescriptions over a 3-year period from 2007 to 2010. The DEA revoked her DEA license and the doctor surrendered her medical license to the California State Medical Board in 2010. In March 2012, this physician was charged with murder in the drug deaths of three of her patients. How can State and Federal government ensure that unscrupulous physicians like this one, who prescribe drugs with no medical purpose, are charged and prosecuted for their actions?**

Answer:

Prosecutors and law enforcement need resources to tackle these massive multi-jurisdictional investigations. Investigations of this nature trigger not only local and state law enforcement resources, but law enforcement resources across state lines (nationally), as well as many regulatory agencies. Not only are the investigations highly technical and expensive, the prosecutions are extremely specialized and require particular training and expertise. In response, Ohio Attorney General Mike DeWine formed a special unit of prosecutors, who travel around the state of Ohio to assist in investigations and lead prosecutions of these unscrupulous prescribers and drug traveling organizations. This kind of specialized unit is vital to the effective prosecution of these massive cases. In addition, Ohio has been a leader in working with Federal, State and local law enforcement agencies and regulatory agencies to coordinate, cooperate, and share information around

these highly technical and specialized investigations and prosecutions. In order to be successful in a nationwide fight against this scourge, we must do a better job at the Federal, State and local levels of cooperating and sharing information, techniques, and community efforts to tackle this silent killer.



U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

April 23, 2013

The Honorable Lee Terry
Chairman
Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph Rannazzisi, Deputy Assistant Administrator of the Drug Enforcement Administration, before the Subcommittee on March 1, 2012, at a hearing entitled "Prescription Drug Diversion: Combatting the Scourge." 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 that reads "Peter J. Kadzik".

Peter J. Kadzik
Principal Deputy Assistant Attorney General

Enclosure

cc: The Honorable Jan Schakowsky
Ranking Member

**Responses to Questions for the Record
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration**

**Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce
U.S. House of Representatives**

**“Prescription Drug Diversion: Combating the Scourge”
March 1, 2012**

The Honorable Mary Bono Mack

- 1. A number of States have had great success in identifying and stymying drug diversion. Are you concerned that these crackdown efforts, which will make prescription drugs harder to find on the black market, will create new problems? Will it move abusers from one type of drug to another, legal or otherwise?**

Response:

Illicit demand is the primary factor driving the diversion of controlled substance pharmaceutical drugs. Pharmaceutical drugs that contain controlled substances can be addictive. If a person becomes addicted, he or she may seek out these substances to support the addiction. If the original drug source is no longer available, for example, because a practitioner will not prescribe the substance or the individual can no longer pay for the drug, abusers may resort to other methods of acquiring the drug. The methods utilized to divert controlled substances vary depending on the sophistication of the individual or organization involved and the degree of accessibility to the drug. There are many methods of diversion, and once one method is foreclosed or unsuccessful, addiction can force abusers to move on to another diversion method. For example, some individuals may seek other practitioners to issue a prescription and others may resort to theft or unlawful purchase without a prescription. Still others may resort to acquiring different drugs that provide a similar, addictive high. In other words, if one particular drug is not available for diversion, abusers may simply abuse a different drug. Law enforcement agencies across the country are reporting to DEA that they are beginning to observe young people who became addicted to opioid prescription drugs yet cannot continue to pay for them and who have therefore turned to heroin—a cheap alternative to prescription opioids.

In addition, some pharmaceutical manufacturers of prescription opioids have developed and marketed “abuse resistant” formulations. While well intentioned, these efforts are useless against those drug abusers and drug seekers who can circumvent this safeguard by simply increasing the amount of drug taken or switching to a different drug to abuse. In another example, law enforcement efforts and the enactment of the Ryan Haight Online Consumer

Protection Act virtually eliminated domestic-based internet distribution operations as a source of diversion by 2009. However, rogue pain clinics quickly emerged as the new source of diversion. The state of Florida enacted legislation to curb the explosion of illegitimate pain clinics and over the past few years, DEA, working with state and local counterparts, has helped to slow the growth of illegitimate pain clinics as a source of diversion through intensified enforcement efforts. In addition, some states have the authority to forward any suspicious prescribing practices after reviewing PDMP data to law enforcement or licensing boards, if warranted.

DEA is concerned with all efforts to divert controlled substances and will continue to focus its resources on preventing diversion regardless of the source or method.

2. **HDMA testified that distributors often report suspicious orders to the DEA based on the Industry Compliance Guidelines, which DEA vetted in advance of publication. When a distributor reports a suspicious order, what does DEA do? How does the agency follow up? How does it investigate? Does the agency audit the ordering pharmacy or dispenser?**

Response:

The suspicious order reporting requirements are set forth in 21 C.F.R. § 1301.74(b), not in the Industry Compliance Guidelines. The regulation states that manufacturers and distributors “shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” This requirement is rooted in the Controlled Substances Act at 21 U.S.C. §§ 823(a)(1), 823(b)(1), 823(d)(1), and 823(e)(1), which provides that manufacturers and distributors must maintain effective controls against the diversion of controlled substances in order for their registrations to be in the public interest. A registration that is inconsistent with the public interest is subject to revocation. 21 U.S.C. § 824(a)(4). As such, every manufacturer and distributor has the responsibility not only to have a system that discloses suspicious orders, but also to report each suspicious order and not to fulfill any suspicious orders unless and until the suspicion is removed. It is important to note that even if a registrant establishes a reliable suspicious order monitoring system, if the registrant ignores the system or fails to follow the procedures outlined by the system, the system is not an effective control against diversion.

DEA reviews suspicious order reports submitted by DEA registrants and will conduct investigations as appropriate. Depending on the facts and circumstances, DEA may also analyze the suspicious order report and compare it to other data such as Automated Reports and Consolidated Ordering System (ARCOS) data (sales/purchase information on select pharmaceutical drugs). If warranted, DEA will utilize all the tools available to it, including voluntary inspections and Administrative Inspection Warrants, to aid investigators in conducting a review of records and a thorough audit of a firm’s pharmaceutical controlled substance transactions.

3. **Your testimony described DEA's efforts to reduce prescription drug diversion, including implementation of enhanced regulatory oversight. How does DEA maintain effective oversight of the 1.4 million DEA registrants authorized to prescribe, distribute, or sell controlled substances? In light of the increased diversion of the legal supply of controlled substances by DEA registrants, would the DEA's oversight effectiveness be improved if the number of DEA registrants was fewer?**

Response:

The Controlled Substances Act requires DEA to register practitioners to dispense controlled substances if they are authorized to dispense controlled substances under the laws of the state in which they practice. DEA may only deny an application if the registration would be inconsistent with the public interest, which is determined upon consideration of five enumerated factors. 21 U.S.C. § 823(f). Each of the five factors pertains to the specific applicant's conduct and does not permit consideration of the number of registrants to be regulated.

Of the 1.4 million registrants, approximately 1.3 million are "practitioners," which means a "physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 21 U.S.C. § 802(21). DEA believes that routine compliance inspections, outreach and education, and the deterrent effect of DEA's enforcement actions combined with state-level licensing and regulatory programs help keep the vast majority of registrants within this category in compliance with their responsibilities under the Controlled Substances Act and its implementing regulations.

Through its Diversion Control Program, DEA has personnel (Diversion Investigators, Special Agents, and Intelligence Research Specialists) positioned across the United States and abroad who are dedicated solely to conducting pharmaceutical and chemical related inspections, investigations, and other related compliance and enforcement activities designed to ensure compliance by all registrants. To support and strengthen DEA's Diversion Control Program, the Administration requested additional provisions through its Fiscal Year 2012 and Fiscal Year 2013 budget submissions to Congress. Congress approved these positions and DEA is moving forward to recruit, hire, and train individuals to fill them. As described in DEA's Statement for the Record, DEA has been expanding the use of Tactical Diversion Squads across the United States. These squads combine the skill sets of Special Agents, Diversion Investigators, and state and local law enforcement officials in a concerted effort to eradicate various schemes designed to divert large quantities of controlled substance pharmaceuticals.

4. **The Committee is considering all options to address the problem of illegally diverted controlled substances, including new on-dose technologies and systems that can monitor controlled substances and help determine how these drugs end up outside of authorized supply channels. We are aware of current technologies, such as nanoencryption and taggants, which can provide an unlimited amount of information on each and every pill,**

which is crucial to tracking the pills because these drugs are rarely found in their original packaging. The information on each pill would enable authorities to know with forensic certainty the authenticity of a product, the origin of its manufacturing location, the authorized wholesaler, and the intended geographical destination. These technologies could also enable law enforcement professionals to effectively and covertly audit supply chain partners and successfully detect where diversion problems exist before they result in criminal consequences. Does the DEA believe this kind of technology would be helpful in monitoring and protecting the supply chain and detecting product?

Response:

DEA is unaware of any studies evaluating the effectiveness of these technologies in monitoring or protecting the drug distribution supply chain.

5. A physician in Los Angeles wrote more than 27,000 prescriptions over a 3-year period from 2007 to 2010. The DEA revoked her DEA license and the doctor surrendered her medical license to the California State Medical Board in 2010. In March 2012, this physician was charged with murder in the drug deaths of three of her patients. How can States and Federal government ensure that unscrupulous physicians like this one, who prescribe drugs with no medical purpose, are charged and prosecuted for their actions?

Response:

DEA's goal is to protect the public health and safety while ensuring an adequate supply of pharmaceutical controlled substances for legitimate medical use. To that end, DEA maintains a robust Diversion Control Program and works diligently to ferret out those registrants who are not in compliance with the Controlled Substances Act and its implementing regulations. DEA works closely with its state and local counterparts to exchange relevant information and intelligence related to the diversion of controlled substance pharmaceuticals. Investigations are ultimately referred to federal or state prosecutors for further action where warranted.

During the course of an investigation, DEA personnel work closely with Assistant United States Attorneys and prosecutors from the Criminal and Civil Divisions of the Department of Justice to develop cases in order to prosecute violators. For example, Dr. Paul Volkman, a physician in an Ohio pain clinic, was the subject of a DEA investigation. Dr. Volkman was responsible for illegally dispensing significant quantities of oxycodone which ultimately lead to the overdose deaths of at least four of his "patients." In February of 2012, Dr. Volkman was sentenced in federal court to four life terms.

The Honorable Bill Cassidy

6. Does the Drug Enforcement Administration identify and have the DEA numbers of the doctors who prescribe an abnormally high volume of controlled drugs? If not, why not? If so, are these doctors flagged and monitored more closely? In concept, this is similar to what the TSA maintains for suspicious travelers, except to monitor physicians with unusual prescription writing practices. If such a practice is not currently in place, why? Are there impediments in the law that prevent DEA from tracking and monitoring questionable prescription writing practices that Congress needs to rectify with legislation?

Response:

The Controlled Substances Act exempts practitioners (e.g., physicians) from the requirement to keep prescription records, with limited exceptions. 21 U.S.C. § 827(c)(1). In addition, the Controlled Substances Act requires registered internet pharmacies to report to DEA the total quantity of controlled substances the pharmacy dispenses each month, but only if certain dispensing thresholds are met. 21 U.S.C. § 827(d)(2). DEA does not have further authority to require that prescription or dispensing information be reported to DEA. However, this type of data (i.e., prescribing and dispensing information) is typically maintained at the state level through Prescription Drug Monitoring Programs (PDMPs). PDMPs aim to detect and prevent the diversion and abuse of prescription drugs at the retail level where no other automated information collection system exists, and to allow for the collection and analysis of prescription data more comprehensively than states without such a program can accomplish. Currently, 49 states have such a PDMP or legislation in place to establish a PDMP. Depending on the various state laws, DEA can directly access investigation-specific data from these systems or request the information through the state agency operating the PDMP.

The Controlled Substances Act requires only manufacturers to report to DEA every controlled substance sale, delivery or other disposal, and each distributor to report to DEA every *narcotic* controlled substance sale, delivery, or other disposal. 21 U.S.C. § 827(d)(1). DEA uses this information for various purposes, including compliance and enforcement activities.

The Honorable David McKinley

7. What factor(s) does the DEA take into account when determining which pharmacies are receiving excessive orders of controlled substances?

Response:

Neither the Controlled Substances Act nor its implementing regulations expressly prohibit pharmacies from making “excessive” orders of controlled substances. Rather, the regulations state that *manufacturers* and *distributors* “shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his or her area of suspicious orders when

discovered by the registrant. *Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*" 21 C.F.R. § 1301.74(b) (emphasis added). This requirement is rooted in the Controlled Substances Act at 21 U.S.C. §§ 823(a)(1), 823(b)(1), 823(d)(1), and 823(e)(1), which state that manufacturers and distributors must maintain effective controls against the diversion of controlled substances in order for their registrations to be consistent with the public interest. A registration that is inconsistent with the public interest is subject to revocation. 21 U.S.C. § 824(a)(4). As such, every manufacturer and distributor has the responsibility not only to have a system that discloses suspicious orders, but also to report each suspicious order and not to fulfill any suspicious order unless and until the reason for the suspicion is no longer an issue.

However, a pharmacy investigation can be initiated on the basis of a variety of sources, tips and leads. For example, DEA may receive information about a rogue pharmacy from state medical or pharmacy boards, state or local law enforcement agencies, patients, or employees. These investigations, however, are not focused on determining whether or not a registrant is receiving "excessive orders" of controlled substances, but rather they are focused on determining whether or not diversion is occurring and who is responsible for the diversion.

Through its ARCOS database, DEA can identify large and potentially suspicious orders of controlled substances purchased by DEA registrants, including pharmacies. That information is then analyzed with other intelligence and investigative information to identify potential sources of diversion. Other factors that DEA considers may include, but are not limited to: whether there is an active or previous investigation of the purchaser, the purchaser's experience with controlled substances, the purchaser's customers, the type and strength of drug(s) ordered, frequency of orders, what other drugs are or are not being ordered, orders deviating substantially from similar customers, other erratic patterns, and any association with known diversion schemes such as pill mills.

8. Does the DEA have guidelines for wholesalers and/or pharmacies regarding what constitutes excessive orders? Does the DEA use metrics such as dosage units per month?

Response:

As discussed above in response to Question 1, suspicious orders "*include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*" This is a non-exhaustive list of factors that may indicate an order is suspicious. DEA does not use metrics or dosage units per month as the sole determinant of a suspicious order. In fact, there have been circumstances in which pharmacies intentionally place multiple orders under a certain threshold in order to avoid detection. Distributors are still responsible for being cognizant that such activity might occur, and to maintain a system to disclose suspicious orders and prevent circumvention.

Beginning in August of 2005 and continuing to the present, DEA has and continues to meet with wholesale distributors on an individual basis to remind them of their responsibilities

and to provide them with information that may assist them in identifying suspicious orders including current trends and related diversion schemes.

9. **When determining which pharmacies to target, does the DEA take into account mail order pharmacies? Mail order pharmacies dispense large quantities of controlled substances to patients they do not have a personal relationship with nor do they have a relationship with the prescribers whose prescriptions they fill.**

Response:

DEA does not “target” any specific registrant group or category. Investigations may be initiated as a result of information from an array of sources. For example, DEA works with state medical and pharmacy boards and state and local law enforcement agencies, which foster the exchange of information. DEA also receives information or tips and leads from a variety of sources to include employees, patients, pharmacists, and doctors. DEA also monitors ARCOS data that captures sales and distribution information on a limited number of controlled substances.

10. **There are examples of independent community pharmacies being targeted by wholesalers/DEA for no transparent or stated reason, often times resulting in all substance orders being completely halted. This is causing hardships for independents that are primarily located in and service rural populations. Is the DEA targeting independent community pharmacies to a higher degree than chain pharmacies? There is a perception that independents are being targeted for reasons beyond their control such as a lack of ability to self-warehouse, perceived less stringent internal controls, and/or decreased legal capabilities, among others.**

Response:

DEA initiates investigations as a result of information received from external sources or internal analysis. These investigations, however, are not initiated because of any specific registrant category or sub-category (e.g., independent vs. chain pharmacy). The investigations are focused on the facts of a particular case or diversion scheme. For example, between 2005 and 2009, many DEA diversion investigations were initiated against rogue internet pharmacies. The results of those investigations revealed that most, if not all, of the domestic-based internet pharmacies were independently owned pharmacies.

As previously stated, distributors of controlled substances are required under the regulations to “...*design and operate a system to disclose to the registrant suspicious orders of controlled substances. . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*” 21 C.F.R. §1301.74(b) (emphasis added). These registrants are also required to report these suspicious orders to the DEA. If a registrant identifies what they believe is a suspicious order, they have an obligation not to ship that order to their customer unless the suspicion has been removed.

The Honorable Edolphus Towns**11. Should the DEA introduce more targeted protocols in order to alert pharmaceutical wholesalers if there is a discrepancy?****Response:**

Under the Controlled Substances Act, manufacturers and distributors must maintain effective controls against the diversion of controlled substances in order for their registrations to be consistent with the public interest. 21 U.S.C. §§ 823(a)(1), 823(b)(1), 823(d)(1), and 823(e)(1). A registration that is inconsistent with the public interest is subject to revocation. 21 U.S.C. § 824(a)(4). As such, every manufacturer and distributor has the responsibility not only to have a system that discloses suspicious orders to the registrant, but also to report each suspicious order and not to fulfill any suspicious order unless and until the suspicion is removed. 21 CFR § 1301.74(b). Wholesale distributors are in the best position to know their own customers' business practices and consider all of the circumstances to determine whether an order is suspicious. Usually, DEA's information with respect to a diverting pharmacy is information that can be gleaned through public resources or a site visit that includes observations of clientele and the surrounding area (e.g. long lines out the door, loitering in the parking lot, multiple cars with out-of-state plates, etc.), as well as some targeted questions about clientele, reasons for erratic or otherwise unusual ordering patterns, and the owner's experience with controlled substances. Even so, DEA, through its Distributor Initiative Program, has and continues to meet with wholesale distributors to remind the firms of their responsibilities and to provide information on trends and possible "red flags." It is important that registrants remain vigilant that any such system they use be flexible enough to adapt to evolving trends and emerging diversion schemes.

12. Are wholesalers and retail pharmacies being asked to play more of a law enforcement role?**Response:**

No. The applicable laws and regulations have not changed in more than 40 years. In order to maintain a closed system of distribution, the Controlled Substances Act specifically requires registrants to police themselves by maintaining effective controls against diversion to ensure that they are not contributing to or facilitating diversion. This is critical to preventing the diversion of powerful controlled substance pharmaceuticals. Wholesalers are required to identify and report suspicious orders made by pharmacies or dispensing practitioners. 21 C.F.R. §1301.74(b). Pharmacists also have a critical role in dispensing controlled substances. Pursuant to 21 C.F.R. §1306.04(a), "*A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.*" (Emphasis added).

13. How often does the DEA conduct site visits to retail pharmacies? Is the responsibility for site visits left to the wholesalers?

Response:

As with other DEA practitioner registrants, pharmacies are regulated by state pharmacy boards as well as DEA. Most often, site visits of pharmacies are conducted by state regulatory authorities prior to the issuance of state controlled substance licensure. Generally speaking, DEA conducts on-site visits of pharmacies as the result of an investigation into unlawful or suspicious activity by the pharmacy, a pharmacy employee, or another registrant or other entity connected with the pharmacy.

For the past several years, Florida has been the epicenter for rogue pain clinics. Due to changes in state law prohibiting the dispensation of controlled substances directly from these clinics, DEA has seen a large increase in new pharmacy applications within that state. Upon review, it was determined that many of these new applications required additional scrutiny. Subsequently, DEA began conducting a comprehensive and detailed review of these new applicants, including site visits and in-person applicant interviews. Upon consideration of all of the available information, DEA was positioned to determine whether the pharmacy's registration would be consistent with the public interest, and DEA could either grant the registration or issue a show cause seeking to deny the application.

In fulfilling their statutory and regulatory responsibilities, wholesalers may find it necessary to conduct on-site visits if circumstances warrant, as part of their ongoing responsibility to maintain effective controls against diversion and/or their responsibility to identify and report suspicious orders.

14. How do you make sure that certain pain killers are available for legitimate purposes while at the same time cracking down on abusers?

Response:

DEA investigations are typically focused on individuals or organizations responsible for the distribution or supply of controlled substances rather than on individual abusers. Through its regulatory oversight, DEA works to ensure that DEA registrants comply with all aspects of the Controlled Substances Act and its regulations. By doing so, DEA strives to ensure that the closed system of distribution remains closed and that all sales, distribution and dispensing are for legitimate purposes.

The Honorable Mike Ross

- 15. I understand that distributors fill the orders they received based on the information they have, and that these distributors lack the full scope of information that shows which pharmacies buy oxycodone from multiple distributors. Isn't there a better way to approach this problem, like for instance, more collaboration between the DEA and the supply chain through better information sharing so that you can work with the suppliers instead of forcing them to police the problem in the dark?**

Response:

Wholesale distributors are required to report to DEA purchases, sales, and distribution data regarding narcotic controlled substances. 21 U.S.C. §827(d)(1). DEA does not share this information with other distributors because it is considered confidential proprietary information by both the purchaser and the seller. Wholesalers, however, are not prohibited from sharing this information with each other.

It is important to emphasize that over the past several years, DEA has initiated administrative action against several wholesale distributors who sold millions of dosage units of pharmaceutical controlled substances to retail pharmacies that subsequently diverted the substances under circumstances in which the distributors knew or should have known diversion was occurring. Had these wholesale distributors accessed and analyzed their own data, the suspicious nature of the orders would have been apparent.

- 16. If a distributor stops supplying a pharmacy due to a suspicious order, what does the DEA do? Do they automatically take away the pharmacy's registration, and if so, how often and how quickly? Do you inform all distributors that the registration has suspended or surrendered? If not, why not?**

Response:

If a distributor supplies DEA with a suspicious order report, the local DEA Field Office conducts a review, and if warranted, an investigation is initiated. DEA cannot automatically take away a pharmacy's DEA registration. The Controlled Substances Act and the Administrative Procedures Act require DEA to provide notice of the proposed revocation in an Order to Show Cause (OSC) and an opportunity for a hearing before an administrative law judge. Furthermore, depending on the facts and circumstances, the investigation may also be presented to an Assistant United States Attorney for criminal or civil prosecution.

If DEA issues an OSC against a registrant, that registrant is authorized to handle pharmaceutical controlled substances until the matter has been finally adjudicated. All Final Orders regarding registrations are published in the Federal Register. To verify the validity of a DEA registration DEA registrants may also access DEA's registration validation database any time at www.DEAdiversion.usdoj.gov.



April 6, 2012

The Honorable Mary Bono Mack
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing and Trade
2125 Rayburn House Office Building
Washington, DC 20515


Dear Chairwoman Bono Mack:

Thank you for the opportunity to testify before the Subcommittee on Commerce, Manufacturing and Trade on March 1, 2012 at the hearing entitled "Prescription Drug Diversion: Combating the Scourge."

I have attached my response to the questions for the record, along with three documents to be considered as part of the hearing record: HDMA's Industry Compliance Guidelines (2007), the DEA's list of "*Suggested Questions a Distributor should ask prior to shipping controlled substances*" (2009) and HDMA's Questions for the DEA (2011).

Thank you for your leadership and we look forward to working with you on the extremely important issue of prescription drug abuse.

Sincerely,


John M. Gray
President and CEO

The Honorable Mary Bono Mack

1.

a. What tools do distributors use to spot unusual order increases by pharmacies?

Wholesale distributors typically spot unusual order increases by analyzing trends in their own internal product ordering data systems and records of their customers' prior orders for controlled substances. These records include the number of products ordered, the package size, the product's National Drug Code (NDC) or drug class, along with additional information maintained about each customer and their business.

Distributors may also analyze other data, such as their own Automation of Reports and Consolidated Orders System (ARCOS) data to compare against all customer orders to help identify unusual order increases. U.S. Drug Enforcement Administration (DEA) regulations require manufacturers and distributors to provide ARCOS data to DEA on a regular basis. ARCOS data includes inventories, acquisitions, and dispositions of all substances in Schedules I and II, as well as all narcotic and Gamma-Hydroxybutyric Acid (GHB) substances in Schedule III.¹

It is important to note, however, that "unusual order increases" may have legitimate and even ordinary explanations. A customer's increase in ordering is not, in and of itself, evidence of diversion.² Wholesale distributors monitoring for suspicious orders may use such circumstances as unusual order increases as a reason for further inquiry.

b. Are there other red flags that distributors look for in their anti-diversion efforts?

Distributors take their anti-diversion efforts extremely seriously and focusing on quantities alone is not sufficient to identify potentially suspicious orders. Distributors will use a number of other factors to analyze orders. As outlined in HDMA's Industry Compliance Guidelines (ICG) (attached), distributors often perform due diligence on their customers, such as asking them questions about their business and the types of products they intend to purchase, whether their facility has been inspected by DEA or the state regulatory authority (for most states, this is the Board of Pharmacy), and other information that may help distributors evaluate their customers and their orders.

As part of their efforts to monitor for suspicious orders, distributors may also ask for other information that may either justify particular customer ordering patterns or indicate possible diversion, such as the percentage of controlled substances purchased as compared to non-controlled substances, the variety and types of controlled substances purchased, the percentage of sales reimbursed by insurance compared to cash sales, or the location of a customer relative to other healthcare entities such as hospitals or long-term care facilities that would explain particular ordering patterns. We ask that a copy of the HDMA ICGs (Attachment 1) be submitted for the record in conjunction with these responses.

¹ 21 C.F.R. § 1304.33 (Reports to ARCOS (Automation of Reports and Consolidated Orders System)). Wholesale distributors do not handle Schedule I controlled substances; only manufacturers can lawfully handle Schedule I controlled substances.

² Carlos Gonzalez, M.D., Decision and Order, 76 Fed. Reg. 63,118, 63,138, cols. 2-3 (Oct. 11, 2011) (final order revoking registration despite rejection of evidence as to volume).

Unfortunately, due to United States anti-trust laws, distributors are unable to determine whether a customer is ordering from another distributor or multiple distributors. If it were available, such information could be factored into a distributor's evaluation of whether orders should be deemed "suspicious" and reported to DEA.

c. How do distributors react when they see a potential red flag?

There are many ways that a wholesale distributor will react if they have a concern about a particular order. If the concern is in relation to a specific order, the wholesaler will typically stop shipment of the order, and contact the customer to determine whether the customer can explain the reason for the order. In some cases, the customer may not have intended to place an order that might be viewed as "unusual". This may happen for example, if the order has a "typo" and a pharmacy placed an order for 1000 units when they meant to order only 100. Once the order is verified, the distributor will make whatever adjustments are necessary (if needed) and ship the product.

If the initial review does not quickly resolve the order in question, the distributor typically keeps the order "on hold" while they conduct a more in-depth review into the order or the customer. If the distributor is unable to satisfactorily resolve the reason for the order, the distributor will determine that the order is "suspicious," they will not fill the order and will notify the DEA as required by 21 C.F.R. § 1301.74(b).

If more general questions about a customer arise, the distributor may conduct a more in-depth background check of the customer. If they reach a decision that it is not appropriate to continue to do business with a particular customer, the distributor typically informs the DEA of their intent to discontinue selling controlled substances to that particular customer.

d. Is there an industry standard code of conduct in such events?

Although HDMA has a guidance document, the ICG, that is useful for our members in conducting due diligence and reporting if/when they find a suspicious order, we have not further developed a standard code of conduct as described in the question because:

- development of such a code of conduct may mean reaching agreements and/or directing decisions which would risk violating U.S. anti-trust laws;
- unless DEA were to create the code of conduct (or specifically "approve" an HDMA version), distributors would have no assurances that they will be in compliance if they follow it and they would still be subject to DEA sanctions; and,
- further DEA guidance on what constitutes a "suspicious order" beyond the reference in the regulation is needed.

2. You referenced the Industry Compliance Guidelines that guide distributors in evaluating customer orders for controlled substances and for reporting suspicious orders to the DEA.

a. What constitutes a suspicious order?

"Suspicious orders" are not defined in the DEA regulations. Rather, the regulations give three examples of circumstances that constitute "suspicious orders." Specifically, 21 C.F.R. §1301.74(b) states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when

discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

This standard is very subjective and day-to-day implementation is very complex. Thus, HDMA has sought further clarification of the regulation's practical application.

b. What is the mechanism for reporting such orders to the DEA?

As required by the implementing regulations, once the distributor has made the determination that an order is suspicious, a phone call or other communication to report the order to the Field Division Office of DEA is required (unless DEA provides other direction). HDMA's guidance recommends that the distributor provide additional documentation in writing to DEA upon request.

c. Is there room for improvement in this reporting system? If so, where?

The actual process for reporting "suspicious" orders is currently not a problem. The most important concern is in the lack of clarity about what is considered "suspicious." Moreover, it is unclear what the internal process is within DEA for how DEA follows up on such reports.

d. Do you have any idea how frequently your members make such reports?

HDMA does not track this information. HDMA members report "suspicious orders" directly to DEA.

3. You stated that you believe defining what is a suspicious order based on volume and national averages alone oversimplifies the problem. Do you not believe it is possible to determine, based on current and past patterns, to develop regional averages that could be used to flag potential diversion problems?

Analytical techniques could be used to develop regional averages. However, the value of any average, whether national or regional, can be extremely limiting. Other factors, such as patient demographics, the pharmacy's proximity to large population centers or to medical care facilities, the pharmacy's size, hours of operation, variability in medical practice (which can occur even on a regional basis), and a host of other conditions are very important for determining whether the ordering volume is appropriate. We believe DEA should provide additional information such as the overall volume of shipments in a given area and information as to whether certain companies are ordering from multiple suppliers.

The Honorable Edolphus Towns

1. Mr. Gray, thank you very much for your testimony. In your comments you talked about numerous times that the distribution industry has reached out to the DEA. Can you share with us what type of a response you received from the DEA? Would it be correct to assume that the industry would like more clarification and direction from the DEA?

HDMA and its members have received information from DEA concerning our members' responsibilities under the Controlled Substances Act (CSA) and related regulations. However, our members have also asked DEA detailed questions seeking clarification on practical, day-to-day implementation and direct application of the laws and regulations but have yet to receive such guidance.

Determining when an order or a customer may be “suspicious” is a highly complex undertaking that, if handled incorrectly, could result in jeopardizing patient treatment. Distributors do not control customer DEA registrations under the CSA, nor do they have the legal authorizations (*e.g.*, inspection authority, subpoena power,) or other tools (*e.g.*, industry-wide ARCOS and other data) that DEA has that could be used to reinforce distributors’ efforts to determine whether customers intend to use the drugs for illicit purposes.

This is further complicated by the current focus of the DEA on “suspicious order patterns” rather than a single suspicious order. DEA has indicated that total volume of specific drugs, the level of cash payments for those drugs and significant increases in volume over time are indications of diversion. However, DEA has not been specific as to what constitutes suspicious levels in each of these areas. A clearer definition from DEA would enable the industry to be more effective in identifying potential diversion of controlled substances.

Distributors are seeking a true partnership with the DEA and would request that the Agency be more forthcoming with information. Too often, the DEA response is that they cannot tell distributors who to sell to or what to do. While distributors must make certain decisions on their own, DEA can provide much needed information such as trends in certain geographic areas and share non-confidential information about ordering patterns. We note that the DEA has recently again raised the fees on DEA registrants. Some of this funding should be devoted to helping registrants improve the system for detecting diversion.

Thus, we continue to seek further guidance from DEA on specific issues related to implementation of the law and the regulations governing DEA registrants. Clearer direction and firmer support from DEA, including answers to the twelve pages of questions about wholesale distributors’ implementation responsibilities submitted to DEA in June of 2011, would enable distributors to more effectively work with DEA towards our mutual goal of reducing prescription drug abuse. We ask that a copy of the questions HDMA submitted to the DEA (Attachment 2) be included in the hearing record in conjunction with this response.

2. While I certainly agree that the distributors have an important role to play in the war against prescription drug abuse, it sounds to me that the distributors are not only required to know their customers, but to know their customers’ customers as well. Is this correct?

Yes. DEA has made it clear one of our members’ responsibilities is to “know your customer.” Primarily through verbal communications, DEA has also conveyed to our members an expectation that they will know their customers’ customers. This expectation is also evident by the questions DEA suggested that distributors ask pharmacies and other customers in their 2009 list of “*Suggested Questions a Distributor should ask prior to shipping controlled substances.*” Please see Attachment 3. The following are examples of the questions DEA expects distributors to ask their pharmacy customers:

- Has the pharmacy ever refused to fill prescriptions for a practitioner? If so, why and who?
- Are there particular practitioners who constitute most of the prescriptions it fills? Who are these practitioners (Name and DEA registration number)?
- Does the pharmacy have any exclusive contracts, agreements, arrangement, etc. with any particular practitioner, business group, investors, etc. If so, explain those arrangements and/or obtain copies of those agreements.

While DEA provided these suggested questions, there is no specific regulatory provision that

requires a pharmacy to answer these questions and limited ability for a wholesale distributor to determine whether the questions have been answered truthfully. And, DEA has provided very little additional guidance on what the range of acceptable answers may be. It remains unclear what responses would be acceptable (or not). Distributors do not write prescriptions; therefore they have no way of knowing the clinical inputs that went into why a licensed medical professional believes there is a medical use for that script. We do not even know the medical professional who is writing the script. We do not fill prescriptions; therefore we do not see who is getting the prescription filled. What DEA clearly wants us to do is know our customer's customer, which we cannot do.

3. Do distributors have access to the types of information they need to perform this task appropriately?

No. Distributors have access to some information, but not all, that they need. For example, implementing regulations under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which safeguard patients' privacy rights, prevent distributors from accessing certain information including individual prescriptions and patient data.³ While a pharmacy may provide certain information to a distributor about their businesses and prescription fulfillment practices; the wholesale distributors have no means of verifying this information's accuracy. Further, distributors are not allowed to see if a pharmacy is using multiple distributors or if they have been cut off or are on any kind of restrictions from another distributor. DEA, however, either has that information or access to it under their investigatory authority. Distributors are being held responsible for knowing information without having the statutory or regulatory authority to do so.

For instance, how do you know whether a prescription is for a legitimate medical need?

We don't. Nor can we. The decision to prescribe controlled or not, is made by a trained and state licensed practitioner, such as a physician or a nurse practitioner. The prescription may be filled by another state-licensed learned intermediary, the pharmacist. In the case of controlled substances, both the doctor and the pharmacist must also be registered with DEA. Wholesalers do not have the medical expertise, access to prescriptions, patients or patient-specific data to determine if a prescription is for a legitimate medical need. That determination must be made by the prescriber and a corresponding responsibility is placed on the pharmacist filling the prescription.⁴

How do you know where all of the patients reside who fill their scripts at the pharmacy? Do you have access to that information?

No. HDMA members are precluded access to patient-specific data, including patient addresses by the privacy restrictions in HIPAA.

³ Covered entities are precluded from using or disclosing a patient's "protected health information" ("PHI") (i.e., "individually identifiable health information") absent a patient's specific written "authorization," or in certain limited circumstances not relevant here. 45 C.F.R. § 164.502(a)(1); see also 45 C.F.R. § 164.506(a) and (c); 45 C.F.R. § 164.502(a)(1)(ii) ("[a] covered entity may not use or disclose protected health information, except . . . to carry out treatment, payment, or health care operations . . .").

⁴ DEA's regulations acknowledge this responsibility on the prescriber and dispenser of controlled substances. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a).



Industry Compliance Guidelines

Attachment 1

**HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)
INDUSTRY COMPLIANCE GUIDELINES:
REPORTING SUSPICIOUS ORDERS
AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES**

Introduction

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of medicines. Manufacturers, distributors, pharmacies and healthcare practitioners share a mission and responsibility to continuously monitor, protect and enhance the safety and security of this system to combat increasingly sophisticated criminals who attempt to breach the security of the legitimate supply chain.

The *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, have been developed as part of HDMA member distributors' ongoing commitment to the safe and efficient distribution of all prescription medicines including controlled substances. These Industry Compliance Guidelines are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply. They have been prepared in recognition of a growing problem of misuse and diversion of Controlled Substances (CS) and the critical role of each member of the supply chain in helping to enhance security.

At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers. Due diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.

These Industry Compliance Guidelines can help identify facts and information about controlled substance product orders, and the customers placing the orders.

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HDMA
Healthcare Distribution
Management Association

History

In 1970, Congress enacted into law the Controlled Substances Act (CSA) as part of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides the Drug Enforcement Administration (DEA) within the Department of Justice (DOJ) with the authority to regulate the manufacture, importation, possession and distribution of certain drugs. An additional federal agency, the Food and Drug Administration (FDA), and individual states, regulate many other aspects of drug supply chain safety and security. The CSA also created a closed system of distribution for those authorized to handle CS. Since its enactment in 1970, the CSA has been amended several times, including by the following statutes:

- The Psychotropic Substances Act of 1978;
- The Controlled Substances Penalties Amendments Act of 1984;
- The Chemical Diversion and Trafficking Act of 1988;
- The Domestic Chemical Diversion and Control Act of 1993;
- The Federal Analog Act; and
- The Methamphetamine Precursor Control Act which was superseded by the Combat Methamphetamine Epidemic Act of 2005.

The regulations in Title 21, Code of Federal Regulations (C.F.R.) part 1300 to 1316 apply to all individuals and firms desiring to conduct business in CS. All such individuals and firms must be registered with DEA, and are required to maintain complete and accurate inventories and records of all transactions involving CS, as well as security for the storage of controlled substances. Additionally, Sections 823(b) and (d) of the CSA call for the maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.

In addition, distributors are required by 21 C.F.R. § 1301.74(b) to report suspicious orders of CS:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [Emphasis added.]

Distribution Industry Commitment to Prevent Diversion of CS

Although distributors have been required to identify and report “suspicious orders” of CS and listed chemicals, increasing concerns about the potential misuse of prescription CS have elevated awareness within the supply chain and have led to increased expectations by DEA. Therefore, HDMA developed these Industry Compliance Guidelines to further scrutinize purchase orders for these products. For example, in public statements to Congressional Committees, DEA has noted

the growing problem of diversion and abuse of controlled pharmaceuticals, and has indicated the agency is taking stronger measures to address this matter.¹

With the strong endorsement and expertise of our members, the Healthcare Distribution Management Association (HDMA) has developed the following Industry Compliance Guidelines for preventing diversion and reporting suspicious orders. We believe that implementation of these guidelines will help ensure that CS are appropriately distributed to supply chain customers involved in the legitimate dispensing of these important pharmaceutical products to patients, and will help distributors identify possible diversion activities.

OUTLINE

The *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, contains the following elements:

- I. Know Your Customer Due Diligence
 - II. Monitoring for Suspicious Orders
 - III. Suspend/Stop an Order of Interest Shipment
 - IV. Investigation of Orders of Interest
 - V. File Suspicious Order Reports With DEA
 - VI. Employees, Training and Standard Operating Procedures (SOPs)
 - VII. Additional Recommendations
- Glossary of Abbreviations*

¹ See testimony provided by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; December 13, 2005, July 26, 2006, September 18, 2007, and June 24, 2008; and by Michele M. Leonhart, Acting Administrator, Drug Enforcement Administration, United States Department of Justice, March 12, 2008.

I. KNOW YOUR CUSTOMER DUE DILIGENCE**a. Introduction**

Before opening an account for a new customer, the distributor should (i) obtain background information on the customer and the customer's business; (ii) review that information carefully, and, where appropriate, verify the information; and (iii) independently investigate the potential customer. To help ensure that the Industry Compliance Guidelines remain robust and adaptable, the "Know Your Customer Due Diligence" phase also describes "Additional Recommendations and Documentation" containing further suggestions for managing the distributor's procedures.

A distributor may tailor this part of its customer evaluation procedure to the type of customer under review. If a distributor does so, it is recommended that the distributor categorize each potential customer according to the customer's DEA "Business Activity" type as indicated on the customer's DEA registration certificate; for example, Retail Pharmacy, Hospital/Clinic, Practitioner or Distributor.

The following steps are recommended.

b. Information Gathering

All information requested by a distributor should be provided by the owner of the potential customer, the pharmacist in charge; or, in the case of a non-pharmacy customer, an equivalent designee. Each completed application, questionnaire or other document providing information requested by the distributor from the potential customer should be signed by the potential customer's owner, pharmacist in charge or equivalent designee. The signature should be notarized or should be accompanied by the statement: "*I declare under penalty of perjury that the foregoing is true and correct. Executed on [date].*"

The information gathering step would include:

- Provide potential customer with a credit application;
- Provide potential customer with a background questionnaire requesting the following information:
 - Business background,
 - Customer base,
 - Average number of prescriptions filled each day,
 - Average number of CS item prescriptions filled each day,
 - Percentage of CS purchases compared to overall purchases,
 - Verification of physical security controls for CS storage,
 - Questions based on DEA guidance and communications,
 - Copies of all their state and federal licenses and registrations,
 - If the potential customer is not currently conducting Internet prescription fulfillment, certification that they are not doing so, and will notify the distributor before conducting Internet prescription fulfillment;

- If the potential customer is conducting Internet prescription fulfillment, obtain the following information from any potential customer utilizing the Internet to receive and fill prescriptions:
 - The date the potential customer began conducting Internet prescription fulfillment,
 - Products the potential customer expects to purchase,
 - The quantity of each product the potential customer expects to purchase,
 - Practitioners who will be writing prescriptions that will be filled by the potential customer, including each practitioner's DEA and state registration and license numbers, address, telephone number(s), and other relevant contact information, and
 - National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (NABP VIPPS) check.
- Names of individuals authorized to sign DEA Form 222²,
- A description of how the pharmacy/dispenser fulfills its corresponding responsibility to ensure that the prescriptions they receive are issued for a legitimate medical purpose (as required in 21 C.F.R. § 1306.04),
- Inspections:
 - Indicate whether DEA has audited/inspected the pharmacy/dispenser over a period of at least the last two (2) years and if so, explain why,
 - Indicate whether the pharmacy/dispenser has been inspected by the state regulatory/inspection authority such as the State Board of Pharmacy, and
- Identification of physicians and other treatment centers that are the potential customer's most frequent prescribers or highest purchasing doctors.

c. Information Review

After the information is received from the potential customer, it should be reviewed thoroughly. The review should include the following steps:

- Verify that the credit application is complete, and carefully review the information submitted;
- Verify that the customer background information supplied is complete, and carefully review the information submitted;
- Verify that the answers to the questions based on DEA guidance and communications are complete, and carefully review the information contained; and
- Verify the potential customer's state and federal licenses, registrations and CS schedule authorizations.

² See: 21 C.F.R. § 1301 regarding "Orders for Schedule I and II Controlled Substances" for DEA's regulations for ordering these products by means of either DEA Form 222 or electronically, including signature requirements.

d. Independent Investigation

The distributor should independently investigate the potential customer as follows:

- Check with the distributor's local DEA office for any information regarding the potential customer, such as DEA actions against the potential customer³;
- Check with state oversight authorities, including the state Board of Pharmacy (for a potential pharmacy customer) and Board of Medicine (for a potential physician customer) to request further background information, such as state actions against the potential customer (some states may provide readily accessible information through the state's Web site);
- Check the DEA Web site and the Federal Register for any actions against the potential customer; and
- Conduct an Internet search to determine whether any potential Internet business can be identified as relating to the potential customer and whether there is any other relevant information that could affect the decision to do business with the potential customer.

e. Additional Recommendations and Documentation

It is recommended that:

- Individuals selected to develop questionnaires for part (a) and to conduct reviews and investigations under parts (b) and (c) above should receive appropriate training.
- The distributor should update the questionnaire(s) periodically, particularly if a concern arises during an investigation.
- The performance and results of all steps in the customer review process should be fully documented as to each potential customer, and such documentation should be retained in an appropriate file.
- After completing the steps outlined above, the reviewer of the potential customer should sign and date the information (in a designated location of the file) to indicate that the reviewer has conducted a thorough/complete review, and that the information contained in the file is accurate and complete to the best of his/her knowledge.
- A distributor may seek further information about a potential customer, including when the distributor determines that obtaining further background information, confirmation, or verification is warranted.
- The distributor may include provisions for notification of state and federal authorities of an unlawful activity identified under the "Know Your Customer Due Diligence" as required by local, state or federal law.

³ Depending on the direction received from the local DEA office, the distributor may consider contacting the potential customer's local DEA office for further information regarding the potential customer.

II. MONITORING FOR SUSPICIOUS ORDERS

a. System Design

It is recommended that a distributor develop an electronic system, with accompanying written Standard Operating Procedures (SOPs), to meet the DEA's requirement in section 1301.74(b) that a distributor "design and operate a system to disclose to the registrant suspicious orders of controlled substances" (emphasis added). Distributors should assign responsibilities for identifying and investigating potentially suspicious orders, and for reporting suspicious orders. Specific elements of the monitoring system are further described below.

b. Identify Product and Customer Characteristics

Separate/classify/group customers into appropriate/different classes of trade. For example, retail pharmacies, hospitals, doctors, or dentists.

Separate the CS the distributor sells into groups or "families" of drugs (e.g., all CS items containing codeine). The following information may be useful for identifying the "families" of drugs:

- A distributor may use the DEA Web site to obtain DEA's designation of a drug's "controlled substance code number" to aid in developing a drug "family" for purposes of defining a threshold.⁴
 - (See: <http://www.deadiversion.usdoj.gov/schedules/schedules.htm> or <http://www.usdoj.gov/dea/pubs/scheduling.html>)
- Distributors may also use the National Technical Information Service (NTIS) system, which (i) identifies each individual CS Stock Keeping Unit (SKU) by National Drug Code (NDC) number, (ii) lists the active ingredient and (iii) lists the corresponding DEA controlled substance code number. The DEA controlled substance code number is set up by NDC number. An electronic copy of this information may be used to help identify the drug "families."
- Alternatively, a distributor may choose to identify "families" of drugs and track the dosage unit (e.g., tablet) order levels for each SKU.⁵
- A distributor should maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or new "Drugs of Concern" as the information is developed by the agency. Such new information should be made part of the identification of particular CS drugs or "families" to be monitored, as appropriate.

⁴ For further information on the controlled substance code numbers, see 21 C.F.R. § 1308.03.

⁵ This method may present implementation challenges due to of the different strengths of the drugs.

c. Develop “Thresholds” to Identify Orders of Interest

“Thresholds” for identifying orders of interest, *i.e.*, orders that warrant follow-up inquiry to determine whether they are suspicious, may be made by using averages shipped to a particular customer facility that are consistent with the class of customers to which the particular customer belongs. It is recommended that distributors develop such thresholds by calculating the average single order and the average monthly order per “family,” per customer, and class of trade.

When evaluating thresholds, orders of “unusual size” and “unusual frequency” can be used to signal that an order may need further review. Distributors are also encouraged to structure their thresholds to support evaluation of whether the order deviates substantially from a normal pattern and/or is of unusual frequency. The following examples may aid in developing the thresholds:

- Patterns of ordering such as comparing the present order to:
 - past orders from the same customer (including the frequency of orders),
 - orders for extraordinary quantities outside of normal purchasing patterns typically followed by the customer or by other customers within the same class of trade, and
 - geographical area(s) of the country they service (e.g., orders from other establishments of the same type in the locale or region),
- Orders of more than one controlled substance that are known to be taken together (combinations) outside of normal prescribing and patient treatment practices, and
- DEA/State input.

Distributors are also encouraged to consider the following when developing “thresholds”:

- Quantities of products the dispenser initially indicated during the “Know Your Customer Due Diligence” phase that it expected to purchase;
- A minimum of six months sales history and a maximum of 24 months sales history are recommended; Maintain contact with DEA through the local field office or the Office of Diversion Control’s Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or emerging local or regional concerns; such new information may be used to adjust thresholds as appropriate; and
- Thresholds for all new customer accounts should be established at the lowest level indicated by information obtained during the “Know Your Customer Due Diligence” review.

d. Cumulative Reviews/Thresholds

A very important component of the system will be to include a mechanism for periodic review of cumulative orders from the same customer over time, to evaluate trends in purchasing patterns. This would include, for example,

- A mechanism to compare percentages of orders for CS (individual products and/or “families”) to orders of non-CS prescription drugs so as to identify a shift in a customer’s business focus that may warrant further review.

- Determining if the purchaser's ordering pattern, for a period of several months, shifts in a manner inconsistent with their previous ordering patterns or inconsistent with the class of trade for that customer (e.g., a pharmacy that orders relatively few controlled substances over several months suddenly places a large order or several large orders in a concentrated period of time.)

e. Supplemental Mechanisms for Determining Orders of Interest

Distributors are encouraged to recognize that their methods for identifying an "Order of Interest" do not need to be limited to an electronic "threshold" system. Based on the distributors' knowledge of his/her customers, overall drug purchasing trends, information available from DEA and elsewhere, distributors are encouraged to allow for alternative criteria, in addition to those incorporated into the electronic system, to serve as indicators of an order of interest.

III. SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT

If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

Ideally, the electronic system would contain a process to automatically "block" the order or otherwise stop the ordered product from being shipped. The distributor may, however, ship any non-CS included in the order and any other CS products as to which the order did not exceed a threshold or otherwise become characterized as an order of interest. A distributor may choose to report an order of interest to DEA immediately as a suspicious order or may first investigate the order as described in Section IV below and report it at the conclusion of the investigation if, but only if, it is determined to be a suspicious order.

IV. INVESTIGATION OF ORDERS OF INTEREST

a. Preliminary Steps

If a product order meets or exceeds a threshold, and is thereby identified as an order of interest (or on other grounds is characterized as an order of interest), it is recommended that the distributor examine the order further. The examination is intended to aid the distributor in reaching a decision to either ship product to fill the order or to continue to hold the order. Further examination will also aid in determining whether and when to report the order to DEA under 21 C.F.R. § 1301.74(b).

The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest.

It is recommended that the distributor designate a person with suitable training and experience to investigate orders of interest.

b. Initial Review

When initially reviewing an order of interest, a distributor should first examine the specific drug code product order to determine whether the reasons the order met or exceeded the thresholds, or on other grounds was characterized as an order of interest, are not “suspicious” or whether the order warrants still further examination. The examination may include obtaining additional verification from the customer that placed the order. For example, the customer may be able to identify whether the order contained an error, or whether there has been a change in the customer’s business circumstances that warrants a shift in its purchasing practices that can be readily identified.

c. Investigating the Order

If, after initial review, it is determined that the order should be examined further, it is recommended that the distributor conduct an additional review as quickly as possible. The following elements are recommended as part of the additional review:

Review prior orders

The distributor should review the customer’s past purchasing history for trends/discrepancies to determine whether:

- The distributor had to investigate a prior order and the circumstance and results of any prior investigation, including whether a prior order exceeded the same or a different threshold, and how the present order compares to the past order(s) of interest;
- There has been an increase (or decrease) in orders for this “group” or “family” of CS products;
- There has been other unusual activity, such as “spikes” in prior orders (e.g., a pattern of ordering over several months where the customer has placed no orders, followed by a month with a large order);
- There has been a decrease in orders for other products, (potentially indicating a shift in focus or customer base);
- There has been a change in the customer’s operating environment (e.g., a new medical establishment recently opened in the customer’s neighborhood);
- There has been a change in availability of drugs (such as a new drug dosage form that has recently been approved by FDA) identified as a Drug of Concern by DEA’s Office of Diversion Control; and
- There are end-of-year C-II quota issues.

Interview customer

Ask: Why is there an “unusual” order? What will you do with it? Who is prescribing it? (Who, what, when, where, why, how?)

Verify customer input – (where appropriate)

How and what information provided by the customer needs to be verified will be determined on a case-by-case basis, but examples of information that could be verified include:

- If a customer says there is a new medical establishment located nearby, verify the establishment's existence, name, address, practitioner(s) names and DEA registration numbers.
- If the customer says it called DEA, verify that it actually did so.
- If the customer states that a natural disaster destroyed its pharmacy and that it must restock, verify the disaster.
- If the customer claims it "lost" a shipment, verify the loss⁶.

Additional Information

The distributor may seek additional information about the order and/or the customer who placed the order if, during the examination, it is determined that further confirmations or background information is warranted.

d. Documentation

All investigations should be fully documented, and all records of the investigation should be retained in an appropriate location within the firm (such as with other records relating to the particular customer).

At a minimum, documentation should include the name(s), titles(s) and other relevant identification of the representative of the customer contacted (e.g., "pharmacist in charge"), dates of contact, and a full description of questions asked and requests for information made by the distributor and of information provided by the customer. The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." That statement should be signed and dated by the reviewer. Copies of any written information provided by the customer should also be retained as part of the documentation of the investigation.

e. Shipment and Reporting Decisions (under 21 C.F.R. § 1301.74(b)); SOPs

At an appropriate point in the examination process, the distributor will decide how to resolve the order, specifically, whether the order is "suspicious," and should be reported. Employees should be selected and authorized to make shipment and reporting decisions based on their knowledge of DEA requirements, the distributor's business, customers and other relevant factors. (Further recommendations as to reporting to DEA can be found in Section V below.)

Orders that are determined to be "suspicious" should be reported to DEA under § 1301.74(b) immediately upon being so determined. It is assumed that the order will continue to be placed on

⁶ Distributors should also determine whether there is an obligation to report the loss under 21 C.F.R. § 1301.76(b).

hold and/or cancelled, once it has been identified as “suspicious.” An exception can be made if the distributor subsequently obtains additional or alternative information that leads to the conclusion that the order was misidentified as “suspicious,” and/or is consistent with the pharmacy/dispenser’s practice. In such instances, the order may be shipped. Full documentation of the reasons for the conclusion is recommended.

Each distributor is encouraged to develop SOPs that:

- Describe how an initial review and investigation will be conducted;
- Reflect the distributor’s and its customers’ business conditions;
- Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;
- Include a process and/or guidance/criteria for making the final determination that an order is, or is not, “suspicious”;
- Define a process for reporting to DEA under 21 C.F.R. § 1301.74(b); and
- Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.

f. Future Customer Orders

In instances where a distributor concludes that an order is (or remains) “suspicious” after conducting an investigation, in addition to notifying DEA, it is recommended that the distributor evaluate its business relationship with the customer that placed the order. The distributor may consider whether to subject future orders from the same customer for the same drug code product (or all CS) to more rigorous scrutiny than was applied before the determination that the order is suspicious. A distributor may also consider whether to cease filling all future orders of the drug code product (or all CS) placed by that customer.

V. FILE SUSPICIOUS ORDER REPORTS WITH DEA

a. Immediate DEA Notification

Under 21 C.F.R. § 1301.74(b), orders designated as “suspicious” must be reported to DEA “when discovered.” Once the distributor has made the determination that an order is suspicious, a phone call to report the order to the local DEA office is recommended to meet this requirement (unless DEA provides other direction). The distributor should provide additional documentation to DEA upon request.

Additional considerations:

- Even if there is some ambiguity regarding a customer or an order’s status, occasions may arise when the intended use of an order is questionable. For example, the distributor may identify information that leads them to believe that a potential customer, prior to entering a formal business arrangement with that customer, may

intend to order CS products with a frequency, volume or other indicator that could be considered "suspicious." In such instances, the distributor should provide DEA with a report of this information under 21 C.F.R. § 1301.74(b).

- Distributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report "when discovered."

b. Correspondence for Reporting

It is recommended that all correspondence to DEA (containing reports of suspicious orders) should be sent registered mail with a return receipt requested, by electronic mail or by another system that creates for the distributor a permanent record that DEA has received the notification. Although correspondence to the local DEA office is encouraged as a follow-up to a telephonic notification, distributors are encouraged to discuss with the local DEA office whether that office prefers to receive a follow-up written notice and the form for such notice.

The cover letter for reports of suspicious orders may read: "This report is submitted to you in accordance with the requirements of 21 C.F.R. § 1301.74(b) and is for (company name)." When the return receipt is received, it should be stapled to the cover letter as proof of submittal. (It is suggested that the distributor title the report "21 C.F.R. § 1301.74(b)" report.)

In some states, additional reporting requirements may apply. Each distributor should determine whether a state report is required, and should comply accordingly.

It is recommended that the same person conduct the investigation, decide (perhaps in consultation with one or more superiors) whether or not to cancel the order, and also provide the report to DEA.

c. Documentation

All additional contact with DEA, either by telephone or in person, should be documented; and a record of the contact should be maintained.

VI. EMPLOYEES, TRAINING AND STANDARD OPERATING PROCEDURES

a. Employees/Training

Individuals working in CS areas should be screened and selected for their attention to detail, ability to recognize the importance of accuracy, length of tenure with the company and work ethic.

It is recommended that employee training:

- Include a review of DEA rules and regulations;
- Fully cover the firm's procedures for compliance;

- Include backup training to cover instances when the employee primarily responsible for monitoring for suspicious orders will not be available (e.g., due to vacation leave or sick leave); and
- Provide for periodic retraining.

It is recommended that training be conducted for all personnel involved in:

- Receiving, shipping, handling and record-keeping with respect to CS items;
- Sales, or in establishing new accounts and persons who interact with customers; and
- Reviewing, investigating and/or deciding whether to fill orders.

All such training should be documented, and the documentation should be maintained.

b. SOPs

It is recommended that, to implement these Industry Compliance Guidelines, specific written company SOPs be developed and maintained.

VII. ADDITIONAL RECOMMENDATIONS

It is recommended that a distributor include in its “system” provisions for:

- Periodic internal audits of suspicious orders, compliance procedures and results;
- Periodic reviews and revisions of internal SOPs for compliance with §§ 1301.71(a) and 1301.74(b) and new DEA guidance, as well as employee training requirements/procedures;
- Periodic review of the distributor’s system for monitoring for suspicious orders, including the system design and the thresholds, to determine whether revisions should be developed. For example, if the FDA approves a new controlled substance, or a new indication for use of an existing controlled substance, or if DEA makes new information available regarding a Drug of Concern, revisions to the thresholds may be needed; and
- If appropriate, update customer and/or order records on the basis of information obtained while investigating an order under Section IV above.

Glossary of Abbreviations

Abbreviation	Explanation of Term
ARCOS	Automation of Reports and Consolidated Orders System
C.F.R.	Code of Federal Regulations
C-I, C-II, C-III, C-IV, C-V	References the DEA's designation of individual controlled substances into one of the five levels under 21 C.F.R. §1308
CS	Controlled Substances has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.)
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DOJ	Department of Justice
FDA	Food and Drug Administration
HDMA	Healthcare Distribution Management Association
NABP	National Association of Boards of Pharmacy
NDC	National Drug Code
NTIS	National Technical Information System
SKU	Stock Keeping Unit
VIPPS	Verified Internet Pharmacy Practice Sites

Attachment 2

**Questions for the Drug Enforcement Administration (DEA) Regarding Requirements for
Suspicious Orders Monitoring and Reporting
Submitted by the Healthcare Distribution Management Association (HDMA)
June 1, 2011**

The following are general questions about wholesale distributors' responsibilities for controlled substances suspicious orders monitoring and reporting.

1. During a wholesale distributor's efforts to fulfill the U.S. Drug Enforcement Administration's (DEA) expectations to "know your customer," current business practices for many Healthcare Distribution Management Association (HDMA) members include the following measures:

- Wholesale distributors request that potential customers, prior to opening an account with the wholesale distributor, answer questions about their business based on the "Information Gathering" examples contained in the HDMA INDUSTRY COMPLIANCE GUIDELINES (ICG): REPORTING SUSPICIOUS ORDERS AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES, Section I.b. (See http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf).
- Wholesale distributors' sales and inside sales staff are trained to be alert during routine communications with customers for signs that a customer's intentions in purchasing the product may raise questions, and to report to appropriate designees within their companies, any such questions regarding a prospective customer's intentions and/or activity so that the wholesale distributor may, if warranted, conduct further review of the customer.
- If the wholesale distributor has reason to believe, based on a system for tracking product orders such as that described in Section II of the HDMA ICG, that a customer, or a customer's order(s) have changed in such a manner as to suggest different ordering patterns for controlled substances, they will follow up with an additional, more extensive, review of that customer and/or the order in question.
- Wholesale distributors will report to DEA when appropriate pursuant to 21 C.F.R. § 1301.74(b).

Questions

- A. Does DEA agree that the frequency of customer review described above meets the Agency's "know your customer" expectations?
- B. If not, HDMA requests that DEA elaborate on the Agency's expectations.

2. During its "know your customer" efforts, a wholesale distributor may also find a customer (or potential customer) is, to the best of the wholesale distributor's ability to ascertain, following applicable laws, placing orders that are not "suspicious" for their class of trade and has not otherwise given indications of questionable business practices. At the same time, the wholesale distributor may have lingering questions about the customer's intentions.

As a hypothetical example, suppose a customer is an owner and/or operator of more than one pain treatment clinic. The clinics maintain all required state and federal licenses/registrations,

Questions for the Drug Enforcement Administration
By HDMA
June 1, 2011

patients are given physical exams, they accept all appropriate forms of payment, and, to the best of the wholesale distributor's ability to ascertain, follow applicable laws and regulations. However, this customer owns and operates only pain clinics, is not affiliated with other treatment programs (e.g., physical therapy) and plans to open more pain treatment clinics, potentially increasing their purchase or prescribing volume.

Questions

- A. Based on DEA's extensive experience, on ARCOS or on other data, can DEA provide guidance as to when and under what circumstances the wholesale distributor may continue to sell to the customer meeting this description, or, conversely, when they should cease distribution and report a customer operating as described above to DEA?
 - B. Does DEA have further guidance on other sources of information wholesale distributors might use to evaluate such customers?
 - C. If DEA's answer is that it is the wholesale distributor's "business decision" whether to sell, and the wholesale distributor proceeds to sell to this customer, will DEA communicate to its field offices that they should not take action against the wholesale distributor in the absence of additional indications of questionable practices and no indication of negative information about the customer from DEA?
 - D. If the wholesale distributor ceases to sell to this customer and reports them to DEA, (whether or not the wholesale distributor has more definitive information leading them to question the customer than described above) is 90 days an ample time frame for the wholesale distributor to conclude that DEA's evaluation of the customer's actions are consistent with the public interest? If not, what is an appropriate amount of time?¹
 - E. What guidance or criteria can DEA provide to wholesale distributors for use in assessing whether a pain care medical practice is considered "legitimate"? Information that would be helpful to wholesale distributors includes a definition of "legitimate" pain care clinic or medical practice and a comprehensive comparison of the characteristics of a legitimate pain care clinic versus "rogue" pain clinics (pill mills) that wholesale distributors may directly apply to their "know your customer" efforts.
 - F. Where can the regulated industry obtain a description of DEA's updated methodologies and/or processes for keeping such guidance or criteria current?
3. When a wholesale distributor receives a request to provide controlled substances (either from a newer customer or an existing one) who indicates they wish to increase controlled

¹ HDMA would like to note why the answer to this question is important. If the former customer truly is questionable, but retains a valid DEA registration, they are free to pursue "wholesaler shopping" until they find one or more that have monitoring systems with different criteria for determining what is "suspicious". If the customer is not questionable, then the wholesale distributor that closed the account is effectively penalized for maintaining a rigorous compliance program by being placed at a competitive disadvantage. Ultimately, the public is disadvantaged most because either a criminal activity is allowed to continue or because the known benefits that competition brings to the marketplace are lost. Clearly, none of these outcomes are desirable.

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substance orders, most wholesale distributors provide the customer with a questionnaire about their business. (Note: as described in #1 and #2 above.)

A wholesale distributor staff member then carefully reviews the customer's response to determine if there is anything questionable in the answers that requires further assessment. (See the ICG Sections I.b. for recommendations on information about the customer the wholesale distributor could request, and I.c. for suggestions on reviewing the customer information, as well as the DEA guidance provided on October 20, 2009 titled: "*Suggested Questions a Wholesale distributor should ask prior to shipping controlled substances*")

The ICG also recommends that the wholesale distributor ask the customer (owner, "Pharmacist in Charge," or an equivalent designee) to sign a statement that the answers are accurate.

Questions

- A. Based on DEA's extensive experience with registrants who furnish controlled substances to their patients, can DEA identify the types of responses to the questions we ask these customers that the Agency believes are most likely to lead the wholesale distributor to conclude that further due diligence is warranted?
 - B. If a customer is otherwise acceptable, subsequently does not place an order determined to be suspicious, and the wholesale distributor conducts periodic updates of its "know your customer" information, can the wholesale distributor accept the responses and the signed statement as documentation that the customer is purchasing the product for legitimate purposes? If they cannot, please elaborate on what is acceptable for this purpose.
4. When a wholesale distributor reviews a potential customer who wishes to purchase controlled substances, they likely seek:
- appropriate information, such as that described in the HDMA ICG;
 - answers to questions such as those posed in DEA's October 20, 2009 guidance "*Suggested questions a wholesale distributor should ask prior to shipping controlled substances;*"
 - the information about internet pharmacies discussed in the preamble to the interim final rule: "*Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008*" [73 Fed. Reg. 15596 (April 6, 2009)]; and
 - guidance provided during DEA's meetings with, and presentations to, wholesale distributors.

Questions

- A. Is there any other information wholesale distributors should observe during our "know your customer" efforts that are not included in the above bullet points?
- B. Does DEA have methodologies and/or processes for keeping such guidance or criteria current that they can share with wholesale distributors?

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5. Due to the Health Insurance Portability and Accountability Act (HIPAA) privacy rules restricting access to patient information and records, pharmacists and practitioners cannot divulge patient records. Therefore, neither the ICG nor wholesale distributors' individual procedures call for review of a customer's patients.

Questions

- A. Does DEA agree that given the law cited above, wholesale distributors are not expected to seek information about a customer's patients?
- B. If DEA believes customers' patients should be included in the wholesale distributors' reviews, please provide legally compliant suggestions regarding avenues of inquiry that could be used in lieu of patient records.
- C. Additionally, please provide specific guidance and/or examples of when and how such avenues of inquiry can be pursued.

The following questions pertain to prescribers or to relationships between prescribers, pharmacies and the wholesale distributor

6. Due to the changes in reimbursement rates and healthcare reform measures, non-pharmacy Healthcare Provider (HCP) models are evolving. More individual practitioners, Accountable Care Organizations (ACOs) and other HCPs have told wholesale distributors that they wish to start, or increase, purchasing of controlled substances to furnish/dispense/administer directly from their offices.

Given these new and/or significantly changed models, wholesale distributors, which are not experts in providing healthcare to patients, have little or no ability to determine how to group these HCPs into classes of trade, as described in the ICG in Section II, and have limited data on which to base "thresholds" to signal purchasing patterns that may need further review under a suspicious order monitoring system. Further, these patterns are continuously changing so that determining what is "suspicious," even based on relatively recent data, may not accurately identify questionable orders.

Questions

- A. Section II.c. of the HDMA ICG recommends developing "thresholds" for customers grouped into "classes of trade" to signal that an order may represent an unusual pattern suggesting the need for further review. Using ARCOS or other data, we would appreciate DEA's guidance on what types of registrants (practitioners and non-pharmacy HCPs) should be grouped together into a "class of trade" for purposes of determining "thresholds," based on a HCP model that calls for office dispensing/administering.
- B. If more than one class of trade should be formed for these HCPs, can DEA specify how to group these registrants together into several classes of trade for purposes of evaluating ordering patterns?

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- C. Since wholesale distributors have limited baseline data, can DEA provide further guidance on how to evaluate patterns of ordering for these HCPs that should lead to considering an order to be questionable (described as an "Order of Interest" under Section II.c. of the ICG)?

7. The following questions pertain to practitioners who order controlled substances directly from wholesale distributors with the intention of furnishing, administering or dispensing them directly from their offices.

Questions

- A. Does DEA have a list of practitioner specialties that would appropriately purchase (for administration/dispensing within their practices) controlled substances that can be provided to wholesale distributors?
- B. Has DEA provided guidance on the types and acceptable amounts of controlled substances and/or combinations of controlled substance products, by practitioner specialty (e.g. Family Practice) or on type of treatment needed (e.g., palliative care vs. cancer treatment vs. general surgery), or other criteria such as patient demographics (e.g. percentage of elderly vs. other age ranges within their practice) that would be appropriate for furnishing to patients directly from the practitioners' practice?
- C. If such guidance exists, HDMA requests that DEA make these guidances available to wholesale distributors. If not, can DEA recommend where wholesale distributors could obtain such guidances?
- D. As part of its request for ARCOS data, HDMA would like to ensure that the request includes aggregated data on individual physicians/practitioners. Specific data, to include aggregated data for specific individual physician/individual practice registrants, would be the most helpful.

8. The following questions are very similar to those in # 7 above but pertain to practitioners who prescribe, rather than purchase, controlled substances.

Questions

- A. Does DEA have a list of practitioner specialties that may be expected to prescribe higher quantities of controlled substances?
- B. What controlled substances and/or combinations of products are appropriate for prescribing by the various specialties?
- C. If such guidance exists, HDMA requests that DEA make them available to wholesale distributors. If not, can DEA recommend where wholesale distributors could obtain such guidances?

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The following questions pertain to DEA's guidance dated October 20, 2009, entitled "Suggested Questions a Wholesale distributor should ask prior to shipping controlled substances" ("guidance" or "DEA guidance")

9. The guidance's pharmacy-related questions include several that pertain to a pharmacy's other suppliers. These questions include:
- *Who is the pharmacy's primary supplier?*
 - *Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?*
 - *If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?*
 - *What ratio will you be supplying compared to other suppliers?*

While we understand these questions' underlying purpose, wholesale distributors are subject to the U.S. anti-trust laws. Thus, asking these questions may place them in the position of stepping over the line into areas these laws restrict.

Questions

- A. Has the DEA discussed these questions, in the context of the Agency's "know your customer" guidance for wholesale distributors, with their colleagues in the Anti-Trust Division of the Department of Justice (DOJ)? If not, HDMA requests that DEA receive from DOJ an opinion as to whether these questions should be part of this guidance and part of the wholesale distributor's "know your customer" efforts.
- B. Can DEA provide a mechanism for the wholesale distributor to verify the customer's answers with the Agency about other suppliers?
- C. (The following question is applicable providing that the DOJ is in agreement that these questions are acceptable.) During the course of conducting their due diligence regarding a new customer, a wholesale distributor may find no questionable business practices at a pharmacy but the pharmacy is unwilling to answer any or all questions related to their other suppliers. Is it acceptable for the wholesale distributor to ship controlled substances to this pharmacy as long as this customer's controlled substances orders are not identified as "suspicious" and no other red flags are raised during the course of the business arrangement?
- D. If not, can DEA provide guidance or criteria for when a refusal to answer these questions about other suppliers would indicate that the wholesale distributor should either conduct further inquiry into the customer's business practices and/or should not ship to the pharmacy in question?
- E. Would DEA be willing to revise the third question as follows: *If the pharmacy states that you are not their only supplier, ask the pharmacy what controlled substances they will be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?*

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10. Another pharmacy question reads as follows: “*Is the pharmacist comfortable enough with the prescribing practices of any or all practitioners for which they fill, **to stake their professional livelihood on it?***” (Emphasis added) HDMA notes that the phrase “...to stake their professional livelihood on it?” seems to indicate that the pharmacist, who has healthcare training but not necessarily medical training or legal authority over prescribers, and does not perform physical exams of their patients, should know with certainty that every physician or other prescriber for which they fulfill prescriptions is prescribing appropriately.

Questions

- A. Would DEA consider rephrasing this question as follows: “*Is the pharmacist comfortable with the prescribing practices of any or all practitioners for which they fill, and do they acknowledge, in writing, that they are carrying out their corresponding responsibilities to ensure that the prescriptions they receive are issued for a legitimate medical purpose as required under 21 C.F.R. § 1306.04*”
- B. If not,
 - a. Would DEA further define their intention in recommending that wholesale distributors ask this question?
 - b. What is DEA’s expectation that a pharmacist should have certainty?
 - c. Can the Agency define what is meant by this question and/or provide criteria or guidance for how the wholesale distributor should evaluate the response if the pharmacist states that they cannot stake their professional livelihood on the prescribing practices of every practitioner for which they fill prescriptions?

11. Under “Possible questions for a practitioner”, is one that reads: “*Has the practitioner ever been disciplined by any state or federal authority?*” This question implies an extended search for disciplinary action going back through the practitioner’s entire professional lifetime, and potentially including disciplinary actions unrelated to patient or pharmaceutical safety, security or prescribing practices (e.g., employment discrimination, workplace harassment, tax issues). When answering these questions, please assume that no other red flags are raised during the wholesale distributors’ due diligence efforts in reviewing a practitioner or during suspicious orders monitoring.

Questions

- A. Does DEA agree that a review extending back two years and only to activities related to patient or pharmaceutical safety, security and prescribing or filling practices is appropriate?
- B. If not, what period of years does DEA believe would be an adequate length of time?
- C. If DEA believes that the length of the review should not be specified in terms of a time frame, but rather based on the wholesale distributor’s ability to adequately establish the credibility of the practitioner, could the Agency provide guidance and/or criteria for:
 - a. what further information should be sought;

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- b. how the wholesale distributor would go about evaluating that information to determine the practitioner's credibility; and
 - c. then, how to link that information to the time frame over which the search for disciplinary actions should be pursued?
- D. If DEA believes a review of disciplinary actions that do not involve pharmaceutical safety, security or prescribing/filling practices, is necessary even if no other red flags are raised, HDMA requests that DEA provide:
- a. guidance on the types of disciplinary activities that should be sought and how they should be factored into the decisions as to whether to accept orders from this customer; and/or
 - b. examples of instances where the Agency found that a disciplinary activity occurred outside of those involving pharmaceutical safety, security or prescribing/filling practices, and where no other reason to question the practitioner was found, but where the disciplinary action may have indicated that further review of a practitioner, or a decision not to ship controlled substances to them was warranted.

12. Another question reads: *"How many patients is the practitioner presently treating (day, week and month)?"*

Questions

- A. Does DEA have guidance on an appropriate number (such as an average or range) of patients for an individual practitioner to treat, preferably by specialty?
- B. Is the Agency aware of any guidances from professional societies, or similar knowledgeable sources, regarding this issue that DEA believes is appropriate for wholesale distributors to use as reference for their suspicious orders monitoring programs?
- C. HDMA requests that DEA advise wholesale distributors on how they may access such guidances.

13. Although HDMA has been willing to furnish to its members the guidance referenced in these questions and other guidances DEA might provide, we may not be able to attend every industry meeting where such information is provided. Further, HDMA is only able to circulate them to our own members, yet there are other legitimate wholesale distributors who are not HDMA members that should be aware of them.

Questions

- A. Did DEA make the guidance questions available through DEA's Regional Offices?
- B. Did DEA inform all wholesale distributor registrants through official correspondence?

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- C. If DEA did not, would DEA be willing to do so if they plan on releasing further such guidances?
- D. Additionally, if DEA did not, is there any binding responsibility upon a registrant to ascertain answers to these questions?

Additional Questions Related to Monitoring for Suspicious Orders

14. In 2011, a number of states have been considering new laws that would require wholesale distributors to provide sales data similar to what they provide to DEA in ARCOS reports. Wholesale distributors maintain large volumes of data, including data on all products, not just controlled substances, so that submitting separate reports to different agencies can pose significant IT and cost challenges. Additionally, some states unknowingly request data that differs from ARCOS either in the data fields and/or frequency of reporting, compounding these challenges.

Question

- A. HDMA believes it may be very important for all agencies to work with the same data sets during a prosecution. Given the importance of good communication and coordination among local, state and federal agencies regulating controlled substances, would DEA consider establishing a mechanism for states to have access to the ARCOS data assuring local, state and federal agencies will be working with the same data?

15. Wholesale distributors often hear from their customers that their competitors either do not have controlled substances monitoring programs (CSMP) or the competitors' programs are not as strict. Lack of consistency creates an "unlevel playing field" for wholesale distributors. It also undermines DEA's security intentions because customers are free to conduct "wholesale distributor shopping" until they find one who's CSMP is less sophisticated or has an unknown loophole that doesn't identify their orders as "orders of interest."

Question

- A. How does DEA ensure that requirements are enforced across the board and uniformly for all levels of the pharmaceutical supply chain? For example, are there internal guidelines for DEA staff to help ensure uniformity?

16. HDMA noted the DEA action taken in late February 2011 under "Operation Pill Nation" resulted in arrests at a number of clinics. Further, as explained in the Miami Herald of February 23, 2011, a number of physicians have either voluntarily surrendered their DEA registrations or were arrested.

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Questions

- A. Can DEA release the names and/or registration numbers of the physicians who were involved in these actions? There are over 1,000,000 physicians registered with DEA, and currently, verification can only be performed through a "one-by-one" keying in of each physician customer into DEA's data base. Direct notification to wholesale distributors would be very helpful.
- B. Similarly, names of the clinics out of which these physicians operated were not published in the press reports. Could DEA release either names and/or registration numbers of these facilities?

17. On July 7, 2010, HDMA submitted a letter to then-Acting Administrator Leonhart reiterating HDMA's verbal requests for DEA to provide aggregated, blinded ARCOS data so that distributors could evaluate when fulfillment of customer orders may first require further due diligence. At the DEA/HDMA meeting on Dec. 7, 2010, DEA staff indicated a concern that if they were to release ARCOS data, even if it were aggregated, some wholesale distributors might be able to determine what their competitors are selling, potentially resulting in confidentiality breaches. During a presentation at the most recent Distribution Management Conference (DMC – March 7, 2011), Cathy Gallagher, in reference to the request for ARCOS data, essentially indicated that existing regulations do not allow DEA to identify a registrant's other suppliers.

Questions

- A. Do these statements represent DEA's official response to HDMA's letter?
- B. Therefore, has DEA reached a final decision that the Agency will not release aggregated ARCOS data?
- C. If DEA cannot provide the requested ARCOS data, about quantities and types of purchases from other wholesale distributors, can DEA tell wholesale distributors how many other wholesale distributors the registrant is buying from?

18. The following questions refer to the status of suggestions HDMA made at the December 7, 2010 meeting between DEA and HDMA.

Questions

- A. HDMA had suggested that DEA review and update the 2006 and 2007 "letters to industry" sent to wholesale distributor registrants.² Can DEA tell us the status of this request?

² Letters from Joseph T. Rannazzisi to wholesale distributor registrants issued on September 27, 2006, February 7, 2007 and December 27, 2007.

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- B. DEA indicated that its procedures for suspending or restricting a wholesale distributor's DEA registration often include sending the registrant a "Letter of Admonition" outlining concerns with the registrant's compliance. Do DEA's procedures require the Agency to issue a written warning where there is not a finding that continued registration would constitute an imminent danger to the public health and safety before suspending a wholesale distributor's registration?

19. In our meeting with DEA on July 17, 2008, HDMA noted the incongruity of DEA's increases in quota sizes and the expectation that wholesale distributors will cut back on distribution. At the time, DEA seemed to understand that there needs to be a better connection between the size of the quotas and the expectations for wholesale distributors to curtail shipments if there are questionable orders.

Question

- A. How has DEAA's wholesale distributor initiative affected DEA's decisions on quotas? For example, we note that manufacturers received their full requested quotas for oxycodone for 2011.

20. HDMA asks if DEA would be willing to encourage collaboration and provide information to the mutual benefit to both parties by aiding wholesale distributors in determining appropriate additional due diligence measures and/or revisions in selling/shipping practices.

Questions

- A. In this light, would DEA be willing to support this effort through any or all of the following:
- a. Providing the names and/or registration numbers of all parties involved in the actions similar to that of "Operation Pill Nation"?
 - b. Reestablish the notification system to all wholesale distributors when a single wholesale distributor has refused to deal with a particular practitioner registrant?
 - c. Although DEA's website identifies pain clinics or other registrants where DEA has taken specific enforcement action, the reports are somewhat delayed. Can DEA expedite making this information available?
- B. If a registrant asks for a meeting with a DEA field office to discuss issues and seek clarification, is the field office obligated to have the meeting?

21. It is our understanding that at the start of an inspection, DEA will provide the registrant with a copy of DEA Form-82, but typically does not provide a written report to the registrant at the end of the inspection. As part of a wholesale distributor's due diligence, they may ask a potential customer if/when the customer was last inspected by DEA, and for a copy of any

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documentation related to the inspection. However, some pharmacies respond to such requests by stating that although they were inspected, DEA never leaves behind any documentation of the inspection.

Questions

- A. Can DEA clarify what form of inspection documentation a customer receives at the beginning and at the conclusion of a DEA inspection, specifically:
- a. Does DEA provide each registrant, including pharmacies and other healthcare providers, with a copy of DEA Form-82 at the beginning of each inspection?
 - b. At each inspection's conclusion, does DEA provide the registrant with any form of written communication about the results of the inspection?
 - c. If not, is there an alternate means by which wholesale distributors may find out the results of a customer's inspection so that they may factor DEA's findings into their "know your customer" efforts?

HDMA appreciates the opportunity to submit these questions to the Drug Enforcement Administration. If there are any questions, please contact Anita Ducca, Vice President, Regulatory Affairs at 703-885-0240 or aducca@hdmanet.org.

Attachment 3

Suggested Questions a Distributor should ask prior to shipping controlled substances.

This list of questions is not intended to be all inclusive nor should it be interpreted that every situation or registrant activity is covered. This questionnaire is provided to assist for the distributor to formulate a better understanding of who their customers are and whether or not they should sell them controlled substances. It is incumbent upon you, the distributors, to ensure that sales to your customers are for legitimate purposes. It is further incumbent upon you to identify illicit or suspicious activities which may result in the diversion of controlled substances.

The use of this questionnaire should not be construed in any manner to be a mechanism or means that you have fully met the criteria and actions required by 21 USC 823 or other state and federal laws that are applicable.

Possible questions for a pharmacy:

- Does the pharmacy fill prescriptions via the Internet? If so, is the pharmacy registered with the DEA under the Ryan Haight Act?
- Is this a mail order pharmacy (fills prescriptions for insurance, etc.)?
 Note: A pharmacist may claim to be mail order pharmacy but may actually be operating as an Internet pharmacy. Do not accept the response to this question at face value.
- Is the pharmacy licensed in all states for which it mails or fills prescriptions?
- Does the pharmacy report to all states that have prescription monitoring programs in which their customers reside and to whom they dispense?
- Does the pharmacy provide services for any specialty customers such as Long Term Health Care, Hospice Centers, Assisted Care Living Facilities, etc.?
- Does the pharmacy have staff or a private firm that solicits practitioners to get more business?
- What is the pharmacy's ratio of controlled vs. non-controlled orders?
- Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?
- What are the hours of operation of the pharmacy?
- Does the pharmacy offer a full assortment of sundries to its customers (e.g., aspirin, snacks, cosmetics, etc.)?
- Does the pharmacy have security guards on the premises? If so, why?
- What methods of payment does the pharmacy accept (cash, insurance, Medicaid, and in what ratios)?
- Who is the pharmacy's primary supplier?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- If this is a new account, why does the pharmacy want you to be their supplier?

- If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?
- What ratio will you be supplying compared to other suppliers?
- Does the pharmacy fill prescriptions for out of state customers? If so, for how many out of state customers does the pharmacy fill (ratio or approximate number)?
- If the pharmacy fills prescriptions for Pain Management or other specialty practitioners (diet, oncology, etc.), is the pharmacist comfortable with the prescribing practices of the practitioner?
- Has the pharmacist questioned or been uncomfortable with, the prescribing practices of any practitioner?
- Has the pharmacy ever refused to fill prescriptions for a practitioner? If so, why and who?
- Are there particular practitioners who constitute most of the prescriptions it fills? Who are these practitioners (Name and DEA registration number)?
- Does the pharmacy have any exclusive contracts, agreements, arrangements, etc., with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements.
- Is the pharmacist comfortable enough with the prescribing practices of any or all practitioners for which they fill, to stake their professional livelihood on it?
- Does the pharmacy supply, order for, or sell to any practitioners or other pharmacies?
- How does the pharmacy sell/transfer controlled substances to other pharmacies or practitioners? Via a prescription, sales invoice, or DEA Form-222? (Transfer by prescriptions is not authorized.)

Possible questions for a practitioner:

- What is the practitioner's specialty, if any (family practice, oncology, geriatrics, pain management, etc.)?
- Do the controlled substances being ordered correspond to his specialty or the treatment he provides?
- What method of payment does the practitioner accept (cash, insurance, Medicare) and what is the ratio of each?
- Has the practitioner ever been disciplined by any state or federal authority?
- How many patients does the practitioner see each day? What is his weekly average?
- Does the practitioner prescribe as well as dispense?
- Why does the practitioner prefer to dispense as opposed to prescribe?
- Who was the practitioner's previous supplier? Are they still ordering from this supplier? If not, why are they looking for a new supplier?
- Do the hours of operation and the facility accommodate the type of practice being conducted?
- Does the practitioner's office have security guards on-site? If so, why?

- Are all applicable state, federal, local licenses current and are they issued for the registered address at which the practitioner is practicing?
- Does the practitioner see out of state patients? If so,
 - From what states,
 - How many,
 - Approximate ratio of out of state compared to local, and
 - Why, specifically, they travel so far to see him?

- Can the practitioner provide a blank copy of an agreement which they enter into with a patient, specifying the course of treatment, the patient rights and responsibilities, and reasons for termination of treatment?
- Does the practitioner conduct random unannounced drug testing?
- What measures does the practitioner employ and/or monitor to prevent addiction and diversion of controlled substances?
- Is there more than one practitioner dispensing controlled substances from the registered location?
- Do you order for just yourself or for the whole clinic?
- What controlled substances are you currently dispensing? (If only one or two controlled substances are being ordered, have the practitioner fully explain why he administers or dispenses only these specific controlled substances.)
- In what dosage levels is the practitioner dispensing (2 tablets, 4 times a day, for 30 days, or 90, 120, 240 a week, month).
- Does the practitioner prescribe as well as dispense to his patients?
- Does the practitioner prescribe the same controlled substances as were dispensed to the patient?
- How many patients is the practitioner presently treating (day, week, and month)?

Should you have any additional questions, concerns or issues beyond what has been presented it is strongly recommended you contact your local DEA Office.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3841

March 26, 2012

Mr. Joe Harmison, R.Ph.
Owner
DFW Pharmacy
DFW Prescriptions
2701 Osler Drive, Suite 1
Grand Prairie, TX 75051

Dear Mr. Harmison,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Thursday, March 1, 2012, to testify at the hearing entitled "Prescription Drug Diversion: Combating the Scourge."

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 respond to these questions by the close of business on Monday, April 9, 2012. Your responses should be e-mailed to the Legislative Clerk, in Word or PDF format, at Kirby.Howard@mail.house.gov.

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: G.K. Butterfield, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade

Attachment

The Honorable Mary Bono Mack

- 1. In your testimony, you suggested that health providers should have access to complete patient medication profiles. Do any PBMs do that now? If not, do you have any idea why not?**

PBMs do not always send us complete edits related to when a certain patient has filled the same prescription somewhere else or has used another doctor – also the PBMs do not normally do this by drug class as the edits are based on a specific drug only. In essence, a patient could have picked up a prescription from a different doctor at a different pharmacy then come to my pharmacy a few days later and I would only receive a reject for refill-too-soon if the prescription was for the exact same drug they had previously filled. Most PBMs do not send edits if, for example, the drug they tried to get in my store was in the same general drug class as the one filled previously.

Community pharmacists mainly only have access to the prescriptions their patients have filled at their store, including over-the-counter products and herbals that are self-reported. Unless the PBM decides to deny the claim, we will get an edit saying the exact same drug was filled at another pharmacy and it's being refilled too soon. The reject will tell you the date the prescription was filled but not the pharmacy it was filled at.

Community pharmacies are asking that PBMs give us access to more information than is currently available because they keep a record of all pharmacy claims and should be able to flag if a patient is doctor and pharmacy shopping and the prescriptions are being paid by a third party.

- 2. You testified that PBMs that distribute via mail order often fill a prescription with large quantities. Is the quantity of a medication determined by the PBM or the prescribing doctor? If a PBM, or any**

pharmacy for that matter, receives a prescription for a large quantity of pills, do they have the discretion to dispense fewer doses?

In the two states in which I am licensed to practice pharmacy, the pharmacist is allowed to reduce the quantity filled but it is always the prescriber who determines the amount to be dispensed. Pharmacists need prescriber authorization to increase any quantities but do not need authorization to decrease the quantities.

The Honorable Edolphus Towns

- 1. I understand that too much volume is one of the “red flags” that the DEA considers in determining whether a pharmacy is filling legitimate prescriptions. Do you believe that the overall volume of a specific controlled substance is enough information to make a decision about the risk of diversion?**

No, overall volume is not enough information to make a decision but can be a contributing factor. Other factors such as location of pharmacy, patient mix, prescriber mix, and knowledge of patients and their conditions all play a role.

- 2. Do you believe that the DEA should set a specific quota and a process for that quota to be reevaluated when circumstances change at a pharmacy?**

If I understand this question correctly, no there should not be a specific quota set for controlled substance ordering at any given pharmacy due to the contributing factors listed above. There should not be an arbitrary power to say we think a pharmacy is ordering too much. What would be helpful is for DEA to issue guidance documents that include more objective information related to the patterns that trigger suspicious ordering inquiries.



April 9, 2012

The Honorable Mary Bono Mack
 Chairman
 Subcommittee on Commerce, Manufacturing, and Trade
 U.S. House of Representatives
 Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, DC 20515-6115

Dear Representative Bono Mack:

Thank you for the opportunity to respond to your questions from our testimony before the Subcommittee on Commerce, Manufacturing, and Trade on March 1, 2012, at the hearing entitled "Prescription Drug Diversion: Combating the Scourge." The questions presented in your correspondence of March 26, 2012, and our responses are provided below.

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 P.O. Box 1417-D99
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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 more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 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 \$900 billion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.81 in other industries, for a total economic impact of \$1.76 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

We have provided the text of your questions below in **bold**, followed by our responses in plain text:

The Honorable Mary Bono Mack

- 1) **In your testimony, you described the initiatives chain stores have established to maintain the security and integrity of the controlled substances and their distribution.**
 - a) **What percentage of prescription drug inventory is diverted through illegal means such as theft or fraud?** NACDS does not maintain statistics on the percentage of prescription drug inventory that is lost or diverted.

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- b) **How do you monitor and address diversion that occurs through legal channels, such as over-prescribing or doctor shopping by patient addicts?** It is our understanding that all diversion is illegal. As such, there cannot be diversion through legal means. NACDS does not monitor or specifically address illegal activities; we leave that to the experts in those efforts such as DEA and other law enforcement officials.
- c) **How do you address unusual increases in sales of painkillers and other controlled substances by a particular pharmacy or several pharmacies located near each other?** We support state prescription drug monitoring programs and other tools that may be useful for law enforcement investigations.
- 2) **Do your members have a policy to cease filling orders for suspect prescriptions? Is the policy actionable if not followed?** Each of our member companies has its own policies and procedures for preventing prescription drug diversion, such as the examples we provided in our written and oral testimony.
- 3) **You described a number of anti-diversion efforts pharmacies undertake targeted at internal theft and theft deterrence, such as background checks, extensive training, and maintaining electronic inventories, but those efforts do not address diversion that occurs via the pharmacy customer. What do pharmacies do when presented with a fraudulent prescription or a prescription written by a doctor with questionable prescribing patterns?** Each of our member companies has its own policies and procedures for preventing prescription drug diversion. These policies and procedures would also include the pharmacist's responsibility and professional judgment in determining whether a prescription has been written for a valid purpose.
- 4) **You described various efforts utilized by some – but not all – pharmacies to detect and prevent diversion such as maintaining employee training, maintaining perpetual inventories with random audits, the use of security cameras, maintaining employee codes of conduct, and requiring employee drug testing. Is there anything that all pharmacies, universally, are doing to detect and prevent diversion? Is there anything that all pharmacies can and should do, beginning immediately?** Each of our member companies has its own policies and procedures for preventing prescription drug diversion. NACDS is not aware of any specific policies or procedures that are universal among pharmacies. Again, our prior testimony provided examples of what our members do.
- 5) **You testified that some pharmacies maintain systems that would trigger an internal investigation if there is an exceptionally large or unusual order of controlled substances. What percentage of pharmacies utilizes such a system? For those pharmacies that employ these systems, do they report these unusual orders to the DEA or local law enforcement? If not, should they report such**

orders to the DEA or local law enforcement? NACDS does not maintain statistics on the percentage of pharmacies that utilize any specific systems or policies, nor do we have specific details about systems that trigger internal investigations.

The Honorable Edolphus Towns

- 1) **What happens when a pharmacy is filling legitimate prescriptions, but has a mix of business that creates high purchases of controlled substances and they are cut off by their supplier?** NACDS is not aware of any of our member pharmacies that have been cut off by a supplier.
- 2) **Can they find another supplier, or do they go out of business? What happens to their patients?** Since NACDS is not aware of any of our member pharmacies that have been cut off by a supplier, we do not have the necessary information to answer this question.

Again, Representative Bono Mack, we thank you for the opportunity to provide answers to your questions about our testimony. We hope that we have been able to convey our perspectives to you, as well as answer your questions to your satisfaction.

Sincerely,



Kevin N. Nicholson, R.Ph., J.D.
Vice President
Government Affairs and Pharmacy Advisor

cc: The Honorable G.K. Butterfield, Ranking Member, Subcommittee on Commerce,
Manufacturing and Trade
The Honorable Edolphus Towns

April 9, 2012

The Honorable Mary Bono Mack
Chairman, Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Bono Mack:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide responses to the follow-up questions submitted after the March 1, 2012, Subcommittee hearing entitled, "Prescription Drug Diversion: Combating the Scourge." As you know, PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2010, PhRMA member company investments in researching and developing new medicines for patients totaled \$49.5 billion.

The Honorable Mary Bono Mack

- 1. You testified that PhRMA supports increased licensure requirements for wholesale distributors. Please explain. Do the requirements currently lack in some regard? If so, please describe those deficiencies.**

As stated in my testimony, in the U.S., prescription medicines, including controlled substances, typically are sold by a manufacturer to a wholesale distributor, who may in turn sell the product to one or more wholesale distributors, or to an independent or chain pharmacy, at which point the medicine may be dispensed to a patient upon the pharmacy's receipt of a prescription from a licensed health care professional with prescribing authority for an individual patient. Each of these actors in the supply chain are separate legal entities who take ownership of the medicine as it travels through the supply chain until it is dispensed to a patient, and they are licensed and overseen by the relevant state licensing authority. Further, a patient may not legally obtain a prescription medicine, including a controlled substance, without a prescription from a health care practitioner authorized to write a prescription. Thus, each entity in the prescription drug supply chain – from primary and secondary wholesalers, to licensed pharmacists working in licensed independent and chain pharmacies, to physicians and other licensed health care prescribers – must do their part to help prevent the diversion of medicines to help prevent inappropriate use or misuse. The responsibility to prevent diversion must be equally shared.

While three major wholesale drug distributors dominate the primary market, there are a much larger number of both licensed primary and secondary distributors. Currently, the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Prescription Drug Marketing Act, provides that no person may engage in the wholesale distribution in interstate commerce of prescription drugs unless such person is

licensed by the state in accordance with federal minimum guidelines.¹ These federal minimum guidelines are set out in Food and Drug Administration (FDA) regulations at 21 C.F.R. Part 205.

PhRMA supports efforts to strengthen these minimum state licensure requirements for wholesalers and distributors. Weaknesses in the oversight of the wholesale drug industry have been identified in many states.² These weaknesses would permit unscrupulous individuals to obtain wholesale distribution licenses for operations that deal in diverted and counterfeit drug products. PhRMA believes that licensure requirements should be strengthened consistently across all states to prevent diverters and counterfeiters from re-locating to states without strong licensure requirements.

The House Energy & Commerce Committee also recognizes the need to increase federal licensure requirements for wholesale distributors, as reflected in HR 3026, the "Safeguarding America's Pharmaceuticals Act of 2011." Provisions in section 8 of the bill would raise the minimum federal guidelines for states to license wholesale distributors. Among other things, section 8 of HR 3026 would: (1) require distributors to establish and maintain drug distribution records; (2) require payment to a state of a bond or other equivalent means of security in an amount deemed appropriate by the state; (3) require distributors to conduct mandatory background checks and fingerprinting of the wholesale distribution facility manager and his or her designated representative; and (4) require the establishment and implementation of qualifications for key personnel within the facility. These requirements will help level the playing field for wholesale distributors to be licensed by the states.³

2. You testified that DEA registrants must report thefts within one business day, yet Attorney General Haslam testified that many times theft of cargo shipments goes unreported. Why would cargo shipments go unreported?

The Drug Enforcement Administration's (DEA's) regulatory authority extends to controlled substances. Thus, the requirement to notify DEA of any theft or loss of a controlled substance does not extend to prescription drugs that are not controlled substances. The Food and Drug Administration (FDA) urges reporting of cargo thefts of all FDA-regulated products, not just prescription drugs, to the FDA's Office of Criminal Investigations. Many companies report these thefts to FDA and these reports are regularly publicized on the FDA website.⁴

PhRMA and many of its member companies are also part of a coalition seeking federal legislation to increase federal penalties for cargo theft of all medical products, not just prescription drugs, the

¹ 21 U.S.C. § 353(e)(2).

² See e.g., First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (Florida Grand Jury Report), 2003, available at:

<<http://myfloridalegal.com/pages.nsf/Main/09558F82389E020785256CDA006DB01A>>.

³ See also, FDA, "Combating Counterfeit Drugs, A Report of the Food and Drug Administration," (Feb. 18, 2004 at 18, available at: <<http://www.fda.gov/Drugs/DrugSafety/ucm173438.htm>> ("If a state strengthens its licensing requirements while a bordering state does not, the counterfeiters and illegitimate wholesalers will likely move into the bordering state.")

⁴ See FDA website, "Cargo Thefts," <<http://www.fda.gov/ICECI/CriminalInvestigations/ucm182888.htm>>.

Coalition for Patient Safety and Medicine Integrity. A bill introduced by Rep. Sensenbrenner and five cosponsors late last month, HR 4223, the "SAFE DOSES Act," if enacted, would do just that.

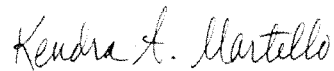
- 3. Much of your testimony focused on prescriber and patient education regarding the dangers related to and proper usage of controlled substance pharmaceuticals. The problem with education is that education efforts only work on people willing to use these medications properly. The fruit of State efforts, like Florida, demonstrates that much of drug diversion is by those who want to intentionally misuse these drugs or by those who intentionally prescribe in contravention of medical standards. What can you and your member companies do to address those individuals' misuse and nefarious prescribing of these hyper-addictive medications?**

PhRMA's testimony detailed the great length that PhRMA member companies take to help prevent diversion of controlled substances and prescription drugs. Our April 14, 2011, testimony before this Subcommittee also detailed the extensive educational efforts that we and our members have taken to help educate the public about proper disposal of unused medicines to help prevent diversion and the danger of misusing and abusing prescription drugs generally. Additionally, PhRMA's educational efforts related to these issues can be easily accessed by visiting our home page at: <http://www.phrma.org/issues/prescription-drug-abuse>. Most recently, PhRMA is pleased to announce its support of the National Governor's Association's Prescription Drug Abuse Policy Reduction Academy. This one year pilot involving six states will bring together governors' health and criminal justice advisors, state health officials, attorneys general, state chief information officers, legislators, physicians and allied health professional groups to help address issues surrounding prescription drug misuse and abuse.⁵

Finally, as outlined in my testimony, the FDA released in November 2011 a draft blueprint on prescriber education for long-acting and controlled release opioid products. When finalized, this effort will help ensure that prescribers are educated about the proper use of these products, while also recognizing the need for a "careful balance between continued access to these necessary medications and stronger measures to reduce their risks."⁶

PhRMA appreciates the opportunity to respond to these additional questions. Should you wish to discuss our response, please feel free to contact me at 202-835-3549.

Sincerely,



⁵ See PhRMA Statement on National Governor's Association's Prescription Drug Abuse Reduction Policy Academy. available at: <http://www.phrma.org/media/releases/phrm-statement-on-national-governors-associations-prescription-drug-abuse-reduction-policy-academy>.

⁶ See, FDA home page at: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>.



April 9, 2012

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce,
Manufacturing, and Trade
104 Cannon House Office Building
Washington, DC 20515

The Honorable G.K. Butterfield
Ranking Member
Subcommittee on Commerce,
Manufacturing, and Trade
2305 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Bono Mack and Ranking Member Butterfield,

GPhA would like to submit the following in response to your recent additional questions for the record for the March 1, 2012, hearing before the Subcommittee on Commerce, Manufacturing, and Trade entitled "Prescription Drug Diversion: Combating the Scourge."

The Honorable Mary Bono Mack

1. How would you describe the framework for cooperation between healthcare professionals such as your members and the government?

The level of cooperation between industry and the Food and Drug Administration (FDA) has never been greater. The two historic user fee agreements, the Generic Drug User Fee Act (GDUFA) and the Biosimilars User Fee Act (BSUFA), recently negotiated by industry and FDA and currently awaiting approval by the Congress, represent only a small measure of our ongoing collaboration. It is our hope that this collaboration will continue and extend throughout all of our interactions with the agency.

2. You testified that your industry has invested millions of dollars in technology to ensure prescription drugs reach their destinations safely and securely, including through the use of GPS tracking employed once drugs leave the labs. If industry uses technology, sometimes multiple layers of technology, to prevent diversion from occurring between the manufacturer and the distributor, how does such significant diversion occur? If not at the manufacturing link in the chain, then where?

As you have noted, as an industry we have invested millions of dollars in technologies and delivery systems to help assure that our products reach their destination safely and securely. As a result, the shipment of prescription drugs from manufacturers to authorized distributors is the most secure link in the supply chain. Diversion occurs at many points in the supply chain, but most significantly after the product leaves the authorized distributor, which is why the cooperation of all stakeholders will be required if we are to truly address the issue of drug diversion.

3. You referenced your work with the Pharmaceutical Distribution Security Alliance on securing the drug supply chain by associating unit data with lot numbers. It appears these efforts are targeted chiefly at theft. Is that where you believe the majority of drug diversion occurs?

The Pharmaceutical Distribution Security Alliance (PDSA) drug tracking model, RxTEC, is focused on preventing counterfeit, diverted (stolen), and adulterated products from entering the legitimate drug supply chain and enabling the supply chain to react more quickly when a breach has occurred. The PDSA proposal would establish strict federal wholesaler licensing requirements, which do not exist today. The new requirements are intended to ensure that bad

actors are not able to introduce adulterated or counterfeit product into the system. For instance, if the PDSA model had been in place, the recent case of counterfeit Avastin reaching patients would not have occurred. The counterfeit Avastin product was sold by a non-authorized distributor. The PDSA model would have prevented the product from entering the drug supply by virtue of the omission of that distributor from Genentech's list of approved distributors. Additionally, the PDSA model would enable a much more efficient recall of product based on the lot-item associations that would be established by the RxTEC model. Generic and brand manufacturers have committed to serializing individual units of medicine and to maintaining a database that would allow regulatory authorities or other stakeholders to verify the legitimacy of those serial numbers, which could also have been done in this instance.

Stakeholders throughout the supply chain view the RxTEC model as an advancement that will enable uses in the receiving and shipping process that will be of benefit beyond regulatory compliance, deliver greater patient safety, and greater efficiency in the supply chain. Today, wholesalers do not record the lot data, but using the RxTEC code, wholesalers will be able to track particular lots of product sold to particular customers. Pharmacy, unlike today, will also know with certainty which lots they have received and where the products came from. The lot data associated with shipments is collected by scanning the RxTEC code during the "picking" process for outbound shipments. Using the RxTEC code, wholesalers also intend to record date of receipt of particular lots of inbound product. Thus, in the event of a recall, wholesalers would know what customers they had shipped a particular lot to, the quantity of that shipment, and have means to enable their customers to understand whether they had ever received the particular lot being recalled. Lot control is an enormous advancement over current practices and wholesalers have agreed to various means of using the serial number portion of the RxTEC code within their internal processes. For instance, such capabilities would have ensured that recalled Heparin would have been accounted for, rather than lingering on the shelves of hospitals or pharmacies, as was the case.

4. In your testimony, you fairly pointed out that your members do not directly consumer-facing and are thus limited in how they can track and address drug diversion that occurs at that level. Do your members receive information one step above the consumer, at the prescriber-level, such as which doctors prescribe specific medications and how much they prescribe?

The shipment of prescription drugs flows from the manufacturers to the authorized distributors and then from the authorized distributors to the healthcare professionals (retail pharmacy, clinic, hospital, etc.). As such, manufacturers do not have access to detailed prescriber-level information.

Sincerely,



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