OXYCONTIN AND BEYOND: EXAMINING THE ROLE OF FDA AND DEA IN REGULATING PRESCRIPTION PAINKILLERS

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATORY AFFAIRS

OF THE

COMMITTEE ON GOVERNMENT REFORM

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OXYCONTIN AND BEYOND: EXAMINING THE ROLE OF FDA AND DEA IN REGULATING PRESCRIPTION PAINKILLERS

TUESDAY, SEPTEMBER 13, 2005

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATORY AFFAIRS,
COMMITTEE ON GOVERNMENT REFORM,
Boston, MA.

The subcommittee met, pursuant to notice, at 11 a.m., in Oliver Wendell Holmes Courtroom #2, Supreme Judicial Court of Suffolk County, Boston, MA, Hon. Candice Miller (chairwoman of the subcommittee) presiding.

Present: Representatives Miller, Tierney, and Lynch.

Staff present: Edward Schrock, staff director; Dena Kozanas, counsel; Alex Cooper, clerk; and Krista Boyd, minority counsel.

Ms. MILLER. Good morning. I'd like to call the hearing to order. I want to welcome everyone here this morning. This is a very, very unique and historic occasion I think as well, and very appropriately so, since we are in such a historic setting here in this courtroom. The courtroom, apparently, was at one time used by Oliver Wendell Holmes, as we were hearing from the court clerk this morning, and this is really a historic jewel and treasure, certainly not only for the people in Boston, but our entire Nation I think.

And, actually, before I got this job as a Member of Congress, my former job was Secretary of State in Michigan, where I had an odd appendage of those duties and responsibilities of being my State official historian. So, I'm very big on historic renovation and restoration, and it is wonderful, and hats off to the people of Boston that they invested their capital in making sure that they preserve a place like this for future generations. It's very, very important for that to happen certainly.

And, if you see anyone taking my picture during this it is because my husband is also a judge, and I have to make sure he sees a picture of me sitting in a courtroom like this, a little bit different than the courtroom that he has. But, we are here today on very serious business. As I say it's a historic thing where we are really attempting to bring Washington out of the Beltway and to where a lot of the decisions are made on very important issues. We are here today to examine the regulatory relationship between the U.S. Food and Drug Administration and the Drug Enforcement Agency in regulating Schedule II prescription painkillers, specifically known as opioid analgesics, such as OxyContin.

And, I certainly want to thank my colleague, Representative Lynch, who is the ranking member of this subcommittee, for bringing such an important issue to our attention. I certainly appreciate the devotion and the passion that he has shown to this issue, and to so many others, and to the city of Boston by requesting actually that our subcommittee travel here. He and I talked about the possibility of doing something like this for the last number of months, and tried to work out all the dynamics of it, but I think it is very important that we do bring these kinds of issues that sometimes can get—we have so many things going on in Washington it's difficult to focus sometimes on a particular issue. And so, I certainly want to thank him for making sure that we do get out Boston and talk about this, because it is such a huge problem here.

The abuse of prescription drugs is certainly not a new phenomenon. However, the problem of abuse and diversion of such drugs has become increasingly more noticeable. Addiction and overdoses to prescription drugs are receiving more attention, particularly in the aftermath of OxyContin.

There is a dichotomy with prescription drugs. On one hand, these drugs have a very legitimate medical use, and may be the only possible relief, quite frankly, for patients suffering from chronic pain, such as cancer patients. But then, on the other hand these drugs are very dangerous, and even deadly when they are misused or exploited.

Some people will suggest sometimes that drug companies, perhaps, have too much of an influence in Washington, DC, and that they are protected because of that influence. And, quite frankly, there is a choking grain of truth to that, I believe. In fact, in my home State of Michigan we share a common border with the Nation of Canada, so many of our residents are often going across the border to avail themselves of much cheaper drugs. Canadian citizens pay a much cheaper price for many drugs than they do in America, and so I have been on the opposite end of the equation as well with drug companies on the issue of reimportation.

But, in this particular instance, I think, perhaps, there's no one person or group that can be blamed for this epidemic. The abuser of painkilling drugs is, I think, a true test for us, trying to find a sense of balance for all the different parties who are involved, the government, the medical community, and the pharmaceutical industry as well.

The FDA and the DEA are two agencies responsible for regulating prescription painkillers. The FDA has the job of testing new drugs and specifying how the drug may be marketed, prescribed and used. The DEA is responsible for monitoring the distribution and prescription of these drugs to prevent their illegal use. And, many times the FDA and the DEA are an effective duo in fighting the war against prescription painkiller abuse, but then there are also times when the FDA and the DEA would benefit from a stronger relationship.

So, I'm looking forward to hearing the exchange of ideas today, so that we may, hopefully, find some new approaches to the problem of prescription painkiller abuse and diversion.

At this time, I'd certainly like to recognize my distinguished colleague, Representative Lynch, for his opening statement.

[The prepared statement of Hon. Candice S. Miller follows:]

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MEMORANDUM FOR MEMBERS OF THE GOVERNMENT REFORM SUBCOMMITTEE ON REGULATORY AFFAIRS

FROM: Candice S. Miller, Chairman /s/
Stephen F. Lynch, Ranking Minority Member /s/

DATE: September 7, 2005

SUBJECT: Briefing for September 13, 2005 Field Hearing, "OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers"

On Tuesday, September 13, 2005, at 11:00 a.m. at the Supreme Judicial Court of Suffolk County, John Adams Courthouse, Oliver Wendell Holmes Courtroom #2, One Pemberton Square, Boston, Massachusetts, the Government Reform Subcommittee on Regulatory Affairs will hold a field hearing to examine the regulatory relationship between the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) in regulating Schedule II prescription painkillers, specifically opioid analgesics such as OxyContin.

Federal Regulation of Prescription Drugs

FDA is one of two agencies with primary responsibility for regulating opioid analgesics (painkillers that suppress the perception of pain and calm emotional responses by decreasing the number of pains signals sent to the central nervous system). Under the Food, Drug, and Cosmetic (FD&C) Act, FDA is responsible for ensuring that drugs are safe and effective. FDA has regulatory authority over the approval, labeling, manufacturing, and marketing of prescription drugs.

In approving a new drug, FDA performs a benefit-to-risk analysis to determine whether the benefits of the drug support approval even in light of the drug's potential risks. FDA evaluates whether studies submitted by the manufacturer provide "substantial evidence" that the drug is safe and effective. However, this is a case-by-case determination by FDA; there is no statutory standard for what is safe enough. One of the risks evaluated by FDA is a drug's potential for abuse. If a drug has a potential for abuse, the drug manufacturer must give FDA data related to abuse, data on overdoses, and a proposal for scheduling under the Controlled Substances Act (CSA).

FDA also reviews and approves the labeling for a new drug. A drug's labeling provides information about the drug, how the drug is intended to be used, and the risks associated with taking the drug.

Once a drug is approved and goes to market, FDA is responsible for monitoring the safety of the drug. Drug manufacturers are required to report to FDA any serious and unexpected adverse reactions to the drug within 15 days of receiving information regarding an adverse event.

One of the issues identified with the widespread use of OxyContin and other Schedule II opioid analgesics is that doctors are writing "off-label" prescriptions, where a doctor prescribes a drug for a use not indicated in the drug's labeling. FDA has no regulatory authority to prevent off-label prescriptions. FDA can only request that a company change its label based on information that becomes available after the drug's initial approval. FDA does not have the regulatory authority to require a company to change its label. However, FDA ultimately has the authority to revoke a drug's approval.

FDA is required to notify DEA if a drug has a potential for abuse. FDA evaluates whether a drug under review requires abuse liability studies, scheduling under the CSA, or a risk management program aimed at reducing diversion and abuse of the drug. FDA now requires controlled-release, high-strength opiates to include a "black box" warning in the drug's labeling warning of the drug's potential for abuse. The black box warning is also required to be prominently displayed in any promotional materials for the drug.

FDA recently formed a federal Anesthetic & Life Support Drugs Advisory Committee, which held meetings in September 2003. One of the recommendations made by the advisory committee was that FDA should encourage drug manufacturers to submit risk management plans addressing diversion and abuse when they apply for FDA approval of a new Schedule II opioid. A December 2003 GAO report made a similar recommendation. FDA has stated it agrees with these recommendations and that each risk management plan should address: "identification of appropriate patients; assuring the safe and informed use of the product by both practitioners and patients; and monitoring for adverse outcomes, including misuse, overdoses, abuse, and diversion."

Another agency responsible for regulating Schedule II opioid analgesics is DEA. Under the CSA, DEA is responsible for preventing, detecting, and investigating the illegal use of prescription drugs through its regulatory authority over the manufacturing, distribution, and dispensing of these drugs.

Before FDA approves a drug that is prone to abuse, DEA recommends what CSA schedule should apply to the drug. The CSA defines five schedules of drugs that have a potential for abuse. Schedule I drugs have a high potential for abuse and have no approved medical use. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and abusing these drugs can lead to severe psychological or physical dependence. Drugs that fall under Schedules III-V have approved medical uses and decreasing levels of potential abuse.

Schedule II drugs are subject to the strictest regulations of any legal drug. Manufacturers at all stages of the process of making and transporting Schedule II drugs have to register with DEA. These drugs must be manufactured in a secure facility, transported and stored with caution, and the drugs must be tracked with an inventory system. Schedule II drugs can only be provided with a non-refillable prescription. Physicians are required to register with DEA before prescribing narcotics, including opioid analgesics. However, physicians are licensed at the state level and state law governs physicians' and other health care professionals' prescribing and dispensing of prescription drugs.

DEA sets annual quotas limiting the production of raw materials used to make specific controlled substances. For example, DEA limits the amount of oxycodone that can be produced in the United States during a given year. DEA bases its quotas on a variety of factors including the previous year's sales. However, DEA only has the authority to set a quota on the raw materials used to make a drug; DEA cannot set a quota on the drug itself.

Recognizing the increase in abuse and diversion of OxyContin, in May 2001, DEA implemented an OxyContin Action Plan. DEA's plan aims to: 1) enhance coordination with federal, state, and local governments; 2) use regulatory authority to make it harder for abusers to get OxyContin; 3) increase cooperation with drug manufacturers; and 4) increase public outreach efforts to improve education regarding the dangers of OxyContin. In 2004, DEA reported that since implementing its OxyContin Action Plan, it has pursued over 400 OxyContin investigations which have resulted in approximately 600 arrests.

DEA is working with states to develop Prescription Drug Monitoring Programs to prevent diversion. These state programs track information about OxyContin prescriptions at the point of sale, typically the pharmacy.

Prescription Painkiller Abuse: Focus on OxyContin

Prescription drug abuse has become an increasing concern in recent years. According to the National Survey on Drug Use and Health Effects, in 2003, an estimated 4.7 million Americans over the age of 12 were currently using prescription painkillers for non-medical purposes. According to FDA, abuse of opioid analgesics, such as OxyContin, has risen in recent years. In 2003, an estimated 2.8 million Americans had, at some point in their lives, used OxyContin for non-medical purposes. This is up from 1.9 million in 2002. Though abuse of opioid analgesics is a serious problem warranting attention from federal, state, and local governments, it is important to point out that these drugs play a vital role in the management of severe, chronic pain.

The City of Boston has experienced the problem of prescription painkiller abuse. According to a 2005 DEA fact sheet on Massachusetts, OxyContin continues to be an "extremely popular" substitute for heroin. A survey conducted by the Office of Drug Control Policy in 2002, OxyContin was second only to heroin as the drug of abuse among patients in non-methadone treatment programs in Boston.

OxyContin, a drug manufactured by Purdue Pharma L.P., was approved by FDA in 1995 as a time-release tablet intended for the treatment of moderate to severe pain in patients who are

expected to need continuous opioids for an extended period of time. OxyContin is different from previously approved pain relievers in that it contains higher amounts of oxycodone and is designed to release the oxycodone slowly over a period of time (12 hours). FDA initially approved the marketing of 10, 20, and 40 milligram OxyContin tablets and Purdue later won approval to market 80 and 160 milligram tablets. However, Purdue discontinued the 160 milligram tablet in 2001 amid increasing concerns about patients and drug abusers becoming addicted to and abusing OxyContin. According to DEA, the fact that OxyContin contained such a high level of oxycodone may have made OxyContin a bigger target for abuse and diversion.

Purdue Pharma extensively marketed OxyContin and sales of the drug increased quickly after its approval. According to GAO, more than 14 million prescriptions for OxyContin were filled in 2001 and 2002, totaling almost $3 billion in sales. The introduction of OxyContin also coincided with an increased national focus on pain management.

Reports of OxyContin addiction and abuse started appearing in 2000, particularly in rural areas of the eastern United States. The problem of OxyContin addiction, diversion, and abuse spread rapidly throughout the country. In July 2001, FDA collaborated with Purdue in developing a risk management plan for OxyContin. This plan included changes to the drug's label, efforts to educate healthcare professionals about the dangers associated with OxyContin, and developed a tracking system to identify OxyContin abuse.

Several generic versions of OxyContin have been approved by FDA. With the introduction of the generic forms of OxyContin to the market, one of the issues that will likely arise is what regulatory measures the government will take to prevent the abuse and diversion of these drugs.

Witnesses

The invited witnesses for the September 13, 2005 hearing are: Dr. Robert Meyer, Director, Office of Drug Evaluation II, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; Joseph Rannazzisi, Deputy Chief of Enforcement Operations, Drug Enforcement Agency; State Senator Steven Tolman; State Representative Brian Wallace; John McGahan, Executive Director, Cushing House; Dr. Janet L. Abrahm, Co-Director of the Pain and Palliative Care Programs at Dana Farber Cancer Institute and Brigham and Women's Hospital and Associate Professor of Medicine and Anesthesia at Harvard Medical School, on behalf of the American Cancer Society.

Mr. LYNCH. Thank you, Madam Chair.

First, I'd like to begin by thanking the clerk of the SJC, Maura Doyle, who has so graciously offered us the use of this beautiful courtroom for the conduct of this hearing. Maura is a dear friend, and she's done a wonderful job here in the court, and I think that the grace and the beauty of this courtroom is a reflection of her hard work.

I remember not too long ago fighting for the Courthouses Bond Bill that actually got a lot of this work done, and it really is, as Chairman Miller has said, it's a jewel, it's a real treasure, and it's great to see the historic preservation here in this room, and I think it lends credibility to all the acts that go on here, and, hopefully, that will continue today.

I want to thank as well the citizens of Massachusetts, because this is truly their building.

As well, I'd like to begin by welcoming Chairman Candice Miller to the 9th Congressional District here in Boston. Madam Chair, I thank you for your willingness to travel here to Boston and agreeing to hold this important field hearing.

This is an example of bipartisanship. There is much in the press about the fighting, the squabbling, between Democrats and Republicans in Washington, DC. What you don't hear is the work that goes on together when we, as Members of Congress and as Americans, recognize that there's a problem that needs to be worked on. And, in that spirit we are here today, and we are joined as well by my esteemed colleague, Representative John Tierney, who originally served on this Government Reform Committee. He has since moved to the powerful Intelligence Committee, but he has left me behind to carry on some of the priorities that he established when he was on the committee, and he has been a mentor to me since arriving in Congress and I appreciate his friendship and his participation here today.

The focus of this hearing is entitled, "OxyContin and Beyond: Examining the Role of the Food and Drug Administration and the Drug Enforcement Agency in Regulating Prescription Painkillers." I think it's important at the very outset to clarify that this hearing is not just about any particular piece of legislation. Rather, we are here to examine the recently amended and accelerated FDA drug approval process that has somehow allowed a series of drugs to come onto the market, to make their way to our pharmacies, only to be removed by either the force of litigation or government pressure after fatalities and widespread injury to consumers.

Unfortunately, we have a lot of examples of that. We have the examples of Vioxx, the Cox II inhibitor, with 27,000 heart attacks and sudden cardiac deaths before it was eventually pulled from the market. But, it received FDA approval.

The example of ephedra, an appetite suppressant, with 1,000 reports of serious health complications for its use in at least 100 ephedra-related deaths, also which received FDA approval.

OxyContin, produced by Purdue Pharma, with hundreds dead from overdose and thousands, perhaps, tens of thousands, hopelessly addicted, and that's based on 2002 data, and most recently Palladone, a potent narcotic painkiller twice as powerful as

OxyContin, and also produced by Purdue Pharma, which was pulled from the market 9 months after its initial FDA approval.

These developments, in and of themselves, would be serious, but it's important to note that in the case of Purdue Pharma a Federal Appeals Court has recently ruled that their patent rights are invalid because, specifically, Purdue Pharma had lied to the U.S. Patent and Trademark Office on its original application for OxyContin.

The revocation of the exclusive patent rights ironically will now allow other pharmaceutical companies to produce generic versions of OxyContin, which will result in a wider availability and, therefore, greater potential for abuse.

This issue, like most for legislators, came to my attention through our local experience with OxyContin. We are here today because too many people in our communities and neighborhoods are struggling with the problem of prescription painkiller abuse, as well as the misprescription of these drugs, most notably OxyContin.

According to a recent survey, OxyContin abuse was second only to heroin, second only to heroin, as the drug abuse among patients in non-methadone treatment programs in Boston. However, this problem is not just confined to this city, and it's not just a problem impacting the inner cities of our Nation. Rural communities such as Maine, West Virginia, Kentucky, as well as suburban communities from Arizona to Ohio, are all grappling with the problem of OxyContin abuse and diversion.

In 2003, an estimated 2.8 million Americans has at some point in their lives used OxyContin for non-medical purposes, a significant increase from the 1.9 million in 2002.

We are also very much aware that narcotic painkillers, such as OxyContin, can be used successfully by chronic pain sufferers, including cancer patients to relieve pain. In fact, Purdue Pharma originally presented the drug as being specifically targeted for cancer patients and severe and chronic pain sufferers.

I find it remarkable that this drug was put on the market without any study pointing to its addictive properties, which leads to the underlying question we have for the FDA and the DEA. Knowing the power of these drugs, knowing the pervasiveness of modern marketing techniques, and also taking into consideration the astounding profit motive for drugs that create, literally, customers for life, the question to us is, how addictive will we allow these drugs to become and still be legally marketed.

Also, there is a compounding difficulty here in the fact that absent the significant number of deaths related to these drugs, such as we have had with Vioxx, ephedra, and I'd argue OxyContin, once a drug receives approval through the FDA process it is virtually impossible to require further research to improve its safety. That condition, in itself, leads legislators to an inescapable conclusion where the only option we have is to recommend the banning of that pharmaceutical, and admittedly, that is not the ideal solution.

However, much remains unknown about those accidental addicts, patients who are legitimately prescribed narcotic painkillers such as OxyContin by their doctors and yet become addicted. The story of OxyContin, its approval from the FDA, its marketing strategy,

and its abuse and diversion, all illustrate the inability of our current regulatory framework to appropriately address the problem.

This problem is inherent in controlled substances, because their active ingredient is OxyContin, oxycodone was a known quantity to the FDA. Oxycodone was not given any special consideration with regard to its potential for abuse and diversion during its approval process.

OxyContin and Purdue Pharma understood a drug approval process that examines its safety and efficacy when used as directed, therefore, the FDA, the DEA, physicians and patients who are caught unaware of the addictive potential of this drug and its attraction to those who would abuse it.

I believe that there are several concrete ways in which this issue can be addressed through the regulatory process and by legislation if necessary. It's my hope and expectation that through this field hearing we can explore possible avenues on the Federal level, as well as the State level, to address the overarching problem.

We know the significant growth in the use of OxyContin to treat patients suffering from chronic pain has been accompanied by widespread reports of abuse and diversion that have devastated individuals and their families, and in some cases have led to death. However, the concern around OxyContin is about both those abusing the drug and those who are breaking the law to gain access to the drug, but also to those individuals who are legally prescribed the drug for pain control but became addicted.

Before the product OxyContin ever came to the commercial market, the manufacturer, Purdue Pharma, recognized its potential blockbuster status. However, when Purdue Pharma began to expand the market for OxyContin to include patients who suffered from non-cancerous, moderate to severe, acute and chronic pain from broken bones, dental pain and lower back pain, we began to see the consequences of Purdue Pharma's irresponsible marketing. Frankly, as this drug was prescribed more and more, we began to see more and more addiction.

Not enough is known to date about the phenomenon of addiction that is the result of medical care, and yet an alarming number of patients may be becoming addicted, specifically, to prescription pain medication after legitimately receiving a prescription for such treatment.

According to a 2004 survey conducted by the Opiate Dependency Treatment Center, the world renowned Weissman Institute in California, 44 percent of the respondents there dependent on OxyContin were initially prescribed that by a physician. We simply need a better understanding of the science of addiction to ensure that patients and doctors have all the information necessary to move forward with appropriate treatment plans.

Moreover, comparative studies are needed to assess the relative addictiveness, efficacy and safety of available drugs. Although undoubtedly much good clinical science is undertaken in drug trials done by pharmaceutical companies, it is also true that there are too many opportunities in the current system for manipulation. As a result, medicines may come on the market before they have been properly vetted, or without having enough information to provide

to patients and to doctors, specifically, about a drug's potential for abuse and addiction.

For instance, we have much to learn from our recent experience with the drug Palladone, a potent narcotic painkiller which is twice as powerful as OxyContin. On September 24, 2004, the FDA approved Palladone, a new 24-hour extended release, morphine-based medication with a high potential for abuse. The FDA said it incorporated elements from the National Control Strategy into the approval process for Palladone.

For example, the FDA required the inclusion of a black box warning on the drug's label and medication guide. Additionally, the FDA required the manufacturer to implement a Palladone risk management plan. However, less than 9 months after its initial approval, on July 13, 2005, Palladone was abruptly withdrawn from the market by the FDA, because of evidence that the drug's interaction with even minor amounts of alcohol in the patient's system could lead to death.

It is also noteworthy that Palladone had been approved by the FDA in September 2004, and yet the FDA stated it did not receive adequate data from the Purdue Pharma company until later, which ultimately led to the drug's withdrawal from the marketplace.

Because Purdue Pharma is responsible for undertaking clinical trials and then picks and chooses the data it presents to the FDA for approval, problems can arise after a drug has already been approved and marketed. Many times the problem is not uncovered until the drug is exposed to thousands of patients who report adverse reactions.

Thankfully, in the case of Palladone previous data highlighted the problem so that there were no reported adverse reactions in the patient population. The potential for harm illustrated by this case is enormous. It is clear that the FDA, the DEA, and Congress, need to do a better job in this area.

As described earlier, OxyContin addiction and abuse has severely affected my district and the people I represent, as well as many communities nationwide. The experiences of the FDA and the DEA in regulating OxyContin and other Class 2 controlled substances provides us with a powerful case study.

Although both the FDA and the DEA learned many valuable lessons from the OxyContin experience, it is clear that there is more that can be accomplished through the regulatory process.

I look forward today to hearing from Doctor Robert J. Meyer from the FDA, and Joseph Rannazzisi from the DEA about their experience with OxyContin and how they are applying those lessons. Additionally, we have the distinct honor of hearing from two outspoken leaders and energetic advocates of the people I represent in my friend Steven Tolman who is here from Watertown, and my dear friend and neighbor Representative Brian Wallace from south Boston. I look forward to hearing both their perspectives as State leaders on how they've addressed the issue of prescription painkiller abuse, specifically, OxyContin.

Also, Doctor Janet L. Abrahm from the Dana Farber Cancer Institute is here, representing the American Cancer Society, to explain to us how these powerful drugs benefit the patients she sees every day. I know Doctor Abrahm will want to work with us here

on the committee to ensure that her patients have access to the pharmaceuticals they need, but are also protected from harm.

And finally, my good friend John McGahan is here to talk about the work he does with the Gavin Foundation and the adolescents and families here at the Cushing House in south Boston. These two community institutions have been working non-stop to treat men and women, young and old, who are addicted to drugs and alcohol. It is my understanding that of the 16 beds that are at the Cushing House, which is a residential rehab facility for adolescents, of those 16 beds all 16 are now occupied by adolescents who are currently addicted to heroin, but who have been led to that addiction by a previous addiction to OxyContin, which is a troubling statistic.

I think we'll all find the testimony disturbing but enlightening.

Once again, I want to thank everyone for attending this hearing today, I really do believe that together we can come up with some potential legislative and regulatory fixes on the Federal level that will keep our communities, and our families, and our children safe.

Thank you again, Madam Chair, for recognizing the importance of this topic, and for attending today's hearing. I yield back.

[The prepared statement of Hon. Stephen Lynch follows:]

OPENING STATEMENT
REPRESENTATIVE STEPHEN F. LYNCH
SEPTEMBER 13, 2005 FIELD HEARING

OXYCONTIN AND BEYOND:
EXAMINING THE ROLE OF FDA AND
DEA IN REGULATING PRESCRIPTION PAINKILLERS

FIRSTLY, I WOULD LIKE TO BEGIN BY WELCOMING CHAIRMAN CANDICE MILLER TO THE 9TH CONGRESSIONAL DISTRICT HERE IN BOSTON, I THANK YOU FOR YOUR WILLINGNESS TO TRAVEL HERE TO BOSTON AND AGREEING TO HOLD THIS IMPORTANT FIELD HEARING.

THE FOCUS OF THIS HEARING HAS BEEN DESCRIBED AS "OXYCONTIN AND BEYOND: EXAMINING THE ROLE OF THE FOOD AND DRUG ADMINISTRATION (FDA) AND THE DRUG ENFORCEMENT AGENCY (DEA) IN REGULATING PRESCRIPTION PAINKILLERS."

I THINK IT IS IMPORTANT TO CLARIFY THAT THIS HEARING IS NOT JUST ABOUT ANY PARTICULAR PIECE OF LEGISLATION.

RATHER WE ARE HERE TO EXAMINE THE RECENTLY AMENDED AND ACCELERATED FDA DRUG-APPROVAL PROCESS THAT HAS SOMEHOW ALLOWED A SERIES OF DRUGS TO COME ONTO THE MARKET, MAKE THEIR WAY INTO OUR PHARMACIES, ONLY TO BE REMOVED BY THE FORCE OF LITIGATION AND GOVERNMENT PRESSURE AFTER FATALITIES AND WIDESPREAD INJURY TO INDIVIDUAL CONSUMERS.

UNFORTUNATELY, WE HAVE MANY EXAMPLES: VIOXX, THE COX-2 INHIBITOR, WITH 27,000 HEART ATTACKS AND SUDDEN CARDIAC DEATHS BEFORE IT WAS EVENTUALLY PULLED FROM THE MARKET; EPHEDRA, AN APPETITE SUPPRESSANT WITH 1,000 REPORTS OF SERIOUS HEALTH COMPLICATIONS FROM ITS USE AND AT LEAST 100 EPHEDRA-RELATED DEATHS; OXYCONTIN, PRODUCED BY PURDUE-PHARMA WITH HUNDREDS DEAD FROM OVERDOSE AND THOUSANDS HOPELESSY ADDICTED—AND THIS IS 2002 DATA; AND MOST RECENTLY PALLADONE, A POTENT NARCOTIC PAINKILLER TWICE AS POWERFUL AS OXYCONTIN AND ALSO PRODUCED BY PURDUE-PHARMA, PULLED FROM THE MARKET NINE MONTHS AFTER INITIAL FDA APPROVAL.

THESE DEVELOPMENTS IN AND OF THEMSELVES WOULD BE SERIOUS BUT IT'S IMPORTANT TO NOTE THAT IN THE CASE OF PURDUE-PHARMA A FEDERAL APPEALS COURT HAS RECENTLY RULED THAT THEIR PATENT RIGHTS ARE INVALID BECAUSE PURDUE-PHARMA

HAD LIED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE ON ITS ORIGINAL APPLICATION.

THE REVOCATION OF EXCLUSIVE PATENT RIGHTS WILL NOW ALLOW OTHER PHARMACEUTICAL COMPANIES TO PRODUCE GENERIC VERSIONS OF OXYCONTIN WHICH WILL RESULT IN WIDER AVAILABILITY AND THEREFORE GREATER POTENTIAL FOR ABUSE.

THIS ISSUE CAME TO MY ATTENTION THROUGH OUR OWN EXPERIENCE WITH OXYCONTIN. WE ARE HERE TODAY BECAUSE TOO MANY PEOPLE IN OUR COMMUNITIES AND NEIGHBORHOODS ARE STRUGGLING WITH THE PROBLEM OF PRESCRIPTION PAINKILLER ABUSE, AS WELL AS THE MISPRESCRIPTION OF THESE DRUGS, MOST NOTABLY OXYCONTIN.

ACCORDING TO A RECENT SURVEY, OXYCONTIN ABUSE WAS SECOND ONLY TO HEROIN AS THE DRUG OF ABUSE AMONG PATIENTS IN NON-METHADONE TREATMENT PROGRAMS IN BOSTON.

HOWEVER, THIS PROBLEM IS NOT JUST CONFINED TO BOSTON AND IT IS NOT JUST A PROBLEM IMPACTING THE INNER CITIES OF OUR NATION. RURAL COMMUNITIES SUCH AS MAINE, WEST VIRGINIA AND KENTUCKY AS WELL AS SUBURBAN COMMUNITIES FROM ARIZONA TO OHIO ARE ALL GRAPPLING WITH THE PROBLEM OF OXYCONTIN ABUSE AND DIVERSION. IN 2003, AN ESTIMATED 2.8 MILLION AMERICANS HAD, AT SOME POINT IN THEIR LIVES, USED OXYCONTIN FOR NON-MEDICAL PURPOSES, A SIGNIFICANT INCREASE FROM THE 1.9 MILLION IN 2002.

WE ARE ALSO VERY MUCH AWARE THAT NARCOTIC PAINKILLERS, SUCH AS OXYCONTIN, CAN BE USED SUCCESSFULLY BY CHRONIC PAIN SUFFERERS, INCLUDING CANCER PATIENTS, TO RELIEVE PAIN. IN FACT, PURDUE-PHARMA ORIGINALLY PRESENTED THE DRUG AS BEING SPECIFICALLY FOR CANCER PATIENTS AND SEVERE AND CHRONIC PAIN SUFFERERS.

I FIND IT REMARKABLE THAT THIS DRUG WAS PUT ON THE MARKET WITHOUT ANY STUDY POINTING TO ITS ADDICTIVE PROPERTIES. WHICH LEADS TO THE UNDERLYING QUESTION WE HAVE FOR FDA AND DEA—KNOWING THE POWER OF THESE DRUGS, KNOWING THE PERVASIVENESS OF MODERN MARKETING TECHNIQUES AND ALSO TAKING INTO CONSIDERATION THE ASTOUNDING PROFIT MOTIVE FOR DRUGS THAT CREATE "CUSTOMERS FOR LIFE"— HOW ADDICTIVE WILL WE ALLOW THESE DRUGS TO BECOME AND STILL BE LEGALLY MARKETED?

ALSO, THERE IS COMPOUNDING DIFFICULTY HERE IN THE FACT THAT ABSENT A SIGNIFICANT NUMBER OF DRUG-RELATED DEATHS SUCH AS WE HAVE SEEN WITH VIOXX, EPHEDRA, AND I'D ARGUE OXYCONTIN, ONCE A DRUG RECEIVES FDA APPROVAL IT IS VIRTUALLY IMPOSSIBLE TO REQUIRE FURTHER RESEARCH TO IMPROVE ITS SAFETY. THAT CONDITION LEAVES LEGISLATORS IN A POSITION WHERE THE ONLY OPTION WE HAVE IS TO RECOMMEND THE BANNING OF THAT PHARMACEUTICAL.

ADMITTEDLY, THAT IS NOT THE IDEAL SOLUTION.

HOWEVER, MUCH REMAINS UNKNOWN ABOUT THOSE "ACCIDENTAL ADDICTS" PATIENTS WHO ARE LEGITIMATELY PRESCRIBED NARCOTIC PAINKILLERS BY THEIR DOCTOR AND YET BECOME ADDICTED.

THE STORY OF OXYCONTIN, ITS APPROVAL FROM FDA, ITS MARKETING STRATEGY, AND ITS ABUSE AND DIVERSION, ALL ILLUSTRATE THE INABILITY OF THE CURRENT REGULATORY FRAMEWORK TO APPROPRIATELY ADDRESS THE PROBLEMS INHERENT IN CONTROLLED SUBSTANCES. BECAUSE THE ACTIVE INGREDIENT IN OXYCONTIN, OXYCODONE, WAS A KNOWN QUANTITY TO FDA, IT WAS NOT GIVEN ANY SPECIAL CONSIDERATION WITH REGARD TO ITS POTENTIAL FOR ABUSE AND DIVERSION DURING THE APPROVAL PROCESS. OXYCONTIN UNDERTOOK A DRUG APPROVAL PROCESS THAT EXAMINED ITS SAFETY AND EFFICACY *WHEN USED AS DIRECTED*. THEREFORE THE FDA, DEA, PHYSICIANS AND PATIENTS WERE CAUGHT UNAWARE OF THE ADDICTIVE POTENTIAL OF THIS DRUG AND ITS ATTRACTION TO THOSE WHO WOULD ABUSE IT.

I BELIEVE THAT THERE ARE SEVERAL CONCRETE WAYS IN WHICH THIS ISSUE CAN BE ADDRESSED THROUGH THE REGULATORY PROCESS AND LEGISLATIVELY IF NECESSARY. IT IS MY HOPE AND EXPECTATION THAT THROUGH THIS FIELD HEARING WE CAN EXPLORE POSSIBLE AVENUES ON THE FEDERAL LEVEL AS WELL AS LEARN WHAT OUR COUNTERPARTS ON THE STATE LEVEL ARE DOING.

WE KNOW THAT THE SIGNIFICANT GROWTH IN THE USE OF OXYCONTIN TO TREAT PATIENTS SUFFERING FROM CHRONIC PAIN HAS BEEN ACCOMPANIED BY WIDESPREAD REPORTS OF ABUSE AND DIVERSION THAT HAVE DEVASTATED INDIVIDUALS AND THEIR FAMILIES AND IN SOME CASES HAS LED TO DEATH.

HOWEVER, THE CONCERN AROUND OXYCONTIN IS ABOUT BOTH THOSE ABUSING THE DRUG AND WHO ARE BREAKING THE LAW TO GAIN ACCESS TO THE DRUG AS WELL AS THOSE INDIVIDUALS WHO WERE LEGALLY PRESCRIBED THE DRUG FOR PAIN CONTROL BUT

BECAME ADDICTED. BEFORE THE PRODUCT OXYCONTIN EVER CAME TO THE COMMERCIAL MARKET, THE MANUFACTURER PURDUE-PHARMA RECOGNIZED ITS POTENTIAL BLOCKBUSTER STATUS. HOWEVER, WHEN PURDUE-PHARMA BEGAN TO EXPAND THE MARKET FOR OXYCONTIN TO INCLUDE PATIENTS WHO SUFFERED FROM NON-CANCEROUS MODERATE TO SEVERE ACUTE AND CHRONIC PAIN FROM BROKEN BONES, DENTAL PAIN AND LOWER BACK PAIN, WE BEGAN TO SEE THE CONSEQUENCES OF PURDUE-PHARMA'S IRRESPONSIBLE MARKETING. FRANKLY, AS THIS DRUG WAS PRESCRIBED MORE AND MORE WE BEGAN TO SEE MORE AND MORE ADDICTED.

NOT ENOUGH IS KNOWN TO DATE ABOUT THE PHENOMENON OF ADDICTION THAT IS THE RESULT OF MEDICAL CARE. AND YET, AN ALARMING NUMBER OF PATIENTS MAY BE BECOMING ADDICTED, SPECIFICALLY TO PRESCRIPTION PAIN MEDICATION, AFTER LEGITIMATELY RECEIVING A PRESCRIPTION FOR SUCH TREATMENT. ACCORDING TO A 2004 SURVEY CONDUCTED BY THE OPIATE DEPENDENCY TREATMENT CENTER, THE WORLD RENOWNED WAISMANN INSTITUTE IN CALIFORNIA, 44 PERCENT OF RESPONDENTS DEPENDENT ON OXYCONTIN WERE INITIALLY PRESCRIBED THE PRODUCT BY A DOCTOR.

WE SIMPLY NEED TO BETTER UNDERSTAND THE SCIENCE OF ADDICTION TO ENSURE THAT PATIENTS AND DOCTORS HAVE ALL THE INFORMATION NECESSARY TO MOVE FORWARD WITH APPROPRIATE TREATMENT PLANS.

MOREOVER, COMPARATIVE STUDIES ARE NEEDED TO ASSESS THE RELATIVE ADDICTIVENESS, EFFICACY AND SAFETY OF AVAILABLE DRUGS. ALTHOUGH UNDOUBTEDLY MUCH GOOD CLINICAL SCIENCE IS UNDERTAKEN IN DRUG TRIALS DONE BY PHARMACEUTICAL COMPANIES, IT IS ALSO TRUE THERE ARE TOO MANY OPPORTUNITIES FOR MANIPULATION. AS A RESULT MEDICINES MAY BE COMING TO MARKET BEFORE THEY HAVE BEEN PROPERLY VETTED OR WITHOUT HAVING ENOUGH INFORMATION TO PROVIDE TO PATIENTS AND DOCTORS SPECIFICALLY ABOUT A DRUG'S POTENTIAL FOR ABUSE.

FOR INSTANCE, WE HAVE MUCH TO LEARN FROM OUR RECENT EXPERIENCE WITH PALLADONE, A POTENT NARCOTIC PAINKILLER TWICE AS POWERFUL AS OXYCONTIN. ON SEPTEMBER 24, 2004, FDA APPROVED PALLADONE, A NEW 24-HOUR EXTENDED RELEASE MORPHINE BASED MEDICATION WITH A HIGH POTENTIAL FOR ABUSE. FDA SAID IT INCORPORATED ELEMENTS FROM THE NATIONAL DRUG CONTROL STRATEGY INTO THE APPROVAL PROCESS FOR PALLADONE. FOR EXAMPLE, FDA REQUIRED THE INCLUSION OF A "BLACK BOX"

WARNING ON THE DRUG'S LABEL AND MEDICATION GUIDE. ADDITIONALLY, FDA REQUIRED THE MANUFACTURER TO IMPLEMENT A PALLADONE RISK MANAGEMENT PLAN.

HOWEVER, LESS THAN NINE MONTHS AFTER ITS INITIAL APPROVAL, ON JULY 13, 2005, PALLADONE WAS ABRUPTLY WITHDRAWN FROM THE MARKET BY THE FDA BECAUSE OF EVIDENCE THAT THE DRUG'S INTERACTION WITH EVEN MINOR AMOUNTS OF ALCOHOL IN THE PATIENT'S SYSTEM COULD LEAD TO DEATH.

IT IS ALSO NOTEWORTHY THAT PALLADONE HAD BEEN APPROVED BY FDA IN SEPTEMBER OF 2004, AND YET THE FDA STATED IT DID NOT RECEIVE ADEQUATE DATA FROM PURDUE-PHARMA UNTIL LATER WHICH ULTIMATELY LED TO THE DRUG'S WITHDRAWAL FROM THE MARKETPLACE. BECAUSE PURDUE-PHARMA IS RESPONSIBLE FOR UNDERTAKING CLINICAL TRIALS AND THEN PICKS AND CHOOSES THE DATA IT PRESENTS TO THE FDA FOR APPROVAL, PROBLEMS CAN ARISE AFTER A DRUG HAS ALREADY BEEN APPROVED AND MARKETED. MANY TIMES THE PROBLEMS ARE NOT UNCOVERED UNTIL THE DRUG IS EXPOSED TO THOUSANDS OF PATIENTS WHO REPORT ADVERSE REACTIONS. THANKFULLY, IN THE CASE OF PALLADONE, PREVIOUS DATA HIGHLIGHTED THE PROBLEM SO THAT THERE WERE NO REPORTED ADVERSE REACTIONS IN THE PATIENT POPULATION.

THE POTENTIAL FOR HARM ILLUSTRATED BY THIS CASE IS ENORMOUS. IT IS CLEAR THAT THE FDA, DEA AND THE CONGRESS NEED TO DO A BETTER JOB IN THIS AREA.

AS DESCRIBED EARLIER, OXYCONTIN ADDICTION AND ABUSE HAS SEVERELY AFFECTED MY DISTRICT AND THE PEOPLE I REPRESENT, AS WELL AS MANY COMMUNITIES NATIONWIDE. THE EXPERIENCES OF FDA AND DEA IN REGULATING OXYCONTIN AND OTHER CLASS II CONTROLLED SUBSTANCES PROVIDES US WITH A USEFUL CASE STUDY. ALTHOUGH, BOTH THE FDA AND THE DEA LEARNED MANY VALUABLE LESSONS FROM THE OXYCONTIN EXPERIENCE, IT IS CLEAR THAT THERE IS MORE THAT CAN BE ACCOMPLISHED THROUGH THE REGULATORY PROCESS. I LOOK FORWARD TO HEARING TODAY FROM DR. ROBERT J. MEYER FROM THE FDA AND JOSEPH RANNAZZISI (RAN-AS-ZEE-ZEE) FROM THE DEA ABOUT THEIR EXPERIENCES WITH OXYCONTIN AND HOW THEY ARE APPLYING THOSE LESSONS.

ADDITIONALLY, WE HAVE THE DISTINCT HONOR OF HEARING FROM TWO OUTSPOKEN LEADERS AND ENERGETIC ADVOCATES OF THE PEOPLE THEY REPRESENT IN MY FRIEND SENATOR STEVEN TOLMAN FROM WATERTOWN AND MY FRIEND AND NEIGHBOR

REPRESENTATIVE BRIAN WALLACE FROM SOUTH BOSTON. I LOOK FORWARD TO HEARING BOTH THEIR PERSPECTIVES AS STATE LEADERS ON HOW THEY'VE ADDRESSED THE ISSUE OF PRESCRIPTION PAINKILLER ABUSE—SPECIFICALLY OXYCONTIN.

ALSO, DR. JANET L. ABRAHAM, FROM THE DANA FARBER CANCER INSTITUTE IS HERE REPRESENTING THE AMERICAN CANCER SOCIETY TO EXPLAIN TO US HOW THESE POWERFUL DRUGS BENEFIT THE PATIENTS SHE SEES EVERYDAY. I KNOW DR. ABRAHAM WILL WANT TO WORK WITH US HERE ON THE COMMITTEE TO ENSURE THAT HER PATIENTS HAVE ACCESS BUT ARE ALSO PROTECTED FROM HARM.

AND, FINALLY, MY GOOD FRIEND JOHN MCGAHAN IS HERE TO TALK ABOUT THE WORK HE DOES WITH THE GAVIN FOUNDATION AND THE ADOLESCENTS AND FAMILIES HE SEES AT THE CUSHING HOUSE IN SOUTH BOSTON. THESE TWO COMMUNITY INSTITUTIONS HAVE BEEN WORKING NON-STOP TO TREAT MEN AND WOMEN, YOUNG AND OLD, WHO ARE ADDICTED TO DRUGS AND ALCOHOL. IT IS MY UNDERSTANDING THAT ALL 16 BEDS AT THE CUSHNG HOUSE ARE NOW FILLED BY ADOLESCENTS ADDICTED TO OXYCONTIN. I THINK WE WILL ALL FIND HIS TESTIMONY DISTURBING BUT ENLIGHTENING.

ONCE AGAIN, I WANT TO THANK EVERYONE FOR ATTENDING THIS HEARING TODAY. I REALLY DO BELIEVE THAT TOGETHER WE CAN COME UP WITH SOME POTENTIAL LEGISLATIVE AND REGULATORY FIXES ON THE FEDERAL LEVEL THAT WILL KEEP OUR COMMUNITIES, OUR FAMILIES, AND OUR CHILDREN SAFE.

THANK YOU AGAIN CHAIRMAN MILLER FOR RECOGNIZING THE IMPORTANCE OF THIS TOPIC AND ATTENDING TODAY'S HEARING.

Ms. MILLER. Thank you.

At this time, I'd like to recognize our other distinguished colleague who joins us today, Representative Tierney, for his opening statement.

Mr. TIERNEY. Thank you, Chairman Miller, and I want to thank you for coming down from Michigan, or over from Michigan, to share this hearing with us, and Ranking Member Stephen Lynch, thank you both for inviting me to join you this morning. I am on a leave of absence from this committee, and temporarily over with the Intelligence Committee at their request, but I'm happy to be back with my colleagues, particularly dealing with a matter of import such as this, one that's affecting all of our districts.

And, as Congressman Lynch indicated, it's not just OxyContin, it's the fact that OxyContin is so often, at least in our communities, leading to heroin addiction, where we were discussing earlier where district attorneys tell us that people are buying the OxyContin at about $80 a shot, but finding they get a free bit of heroin involved in that, so that when they run out of money for the OxyContin they can switch over to the heroins. Dealers are certainly at no loss for ways to get new customers, and this is difficult. So, the issue is, how do we identify and provide for the treatment of both that's both chronic and acute, while still preventing the abuse of opiates that lead to a range of social problems.

One side, obviously, is the argument that the opiate analgesics are essential to the treatment of acute pain due to trauma and surgery, and the chronic pain, whether it's due to cancer or non-cancerous origins, and we all have great sympathy for people in that situation, understand the number of doctors and other healthcare providers who insist that this is an essential treatment, but there's a wide range of evidence and communications that also point to some legitimate concern, a very legitimate concern of families, law enforcement officials, and, of course, health professionals themselves, who see the problem that we have with addiction and where that leads us and our communities.

So, there are going to be a number of questions that I hope we can get addressed and, perhaps, even answered today during the course of this hearing.

We know that since 1998, that approximately 450 patents have been filed by over 19 different companies that are attempting to create an abuse-resistant formula for painkilling drugs, so-called antagonists. Why is it taking so long? Should the government provide assistance, or should the government even conduct the research itself?

Sponsors for Schedule II controlled drugs are asked to consider developing strategies for safety programs, why doesn't the FDA require the pharmaceutical companies include those proactive risk management plans in all new applications? Does it have the authority to do so, and would it be a wise thing for them to make that happen?

We are very concerned to the dangers that occur from off-label prescription drugs. Is it a fact that physicians are over prescribing opiate analgesics? Would eliminating the off-label use of OxyContin by requiring specific instructions on distribution, such as mandating that they be prescribed only to patients with cancer or terminal

patients, in order to limit the amount of drugs being circulated, thereby be helpful? What other regulatory actions could the FDA take? Do they have the ability to require these drug companies after the fact to take action? Is there a compliance time that they could enforce? Are their deadlines and powers that the FDA has in order to make them effective?

There are technologies, the so-called "radio frequency identification technology," that would allow us to track these drugs as they move through the supply chain. There are reports that in some instances there might be an interference with existing technologies in hospitals that are other ways not able to be implemented. Is this something we should be looking at? What's the status of RFIT technology? Does the FDA support this technology, and how are they going to make sure that its brought to the market faster if they do?

Programs that are being run through the Department of Education's Office of Safe and Drug Free Schools and SAMHSA have had somewhat successful track records of reducing substance abuse. Many of those programs are geared to gateway drugs, such as alcohol and marijuana. There's no Federal program that we've been able to find that specifically funds prescription drugs or opiate analgesics education, prevention and treatment for students. It's a unique challenge, because many times, due to the fact that they are prescribed, leads people to believe that they are also safe. Would having current education awareness programming expand to this area be helpful, and would it have some impact on the abuse of prescription drugs among students?

Are there Federal guidelines for prescribing pain managements, and would it be effective to institute them, and how would we go about doing that?

And last, as the DEA collects data, can it use that data in a proactive way and more effective way, and speak to the process that's used to analyze data collected from these and other sources? Is our current process adequate or can we do better, and what should we do?

All of these questions are outstanding for today's hearing. I'm thankful for the witnesses taking their time to join us here this morning, and I know that what they have to say will help us graft, hopefully, some Federal direction as to what we can do to, both make sure that patients who are in need of treatment and pain relief will be satisfied, as well as will our social need, to make sure that these opiates and other medications are not abused and do not create the social problems that are now hitting our communities rampantly.

So again, thanks to my colleagues for inviting me to join you today. I think this is going to be a helpful hearing, and I look forward to the testimony by witnesses.

Ms. MILLER. Thank you.

Because the Government Reform Committee is an oversight committee with subpoena authority, we do have as a practice, even when we are outside of Washington, to swear in all of our witnesses. So, if you could please rise, raise your right hands.

[Witnesses sworn.]

Ms. MILLER. Thank you, please be seated.

Our first witness today that the subcommittee will hear from is Doctor Robert Meyer. In 2002, Doctor Meyer was appointed Director of the Office of Drug Evaluation, at the Center for Drug Evaluation and Research, at the FDA. Prior to serving as Director, Doctor Meyer was a medical reviewer for the Division of Oncology and Pulmonary Drug Products. Doctor Meyer also chairs the Agency's Risk Assessment Guidance Working Group, and he's on the FDA Drug Safety Oversight Board.

Doctor Meyer, we want to appreciate you for coming from Washington to Boston, and appreciate your testimony. The floor is yours, sir.

STATEMENTS OF ROBERT MEYER, DIRECTOR, OFFICE OF DRUG EVALUATION II, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; AND JOSEPH RANNAZZISI, DEPUTY CHIEF OF ENFORCEMENT OPERATIONS AND ACTING DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT AGENCY

STATEMENT OF ROBERT MEYER

Mr. MEYER. Good morning, Madam Chair, and members of the subcommittee.

I am Doctor Robert J. Meyer, Director of the Office of Drug Evaluation II, in the Center for Drug Evaluation and Research [CDER], at FDA. I oversee CDER's Division of Anesthetic, Analgesic and Rheumanologic Drug Products, which has regulatory responsibility for the opiate analgesic products, and I appreciate the opportunity to speak to you today about our drug approval process and the role that we have in preventing prescription drug abuse.

FDA is a Public Health agency, with a strong commitment to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely way, and then by monitoring for the safety of these products when they are in use.

FDA is aware of and concerned about reports of prescription drug abuse, misuse, and diversion. We are aware of data showing that abuse of prescription drugs, including narcotics, has grown rapidly, including the abuse of OxyContin. We understand the seriousness of this issue, and sympathize with the families and friends of individuals who have lost their lives or otherwise been harmed as a result of prescription drug abuse or misuse.

We also sympathize with the many pain patients who often suffer needlessly, due to under treatment or substandard treatment. On these matters, FDA must strike a critical balance. While addressing the very important issues of opiate abuse and misuse, FDA must also act in a manner that assures patients who require narcotics for adequate pain control have full, appropriate access to them through informed providers.

Let me speak for a moment about FDA's drug approval process. Under the Food, Drug and Cosmetic Act, FDA is responsible for ensuring that all new drugs are safe and effective. Before any drug is approved for marketing in the United States, FDA must decide whether the studies and other information submitted by the spon-

sor have adequately demonstrated that the drug is, indeed, safe and effective for use according to the drug's labeling.

Since no drug is without risk, FDA's approval decisions always involve an assessment of the benefits and risks for a particular product and its proposed use. When the benefits of a drug are found to outweigh the risks, and the labeling instructions allow for safe and effective use, FDA approves the drug for marketing.

At the time of approval, and sometimes after approval, FDA may develop, in cooperation with the drug sponsors, a plan of interventions beyond labeling to help assure the safe and effective use of the drug. This has recently been referred to as risk management, or risk minimization plans [RMPs], but this practice dates back many years.

These interventions making up an RMP may be varied, but all are aimed at assuring that some known or potential issues regarding the proper use of the drug are addressed by prescribers or patients using the drug.

During the approval process, FDA assesses a drug's potential for abuse. If a potential for abuse is found to exist, the product sponsor is required to provide FDA with all the data pertinent to abuse of the drug, a proposal for scheduling under the Controlled Substances Act, and data on overdoses.

Under the Controlled Substances Act [CSA], FDA notifies the DEA that a new drug application has been submitted for a drug that has either a stimulant, depressant or hallucinogenic effect on the central nervous system, including opiates, because it is then assumed the drug has abuse potential. The FDA recommends a scheduling category and the DEA makes the final scheduling category decision.

Finally, it's important to state that FDA's job is not over after a drug is approved. The goal of FDA's post-marketing surveillance is to continue to monitor marketed drugs for safety, and this is accomplished by reassessing drug risk based on new data learned after the drug is marketed, and when needed by recommending ways to manage that risk.

Let me speak specifically to the approval and regulatory history of OxyContin. OxyContin is a narcotic drug that was approved by FDA for treatment of moderate to severe pain on December 12, 1995. At the time of approval, the abuse potential for OxyContin was considered by FDA to be no greater than other Schedule II Opiate analgesics that were already marketed in the United States, Schedule II being the highest level of control for a legally marketed medical product.

FDA was aware that crushing the controlled-release tablet, followed by intravenous injection of the tablet's contents, could result in a lethal overdose. A warning against crushing the tablet was included in the approved labeling, but FDA did not fully anticipate that crushing or otherwise subverting the controlled-release capsule, followed by oral ingestion, intravenous injection, or snorting, would become so widespread and lead to a high level of abuse.

In response to reports of abuse and misuse of OxyContin, FDA worked with Purdue Pharma to develop a risk management program. The program included adding stronger warnings to OxyContin's labeling, educating healthcare professionals and their

sales staff, and developing a tracking system to identify and monitor abuse.

In July 2001, the warnings and precautions section in the labeling of OxyContin were significantly strengthened. This labeling now includes a boxed, bolded warning, sometimes called a black box, the highest level of warning for an FDA-approved product.

OxyContin's boxed warning informs patients and physicians about the drug's abuse potential, that OxyContin is only for patients with chronic pain, of sufficient severity that requires a controlled-release opiate, and warns about the potentially lethal consequences of crushing the controlled-release tablets.

The indication for use was clarified to reflect that it is approved for the treatment of moderate to severe pain in patients who require around-the-clock narcotics for an extended period.

Let me speak briefly about FDA's collaborative efforts with other entities, including FDA's efforts to address the diversion and illegal sales of approved controlled substances. FDA has met and will continue to meet with a number of government agencies, industry and professional groups, to share information and incites needed to address the broad problem of prescription drug abuse that goes beyond the scope of any single organization. For instance, FDA and DEA have met repeatedly to discuss further ways to prevent prescription drug abuse and diversion. In addition to assisting one another with criminal investigations, both agencies have worked together on initiatives in the following areas: State prescription drug monitoring programs; a joint task force participation focused on illegal sale of controlled prescription drugs; and the assessment of new products with abuse potential.

FDA's enforcement efforts aimed at addressing diversion and illegal sales of approved controlled substances, including opiates like oxycodone, have grown in recent years, while the DEA is the appropriate lead Federal agency responsible for regulating controlled substances and enforcing the Controlled Substances Act, the complexity of the cases and the solutions to the problems of misuse, and overdose, and diversion of prescription drugs, and especially of high concentration opiate analgesic drugs, often benefits from the collaboration of DEA and FDA, as well as State and non-governmental entities.

The FDA's Office of Criminal Investigation is working closely with DEA on criminal investigations involving the illegal sale, use and diversion of controlled substances, including illegal sales over the Internet.

In conclusion, FDA recognizes the serious problem of prescription drug abuse. The agency has taken many steps to address the serious problem, and will continue to act to curb abuse, misuse, and diversion of prescription drugs.

Since this is a problem that is broad in its reach and implications, we are also committed to collaborating with our partners, Federal, State and local officials, professional societies and the industry, to help prevent abuse and ensure that these important drugs remain available to the appropriate patients.

We share the subcommittee's interest and concerns regarding prescription drug abuse, and would be happy to answer questions.

Thank you.

[The prepared statement of Doctor Meyer follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

STATEMENT OF

ROBERT J. MEYER, M.D.

DIRECTOR

OFFICE OF DRUG EVALUATION II
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON REGULATORY AFFAIRS

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

SEPTEMBER 13, 2005

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INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Robert J. Meyer, M.D., Director of the Office of New Drug Evaluation II, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA or the Agency). I oversee CDER's Division of Anesthetic, Critical Care and Addiction Drug Products. This division works closely with CDER's Controlled Substances Staff, which coordinates CDER's activities related to controlled substances and the Drug Enforcement Administration (DEA). I appreciate the opportunity to talk to you today about FDA's role in preventing prescription drug abuse.

FDA is aware of and concerned about reports of prescription drug abuse, misuse, and diversion from approved medical uses. We recognize the seriousness of this issue and sympathize with the families and friends of individuals who have lost their lives as a result of prescription drug abuse and misuse. The Agency has taken many steps to prevent abuse and misuse of prescription drugs, while making sure they are available for patients who need them. FDA is committed strongly to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely manner and monitoring products for continued safety after they are in use.

BACKGROUND

Millions of Americans suffer from chronic pain. Medical and lay literature document inadequacies of the treatment of pain, both from cancer and from non-malignant causes. A consensus statement from the National Cancer Institute Workshop on Cancer Pain indicated that the "under-treatment of pain and other symptoms of cancer is a serious and neglected public health problem." A report by the Agency for Healthcare Research and Quality concluded that, "half of all patients given conventional therapy for their pain…do not get adequate relief." The Joint Commission on Accreditation of Healthcare Organizations regards the evaluation of pain in hospitalized patients as a routine requirement of proper management, akin to assessing temperature, pulse or blood pressure, stating that, "Unrelieved pain has enormous physiological and psychological effects on patients. The Joint Commission believes the effective management of pain is a crucial component of good care. …Research clearly shows that unrelieved pain can

slow recovery, create burdens for patients and their families, and increase costs to the health care system." Pain of moderate to severe intensity affects many aspects of patients' lives, including enjoyment, work, mood, activity level, and ability to sleep or even walk. While a variety of drugs is available for the treatment of moderate to severe pain, for many patients, adequate pain relief will occur only through the proper, informed use of opiates as a part of their treatment.

FDA's goals are to assure that patients who require opioids for pain control maintain appropriate access to them through informed providers, while misuse, abuse and diversion of these products is limited to the extent possible. FDA takes its responsibility in meeting these goals very seriously. Given the broad scope of factors at issue, to achieve these goals it is essential that FDA work in concert with other government agencies, professional societies, patient advocacy groups, industry, and others to share information and coordinate activities.

FDA is concerned about the increasing abuse of prescription opioid drugs. Abuse of opioid analgesics (controlled drugs that include oxycodone, morphine, fentanyl and hydrocodone), has risen steadily over the past five years. By contrast, rates of abuse of illicit drugs have been generally stable over the same time period.

The Substance Abuse and Mental Health Services Administration (SAMHSA), part of the Department of Health and Human Services (HHS), annually conducts the National Survey on Drug Use and Health on a random sample of U.S. households to determine the prevalence of non-medical use of illicit and prescription drugs. According to the 2004 National Household Survey on Drug Use and Health, people who had used pain relievers non-medically at least once during their lifetime increased 7 percent from 2002 to 2004, for a total of 31.8 million Americans.

A significant increase was reported in lifetime (i.e., people who have ever used) non-medical use of pain relievers between 2002 and 2003 among persons aged 12 or older, from 29.6 million to 31.2 million. The prevalence of lifetime non-medical use of oxycodone-containing analgesics increased from an estimated 11.8 million users in 2002 to 13.7 million users in 2003. Lifetime

non-medical use of OxyContin specifically increased from a prevalence of approximately 400,000 in 1999 to 1.9 million in 2002 and to 2.8 million in 2003.

The reported rise of prescription drug abuse is corroborated by data on the consequences of such use. SAMHSA's Drug Abuse Warning Network (DAWN) surveys a national sample of emergency departments (EDs). DAWN captures drug-related visits to EDs, contacts for non-medical use of substances for psychic effects, overdose, dependence, or suicide attempts. ED contacts increased from 69,011 in 1999 to 119,185 in 2002 for narcotic analgesics, both single and combination products. A subset of these data assessing oxycodone (both single and combination products) shows that ED visits increased from 6,429 in 1999 to 22,397 in 2002. For oxycodone sustained-release products, ED mentions increased from 1,178 in 1999 to 14,087 in 2002. The Treatment Episode Data Set (TEDS), also administered by SAMHSA, collects data on admissions to federally funded drug and alcohol addiction treatment programs. Between 1999 and 2003, treatment admissions for opiate drug addiction treatment (exclusive of heroin) increased from 1,382 admissions in 1999 to 9,171 in 2003.

THE FDA DRUG APPROVAL PROCESS

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA is responsible for ensuring that all new drugs are safe and effective. Before any drug is approved for marketing in the U.S., FDA must decide whether the studies submitted by the drug's sponsor (usually the manufacturer) have adequately demonstrated that the drug is safe and effective under the conditions of use proposed in the drug's labeling. It is important to realize, that "safe" does not mean free of risk, and that there always is some risk of potential adverse reactions when using prescription drugs. FDA's approval decisions, therefore, always involve an assessment of the benefits and the risks for a particular product. When the benefits of a drug are thought to outweigh the risks, and the labeling instructions allow for safe and effective use, FDA considers a drug safe for approval and marketing.

During the approval process, FDA assesses a drug product's potential for abuse and misuse. Abuse liability assessments are based on a composite profile of the drug's chemistry,

pharmacology, clinical manifestations, similarity to other drugs in a class, and the potential for public health risks following introduction of the drug to the general population. If a potential for abuse exists, the product's sponsor is required to provide FDA with all data pertinent to abuse of the drug, a proposal for scheduling under the Controlled Substances Act (CSA), Title 21, *United States Code* (U.S.C.) §801 et seq., and data on overdoses.

The CSA requires the Secretary of Health and Human Services to notify the Attorney General through the DEA, if a "new drug application is submitted for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, ..." because it would then appear that the drug had abuse potential (21 U.S.C. §811(f)). HHS has delegated this function to FDA. The Agency assesses preclinical, clinical, and epidemiological data to determine whether a drug under review requires abuse liability studies, scheduling under the CSA, or a risk minimization action plan, (RiskMAP) designed to reduce abuse, overdose, or diversion.

FDA's job is not over after a drug is approved. The goal of FDA's post-marketing surveillance is to continue to monitor marketed drugs for safety. This is accomplished by reassessing drug risks based on new data obtained after the drug is marketed and recommending ways of trying to manage that risk most appropriately.

OXYCONTIN (oxycodone HCl)

OxyContin is a narcotic drug approved by FDA on December 12, 1995, for treatment of moderate to severe pain. The active ingredient in OxyContin is oxycodone HCl (hydrochloride), an opioid agonist with an addiction potential similar to that of morphine. Opioid agonists are substances that act by attaching to specific proteins called opioid receptors, which are found in the brain, spinal cord, and gastrointestinal tract. When these drugs attach to certain opioid receptors in the brain and spinal cord they can effectively block the transmission of pain messages to the brain. OxyContin is formulated to release oxycodone HCl in a slow and steady manner following oral ingestion. The drug substance oxycodone, however, has been marketed in the U.S. for many decades and is available in a wide variety of immediate release dosage forms, including both single entity and combination products.

At the time of approval, the abuse potential for OxyContin was considered by FDA to be no greater than for other Schedule II opioid analgesics that already were marketed in the U.S. Schedule II provides the maximum amount of control possible under the CSA for approved drug products. Based on the information available to FDA at the time of its approval, including the record of other modified release Schedule II opioids, the widespread abuse and misuse of OxyContin reported over the past few years were not predicted. In fact, at the time of its approval, FDA believed that the controlled-release characteristics of the OxyContin formulation, when taken properly, would result in less abuse potential, since the drug would be absorbed slowly and there would not be an immediate "rush" or high that would promote abuse. In part, FDA based its judgment of the abuse potential for OxyContin on the prior marketing history of a similar product, MS-Contin, a controlled-release formulation of morphine that was marketed in the U.S. by Purdue Pharma without significant reports of abuse and misuse for many years. At the time of OxyContin's approval, FDA was aware that crushing the controlled-release tablet followed by intravenous injection of the tablet's contents could result in a lethal overdose. A warning against such practice was included in the approved labeling. FDA did not anticipate, however, nor did anyone suggest at the time, that crushing the controlled-release capsule followed by intravenous injection or snorting would become widespread and lead to a high level of abuse.

FDA COLLABORATES WITH OTHER GOVERNMENT AGENCIES, PROFESSIONAL GROUPS, AND INDUSTRY

The President's 2005 National Drug Control Strategy has recognized the effectiveness of state prescription drug monitoring programs, and called on the pharmaceutical industry, medical community and state governments to become partners in an effort to prevent the illegal sale, diversion, and use of prescription drugs in a way that does not impede legitimate medical needs.

Under the FD&C Act, FDA is responsible for the approval and marketing of drugs for medical use and for monitoring products for continued safety after they are in use, including controlled substances. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. The CSA separates controlled substances into five schedules, depending

upon their abuse potential and medical use. Schedule I controlled substances have the highest potential for abuse and have no medical use while Schedule V substances have the lowest abuse potential. Schedule II substances also have a very high potential for abuse but are approved for medical use. Schedules III, IV, and V substances and drugs have lower abuse potential and fewer controls under the CSA. Some controls that are specific to Schedule II drugs under the CSA include the requirement that DEA grant manufacturing quotas and a prohibition on refills of prescriptions for these drugs.

FDA is continuing to meet with DEA, SAMHSA, the National Institute on Drug Abuse (NIDA), the Office of National Drug Control Policy (ONDCP), the Centers for Disease Control and Prevention, the American Medical Association (AMA), and industry to share information and insights needed to address the problem of prescription drug abuse as described below.

FDA and DEA meet regularly to discuss new ways to prevent prescription drug abuse and misuse. A description of joint investigative efforts is given later in the enforcement section of this testimony. In addition to assisting one another with criminal investigations, both agencies currently are working together on the following initiatives:

- *State Prescription Drug Monitoring Programs* – States that have monitoring programs have shown lower levels of abuse and misuse of scheduled drugs than states that do not have such programs. These programs facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled prescription drugs. Approximately 18 states have some kind of monitoring program in effect. While they vary in resources, methods, and data access by health care professionals, the programs share the objective of preventing and reducing inappropriate prescribing and dispensing, drug diversion, and drug abuse.
- *Task Force Participation* – Agents of FDA's Office of Criminal Investigations (OCI) frequently participate in and/or assist many DEA-led Federal-state task forces throughout the country focusing on the illegal sale of controlled prescription drugs. Both agencies are members of the following working groups: Cross Border Pharmacy Working Group, Permanent Forum on International Pharmaceutical Crime, Interagency Committee on Drug Control, Federal Trade Commission/FDA Health Fraud Working Group, and a working group composed of representatives from HHS (including FDA, SAMHSA, the National Institutes of

Health, and NIDA), DEA, ONDCP, and other agencies to address issues of drug abuse and control under the CSA. In addition, FDA is a member, along with other HHS agencies (SAMHSA and NIDA), DOJ, ONDCP, and other Federal agencies, of the Synthetic Drugs Interagency Working Group, which was established to implement the recommendations of the National Synthetic Drugs Action Plan. Prescription drug abuse is one of the topics that the Working Group's recommendations address.

- *Assessment of New Products With Abuse Potential* – FDA provides DEA with a scientific assessment of a new drug product's potential for abuse and misuse. In addition, DEA often participates in FDA public meetings to provide advice and recommendations to the Agency on scheduled drugs.

In January 2003, FDA and SAMHSA launched a joint prescription drug abuse prevention education effort, with the primary goal of preventing and reducing the abuse of prescription drugs, especially narcotic opiate pain relievers by teens and young adults. This campaign includes brochures and posters, as well as print and television educational advertising highlighting the risks of prescription opiate analgesic abuse. In particular, the campaign highlights the potentially lethal risks of abuse of sustained release opioid analgesics such as OxyContin.

FDA is working with professional societies, including the AMA, to help develop educational programs for physicians regarding sound use of potent opiate analgesics. This effort includes education about the risks of overdose, misuse, abuse, and diversion of scheduled substances as well as ways to manage these risks while ensuring proper treatment of patients with pain.

FDA/DEA ENFORCEMENT EFFORTS TO ADDRESS ILLEGAL PRESCRIPTION DRUG SALES

FDA's enforcement efforts to address the problem of diversion and illegal sales of controlled substances, particularly opiates like long-acting oxycodone, have grown in recent years. DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA. However, the complexity of the cases and the solutions to the problems of misuse, overdose, and diversion of prescription drugs, especially of high concentration opioid analgesic drugs, requires

the collaboration of DEA and FDA as well as state and non-governmental entities. FDA's enforcement efforts to address the problem of diversion and illegal sales of controlled substances, particularly opiates like long-acting oxycodone, have grown in recent years.

FDA's OCI works closely with DEA on criminal investigations when there is a nexus between sales of non-controlled and controlled substances over the Internet. Both FDA and DEA have utilized the full range of regulatory, administrative, and criminal investigative tools available, as well as engaged in extensive cooperative efforts with local law enforcement groups, to pursue cases involving controlled substances. For example, in August 2003, as a result of an extensive, cooperative law enforcement effort that involved DEA and FDA, as well as local and state police in Indiana, the U.S. Attorney's Office announced a 24-count indictment against four individuals who allegedly conspired to dispense prescription drugs, including controlled substances, outside the scope of a legitimate professional practice and absent legitimate medical purposes. Another case conducted by FDA, DEA, the Internal Revenue Service, and the U.S. Attorney's Office resulted in a guilty plea by a medical doctor for the role he played in prescribing prescription drugs via a web-based pharmacy without establishing a patient history or performing a mental/physical exam of patients. The cases cited are just two examples of enforcement actions that have been taken. FDA, DEA, FBI, and the Department of Justice (DOJ) have worked together to pursue other significant Internet pharmacy cases involving prescription drugs, and these enforcement efforts will continue.

Since 2001, FDA's OCI investigations relating to OxyContin have resulted in 66 arrests and 39 convictions. The remaining arrests are pending further judicial action. These are joint cases with DEA. OCI was invited to participate because of a possible nexus with non-controlled drugs under FDA authority. FDA looks forward to continuing our collaboration with DEA to address mutual concerns regarding the abuse, misuse and illegal diversion of OxyContin and other controlled substances; and our efforts to hold criminally responsible those individuals involved in such activities. This relationship will continue to be important as the Federal government addresses the increasing number of websites that offer controlled substances for sale.

On November 15, 2004, in collaboration with DEA, FDA stepped up its efforts to improve the safety and security of the nation's drug supply through the use of radiofrequency identification (RFID), a state-of-the-art technology that uses electronic tags on product packaging to allow manufacturers and distributors more precisely to track drug products as they move through the chain of custody, from the point of manufacture to the point of dispensing. It is similar to the technology used for tollbooth and fuel purchasing passes. FDA launched this effort by publishing a Compliance Policy Guide (CPG) for implementing RFID feasibility studies and pilot programs that are designed to enhance the safety and security of the drug supply. This action continues FDA's commitment to promote the use of RFID by the U.S. drug supply chain by 2007.

FDA SEEKS EXPERT ADVICE FROM NON-AGENCY EXPERTS ON MEDICAL USE OF OPIOID ANALGESICS

FDA routinely convenes panels of non-Agency experts to seek outside advice. Outside experts add a wide spectrum of judgment, outlook, and state-of-the-art experience to drug issues confronting FDA. These expert advisers add to FDA's understanding, so that final Agency decisions more likely will reflect a balanced evaluation. Committee recommendations are not binding on FDA, but the Agency considers them carefully when deciding drug abuse issues.

FDA's Anesthetic and Life Support Drugs Advisory Committee (the Committee), a panel of experts, has met twice within recent years to discuss the medical use of opioid analgesics, appropriate drug development plans to support approval of opioid analgesics, and strategies to communicate and manage the risks associated with opioid analgesics, particularly the risks of abuse of these drugs. The most recent meeting was held in September 2003. This meeting included DEA participation and the Committee included both pain specialists and addiction experts. At this meeting, Committee members again advised FDA that opioid medications are essential for relieving pain. Members emphasized that a balanced approach should be taken to both meet the needs of patients with pain as well as to minimize opiate analgesic misprescribing, abuse, addiction and diversion. They expressed a range of perspectives on the question of imposing restrictions on the prescribing of potent opioids. The pain specialists were concerned

about hurting legitimate patients and reversing the progress in the appropriate treatment of pain as efforts were increased to address abuse and misuse, while the drug addiction experts urged more constraints on use.

THE IMPORTANCE OF RISK MANAGEMENT

Safety or risk assessment combined with efforts to minimize known risks comprise what FDA calls *risk management*. Risk management is the overall and ongoing process of assessing a product's benefits and risks, taking action as necessary to decrease known risks, and then tracking safety and making adjustments as necessary to assure that risks are kept in line with benefits.

As part of risk management, FDA may ask companies to collect specific information to improve the speed and sensitivity of detecting suspected safety problems. When this enhanced data collection is requested by FDA, it is called a pharmacovigilance plan. These exist for many long-acting and potent opioid products and contribute to safe use of the product by detecting, as rapidly as possible, adverse outcomes, including misuse, overdose, abuse and diversion. Once problems are detected there need to be actions to address them.

Actions to minimize risks that go beyond providing an informative package insert are called risk minimization action plans or RiskMAPs. These are strategic safety programs designed to decrease known product risks by using one or more interventions, such as specialized education or restrictions on typical prescribing, dispensing, or use. The small number of RiskMAPs that exist are largely customized programs, although consistent approaches are being sought, for example, in the control of drugs that cause birth defects, such as thalidomide and isotretinoin.

In light of Government Accountability Office (GAO) concerns expressed over OxyContin, FDA recently stated in its guidance to industry on risk minimization efforts, that opiate drug products have important benefits in alleviating pain, but are associated with significant risk of overdose, abuse, and addiction. FDA, therefore, recommended that sponsors of Schedule II controlled

substances, especially the Schedule II extended release or high concentration opiate drug products, consider developing RiskMAPs for these products.

It is FDA's expectation that pharmaceutical manufacturers with new drug applications for potent opiates will submit plans for a RiskMAP that contain a strategy for educating providers and patients on opiate use, as well as means of preventing, detecting, and addressing abuse and diversion. This RiskMAP should be implemented at the time the drug is marketed, particularly for extended-release or high concentration Schedule II opiate drug products. RiskMAPs for individual products would probably vary, depending upon the approved indications and product-specific considerations, including the product's safety profile, but, each RiskMAP would need to address elements such as the appropriate target patient populations and safe use of the product, as well as monitoring for adverse outcomes, including misuse, overdose, abuse and diversion. The Agency's general expectation for addressing issues of safety, including post-marketing surveillance and risk minimization strategies, are detailed in a set of guidances published by FDA in March 2005 as a response to the third authorization of the Prescription Drug Users Fee Act. These guidances can be found on the Agency's web page at the following address: http://www.fda.gov/cder/guidance/index.htm.

In response to reports of abuse and misuse of OxyContin, FDA worked with the manufacturer, Purdue Pharma, to develop a RiskMAP for this product. The program included strengthening OxyContin's warning label, educating healthcare professionals and the sponsor's sales staff, and developing a tracking system to identify and monitor abuse. In July 2001, Purdue Pharma, working in cooperation with FDA, significantly strengthened the warning and precaution sections in the labeling for OxyContin. The labeling now includes a "black box" warning, the strongest warning for an FDA approved product, which warns patients and physicians of the potentially lethal consequences of crushing the controlled-release tablets and injecting or snorting the contents. The indication for use was clarified to reflect that it is approved for the treatment of moderate to severe pain in patients who require around the clock narcotics for an extended period of time.

FDA MONITORS DRUG ADVERTISING AND PROMOTION

FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC), in CDER, is responsible for regulating prescription drug advertising and promotion. DDMAC's mission is to protect the public health by ensuring that prescription drug information is truthful, balanced, and communicated accurately. This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering optimal communication of labeling and promotional information to health care professionals and consumers.

FDA continues to monitor promotional materials for controlled substances, particularly for sustained release products, to ensure that claims are not false or misleading. Also, all product promotional materials must include information from "black box" warnings in the approved labeling. For example, the current approved product labeling for OxyContin contains a "black box" to convey serious risks associated with the use of the product. FDA has taken action against sponsors who violate this requirement or otherwise promote their product in a manner that is false or misleading. The sponsor of OxyContin was cited in May 2000 and January 2003 for advertisements that promoted OxyContin in a manner that is false or misleading. In response, the company agreed to correct the advertisements. In addition, in response to a January 2003 Warning Letter, the company published remedial corrective advertisements in the same medical journals that had run the initial misleading advertisements. We will continue to monitor promotional materials for these products and use our regulatory authority to its fullest extent to ensure that healthcare providers and patients are not subjected to false or misleading claims for these products. As well, FDA's Office of Criminal Investigations remains vigilant to the possibility of criminally fraudulent marketing that may contribute to the problem of dependence.

LETTERS TO HEALTH CARE PROFESSIONALS

When significant changes are made to a drug's labeling, FDA encourages the drug's sponsor to notify health care professionals. For example, after we received reports of OxyContin abuse and diversion resulting in serious consequences, including death, labeling changes were implemented. The sponsor distributed a "Dear Healthcare Professional" letter (issued July 18, 2001) to physicians, pharmacists, and other health professionals. The letter explained recent

changes to the labeling, including additional prescribing information, and highlighted the problems associated with the abuse and diversion of OxyContin.

PATIENT INFORMATION AND EDUCATION

An important component of FDA's strategic plan is to enable consumers to make smarter decisions by providing them with better information to weigh the benefits and risks of FDA-regulated products. FDA's website (*www.fda.gov*) includes information for patients on drug safety and side effects, public health alerts, and general information about major drugs. These web pages provide important information to patients regarding how to use their drug products safely. In an effort to educate health care providers and consumers about the risks associated with OxyContin, FDA created an OxyContin Drug Information web page (*www.fda.gov/cder/drug/ infopage/oxycontin /default.htm*). This page contains valuable information for consumers including the current approved labeling, approval letter, frequently asked questions, and articles on prescription drug abuse.

PALLADONE SUSPENSION

As noted previously, FDA monitors the safety of products after they are approved. On September 24, 2004, FDA approved Palladone (hydromorphone hydrochloride extended-release) Capsules for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock opioid analgesia with a high potency opioid for an extended period of time, generally weeks to months or longer. The active ingredient in Palladone, hydromorphone, is a Schedule II controlled substance.

When FDA approved Palladone, the Agency had evidence from laboratory abuse liability studies that alcohol could be used to extract hydromorphone from Palladone capsules. Neither the Agency nor the drug's sponsor anticipated that this laboratory finding predicted a potential for a life-threatening interaction with alcohol in patients.

Soon after Palladone was approved, FDA received new evidence that "dose-dumping" occurs in

patients if Palladone is taken along with alcohol. The drug's sponsor completed a study in 24 healthy men showing that, compared to taking Palladone alone, concentrations of hydromorphone in the blood were 5.5 times higher on average when the 12 mg Palladone extended release capsules (the lowest dose available) were taken with 8 ounces of 40% alcohol (80 proof, equivalent to typical liquors, such as whiskey).

Lower concentrations of alcohol showed smaller, but still potentially serious effects on the release of hydromorphone from Palladone. Studies showed that taking Palladone with 20% alcohol (equivalent to a mixed drink) or 4% alcohol (equivalent to a typical American beer) increased hydromorphone concentrations 1.9 and 1.03 times higher on average, respectively, compared to taking Palladone alone but some individuals had much higher exposures.

Based on this information, FDA determined that the current formulation of Palladone presented an unacceptable level of risk, even though FDA is not aware of any patients who have had life-threatening side effects from drinking alcohol while taking Palladone. On July 13, 2005, FDA issued a public health advisory to inform patients and health care providers that the sponsor of Palladone agreed to suspend sales and marketing of the drug because of the potential for severe side effects if the drug is taken with alcohol.

CONCLUSION

FDA recognizes the serious problem of prescription drug abuse. The Agency will continue to take steps to curb abuse and misuse of prescription drugs. Since this is a problem that is broad in its reach and implications, we are committed to collaborating with our partners – Federal, state and local officials, professional societies, and industry - to prevent abuse and help ensure that these important drugs remain available to appropriate patients.

I would like to thank the Subcommittee again for this opportunity to testify today on this important issue. I would be pleased to respond to any questions.

Ms. MILLER. Thank you, Doctor Meyer.

Our next witness is Mr. Joseph Rannazzisi. He is the Deputy Chief of Enforcement Operations and the Acting Deputy Assistant Administrator for the Office of Diversion Control at the DEA. He graduated from Butler University with a degree in pharmacy, and from Detroit College of Law at Michigan State University, go green. He has been with the DEA since 1988, first working in Detroit, MI, and then moving to Washington, DC, in 2000.

In his position, Mr. Rannazzisi directs DEA's efforts to prevent the misuse and abuse of controlled substances. We want to thank you for appearing today as well. We look forward to your testimony, sir.

STATEMENT OF JOSEPH RANNAZZISI

Mr. RANNAZZISI. Good morning, Chairman Miller, Ranking Member Lynch, Representative Tierney. I appreciate your invitation to testify today on the status and efforts of the Food and Drug Administration and Drug Enforcement Administration in regulating Schedule II opiates. The non-medical use of prescription drugs is an increasingly serious problem, a new generation of high-dose, extended-release opioid pain medications is producing alarming abuse and diversion statistics, and are creating new challenges for law enforcement. While these new drugs are proven effective in the treatment of chronic pain, they also offer equally increasing risks of abuse and——

Ms. MILLER. Excuse me, could you speak up a little closer to the mic? We are having difficulty hearing you, sir.

Mr. RANNAZZISI. Yes, ma'am.

Ms. MILLER. Thank you.

Mr. RANNAZZISI. OxyContin, Duragesic, and other Schedule II opioids are examples of the drugs most divertable. The potency, purity and quantity of their active ingredients make them more dangerous than ever, providing powerful temptation for abuse. They also encourage new means of diversion, such as "rogue" Internet pharmacies. DEA is taking aggressive action against the threat with our OxyContin National Action Plan.

Boston has an OxyContin problem. DEA investigations show that oxycodone products, such as Percocet, Roxicet, OxyContin, are readily available in Massachusetts. Shipments of OxyContin have been diverted from legitimate distributors. We have seen well-organized doctor shopping rings, individuals that forge or alter prescriptions, and diversion from legitimate prescriptions. Demand has fueled organization distribution.

Now, regulatory control is vital to addressing this problem. Currently, DEA establishes and enforces quotas for Schedule I and II substances, ensuring an adequate uninterrupted supply of controlled substance, both legitimate and medical, and scientific needs, while limiting the amount available for diversion. DEA is also a strong proponent of the State prescription drug monitoring programs, that collect prescription information electronically from pharmacies, to assist in the identification of doctor shoppers and over prescribers. Recently, Federal oversight of the prescription drug monitoring plans was transferred to the Department of

Health and Human Services. DEA looks forward to working with HHS as they take the lead on this effort.

DEA, with DOJ, ONDCP, FDA, and other law enforcement and community partners, have instituted comprehensive initiatives in support of the National Drug Control Strategy. For example, DEA supports the National Strategy through education and recently launched a Web site, www.justthinktwice.com, to provide teens with information on consequences of drug abuse traffic. We've developed public service announcements to appear during Internet prescription drug searches. We are meeting with leading certifying medical boards and encouraging them to develop educational programs concerning the prescribing of controlled substances.

DEA supports the National Strategy's tactic to ensure that treatment resources go where they are needed. Our controlled substances quota is provided for adequate, uninterrupted supplies of treatment drugs, while limiting the amount available for diversion. We also issue registration numbers to physicians who possess waivers to provide opioid addiction treatment within their offices.

The National Strategy targets the economic basis of the drug trade, and we have placed a strong emphasis on seizing the revenue generated by drug traffickers. DEA registrants in violation of regulatory requirements are also subject to significant civil fines, a proven deterrent.

The subcommittee expressed interest in the radio frequency identification security tagging. A detector alerts for bottles taken, but pills may be removed from that bottle. Although almost all the prescription drugs we see are no longer in commercial containers, and we rarely see counterfeited versions of controlled substances. We will continue to monitor and evaluate the usefulness of this technology.

DEA continues to develop new enforcement strategies to address controlled substance diversion and abuse. We are increasing the number of our priority target investigations. We are creating tactical diversion squads throughout the country. We are developing a comprehensive strategy for illicit online pharmaceutical sales, and have created a specialized training seminar for assisting U.S. attorneys on diversion prosecutions.

We are also educating the medical community and drug industry and providing prescription drug information, resources and training to State and local government officials, groups, students, and the general public. We have established an international toll-free, 24-hour tip line, 1–877-RXABUSE, a new Web site, justthinktwice.com and the dea.gov Web site, public service announcements via the internet and e-commerce and e-prescribing initiatives.

DEA is addressing opioid abuse on many fronts. We seek to work with FDA and other agencies to reduce the diversion and abuse of these drugs, while ensuring that a sufficient supply exists to meet the legitimate medical needs.

DEA is vigorously executing the 2005 National Drug Control Strategy, remaining abreast of cutting edge technologies, and actively seeking new approaches to prevent the diversion of legitimate pharmaceuticals.

I want to thank you for your recognition of this important issue, and the opportunity to testify here today. I'll be happy to answer any of your questions.

[The prepared statement of Mr. Rannazzisi follows:]

Statement of
Joseph T. Rannazzisi
Acting Deputy Assistant Administrator
Office of Diversion Control

Before the Committee on Government Reform
Subcommittee on Regulatory Affairs

September 13, 2005

"Status of the Efforts of the FDA and DEA in regulating Schedule II Prescription Painkillers, Specifically OxyContin® and Other Opioid Analgesics"

Chairman Miller, Congressman Lynch, and distinguished members of the Subcommittee, I appreciate your invitation to testify today on the status and efforts of the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) in regulating Schedule II painkillers, specifically OxyContin® and other opioid analgesics.

The Problem

The non-medical use of prescription drugs has become an increasingly widespread and serious problem in the United States. A new generation of high dose, extended release, opioid pain medications have taken the existing threat to a new level. The abuse and diversion statistics are alarming, and the increased popularity of these prescription drugs creates even greater challenges for the medical and law enforcement communities. While these new drugs have proven effective in the treatment of chronic pain, they also offer equally increased risks of abuse and diversion.

OxyContin®, Duragesic®, and other Schedule II opioids are examples of the type of prescription drug that is the highest risk for diversion. The potency, purity and quantity of their active ingredients make them stronger and more dangerous than ever, providing a greater temptation for addicts by offering a high potential for deliberate abuse by those seeking narcotic drugs. These powerful drugs provide strong incentives for diversion through new means, such as "rogue" Internet pharmacies, as well as older methods, like prescriptions written for profit.

Recent drug use surveys have highlighted the gravity of this problem. For example, the non-medical use of prescription drugs ranks second only to marijuana as the most prevalent category of drug abuse. According to the *Monitoring the Future Survey*, there has been a 24 percent increase in past year use of OxyContin® for all grades combined (8th, 10th, and 12th) between 2002 and 2004. The 2004 *National Survey on Drug Use and Health* reported that the drug category with the largest number of recent initiates was non medical use of pain relievers, with an estimate of 2.4 million new initiates.

The DEA understands the importance of aggressive action in this area, and we are addressing OxyContin® diversion and abuse through our comprehensive *OxyContin® National Action Plan*. This plan focuses our enforcement and regulatory investigations on key points of OxyContin® diversion, such as unscrupulous or unethical medical professionals; forged or fraudulent prescriptions; pharmacy theft; and "doctor shoppers" (abusers who move from doctor to doctor seeking prescriptions). Since implementing the *National Action Plan* in April 2001, the DEA has initiated 720 OxyContin® investigations, which have resulted in 812 arrests (as of September 6, 2005).

Prescription drug abuse of opioid medications tends to be concentrated in certain areas of the country. As this committee is well aware, the Boston, Massachusetts, region is one of those areas. DEA investigations have shown that oxycodone products such as Percocet®, Roxicet® and OxyContin® are readily available in the state, and originate from a variety of sources. For instance, law enforcement has intercepted shipments of Oxycontin® that were diverted from legitimate distributors, including the diversion of express mail shipments into the greater Boston area. We have also seen well organized doctor shopping rings, the use of forged or altered prescriptions, and diversion from individuals' legitimate prescriptions.

The demand for diverted pharmaceuticals, particularly pain relievers such as OxyContin®, has fueled illicit organized distribution rings in New England. In November 2004, DEA agents arrested 18 members of an OxyContin® distribution ring who had obtained the drug in New Jersey and transported it to New England for distribution. Two of the members allegedly were associated with organized crime families. In July 2004, DEA agents and local law enforcement officers charged 13 individuals involved in an OxyContin® distribution ring operating in Gloucester, Peabody, and Danvers, Massachusetts. This group was involved in a conspiracy to distribute approximately 35,000 80-milligram OxyContin® tablets with a total street value of over $2 million. The major supplier for this group was a member of the Red Devils outlaw motorcycle gang.

Coordinating Regulatory Responsibilities

As the DEA fights against diversion and drug abuse both here in Boston and across the nation, the proper regulatory control of new pharmaceuticals is vital. Appropriate control mechanisms are particularly important given the strength of the new, extended release products coming on the market.

Currently, the DEA establishes and enforces three types of quotas for Schedule I and II substances. The three are: aggregate production quotas, manufacturing quotas and procurement quotas. The quota system ensures that there is an adequate and uninterrupted supply of controlled substances in Schedules I and II for legitimate medical and scientific needs, while placing limits on the total amount available in order to prevent

diversion. These quotas are established from research through marketing and extensive discussions with the industry that help the DEA establish the potential legitimate market for any new substance.

I would like to make special mention of Prescription Drug Monitoring Programs (PDMPs), which assist states in identifying diversion trends as they emerge. The DEA has strongly supported prescription monitoring programs. PDMPs collect prescription information electronically from pharmacies. The data collected is analyzed by state agencies or third parties and provided to state agencies to assist in the identification of "doctor shoppers" and over-prescribers. The effort often results successful law enforcement and regulatory investigations. In addition, the information collected and analyzed by a state PDMP may be used by doctors to assist in identifying patients whose drug usage is increasing and who may benefit from a referral to a pain specialist or to substance abuse treatment. It may also be used to assist pharmacists in providing appropriate pharmaceutical care.

The DEA's goal is to work with all interested parties to ensure that prescription data pertaining to controlled substances is collected in a cost-effective manner from the largest possible segment of dispensers, while protecting the confidentiality of the collected data and the legitimate practice of medicine. We believe state PDMPs will be able to reach their full potential as one tool in preventing the diversion of controlled substances from legitimate channels. Recently Federal oversight of PDMP's was transferred to the Department of Health and Human Services with the passage of the "National All Schedules Prescription Drug Reporting Act," which was signed into law by the President on August 11, 2005. The DEA looks forward to working with the Department of Health and Human Services as they take the lead on this effort.

National Drug Control Strategy

In addressing the growing problem of pharmaceutical drug abuse and diversion, the DEA, in collaboration with the Department of Justice, the Office of National Drug Control Policy, the FDA, and other law enforcement and community partners, has launched a comprehensive *Prescription Drug Strategy* to address all areas of concern and all sources of diversion. This *Prescription Drug Strategy* is a component of the *National Drug Control Strategy—Stopping Drug Use Before it Starts; Healing American's Drug Users: Getting Treatment Resources Where They Are Needed;* and *Disrupting the Market: Attacking the Economic Basis of the Drug Trade.*

The DEA supports the Strategy through its support of educational efforts by communities, schools, the media, and other organizations. Most recently the DEA launched an anti-drug website for teens, www.justthinktwice.com. This site provides young people with straightforward information on the consequences of drug use and trafficking, including health, social, legal, and international consequences. It will be continually updated to provide current information to teens and will be expanded and refined to reflect the needs of teens. We expect the site to be a valuable resource for

teens seeking information on drugs for their own education or for school research projects.

In addition, in early FY 2005, the DEA began working with its partners to develop public service announcements that will appear automatically during Internet prescription drug searches. These announcements are designed to alert consumers of the potential dangers and the illegality of purchasing controlled substances, particularly pharmaceuticals, over the Internet. Both AOL and Google have responded by instituting voluntary compliance measures and corporate commitments to taking affirmative steps to curtail the illicit sale of pharmaceuticals on their networks. The DEA also is meeting with the leading certifying medical boards, encouraging them to develop educational programs concerning the prescribing of controlled substances, especially high-dose opioids.

The DEA plays a vital role in implementing the second core tactic, *Healing American's Drug Users: Getting Treatment Resources Where They Are Needed*, by establishing quotas for controlled substances. Quotas provide for an adequate and uninterrupted supply of abuse treatment drugs, while limiting the amount available to potential diversion.

The DEA also issues registration identification numbers to treatment physicians with Substance Abuse and Mental Health Services Administration waivers. Under the Drug Abuse Treatment Act of 2000, the Controlled Substances Act (CSA) requirement for a separate Narcotic Treatment Program registration is waived for qualified practitioners to treat opioid addiction using FDA approved Schedule III-V controlled substances. Qualified practitioners are issued unique identification numbers that allow them to provide opioid addiction treatment from their offices. As of September 2, 2005, the DEA has registered 5,840 of these physicians throughout the United States. This registration represents a major effort to improve the quality and delivery of, and expand access to, addiction treatment.

The DEA has established the core tactic, *Disrupting the Market: Attacking the Economic Basis of the Drug Trade* as a priority of the Prescription Drug Strategy. We have increased the time dedicated to pharmaceutical investigations and continue to focus our drug enforcement efforts toward the most significant members of the drug supply chain. Enforcement efforts undertaken by the DEA are aimed at the economic base of drug traffickers; strong emphasis is placed on seizures of financial and other assets.

The DEA seeks to reduce the profitability of the drug trade and increase the costs of drugs to illicit consumers. In other words, the DEA seeks to inflict upon illicit drug business what every legal business fears: escalating costs, diminishing profits, and unreliable suppliers. The DEA's effort to stem the illegal sale of controlled pharmaceuticals has resulted in the dismantling of major organizations and the increasing seizure of assets. DEA Registrants found to be in violation of regulatory requirements under the CSA are subject to significant civil fines. Such civil remedies have proven to be a deterrent to potential violators.

Our work in pursuing these violators has been effective. On June 17, 2005, arrest warrants were issued charging 24 individuals from five states, including Massachusetts, with conspiracy to distribute Oxycodone and conspiracy to commit money laundering. These individuals allegedly were involved in a ring responsible for obtaining Oxycodone, primarily in the form of OxyContin®, in Florida and subsequently distributing the drug in New England. The ringleader allegedly sent money, in amounts of $4,000 to $78,000, in exchange for 500-plus-tablet quantities of OxyContin®. The ring had operated for several years and had obtained hundreds of OxyContin® tablets each week. The charges are a result of a 2½-year investigation involving various state and local law enforcement agencies, the DEA, and the Internal Revenue Service (IRS). This OxyContin® distribution ring is the third such ring dismantled in the New England area over the past year.

The DEA is applying a two-fold strategy in attacking the money laundering aspects of these investigations. In those cases involving illegal distribution via the Internet, credit card and electronic payments are being traced through the various processing layers to identify both the recipients and the final destination of the funds for subsequent seizure. In those investigations involving individual doctors and clinics issuing illegal prescriptions, more traditional financial investigative techniques are being employed to trace and seize their illicit profits.

Radio-Frequency Identification Technology

The subcommittee has expressed interest in Radio-Frequency Identification (RFID). RFID is an emerging technology, based on wirelessly exchanging information between a tagged object and a reader/writer. The benefits of RFID for drug manufacturers or distributors are improved tracking and control of inventory, production, shipping, and receiving.

The use of radio-frequency identification technology is more appropriate for case lots and commercial packages of bottled drugs. While properly placed detectors would alert if a bottle containing a chip were taken, the ease of emptying the commercial bottle and taking only the pills is evident. The overwhelming majority of pharmaceutical controlled substance seizures that the DEA encounters come in loose tablets, dispensed bottles, or plastic bags. The commercial container has been discarded long before the DEA sees the product. We also rarely see counterfeited versions of controlled substances.

The DEA does not regulate or require RFID under our existing security regulations. Still, we will continue to monitor and evaluate the usefulness of RFID technology as a potential deterrent to the diversion of legitimately produced pharmaceuticals at the dosage unit level.

New Approaches to Address Prescription Painkiller Addiction and Abuse

The DEA continues to develop new strategies to aggressively address addiction and abuse of controlled pharmaceutical painkillers. The newer enforcement approaches we have taken include: increasing Priority Target Investigations; creating Tactical Diversion Squads focused on prescription drug diversion at the retail level; developing a comprehensive enforcement and regulatory strategy to address the growing problem of illicit sales of pharmaceuticals on-line; and implementing a specialized training seminar for Assistant United States Attorneys that focuses on prosecution strategies for diversion cases.

In addition, we are taking an active role in educating the medical community and drug industry and providing prescription drug information, resources, and training to state and local government officials, community coalitions, educators, prevention organizations, students, and the general public. Other efforts include establishment of the DEA's international, toll-free 24-hour tip line number, 1-877-RXAbuse, the new teen website www.justthinktwice.com, prescription monitoring programs, public service announcement via the Internet, E-Commerce and E-Prescribing Initiatives, and Risk Management Plans.

Conclusion

The DEA is addressing OxyContin® and other opiod addiction on many fronts, from education to regulation and enforcement. We will continue to work with the FDA and other agencies to reduce the diversion and abuse of these drugs while ensuring that a sufficient supply exists to meet legitimate medical needs. The DEA is vigorously executing the core tactics of the 2005 National Drug Control Strategy, keeping u tp date with cutting-edge technologies, and actively seeking new, innovative approaches to prevent diversion of legitimate pharmaceuticals.

Thank you for your recognition of this important issue and the opportunity to testify here today. I will be happy to answer any questions you may have.

Ms. MILLER. Thank you.

I appreciate both of your testimony.

Taking a few notes as you were speaking here, and I suppose I'd like an answer from both witnesses on this, if I could.

Doctor Meyer, you were speaking about labeling of OxyContin, and we actually have some written testimony here that's been given to the subcommittee from Purdue Pharma, in which they've actually shown us a copy of the box warning that you spoke of, about the labeling on this. I won't read it all to the audience here, but it is a very black box that apparently appears, OxyContin is an opiate agonist and a Schedule II controlled substance with an abuse liability similar to morphine, etc. It goes on about the controlled release, oral formulation, etc.

So, it would seem to any physician or whomever that the labeling is very clear about the dangers of this particular drug. How do you think that the marketing of OxyContin is actually circumventing what is a very clear labeling?

And again, if I could have a response from both witnesses, I'd appreciate that.

Mr. MEYER. Let me say one other thing with regard to the labeling, because it's important to realize that the labeling does inform how the drug is marketed, in terms of print ads and so on. And, in fact, the FDA has issued warning letters in the past for infractions of that, including to Purdue Pharma.

I'm personally unaware of any concerted effort to circumvent that kind of boxed warning, but it is a concern to FDA that despite these kind of warnings, and this goes beyond just OxyContin, the boxed warning is as high a warning as we can give a drug, and they are very prominent in the labeling when you look at it.

Nonetheless, it only goes so far in informing physicians, and I think from my standpoint it's a very important tool to inform physicians about proper use of the drug, but, unfortunately, it's not always heeded.

Ms. MILLER. Mr. Rannazzisi.

Mr. RANNAZZISI. As far as the marketing practices, I believe you have to look back from when the drug was released in the mid 1990's.

Ms. MILLER. Could you get by the mic, I'm sorry, I can't hear you again.

Mr. RANNAZZISI. Oh, I'm sorry.

I believe you have to look back to when the drug was initially marketed in the mid 1990's. Physicians generally rely on what they are told about the drugs from the salesmen that are selling those drugs.

I don't believe that the physicians were adequately notified of what the drug could actually do, and what specific patient population that drug should be targeted toward. And, I think listening to Mr. Lynch and Mr. Tierney, I believe that the doctors, since they didn't know what they had at the time, they maybe prescribed to people that didn't necessarily need the drug, and I think that was a problem.

Ms. MILLER. Doctor Meyer, you had also mentioned about risk management plans [RMPs] as you called them. I'm wondering, are risk management plans always required by the FDA as part of

your approval process, and if so under what authority would that happen? Is it part of statute? Is it a promulgated rule from the FDA? This being a regulatory subcommittee, we're particularly interested in how you did the construct for that. And, as well, if it is, if they have been under that type of a thing, as Representative Lynch mentioned in his opening statement we are now seeing these generic forms of these drugs. Are the generics also forced into the same type of regulatory process under the risk management plan as the original drug was?

Mr. MEYER. When you said does this apply to all drugs, it does not apply to all drugs, but it is our intention, and it's actually our statement in guidance, including some of the recent risk management guidances that were released by the agency, that all potent opiate products would have a risk management plan at the time of their approval.

That is not under specific authority of the FD&C, it's an expectation of the FDA, we work in cooperation with the sponsors to achieve that, and it would apply, and has applied, to the generic drugs as well.

Ms. MILLER. The final question then, is this something that Congress could help you with? Is there something that Congress could do to assist you legislatively, to give you the tools that you need to make sure that is part of the process? I mean, that's really what the purpose of this hearing is today, is so that we can understand better what exactly we can do to give you the tools you need to help.

Mr. MEYER. Understood. I don't believe the administration has taken a position on that matter, so I don't think I could express an opinion. But, you know, as I said, it is not part of the FD&C authority at this point.

Ms. MILLER. Thank you.

I yield to Representative Lynch.

Mr. LYNCH. Thank you, very much.

First of all, I want to thank both of you gentlemen for coming here and offering your assistance to the committee.

Let me begin just by sort of touching on a couple of issues that Madam Chair touched on, and I'm particularly interested in your response, Doctor Meyer.

You mentioned that based on the wording in the label you saw no evidence of anybody trying to undermine the warning on the black box itself.

Mr. MEYER. I said I was unaware of any concerted effort in that regard.

Mr. LYNCH. Any concerted effort.

Mr. MEYER. Yes.

Mr. LYNCH. But, your agency, the FDA, it actually, first of all, they report that Purdue Pharma spent more than any other drug in history, in marketing their drug, more than any drug in history.

Your agency found that they had two misleading advertising campaigns. You cited them. The FDA cited them, gave them warning letters.

One, they had an ad with two guys fishing, and, you know, there was the arthritis, they were pushing OxyContin for the treatment of arthritis. That would seem to be an ad campaign by a company,

in my opinion, to push a drug for people for whom it is inappropriate, and that's what your agency said. The claim was that the treatment of arthritis was completely unsubstantiated, those are your words, your warning letter to the company itself.

Mr. MEYER. Yes.

Mr. LYNCH. So, to sit here today and to say—and that's just one of them, there's another warning letter, there are two different ad campaigns by the company where they inappropriately marketed this thing.

Mr. MEYER. Right.

Mr. LYNCH. This is not a couple of rogue drug detailers who are out there on their own, this is the company, and getting a warning letter from your agency, the FDA, should be a serious event. And yet, even though you warned them twice, you don't think there was any effort to undermine the warning on the label, which doesn't even speak to the issue of addiction, it talks about the potential for abuse, which is another matter.

Mr. MEYER. Well again, when I answered the question I also pointed to those warning letters, but aggressive marketing does not necessarily equal illegal or inappropriate marketing, and this drug was aggressively marketed, no doubt about it. But again, out of all that marketing there were only two ads that the agency found to be violative.

Mr. LYNCH. Well, all I'm saying is, your statement was that you saw no concerted effort to undermine the warning on the label, and all I'm saying is, pushing it to people with arthritis, and doing it in a way that you found to be misleading on two occasions, advertising campaigns by the company to push this drug for a purpose for which it was not approved undermines the warning on the label that says, it's only for this purpose, and also we approved this with certain caution.

Mr. MEYER. Right.

Mr. LYNCH. OK. It just overrides those cautions, and that's the one point I want to make.

Mr. MEYER. Understood, and the agency understood that as well, which is why it issued the warning letters.

Mr. LYNCH. No, I'm happy you did. I'm happy you did. It seemed to be—your statement seemed to be at odds with the evidence, that's all.

One of the question I had in reviewing sort of the way that the DEA and the FDA work together, and it's something that I think having you both here will just help me to understand. If you could both just take a minute, for the benefit of the committee, talk about how—I know that the DEA is responsible for enforcing the Controlled Substance Act, and that the FDA handles the application process, and getting it approved, and making sure that certain studies are conducted when appropriate, but in the process itself at what point, I know there's a a lot that is in your hands, Doctor Meyer, from the application process much earlier than the point at which the DEA gets involved. Can you tell me when that overlap occurs? When does the DEA get into that process on a drug like OxyContin?

Mr. MEYER. Well, on a new drug that has not previously been scheduled, it will occur toward the end of the review process, and

the reason is for that, that the FDA at that point has gone through all the requisite data on use potential, on issues of drug dependence, abuse liability, and so on, and we'll put that together with a recommendation that then goes through the Department for DEA's consideration the scheduling process.

Under a drug that's already been scheduled, there may not be formal interactions prior to the approval, with the exception of discussions about how the approval might impact on the—if it's a Schedule II drug, on the quota.

Mr. LYNCH. OK.

Was that, the latter example, that was the one with respect to OxyContin, because oxycodone had already been out there, right?

Mr. MEYER. Correct.

Mr. LYNCH. OK.

So, let me turn to you, Mr. Rannazzisi, to your knowledge, what was the interaction for this particular drug by the DEA?

Mr. RANNAZZISI. That was way before my time, however, as my colleague said, I believe that was pretty much the process.

We get the information, the medical and scientific data, you know, just, I guess, prior to approval, we run it through our scientists, our pharmacologists run medical and scientific data through their vetting process, and we come to an agreement on if it should be a controlled substance, and what schedule it should be in, and we send it back and then it's scheduled. That's about it.

Mr. LYNCH. OK.

Let me just ask, I know, Doctor Meyer, in your testimony you talked about the approval process and preventing abuse or diversion, if you will, of the drug once it is approved, and that's a very thorny issue because in some cases it is literally beyond the agency's reach and it is unanticipated.

But, with respect to Palladone, now here was a situation where there had been some concern regarding combination with alcohol in the process. OxyContin had been out there for a while, and this was certainly twice as powerful as OxyContin, and given the prevalence of alcohol within our society it is astounding to me, it is astounding that this Palladone got approval, this passed the FDA approval process when even based on your own testimony and what I've got here before me today from the FDA that even a minor amount, a relatively minor amount of alcohol, combined with Palladone could be fatal.

And, if there's anything that can be said on Purdue Pharma's behalf today, at least they pulled it off the market. But, it troubles me greatly that it got through, in terms of the FDA as a gatekeeper to prevent harmful substances from getting out there and getting approved, and getting on the shelves. The system failed with Palladone, and then, you know, we sort of caught up. I don't know if the FDA had all the information it needed or what the problem was, but I see a trend here. More and more powerful drugs, more and more addictive drugs, and how addictive are we going to allow these drugs to become? Even when properly prescribed, they are just so powerful.

I know in your testimony you talked about oxycodone and how it was out there in Percocet, Percodan, whatever it is, and there

was somewhat an assumption this is more of the same, but that's not what I see in my community.

I had a young woman from a very good family come into my office and tell me that she had been prescribed OxyContin for dental pain, and she had a refill, and she had a dependency within a very short time. She went back to her dentist on two later occasions, and she tells me now, she's in rehab, she tells me now she lied to her dentist on other teeth pain, had two more healthy teeth extracted just so she could get that prescription.

So, when somebody tells me it's more of the same, oxycodone has been out there, and that it's nothing new, it's at odds with the evidence, not only the anecdotal evidence from my district, but when I travel throughout the State I have never in my life seen at every single pharmacy, whether it's in the city of Boston or on Cape Cod, or in the Berkshires, every single pharmacy in the State has a big sign in the front window, "We don't sell OxyContin," some in the city of Boston, "We don't carry OxyContin onsite," because of the number of robberies, they don't want to get robbed, and I've never seen that with Percodan, or Percocet, or any other medication. It is astounding the power of this drug.

And, I'm just concerned, how could we have stopped Palladone from getting through? I mean, you know, I'm all for more funding for the FDA, and approving that process, or tightening up the studies that are necessary, and how can we help you to help us and to be a better gatekeeper in terms of this whole process, because it's not just about the drugs we are talking about today, you know, I'm fearful that this next generation, as Mr. Tierney mentioned, all these applications out there, you know, there's a real rush, we are at a very exciting time, you know, in drug development, I think. There are a lot of opportunities out there. There's a lot of investment, and people pushing the envelope. How do we set up a system that anticipates all of that, that power, and some of these drugs that I'm afraid will make OxyContin look like aspirin in about 10 years, and that get out there in the public? How do we help you?

Mr. MEYER. That's a fairly broad question. Let me turn to that in a second.

I did want to make the point as far as the—you point to these more potent products, and I understand your very real concern and hear the tragic story that you relay, but I also understand that there are pain patients out there for whom drugs like Percocet and the short-acting opiates that have less potency do not properly relieve them. So, I think the tension for the pain community, the tension for the FDA, is trying to figure out how to properly address both sides of this equation. We always keep that in mind, so I just wanted to say that as the background.

As far as the situation with Palladone itself goes, that was marketed with the most stringent risk minimization program that we had to date with a potent opiate product, and I think that in many ways that was a good thing. We, I think, went as far as we felt we could in terms of putting that in place, understanding the concerns, very real concerns about this drug from its abuse potential, but also understanding its promise from a therapeutic potential.

The particular situation with this was that this formulation actually looked to be, in many respects, much less abusable than

OxyContin. If it was crushed it didn't release the way OxyContin did.

Quite frankly, it was a regulatory learning from our standpoint that something that in the laboratory could release drug in exposure to high amounts of alcohol could actually do that in the patient setting, and that's why we took the action we did with Purdue's ascension or agreement.

I think that for us, taking that regulatory learning and properly applying it for every case into the future is a firm commitment on our part. And so, I don't think there's a particular lesson there, where, you know, more funding, more effort, in this specific regard would have addressed that.

On the broader issue of how the agency can be helped, I think that's enough of a policy question that I would defer that to others. I think if you'd like an answer to that in writing I'd be happy to seek that from the agency, but I'm a little bit uncomfortable, from my position as a physician rather than a policymaker, in answering that.

Mr. LYNCH. Fair enough.

Before I turn to Mr. Rannazzisi again, I would just like to say, do you think at least—it's also remarkable to me that we never did, with all the pain and suffering—with all the addiction I see, and all the pain and suffering I see outside of the proper people that should be receiving this drug, there has never been, to my knowledge, a study done on the addictive properties of OxyContin, on the addiction itself, and I can find no study, I've asked the FDA if they had any study, they said no, we don't have a study on that, I think that information could be tremendously useful to educate doctors and patients that they say, OK, here's the addiction rate, not the abuse rate, but the actual addiction rate, what is the rate of addiction for people who actually get properly prescribed this drug for, you know, a measured period of time? Do you think that such a study would be helpful to the FDA in measuring the, I think, appropriateness of the drug itself?

Mr. MEYER. I think in general there's an incomplete knowledge of the relative—what some will call like-ability of a drug, of opiate drugs, and how that compares amongst the drugs. It's fairly good data about the potency, in terms of their specific receptor actions or pain actions, but there's been less study in terms of the comparative abuse potential or like-ability of the drug. And, I think that sort of data, not just to the FDA, but for other agencies and other healthcare entities, would be useful data.

Mr. LYNCH. Right. I'm just talking about, for instance, right now Purdue Pharma has—well, early on they said that someone on a low dosage for a long period of time of OxyContin could be off it with very little withdrawal in a couple days. Meanwhile, I've got—and that someone could be on a higher dosage for a long period of time and it would be a matter of a couple of weeks before they were back to normal and would have no withdrawal effects.

And, I've got about 500 people on a waiting list for beds for residential treatment, you know, for the drug itself. So, I'm seeing a great disparity between what they are telling us and what we are seeing, and I think most people who run rehab clinics, you know, if you try to tell them that someone can get off OxyContin after a

long period of time in a matter of a couple of days, they'd just laugh in your face. Same way with people that have been on the drug for an extended number of, you know, weeks at a higher dosage, I just find it astounding.

And, I think if we had some data around that we might be able to at least get a rate at which—and how long it took people to go through the withdrawal process after being on the drug on average, and I think we should really put it on some of these companies before they get their drug approved, especially when we've got the experience staring us in the face right now.

Ms. MILLER. If I could, Representative Lynch, Mr. Tierney has to leave a little bit early, if I could recognize him.

Mr. LYNCH. Sure.

Ms. MILLER. And then, we'll come back to you for a second round of questions.

I recognize Representative Tierney.

Mr. TIERNEY. Thank you very much. I'll try to be a bit brief, if I can.

Doctor Meyer, you are familiar with the concept of an antagonist?

Mr. MEYER. Yes.

Mr. TIERNEY. Would you just briefly describe that for others?

Mr. MEYER. It's, basically, a drug that blocks the receptor, so that the agonist drug, in this case if you are talking about opiates, the opiate receptor is blocked by this so that the agonist drug can't have its effect. It blocks, in effect.

Mr. TIERNEY. And, wasn't that done with some of the morphine-based drugs a while back?

Mr. MEYER. It has been done. There's actually two agonists that are in common use, miloxydone and miltrexone.

Mr. TIERNEY. So, tell me why there's 450 patents out there, 19 different companies that we've been able to track or whatever, that are trying to create this antagonist situation of the abuse-resistant formula for these drugs, why is it taking so long in this instance?

Mr. MEYER. Well, if you think about giving an antagonist at the same time as an agonist, it, basically, means that you are undermining the therapeutic effect of the drug, and a lot of these are aimed at trying to prevent the abuse situation. So, in other words, some of these agonists are not orally absorbed, but can be effective when given intravenously. So, if you put them into a pill, the theory would be, if that pill is crushed up and injected intravenously, it would block that.

Mr. TIERNEY. Right.

Mr. MEYER. Unfortunately, this has just been a very hard scientific and chemistry challenge to get through, even though the agonists—excuse me, the antagonists are not well absorbed orally, they can change the property of the drug, even when given orally. So, there are—it's been a technical challenge that I think has been very hard to get over.

Mr. TIERNEY. Well, should the government get involved in that? Should we do some of our own research? Would that be good policy?

Mr. MEYER. I think that would not be under the FDA, but I think that—well, I guess, again, I would leave that sort of to the policy people within FDA.

Mr. TIERNEY. Well, what about the—I mean, I know at one point in time Purdue was investing some money in one of the companies that was trying to do it, they withdrew their funds, would it be unreasonable to expect that the sponsor of a medicine like OxyContin would be required to continue to keep investing?

Mr. MEYER. I don't think that kind of requirement would be consistent with the authority under the FD&C Act as I understand it.

Mr. TIERNEY. As it currently exists.

So, they get to put it on the market, they get to know that there's a way to attack it, but they don't have to have any obligation to invest in pursuing that avenue, is the way the law is currently written.

Mr. MEYER. If the drug is safe and effective for its proposed use and shown to be in studies, then we approve it.

Mr. TIERNEY. OK.

Mr. Lynch brought up the point of advertising, or inappropriate advertising for this drug. You've cited twice Purdue for that. What about what's told to physicians? You know, how do we assure ourselves that if you take off those inappropriate advertisements from TV that representatives of these companies aren't going in to physicians directly and telling them, you know, you can use off label, because we don't have any particular constraints, as I can see, on physicians from prescribing off label. So, what if the company's representative goes in and says, you know, this isn't such a bad thing for arthritis either, you can just go ahead and write it off label. We don't have to go up on TV, we are just going to send all of our millions out there and do it that way. Do we have any control over that situation, is there any monitoring of it?

Mr. MEYER. Well, that certainly is considered part of the drug advertising, and it needs to be consistent with the labeling. It is a, I believe, an easier thing for the drug advertising people within FDA to assess the print ads which are submitted by the companies than it is to individually assess what's being said to doctors.

That said, if reports come into DDMAD, which is the Division of Drug Marketing and Advertising, about such cases, where a physician or someone else reports that a detail person is saying things inconsistent with the labeling, that is followed up on.

Mr. TIERNEY. Wouldn't it be good policy if we knew that we had a problem with a drug like OxyContin, and we put the black box on there and the labelings, we know that there are some limitations that we want, wouldn't it be a good practice to just require that it can only be prescribed for those things, and that particular pharmaceutical agent couldn't be prescribed off label for any other use until it had gone through some sort of process at the FDA to assure that it wasn't going to create problems?

Mr. MEYER. I would be somewhat—I would be concerned about that, as stating that would necessarily be good policy, because the FDA generally has not wanted to constrict the practice of medicine. We leave that much more to the State pharmacy boards and other entities. In the case of the Controlled Substance Act, some of that also falls within DEA.

But, I believe that allowing physicians latitude to use appropriate judgment for prescription drugs, and here I'm talking broadly, it is a good thing.

Mr. TIERNEY. Well, I think broadly maybe it is, but we are talking here, you know, I'm familiar with one study being done now that says 47 percent of new users of drugs are really from clinicians using off label to their drugs and then reporting what they've done. So, there's a bit of frequency where this is being done, the off label prescribing.

When you know you have a situation like OxyContin, where it's being abused, and where it's highly addictive, why would you in that instance, not in all instances, but say, OK, this one we know, so this one, perhaps, you can only prescribe it for the limited uses on that and you can't go off label with that, unless you come through the FDA ahead of time and tell us what you are going to do with it and we run through some tests on that basis. I mean I wouldn't say you necessarily do it generally, they can never prescribe off label, but when you know you have a problem, why not try to contain that problem?

Mr. MEYER. Again, I would just have concerns about how that might be a slippery slope. But, if you'd like a specific answer to that from the policy standpoint, I'd be happy to get that.

Mr. TIERNEY. I would, indeed, if you would, please.

Mr. MEYER. OK.

Mr. TIERNEY. And, let me just ask one last question on this. Well, let me clarify one issue with you, please. The hearing up here is not as good as it may be down there, I don't know if the others are hearing, but there's a fan going overhead, when you were talking about whether or not the FDA requires pharmaceutical companies to include risk management plans in new applications, did you say that was or was not something that was done?

Mr. MEYER. For new opiates?

Mr. TIERNEY. New opiates, right.

Mr. MEYER. It is our expectation that they will be in place, and it has been since that expectation has been set forth in guidances.

Mr. TIERNEY. OK. So, now it's required.

Mr. MEYER. It is our expectation and it is what has happened.

Mr. TIERNEY. So, you are asking them to do this, but you are not requiring it, is that the deal?

Mr. MEYER. Again, I believe I said earlier, I do not believe that there is a specific authority in the FD&C Act to require a risk management plan, but it is our expectation that they will be in place.

Mr. TIERNEY. That's what I wanted to clarify, because I want to note with my colleagues that's a direction that we may want to look at, is why aren't they required as opposed to just requested, and one of your expectations. We've got a lot of expectations that pharmaceutical companies haven't quite borne out.

And, I'm going to leave it at that at this point in time, because I have time constraints and have to get back to D.C.

But, I want to thank my colleagues, again, thank the witnesses, and apologize to the coming witnesses that I won't be here for their testimony, but we will read it and hear from my colleagues what you have to say.

Thank you.

Ms. MILLER. Thank you, Representative. We appreciate that line of questioning as well.

I might just ask the question of Doctor Meyer, you know, it is, apparently, OxyContin was very revolutionary for pain, and as we are all driving sort of a focus on much of this questioning of what we can do to stop some of the abuse that is unfortunately happening, has the FDA ever had a similar type of a situation with a painkiller in the past, and what did you do in those circumstances, if that's so? In other words, perhaps we can look at best practices or successes you have had in any other similar instances in curbing the abuse.

Mr. MEYER. I'm really unaware of any kind of similar instance where a single entity has become so prevalent and so notorious.

Actually, much less potent drugs are also commonly abused, including things like codeine, but it hasn't had that sort of focus on one specific entity that has really become so widespread.

So, I don't think there is prior learning on this. There is certainly learning going on now, and I can assure you that when the drug was approved in 1995, as I said in my oral, we were not aware that it would have the kind of potential for widespread abuse and misuse, such as its shown, and I think that we certainly learned some important lessons about risk minimization, about education, about tracking and so on, that will certainly be applied and are being applied in the future.

Ms. MILLER. Mr. Rannazzisi, I had asked a question previously of Doctor Meyer about what Congress may be able to do to assist the FDA, let me ask you a similar question. What could Congress do to assist the DEA, as you are struggling, as well as preventing some of the abuse and diversion of these prescription painkillers? Do you have any specific ideas or conceptual ideas that we might explore?

Mr. RANNAZZISI. That would be an issue for our policymakers. I just want to thank you for doing this hearing, though, I mean, that's important, adjusting the focus to this type of drug abuse, prescription drug abuse, something that's been in the shadows for so long, it's good that a committee is taking this and putting it out in the public forum. I think that's important to us, and I think it's important for our parents to understand what their children are doing. Abuse is widespread.

But, if you are asking me a specific recommendation that's a policy matter, and we could get back to you on that from the Department.

Ms. MILLER. All right, we will be submitting that question to your policy department as well.

And, at this time, I recognize Representative Lynch for a second round of questions.

Mr. LYNCH. Thank you, Madam Chair.

Actually, you asked the question of the DEA representative that I was going to ask.

I wish you had come prepared to answer that question, because a lot of blame is being laid at the feet of the DEA for not interdicting, not intervening here, and allowing this problem to go forward.

And, when a committee of Congress asks you, what do you need for us to help you do your jobs, I think it's remiss to come here and

say, well, that's a policy issue. It goes to the very heart of your mission. I have your mission statements right here, both the FDA and for DEA, and I've got to tell you, I'm disappointed. I'm disappointed that you come here, we ask you what you need, you know, this is a problem with bureaucracy, I've got to tell you, you should have come here prepared to say, we need X, Y, Z, this is what we need, and, you know, to do our job we need to have your help. And, you know, that's what I would have if I was sitting in your chair, I would have came with a laundry list. I would have told the Members of Congress exactly what I needed to get my job done, and not we'll get back to you. You know.

So, I guess that's all I have.

Thank you.

Ms. MILLER. Thank you.

Well, we want to thank both the witnesses again for coming to the hearing. You've been somewhat enlightening, not entirely, and we appreciate your testimony, though, very much, and we'll look forward to hearing from the next panel.

At this time we'll take a brief recess.

[Recess.]

Ms. MILLER. We'll call the Subcommittee on Regulatory Affairs back to order, and for our second panel, because Government Reform is an oversight committee we do have subpoena authority, it is our practice, whether we are in Washington, DC, or in the field here, and anywhere else in the Nation, that we swear in our panel. So, if you could please rise and raise your right hands.

[Witnesses sworn.]

Ms. MILLER. Thank you very much.

We will now hear from State Senator Steven Tolman. In 1998, Senator Tolman was elected to the Massachusetts State Senate, after having served 2 years as—two terms actually, as a State representative. He chairs the Mental Health and Substance Abuse Committee. He is also extremely active in his community, serving on the Board of Directors for the Allston/Brighton YMCA.

Senator Tolman, we certainly appreciate your attendance at our hearing here today, we look forward to your testimony, sir.

STATEMENTS OF STEVEN A. TOLMAN, MASSACHUSETTS STATE SENATOR; BRIAN WALLACE, MASSACHUSETTS STATE REPRESENTATIVE; JOHN McGAHAN, EXECUTIVE DIRECTOR, CUSHING HOUSE; AND JANET L. ABRAHM, CO-DIRECTOR, PAIN AND PALLIATIVE CARE PROGRAMS, DANA FARBER CANCER INSTITUTE AND BRIGHAM AND WOMEN'S HOSPITAL, AND ASSOCIATE PROFESSOR OF MEDICINE AND ANESTHESIA, HARVARD MEDICAL SCHOOL

STATEMENT OF STEVEN TOLMAN

Mr. TOLMAN. Well, thank you, Madam Chair, and Congressman Lynch, and I was going to say the other Members, but I can tell you that there is nothing more important that we face in Massachusetts and I applaud your efforts for being here today, knowing how busy you are.

I'm the State Senator from the 2nd Suffolk and Middlesex District. My district includes Allston, Brighton, Watertown, Belmont,

Cambridge, and a very big part of Boston. I'm currently, as you said, the Senate Chair of Mental Health and Substance Abuse, which is a new committee this year, and the new committee in many ways comes out of the silent epidemic that I hope to speak about.

I'd like to commend you for holding the hearing, and I'd like to begin by providing some statistics that illustrate the problems we're facing in Massachusetts.

OxyContin abuse is a crisis of epidemic proportions. In 2002, Boston had the highest emergency department rate of oxycodone, the primary ingredient of OxyContin, in the Nation. In fact, Boston's emergency department rate of 34 per 100,000 people was nearly four times higher than the national average of 9 per 100,000, and it has increased 118 percent since 2000. The number of people who have entered treatment in Boston and reported other opiates, which would include oxycodone, as their primary drug increased, Madam Chair, nearly 250 percent from 2000 to 2004.

OxyContin addiction knows no age, no gender, no ethnic or social economic bounds; it is everywhere. It is breaking parents' hearts. It is ruining good families. It is destroying our communities, and it is killing people, and we have been hit very hard here in Massachusetts. We have seen an increasing number of pharmacy burglaries and armed robberies that have been attributed to the rise of OxyContin abuse. During 2002, there were 166 pharmacy thefts reported in New England, as Congressman Lynch had reported. Madam Chair, 144 of those took place right here in Massachusetts, and some of the people who did it were from good families, not of their character, but suffered a very serious addiction.

In 2002–2003, we ranked third among the 50 States for illicit drug dependence or abuse and had the highest rate in New England among ages of 26 and older. In 2003, there were 11,257 opioid-related emergency department visits and 17,600 opioid-related acute care hospital discharges among Massachusetts residents. In fact, in 2003 we spent over $167 million on opioid-related hospitalizations across the State.

Currently today, Madam Chair, poisonings, which include drug overdoses, are the leading cause of injury death in this State, surpassing for the first time even motor vehicle accidents. They have gone up 128 percent from 1990 to 2003.

Here in Massachusetts, one of the most important things we can do is educate the people on the dangers of OxyContin abuse. Locally, the Boston Public Health Commission has begun airing hard-hitting public service announcements aimed at children between the ages of 12 and 24. To date, they've run 109 radio commercials and have reached an estimated 300,000 people in the target audience. The message has been uniform, OxyContin abuse is on the rise. It is extremely addictive. It leads to heroin, and it will kill you.

Across Massachusetts, the State's Bureau of Substance Abuse Services is also developing a public information campaign in order to educate families on the dangers of OxyContin. This campaign is expected to be rolled out, hopefully, this fall, and it's expected that we will spend minimum of a half a million dollars. It's a start, Madam Chair, but we must do more.

Funding to help those who are addicted is also crucial to dealing with this epidemic. However, Massachusetts has suffered from drastic cuts, as you've heard, on the detox beds. We are down from 1991, there were approximately 950 detox, publicly funded detox beds, in the Commonwealth of Massachusetts, we are at about 450 to 500 beds currently, largely the result of the cuts to Medicaid programs that number has dropped to the 450, and that's a cut of nearly 50 percent during this critical period. With the new supplemental funding through the Federal Government and the State, and funding appropriated to the Bureau of Substance Abuse, some of the beds will be restored, but this deficiency remains a very serious problem.

We must also develop more significant after care and job training programs to accompany our detox. They refer to it as "spin cycle," when you go through the detox you start to feel normal and you don't think you need an additional program. And, in this battle on OxyContin and heroin, Madam Chair, we need to have substantial programs where the people, when they do the detox, they stay and really get the help so that they stay off this drug.

In Massachusetts, we have filed several bills designed to raise the debate on the OxyContin addiction and to address the problems that we are currently facing. Several months ago we filed a bill to ban Palladone, Representative Wallace and I, and thank God, thank God the FDA has taken it off the market, or ordered them to take it off the market. We could only imagine if we doubled the magnification of this problem that we are currently facing with a drug twice as powerful.

We've also filed a bill, and I'm proud to say that I filed a bill to ban OxyContin with the good representative sitting next to me. In Massachusetts, by changing the designation within the Controlled Substance Act, this bill has proven controversial, but it has caught people's awareness, and most importantly it's becoming more prevalent that we have a very serious epidemic on our hands. We are going to continue to fight to get this bill out of the House Rules Committee, to make sure it gets a public hearing, and air it before the entire legislature.

Under the current system, this information is often reported. As I mentioned, in 2003, there were significant opioid-related department visits, over 11,000 among Massachusetts residents, but under the current system this information is often reported 12 to 18 months after the emergency room visits occur. In order to maximize the benefit of this information, we have filed a bill that would require that all hospitals report an opiate overdose to the Department of Public Health within 24 hours, and then we'll be able to geographically identify the problem far more effectively.

It's important to note that this is not a law enforcement tool. Information is not reported to the police, no names, or addresses, or Social Security numbers are reported. Rather, it's designed to gather the demographic characteristics in order to identify the problem within our community, so we can quickly respond and effectively treat those areas most needing help.

Finally, last year the legislature created a commission on OxyContin. To date, the Commission has held several meetings around the State. The next one will take place on September 22nd

in Somerville. I'm hopeful the final report will include innovative, aggressive proposals to deal with the problems of OxyContin and all it has created.

In closing, I cannot tell you how many families have expressed to me the heartache as they try to deal with loved ones who have an OxyContin or heroin addiction problem. During a recent visit to a treatment center, of a young man who I saw grow up and get into serious addiction, while he was in recovery in a group session he said to me, "Steven, the hardest part for me was telling my mom and dad I had an addiction." Madam Chair, I thought he was done, but then he said, "The scariest part is how many of my friends have an addiction and aren't talking to their parents." And, that's the problem. We have people in Massachusetts who are taking this drug to exist, not because they are getting high, because if they don't take it they'll get sick, and they can work, and they can hide this drug, this dreaded disease, they can hide it, and that's how bad this what we refer to as a "silent epidemic." Madam Chair, there's not enough we can do. If I could ban this drug, I would do it today.

OxyContin is not a gateway to heroin. Madam Chair, it's a rocket ship to heroin, and that's what we are seeing throughout our communities. We must attack the problem before it destroys us from within.

Thank you.

[The prepared statement of Mr. Tolman follows:]

Testimony of Senator Steven A. Tolman
Before the Sub-Committee on Regulatory Affairs
Tuesday, September 13, 20005

Good morning Madam Chair—Congressman Lynch—members of the sub-committee. My name is Steven Tolman—I am the Massachusetts state Senator for the 2nd Suffolk and Middlesex District. My district includes Allston, Brighton, and the Back Bay and Fenway neighborhoods of Boston; northwest Cambridge; Watertown; and Belmont. I am currently the Senate Chairman of the Mental Health and Substance Abuse Committee. I would like to commend this sub-committee for holding this hearing and I would like to begin by providing some statistics that illustrate the problems we are facing in Massachusetts.

OxyContin abuse is a crisis of epidemic proportions. In 2002, Boston had the highest emergency department rate of oxycodone—the primary ingredient in OxyContin—in the country. In fact, Boston's emergency department rate of 34 per 100,000 was 3.8 times higher than the national average rate of 9 per 100,000 and was an increase of 118% from 2000. The number of people who entered treatment in Boston and reported "other opiates" (which includes oxycodone) as their primary drug increased nearly 250% from 2000 to 2004.

OxyContin addiction knows no age, gender, ethnic or socio-economic bounds—it is everywhere—and it is breaking parents hearts, it is ruining good families, it is destroying our communities and it is killing people. And we have been particularly hard hit here in Massachusetts.

We have seen an increase in the number of pharmacy burglaries and armed robberies that have been attributed to the rise in OxyContin abuse. During 2002, there were 166 pharmacy thefts reported in New England—144 of those 166 pharmacy thefts took place right here in Massachusetts.

In 2002-2003, we ranked third among the 50 states for illicit drug dependence or abuse; and had the highest rate in New England among those aged 26 or older. In 2003, there were 11,257 opioid-related emergency department visits and 17,580 opioid-related acute care hospital discharges among Massachusetts residents. In fact, in 2003, we spent over $167 million on opioid-related hospitalizations across the state. Currently—today—poisonings—which include drug overdoses—are the leading cause of injury death in this state surpassing even motor vehicle deaths—they have gone up 128% from 1990 to 2003.

Here in Massachusetts, one of the most important things we can do is educate people on the dangers of OxyContin abuse. Locally, the Boston Public Health Commission has begun airing hard-hitting public service announcements aimed at kids aged 12-24 years old. To date, they have run 109 commercials at a cost of $25,900—these commercials reached an estimated 300,000 people in the target audience. The message has been uniform—OxyContin abuse is on the rise, it is extremely addictive, it leads to heroin and it can kill you.

Across Massachusetts, the state's Bureau of Substance Abuse Services is also developing a public information campaign in order to educate families on the dangers of OxyContin—this campaign is expected be rolled out this winter and will cost approximately $500,000. This is a start, but we still must do more.

Funding to help those who are addicted is also crucial to dealing with this epidemic. However, Massachusetts has suffered from drastic and debilitating cuts in detox beds. In 1991, there were approximately 950 publicly funded detox beds in the Commonwealth. These beds were funded by Medicaid and the Bureau of Substance Abuse. Largely as a result of the cuts to

Medicaid programs, that number has dropped to 450 beds—that's a cut of nearly 50%. With new supplemental funding appropriated to the Bureau of Substance Abuse Services, some of those beds will be restored. But, this deficiency remains a serious problem.

In Massachusetts, we have filed several bills designed to raise the debate on the issue of OxyContin addiction and address the problems we are currently facing. Several months ago, we filed a bill to ban Palladone—however, shortly thereafter, Palladone was removed from the market by the FDA.

We have also filed a bill to ban OxyContin in Massachusetts by changing its designation within the Controlled Substances Act—this bill has proved controversial but it has also elevated the debate and largely, I hope, increased people's awareness of this growing OxyContin epidemic.

As I mentioned earlier, in 2003, there were significant opioid related emergency department visits (11,257) among Massachusetts residents. Under the current system, this information is often reported 12-18 months after the emergency department visits occur. In order to maximize the benefit of this information, we have filed a bill that would require that all hospitals report any opioid overdose to the Department of Public Health within 24 hours of the patient's admittance. It is important to note that this is not a law enforcement tool—information is not reported to the police—and no names or addresses or social security numbers are reported at all—rather it is designed to gather demographic characteristics in order to identify the problem areas within our communities so we can respond quickly and effectively to those areas that need the most help.

Finally, last year, the Massachusetts legislature created a commission to study OxyContin. To date, the Commission has held several hearings around the state—the next one will take place in Somerville on September 22. I am hopeful that the final report will include innovative and aggressive proposals to deal with the problems OxyContin has created.

In closing, I cannot tell you how many families have expressed their heartache to me as they try to deal with a loved one who has an OxyContin addiction. A young man with an OxyContin addiction recently told me that the hardest part was telling his parents that he was addicted to OxyContin—I thought he was done—but then he said the scariest part is that there are a lot of kids out there who are not telling their parents. We need to partner more effectively and aggressively with the federal government in this fight. OxyContin is not a gateway to heroin, it is a rocket ship to heroin—and we must attack the problem before it destroys us from within. I would like to thank the sub-committee for their leadership in holding this hearing. It is important that we bring attention to this silent epidemic. I welcome any questions the sub-committee may have.

Thank you.

Ms. MILLER. Thank you very much, Senator.

Now the subcommittee will hear testimony from State Representative Brian Wallace. Representative Wallace took office in 2003. He currently serves on the House Committee on Steering, Policy and Scheduling, also on the Joint Committee of Mental Health and Substance Abuse, as well as the Joint Committee on Tourism, Arts and Cultural Development.

We certainly want to thank you, Representative, for attending our hearing today, and look forward to your testimony, sir.

STATEMENT OF BRIAN WALLACE

Mr. WALLACE. Thank you, and welcome to Boston, Madam Chairman.

I represent the 4th Suffolk District, a seat that was held by some legends, Joe Moakley and Congressman Lynch before me, so I just want to say that I'm honored to be here, and I'm honored to sit in that historic seat.

In 1860, the man who was appointed by President Lincoln to head up the Patent Office in Washington said that there really wouldn't be much need for a Patent Office much longer because everything that could be invented had already been invented, a real visionary I must say.

I'm beginning my testimony today with this little vignette to highlight the fact that people make mistakes, even people in government make mistakes, as strange as that seems. Have there been mistakes made with OxyContin? Absolutely. Will we learn from those mistakes? God, I hope so. Mistakes are going to happen. It's what we do to rectify those mistakes that's important.

I don't think anyone in this room would argue with the fact that the FDA made a mistake in 1898 when they legalized a drug called heroin, which they said was safer than morphine. For a time, some doctors were even championing heroin as a cure for morphine addiction.

In the year 1900, 2 years after heroin was legalized, there were an estimated 300,000 morphine addicts in the United States, including many Civil War veterans who had become addicted while being treated for war-related injuries. The condition was so commonplace it was called, "The Soldiers Disease."

In 1924, some 26 years after it was legalized, the government stepped in and banned the sale of heroin. At that time, in 1924, it was estimated that from 4 to 24 percent of patients who were being treated in drug addiction programs had first been exposed to the medication while being treated by a physician for pain. Does that sound familiar?

Those who do not learn from history are due to repeat it. I don't think Purdue learned anything from history, or they simply chose to ignore it.

I wish the officials at Purdue had spent more time reading about the history of pain medication in this country, rather than reading about their profit margins. And, make no mistake about it, this is all about the bottom line in profit margins.

Families have been ruined, communities in shambles, people dead, people dying a slow death of addiction, people stealing from their neighbors, pharmacies under constant threat, as Purdue

Pharma continues to climb to the magic $2 billion mark with its prized possession, OxyContin.

I think what upsets me the most is the fact that officials at Purdue knew that their drug, OxyContin, had been compromised as early as 1998, and instead or reformulating the drug they chose to flood the country with it.

In 1998, a detailed report on time-release narcotics appeared in a very prestigious medical journal that foretold what lay ahead. The study's bottom line was that release painkillers were potentially more addictive to drug users, not less so, because their narcotic payload was stronger and purer. This was the first time the research appeared to contradict safety concern claims made for the time-release narcotics such as those used by the FDA when it approved OxyContin special label.

In early 1999, a California doctor named Frank Fisher, as well as the owners of a local drugstore, were arrested and charged with murder in connection with the deaths of three of Fisher's patients from drug overdoses that involved OxyContin. Purdue was more than aware of the trial and the ensuing bad publicity that followed.

In the same 1999, Doctor Richard Norton, a doctor from Pennington Gap, VA, told Purdue in detail how people were getting high and overdosing by crushing and chewing OxyContin tablets. That same year 1999, a drugstore owner in Indiana named John Craig was told by a Purdue sales rep that OxyContin couldn't be crushed and couldn't be injected.

One former Purdue district sales manager, William Gergely, told the Florida Attorney General that top company marketing and sales executives at Purdue Pharma were telling their sales reps to tell doctors that OxyContin was non-habit forming. In all, Purdue sales reps were told in their training to tell doctors that less than 1 percent, less than 1 percent of their patients, were in danger of becoming addicted to OxyContin, even as the death toll mounted across the country. Purdue Pharma was well aware of the dangers that its drug OxyContin was causing throughout the country well before the millennium. The signs were there, and people were screaming for help, and there was no shortage of Purdue salesmen or saleswomen.

By 1998, Purdue sales force was standing at 625 people, nearly twice the level prior to the introduction of OxyContin, and because of its sales base bonus system, which were considered to be the most lucrative in the pharmaceutical industry, many sales reps were earning annual bonuses of well over $100,000.

By 2002, Purdue was selling nearly $30 million of OxyContin per week, $30 million per week. And, with the data collected from the Philadelphia-based IMS Health report in hand, Purdue sales reps not only knew how much OxyContin a doctor was prescribing, but they also knew how many prescriptions doctors were writing for competing painkillers, allowing them to tailor their sales pitch.

Doctors were ranked by Purdue according to their prescribing volume as decibels, with a 10 being the highest. Doctors who were classified as decibels 8 through 10 were considered prime targets for OxyContin sales reps. The more doctors bought in, the more money the sales rep received, and the more people died.

I recently filed a bill, along with Senator Tolman, in the Massachusetts House of Representatives to restrict Palladone from getting a foothold in our State. A few months ago, the FDA and Purdue Pharma pulled Palladone, which is a 24-hour time release morphine-based medication. What did Purdue Pharma do when Palladone was pulled? They immediately said they would reformulate Palladone and have it back on the shelves in a short time. It has always been my contention that Purdue Pharma could have reformulated OxyContin, if it had been pulled by the FDA, which it wasn't.

Now, they are facing over 6,500 individual lawsuits from soccer moms, teachers, firefighters, police officers, radio talk show hosts, and other average people, who went to their doctor to get help for a sore shoulder or a sprained ankle and wound up addicted to OxyContin. Many have lost their jobs, businesses and families, but the good news is that Purdue broke the $2 million mark. Congratulations, Purdue.

Thank you.

[The prepared statement of Mr. Wallace follows:]

COMMONWEALTH OF MASSACHUSETTS

MASSACHUSETTS HOUSE OF REPRESENTATIVES
COMMONWEALTH OF MASSACHUSETTS STATE HOUSE, BOSTON 02133-1054

REPRESENTATIVE BRIAN P. WALLACE
4TH SUFFOLK DISTRICT
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TO: CONGRESSIONAL REGULATORY AFFAIRS COMMITTEE

FROM: STATE REPRESENTATIVE BRIAN P. WALLACE

SUBJECT: OXYCONTIN

DATE: 9/27/2005

PAGES: 3

Good morning to this honorable and distinguished committee. I would like to take this opportunity to thank each of you for allowing me to testify before you this morning, and discuss a serious and perplex topic such as Oxycontin.

In 1860, the man who was appointed by President Lincoln to head up the patent office in Washington said there wouldn't be a need for a patent office much longer because everything that could be invented had already been invented. I must add.... This man was a REAL visionary!

I am starting my testimony today with this little vignette, to highlight the fact that people make mistakes. Even people in government make mistakes, if you can believe that. Have there been mistakes regarding Oxycontin? The abbreviated answer: Absolutely. Will we learn from those mistakes? God I hope so. Mistakes are going to happen. It's what we do as elected leaders, which can rectify those mistakes that are important.

I don't think anyone in this room would argue with the fact that the FDA made a mistake in 1898 when they legalized a drug called heroin. At the time, the FDA claimed which the drug was safer than morphine. Consequently, some doctors were even championing heroin as a cure for morphine addiction after the FDA made such claims.

Two years after heroin was legalized there were an estimated three hundred thousand morphine addicts in the United States, including many Civil War veterans who had become addicted while being treated for war-related injuries. The condition was so commonplace it was called, "The Soldier's Disease."

In 1924, some twenty six years after heroin was legalized the Government stepped in and banned the sale of heroin. At that time, in 1924, it was estimated that 9 percent to 24 percent of patients being treated for drug addiction had first been exposed to the medication (Heroin) while being treated by a physician for pain. Does this sound familiar? As the saying goes: Those who do not learn from history are doomed to repeat it; however, I believe Purdue hasn't learned anything from history, or they simply have chosen to ignore it.

I truly wish the officials at Purdue Pharma had spent more time reading about the history of pain medication in this country, rather than reading about their profit margins. And, make no mistake about it; this is all about the bottom line and profit margins. Families have been ruined, communities left ravaged by substance abuse and addiction, people are dead, and people are dying. People are stealing form their neighbor's, pharmacies are under constant threat, and Purdue Pharma continues their climb towards their goal of $2 Billion dollars in revenue, which is delivered through their marquee product, Oxycontin.

I think what upsets me the most is the fact that officials at Purdue knew that their drug Oxycontin had been compromised as early as 1998. And, instead of reformulating the drug, they flooded the country with it. In 1998, a detailed report on time released narcotics appeared in a very prestigious medical journal, which foretold what lay ahead. The study's bottom line was that time released painkillers were potentially more attractive to drug abusers, not less so, because their narcotic payload was stronger and purer. This was the first time that research appeared to contradict safety claims made for time-released narcotics, such as those used by the FDA, when it approved Oxycontin's special label.

In early 1999, a California doctor named Frank Fisher, as well as, the owners of a local drugstore were arrested and charged with murder in connection with the deaths of three of Fisher's patients from drug overdoses that involved Oxycontin. Purdue was more than aware of the trial and the ensuing bad publicity that followed.

In the same year (1999), Dr Richard Norton, a doctor from Pennington Gap Virginia, told Purdue Pharma in detail how people were getting high and overdosing on the powerful drug by crushing and chewing Oxycontin tablets. Again, that same year (1999), a drugstore owner in Indiana named John Craig was told by a Purdue sales representative that Oxycontin couldn't be crushed and could not be injected.

One former Purdue district sales manager, William Gergely, told the Florida Attorney General that top company marketing and sales executives at Purdue Pharma were telling their sales representatives to tell doctors that Oxycontin was "Non-Habit Forming." In reality, all Purdue Pharma sales representatives were instructed through sales training, to tell doctors that less than 1% of their patients were in danger of becoming addicted to Oxycontin, even as the death toll mounted across the country. Now that is creative and consistent messaging!

Purdue Pharma was well aware of the dangers that Oxycontin was posing throughout the country, the signs were there and people were clamoring for help. However, there was no shortage of Purdue Pharma salesmen and women. By 1998 Purdue's sales force would stand at 625 people, nearly twice its level prior to the introduction of Oxycontin. Additionally, Purdue's' sales-based bonus system, which was considered to be the most lucrative in the pharmaceutical industry was delivering annual bonuses well over $100,000 a year to many sales representatives.

By 2002 Purdue was selling nearly $30 Million worth of Oxycontin per week. And, data collected from the Philadelphia-based IMS Health, which provided reports to Purdue sales representatives delivering the necessary information to know how much Oxycontin a doctor was prescribing, and how many prescriptions doctors were writing for competing painkilling drugs. This allowed Purdue sales representatives the ability to tailor their sales pitch.

Through this system, doctors were ranked by Purdue Pharma according to their prescribing volume as "decibels" with a 10 grade being the highest. Doctors who were classified as decibels 8 through 10 were considered prime targets by the sales force. As more physicians prescribed Oxycontin, the more money the sales reps received, and more people died.

I recently filed a bill in the Massachusetts House of Representatives, to restrict Palladone from getting a foothold in our state. A few months ago, the FDA asked Purdue Pharma to pull Palladone, which is a 24 hour time released morphine-based medication. What did Purdue Pharma do when Palladone was pulled? They immediately said they would reformulate Palladone and have it back on the shelves in a short time. It has always been my contention that Purdue Pharma could have reformulated Oxycontin if it was pulled by the FDA. It still hasn't happened. Will it ever happen? I leave that question before you here today.

Currently, Purdue Pharma is facing over 6,500 individual lawsuits from average people who went to their doctors to get help for chronic pain. Many of these individuals, or victims became addicted to Oxycontin. Many have lost their jobs, businesses, and families. However, the good news is that Purdue Pharma reached their specific revenue goals and subsequently broke $2 billion dollars in revenues. Congratulations Purdue.

I would like to thank this honorable panel of distinguished members for allowing me this opportunity to give testimony regarding this import issue before us today.

Ms. MILLER. Thank you very much, Representative. We appreciate that.

Our next witness will be John McGahan. Mr. McGahan is the executive director at the Cushing House in south Boston. The Cushing House is a rehabilitation center for teens with substance abuse problems. He graduated from south Boston Neighborhood Health in 1994, and as the current director he volunteers many hours coaching our youth as well.

We thank you for your participation today, and look forward to hearing your remarks, sir.

STATEMENT OF JOHN McGAHAN

Mr. MCGAHAN. Chairwoman Miller, and Congressman Lynch, on behalf of those whose lives have been impacted by the illegal use and abuse of prescription painkillers, I want to thank you for taking your significant commitment and hard work on this issue, and for the opportunity to testify here today.

My name is John McGahan, and I am the executive director of the Gavin Foundation. The Foundation operates several residential drug rehabilitation programs in the south Boston community. In 1964, the Gavin House opened its doors and over the next three decades the concentration was placed upon treating alcoholic men, 40 to 50 years of age. Since then, the entire landscape of substance abuse treatment has changed.

In the late 1980's and early 1990's, treatment became more complex, because cocaine was the rage and attracted younger clientele. Treatment approaches were altered to allow for this deviation. Just as we thought it couldn't get any worse, OxyContin hit the streets.

Our response has been to expand services to accommodate an even younger clientele, and the overall increased demand for treatment. The Foundation responded to this need in 1996, by creating the Total Immersion Program in partnership with South Boston District Court. This program focuses on individuals whose criminal activity is clearly substance abuse related.

As the flow of prescription painkillers continues to infiltrate the streets of south Boston, the Foundation has expanded services to include Cushing House, a 12-bed adolescent recovery home for boys, in 1999. This program was expanded to 16 in 2004, and we are currently building an addition to accommodate 12 adolescent females.

Unfortunately, even with our current growth pattern, we are unable to provide services to many families that are being devastated as a result of prescription painkiller abuse.

Experiences with treatment abusers of prescription painkillers, particularly, the drug OxyContin, has shown this opiate-based pain reliever is a predominate precursor to heroin use. In fact, every single opiate addicted participant of our program began to abuse OxyContin before they became addicted to heroin.

The legal price of OxyContin is significantly marked-up when sold on the streets. At the current rate of $1 per milligram an OC, the street name for OxyContin is sold as an OC 40 for $40 or OC 80 for $80. Clients report having habits that cost as much as $200 a day.

Some OxyContin users so glorify the effects of the drug that younger siblings and their friends are often coaxed into its use or recruited as a way to get money for their own use. This permeation results in an unbridled spread of its use. As users become addicted, the dose needed to get high, or simply not get sick, continues to increase.

Addiction is inevitable with regular use. OxyContin becomes a critical need, just to feel normal. Stealing to afford the continuous use of the drug is commonplace; family, friends, neighbors, businesses, are all victimized. No one is immune to these larcenous attacks.

Inevitably, the exorbitant cost of OxyContin and the absolute need for relief of a withdrawal pain leads an OxyContin user to the cheaper and very effective remedy, heroin. Heroin is one tenth the cost of OxyContin.

Heroin, now becomes the drug of choice. The stigma attached to its use has blurred for the user, particularly when viewed as an alternative to the high priced prescription pain relievers. Many heroin addicts recall saying that they would never use heroin, but the day came when they didn't have enough money for OxyContin and switched to heroin. When this happens, often the stigma attached to the heroin by the non-user results in even family members abandoning the addict and leaving them to live on the streets.

Overdoses, once feared as the ultimate test for an addict's commitment to drug use, are now commonplace. Emergency responses to overdose has risen dramatically in recent years in south Boston according to the Boston Public Health Commission statistics.

The ancillary medical consequences are severe. OxyContin and other pain relievers are commonly purchased in pill form and crushed. It is then snorted or liquified and injected intravenously. These methods of use increase the chances of the contraction of HIV/AIDS and, increasingly, Hepatitis-C. The incidence of Hepatitis-C has exploded in south Boston, affecting clients in all of our programs.

A little history of a family here. At Cushing House we received a referral in May 2000 from a South Boston Probation Department for an 18 year old male who was illegally using OxyContin and Klonipin, that was being charged with civil disobedience. We interviewed Mike that day and sent him to a medical detoxification unit. Once Mike had medical clearance, he was placed in a Transitional Support Service program, while waiting for a treatment bed.

Mike entered our program on June 12th. Mike was fully participating in the treatment process and had reached the second phase of treatment. Residents in this phase of treatment are reintegrated into the community, either through an education or vocational program or employment. Mike was working during the day and participating in group therapy, individual counseling, and self-help groups in the evening. On August 23rd, Mike was discharged from the program, referred back to the criminal justice system. There was no specific test for OxyContin at that time. His discharge was recorded in the general class of opiate.

The probation department placed Mike in an Intense Outpatient Program pending his trial. He also participated in our program's alumni relapse prevention group. It was at this group he reported

that he was again abusing opiates daily and needed a referral to detox.

The case manager, with Mike's permission, communicated with the probation department the situation, and he was again placed in a detoxification unit and subsequently reentered our program on September 11th.

Mike completed the program on March 3, 2001. While in treatment he achieved his General Equivalency Diploma and completed a Culinary Arts Certificate program. The criminal charges were dropped upon completion of the program and Mike has been an active participant in our alumni group ever since.

Mike has achieved many successes as a result of maintaining sobriety. This success is shared by his parents, who were extremely supportive throughout the treatment process. During the certificate ceremony to celebrate Mike's graduation from the residential component of the program, his 14 year old brother had asked to speak to me in private. I brought him into my office where he began to cry and asked, "Can you do for me what you did for my brother?" I suggested that we let everyone enjoy the day and that I would speak to his parents the next day. When the family was leaving, Mike's mom said to me, "Don't take this the wrong way, but I hope we don't see you for a while."

The next day I called Mike's father and asked him to come and speak with me. He came right in. I had to deliver the bad news that his youngest son Steve was using prescription painkillers, OxyContin. Because Steve was only 14, and not yet a daily user, I referred them to outpatient counseling.

Steve continued to use and now his addiction was interfering with family functions and school work. It is worth noting that Steve was enrolled in the test school, Latin Academy, one of Boston's most prestigious public schools. Steve missed so many days of school due to his addiction he did not pass the 7th grade.

It became obvious that Steve was in need of more intensive treatment and was referred to a detoxification unit and entered our program on June 12, 2001. Steve participated in all aspects of the program and good progress was noted. He successfully completed the program December 7th of that year. While in treatment, Steve was enrolled in a special education program that allowed him to condense the 7th and 8th grades together so that he could rejoin his classmates in the 9th grade. He successfully completed the program and was prepared to rejoin his classmates in the fall.

Unfortunately, Steve began to abuse painkillers before the summer was over. His relapse to prescription painkillers, and specifically OxyContin, quickly turned to heroin use, because he could not afford his $80 a day habit. Steve reported that he felt like he didn't fit anywhere, he couldn't relate to people his own age, felt that he was too young to get sober. He stated that he just wanted to be a kid, but that he had been robbed of his youth.

Steve went to detox and reentered our program on August 8, 2002. He left the program against the treatment team's advice on October 2002, because he didn't think he needed help and he could do it on his own.

I want to remind you that he has a brother at home who is trying to maintain sobriety. He also has an older sister attending high

school, and two loving parents who both work and are doing their best to hold the family together. We can only imagine the day-to-day tension and stress this family had to endure, which all began with the abuse of prescription painkillers.

Steve relapsed almost immediately upon leaving the program. Our case manager continued to work with his parents through the family support group and a referral was made to a short-term treatment facility in the western part of the State.

After completing the short-term program, Steve returned to Cushing House for 191 days. He graduated on July 7, 2003, and now has over 2 years of continuous sobriety. He is a productive member of society and an active member of our alumni group.

This is the story of one of the lucky families, that is if you call having family members in and out of treatment for 3 plus years, being involved in the courts, having your children settle for GEDs, and countless nights wondering where your children are, and if they are alive—lucky.

As a treatment provider and a resident of the south Boston community, I can tell you countless stories of families who have not been so lucky and who have lost loved ones to the streets, jails and overdoses.

Thank you.

[The prepared statement of Mr. McGahan follows:]

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Testimony: Committee of Government Reform, Subcommittee on Regulatory Affairs

September 13, 2005

Chairwomen Miller and Congressman Lynch on behalf of those who's lives have been impacted by the illegal use and abuse of prescription pain killers I want to thank for your significant commitment and hard work on this issue and for the opportunity to testify here today.

My name is John McGahan and I am the Executive Director of the Gavin Foundation. The Foundation operates several residential drug rehabilitation programs in the South Boston community. In 1964 the Gavin House opened its doors and over the next three decades the concentration was placed upon treating alcoholic men 40-50 years of age. Since than the entire landscape of substance abuse treatment has changed.

In the late eighties early nineties treatment became more complex because cocaine was the rage and attracted younger clientele. Treatment approaches were altered to allow for this deviation. Just as we thought that it couldn't get any worse OxyContin hit the streets.

Our response has to been to expand services to accommodate an even younger clientele and the overall increased demand for treatment. The Foundation responded to this need in 1996 by creating the Total Immersion Program in partnership with South Boston District Court. This program focuses on individuals who's criminal activity is clearly substance abuse related.

As the flow of prescription painkillers continues to infiltrate the streets of South Boston the foundation has expanded services to include Cushing House a 12 bed adolescent recovery home for boys in 1999. This program was expanded to 16 beds in 2004 and we are currently building an addition to accommodate 12 adolescent females. Unfortunately, even with our current growth pattern we are unable to provide services to many families that are being devastated as a result prescription painkiller abuse.

Experiences with treating abusers of prescription painkiller particularly the drug OxyContin have shown that this opiate-based pain reliever is a predominate precursor to heroin use. In fact every single opiate addicted participant of our program began to abuse OxyContin before becoming addicted to heroin.

The legal price of OxyCotin is significantly marked-up when sold on the street. At the current rate of 1 dollar per milligram an OC (the street name for OxyContin) is sold as an OC 40 for $40.00 or OC 80 for $80.00. Clients report having habits the cost as much as $200.00 a day.

Some OxyContin users so glorify the effects of the drug that younger siblings and their friends are often coaxed into its use or are recruited as a way to get money for their own use. This permeation results in an unbridled spread of its use. As users become addicted the dose needed to get high or to simply not to get sick continues to increase.

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Overdoses, once feared as an ultimate test of an addicts commitment to drug use, are now commonplace. Emergency responses to overdose has risen dramatically in recent years in South Boston according to the Boston Public Health Commission statistics.

The ancillary medical consequences are severe. Oxycontin and other pain relievers are commonly purchased in its pill form and crushed. It is then snorted or liquefied and injected intravenously. These methods of use increase the chances of the contraction of HIV/AIDS and, increasingly, Hepatitis-C. The incidence of Hepatitis-C has exploded in South Boston affecting clients in all our programs.

<u>Cushing House Case Example of a South Boston Family</u>

We received a referral in May, 2000 from the South Boston Probation Department for an 18 year old male who was illegally using OxyContin and Klonipin that was being charged with a civil disobedience. We interviewed "Mike" that day and sent him to a medical detoxification unit. Once Mike had medical clearance he was placed in a Transitional Support Service program while waiting for a treatment bed.

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Steve continued to use and now his addiction was interfering with family functions and school work. It is worth noting that Steve was enrolled in the test school, Latin Academy, one of Boston's most prestigious public high school. Steve missed so many days of school due to his addiction that he did not pass the seventh grade.

It became obvious that Steve was in need of more intensive treatment and was referred to a detoxification unit and entered our program on June 12, 2001. Steve participated in all aspects of the program and good progress was noted. He successfully completed the program on December 7th of that year.
While in the treatment Steve was enrolled in a special educational program that allowed him to condense the 7th and 8th grades together so that he could rejoin his classmates in the 9th grade. He successfully completed that program and was prepared to rejoin his classmates in the fall.

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I want to remind you that he has a brother at home who is trying to maintain sobriety. He also has an older sister attending high school and two loving parents who both work and are doing their best to hold the family together. We can only imagine the day to day tension and stress this family has had to endure which all began with the abuse of prescription painkillers.

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After completing the short term program Steve returned to Cushing House for one hundred and ninety one (191) days. He graduated on July 7th 2003 and now has over two years of continues sobriety. He is a productive member of society and an active member of our alumni group.

This is the story of one of the lucky families, that is if you call having family members in and out of treatment for three plus years, being involved in the courts, having your children settle for GED's and countless nights wondering where your children are and if they're alive - lucky.

As a treatment provider and resident of the South Boston community I could tell you countless stories of families who have not been so lucky and lost love ones to the streets, jails and overdoses.

Thank you.

Ms. MILLER. Thank you.

Our next witness is Doctor Janet Abrahm. She is a hematologist and oncologist and a palliative care specialist. She is an associate professor of medicine and anesthesia at Harvard Medical School. She is also the co-director of the Pain and Palliative Care Programs at the Dana Farber Cancer Institute, and Brigham and Women's Hospital. She is responsible for developing a disease management program for end-of-life care, a computerized opioid conversion program for in-patient pain management as well.

We appreciate your attendance today, Doctor, and look forward to your testimony.

STATEMENT OF JANET L. ABRAHM

Dr. ABRAHM. Thank you, Chairwoman Miller, Congressman Lynch, and members of the committee.

On behalf of the American Cancer Society, I would like to thank you for this opportunity to testify before the subcommittee today. My name is Doctor Janet Abrahm, and I am the co-director of the Pain and Palliative Care Program at Dana Farber Institute, and Brigham and Women's Hospitals here in Boston.

Twenty-five years ago, when I began to practice, all I could offer someone with pain from widely metastatic cancer was morphine or oxycodone that they had to take every 4 hours. It made them drowsy, and only gave them good pain relief for maybe 2 of those 4 hours.

The availability of morphine and oxycodone in sustained-release preparations has profoundly changed the lives of today's cancer patients, and of their families. Now that they have continuous pain relief, they can even forget for a while that they have cancer.

As the testimonies today have indicated, prescription drug abuse is a serious problem facing our State and our Nation. However, as we assess legislative and regulatory solutions to this problem, we must ensure that we shape policies that will curb abuse without interfering with quality patient care, and worsening under treatment of pain that is unnecessarily destroying the quality of life for nearly half of the patients with advanced cancer today.

Misperceptions and misinformation about the risk of addiction to certain pain medications can lead patients themselves and physicians to avoid the most effective means of pain control. Addiction is a psychological dependence that is associated with compulsive drug abuse and continued use despite harm.

Cancer patients who take their opioids for pain are not addicts. They use their drugs to get back into their lives. Addicts are using the drugs to get out of their lives.

Because drugs like ibuprofen and acetaminophen do not relieve the pain of the majority of cancer patients, we must use Schedule II prescription pain medications, both in immediate and sustained-release forms. Cancer patients lucky enough to respond to treatment stop taking the opioids. Those with advanced cancer, who use sustained-release opioids like OxyContin use them only to relieve their pain, to get back into their families, to get back into their workplaces, to be able to go to church.

We have heard extremely compelling stories today about the abuse that is plaguing south Boston and other communities

throughout our Nation. However, we cannot let our sympathy for these children and for their families prevent us for speaking up for the families who have loved ones suffering from cancer and from other chronic pain.

I have already seen the suffering that comes from physician fears leading to inadequate opioid prescribing and from the stigma of taking opioid medication. I once cared for Mr. R, an African American veteran in his mid 50's, suffering from metastatic prostate cancer. He arrived on a stretcher, accompanied by his wife and his sister. Mr. R's cancer had spread to all the bones of his body, and it was no longer responding to treatment. He had been told to take 600 milligrams of ibuprofen, which is a pain reliever in medications like Motrin, four times a day. His pain was so severe that with his crying wife and sister listening he asked me to help him die.

Mr. R needed more than ibuprofen for his metastatic cancer pain. He needed opioids. African Americans like Mr. R and other minority patients, and children, and the elderly, are unfortunately more likely than Whites to have their pain under treated.

We started him on both a short-acting and a long-acting form of morphine, but even though his pain improved he developed severe nightmares and persistent nausea, and he couldn't eat.

After we switched him to OxyContin the nightmares and nausea resolved. He lived almost pain free for over 2 years after that first day when he asked me to end his life. He was able to sleep, return to church in his case, and even to go on trips with his wife. Control of his pain gave them all back his life.

Mr. L was another veteran I cared for. He had developed multiple myeloma, which is a cancer that weakened his bones and caused him severe pain in his back, and hips and legs. He could not tolerate ibuprofen or aspirin, or any of its relatives that cause bleeding, and the acetaminophen that he took on his own wasn't effective. We couldn't use sustained-release morphine because the morphine had made him delirious, so we chose OxyContin with supplemental oxycodone as needed.

However, when his wife went to the pharmacy to have the OxyContin prescription filled, the other customers treated her like she was a drug addict. She was so ashamed she almost left without filling the prescription, and recounted this story to me in tears.

My patients did not choose to wake up 1 day to hear the words, "You have cancer." On the contrary, people who use OxyContin, who abuse OxyContin, do have a choice. Doctors, nurses, and pharmacists must continue to be held responsible for improper prescribing. However, legislative and regulatory efforts must be focused on the primary sources of the problem, such as pharmacy theft, forgery and diversion operation. Abuse and diversion of the prescription drugs should be addressed directly, without interfering with patient access to essential treatments and without debilitating legitimate medical practices.

The American Cancer Society supports efforts to prevent the abuse and misuse of opioids and stands ready to work with Federal, State and local officials to find avenues to address escalating abuse problems, without contributing to the already gross under treatment of cancer pain and other serious chronic pain.

Toward that end, the American Cancer Society has submitted written testimony for the record.

For my patients, and thousands of others who suffer from persistent pain, OxyContin and other prescription opioid medications are often the only effective and efficient treatment options. When used for legitimate medical purposes, these medications can dramatically improve the quality of life for cancer patients and millions of other Americans who would be forced to live their lives in unbearable chronic pain.

Thank you again for the opportunity to give cancer patients a voice here. I would be happy to answer any questions.

[The prepared statement of Dr. Abrahm follows:]

TO: The Honorable Candice S. Miller, Chair
The Honorable Stephen F. Lynch, Ranking Member
Committee on Government Reform, Subcommittee on Regulatory Affairs

FROM: The American Cancer Society
Presented by Dr. Janet L. Abraham, Dana Farber Cancer Institute

DATE: September 13, 2005

SUBJECT: **Addressing the issue of Schedule II prescription pain medications - their use and abuse**

The American Cancer Society is the nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy, and service. A priority of the American Cancer Society is to ensure adequate pain and symptom control -- essential elements to improve the quality of life for cancer patients. Pain is a major health problem in the United States, especially the kind of pain that is often experienced by individuals with cancer.

Up to 70 percent of cancer patients experience uncontrolled pain at some point during their illness, depending on the stage of the disease.[1,2] Further research indicates that nearly half of advanced cancer patients with pain do not get adequate relief of their pain in spite of the fact that medications and other therapies currently exist to relieve almost all cancer pain. The American Cancer Society believes that our nation must strive to protect and encourage legitimate pain treatment, while addressing the real dangers of prescription drug diversion and abuse. The Society strongly supports a balanced policy toward the regulation of pain medications that are also controlled substances. The Society also supports appropriate law enforcement actions to ensure that controlled substances, including pain medications, are used only in the course of legitimate medical practice. However, the Society strongly opposes efforts to limit the distribution or availability of pain medication to the patients who need them. While we agree that opioid medications should be kept out of illegal or improper hands, the Society opposes law enforcement activities that have unintended, but harmful effects on people with pain. We commend members of the Subcommittee for their leadership in searching for solutions to protect our nation from the devastating effects of prescription drug abuse. However, the American Cancer Society opposes activities that threaten to roll back hard-won progress that has expanded the use of opioids as a viable option for treating pain. Those with legitimate needs should not be made to suffer as a result of the actions of those who violate the law.

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[1] Foley KM. The treatment of cancer pain. *New Engl J Med* 1985;313:84-95.

[2] Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *New Engl J Med* 1994;330:592-6.

The fear of regulatory scrutiny is one of the barriers that inhibits healthcare provider treatment of cancer patients' pain – particularly in cases involving medications such as opioids that have been known to draw the attention of law enforcement and regulatory officials.[3] While federal law permits the appropriate use of opioids for pain management in patients, fear of controlled substances and the agencies that enforce the laws governing them contribute to inadequate treatment of cancer pain. Increasing media reports describing abuse and diversion of opioid pain medications have also heightened patient and provider awareness of the regulatory scrutiny surrounding prescription of these medications. Stigma associated with prescribing these medications may increase patient fear of addiction[4] and may cause providers to choose lower profile and potentially less effective medications.

Misperceptions and misinformation about the risk of addiction to certain pain medications can lead patients and physicians to avoid the most effective methods of pain control. Cancer patients who take opioid medications to treat their pain are *not* drug addicts. In fact, opioid addiction among all pain patients is rare,[5] and appropriate cancer pain management does not result in addiction.[6] Addiction, tolerance, and physical dependence should *not* be confused.

- *Addiction* is characterized by psychological dependence. As defined by the American Medical Association, addiction is "the compulsive use of a substance resulting in physical, psychological or social harm to the user and continued use despite that harm."[7]
- *Tolerance* is when a drug no longer works to keep pain away or when a higher dosage of a drug is needed to treat pain.[8]
- *Physical dependence* describes the experience of withdrawal symptoms in some patients who stop taking pain medications – especially if stopped abruptly. The World Health Organization Expert Committee on Drug Dependence has stated that cancer patients who exhibit signs of physical dependence (i.e., show withdrawal symptoms) cannot be defined as drug dependent.[9] In addition, side effects associated with stopping some pain medications can be avoided by gradually tapering dose when the medication is no longer needed.

The American Cancer Society recognizes there is an important need to improve the quality and increase the use of adequate cancer pain treatment. The Society also recognizes and supports the strong societal interest in assuring the appropriate use of controlled substances. We recognize that diversion of opioids does occur and should be

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[3] Von Roenn JH, Cleeland CS, Gonin R, Hatfield AK, Pandya KJ. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. *Ann Intern Med* 1993;119:121-6.

[4] Jacox A, Carr DB, Payne R, et al. Management of cancer pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, U.S. Department of Health and Human Services, Public Health Service; 1994.

[5] Joranson DE. "Current thoughts on opioid analgesics and addiction." *Symptom Control in Cancer Patients* (Japan) 1995. *6(1)*: 105-110. Available via the Internet at: http://www.medsch.wisc.edu/painpolicy/publicat/95sccp.htm

[6] Joranson DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. JAMA 2000;283:1710-14.

[7] Cancer*care*. "Managing your cancer." Available via the Internet at: http://www.cancercare.org/managing/pain/pain_17964.asp

[8] *Ibid.*

[9] Joranson DE. "Current thoughts on opioid analgesics and addiction." *Symptom Control in Cancer Patients* (Japan) 1995. *6(1)*: 105-110. Available via the Internet at: http://www.medsch.wisc.edu/painpolicy/publicat/95sccp.htm

addressed. However, we are greatly concerned that attention to the misuse of controlled substances has overshadowed and impeded attempts to manage pain. Currently, our nation has not found a proper balance between these two issues and the cost has been at the expense of those who need their pain controlled. The Society believes that concern for cancer pain management should receive equal focus and comparable resources from governments and their agencies at all levels. Doctors, nurses and pharmacists must continue to be held responsible for improper prescribing. However, legislative and regulatory efforts must be focused on the primary sources of the problem, such as pharmacy thefts, forgery, and diversion operations. Abuse and diversion of prescription drugs should be addressed directly without interfering with patients' access to essential treatments and without debilitating legitimate medical practices.

The American Cancer Society strongly supports the primacy of clinical decision-making between patients and health care providers and opposes any efforts that might have an adverse effect on health care providers' willingness and ability to provide pain medication and pain management when treating patients with cancer and other chronic pain. The Society encourages the drug enforcement community to work with the health care community and patient advocates to develop a balanced policy toward controlled substances. A part of this effort should include educating health care providers and patients about the laws and regulations controlling the distribution, prescribing, and dispensing of these critical medications. Towards that end, the American Cancer Society joined 20 other health organizations and the Drug Enforcement Agency by issuing a joint policy statement concerning the "principle of balance" in strategies to promote pain relief while preventing abuse of pain medications. According to this joint policy statement (Appendix A), efforts to curb the abuse and diversion of prescription medications should not negatively impact patients' access to appropriate pain management treatment options.

Building state consensus on quality pain management, decreasing barriers to effective pain management, and developing balanced policies to pain management is also critical. This may include adoption of the Federation of State Medical Boards "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" (Appendix B) in all 50 states, and may also include a consensus policy statement by members of the licensing boards representing all state health care providers. The development of a state advisory council on pain management may also be a proactive solution to improve pain management and to bring together clinicians, policy makers, patient advocates, and drug and law enforcement officials.

The American Cancer Society supports efforts to prevent the abuse and misuse of opioid analgesics and stands ready to work with federal, state and local officials to find avenues to address escalating abuse problems without contributing to the already gross under-treatment of pain.

For cancer patients and thousands of others who suffer from persistent pain, sustained release opioids and other opioid analgesics are often the only effective and efficient treatment options. When used for legitimate medical purposes, these medications can

dramatically improve the quality of life for cancer patients and millions of other Americans who would otherwise be forced to live their lives in unbearable, chronic pain.

Thank you for the opportunity to give cancer patients a voice concerning the Subcommittee's efforts to assess the regulation of Schedule II prescription medications.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May 2004.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*.[1] Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.[2] The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.[3] Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and

society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.
2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA*, 274(20) (1995): p. 1591-1598
3. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to

treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.
Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.
Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.
Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:
Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.
Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.
Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.
Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.
Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.
Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.
Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

A JOINT STATEMENT FROM 21 HEALTH ORGANIZATIONS AND THE DRUG ENFORCEMENT ADMINISTRATION

Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act

As representatives of the health care community and law enforcement, we are working together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need.

Both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical.

Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve.

This consensus statement is necessary based on the following facts:

◆ Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively

◆ For many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief.

◆ Because opioids are one of several types of controlled substances that have potential for abuse, they are carefully regulated by the Drug Enforcement Administration and other state agencies. For example, a physician must be licensed by State medical authorities and registered with the DEA before prescribing a controlled substance.

◆ In spite of regulatory controls, drug abusers obtain these and other prescription medications by diverting them from legitimate channels in several ways, including fraud, theft, forged prescriptions, and via unscrupulous health professionals.

◆ Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties.

◆ Helping doctors, nurses, pharmacists, other healthcare professionals, law enforcement personnel and the general public become more aware of both the use and abuse of pain medications will enable all of us to make proper and wise decisions regarding the treatment of pain.

American Academy of Family Physicians

American Academy of Hospice and Palliative Medicine

American Academy of Pain Medicine

American Alliance of Cancer Pain Initiatives

American Cancer Society

American Medical Association

American Pain Foundation

American Pain Society

American Pharmaceutical Association

American Society of Anesthesiologists

American Society of Law, Medicine & Ethics

American Society of Pain Management Nurses

American Society of Regional Anesthesia and Pain Medicine

Community State Partnerships to Improve End-of-Life Care

Drug Enforcement Administration

Last Acts

Midwest Bioethics Center

National Academy of Elder Law Attorneys

National Hospice and Palliative Care Organization

Oncology Nursing Society

Partnership for Caring, Inc.

University of Wisconsin Pain & Policy Studies Group

Ms. MILLER. Thank you all very much. It's been very enlightening for me. I have to tell you, coming from Michigan, and I don't care where you come from in the Nation, obviously, drug abuse is everywhere, but I am stunned to be here in Boston, and I thank Representative Lynch again for asking that we come here for this field hearing; I'm stunned to hear the statistics of how bad this particular abuse problem is here in Massachusetts and in Boston. I think, Senator, you were saying it was four times the national average at one point, and this may sound like a very simplistic question, but why? Why is it so bad here, so much worse than anywhere else in the Nation? Do you have any—could you enlighten me on any of your own personal observations of why that may be the case here?

Mr. TOLMAN. Whether it's the way it's prescribed too liberally and made it more available for youngsters, or even, you know, construction workers with injuries, I have one example of somebody that—a law firm that allegedly has 58,000 clients who were legitimately prescribed this drug who are now suing the company because of its level of addiction.

In many cases, maybe whether it's all the universities in Massachusetts, sometimes as we grow up and you experiment in life you like to live on the edge, and that you try something like we all did growing up, whether it was a can of beer in the woods or whatever. Unfortunately, the legitimacy of a prescription drug takes a lot of the scare away, where somebody wouldn't go out and try heroin, but if they think there's a legitimate painkiller that might get them high, or do something, whatever, but, unfortunately, what we see is after using this the level of addiction is so bad on the brain, my understanding is it just dries up the endorphins in your brain, but magnifies the receivers, and so that many people just experiment and may try this.

It's very bad in New Bedford, it's not just Boston, it's through this entire State. We have the No. 1 for professional baseball a couple of years ago out of Peabody addicted. It's not just in Boston, it's in Lawrence, it's in Lowell, it's in Springfield, it's geographically all over the State. And, the scary part about it is, we don't have the specific answer, Madam Chair, to your question as to why, whether it's the harbors, because New Bedford is riddled with it, and Fall River, or maybe here.

But, most importantly, the piece is, is that you don't have the stigma of how dangerous this drug is, and that's what we have to get the message out.

The good doctor talked about those patients, patient R and patient L, and I can relate to that, I lost a sister to breast cancer last summer, and I know that drug may have relieved her of some pain, and I respect and understand that concept. And, I loved my sister-in-law, but I also weigh the damage, not just to one family, but to communities, and it far magnifies, outweighs, you know, the legitimate prescription of this drug, because they've gone beyond patient R and patient L, and now, Madam Chair, we have this in generic forms being made in Israel and imported, I think there's two firms out of Pennsylvania. So, we are having more of it on the street.

And, unless we aggressively say, hey, for the good doctor's needs maybe, there may be a need for this drug, but it is far, far too often

prescribed, and certainly the significance of the addiction is beyond anything I have ever seen in my life. And, I was a union rep in the labor movement, and I saw crack in the minority neighborhoods, and that was the most devastating thing that I have seen in the 1980's. This magnifies it by 10.

Ms. MILLER. Representative I might ask you, along the same lines, what are your personal observations of why this is actually happening here? You spoke in your testimony about the pharmaceutical industry, perhaps, with their marketing toward particular doctors, do you think they find particularly fertile ground here for that kind of a thing? Is that part of it? And, I do recognize both you gentlemen have introduced legislation to actually ban OxyContin. Do you think if that were to be successful that would—it would obviously have an impact, but would they just then be looking at one of these generics, or what can we look forward to?

Mr. WALLACE. To be quite honest with you, I don't think OxyContin is going to be banned, and for a number of reasons. First of all, I would love to see OxyContin banned, Madam Chairman, if there was a tamper-proof OxyContin pill that was made, and I think that is what the magic bullet is. There's a pharmacy, a lead pharmacy now, I think out of Philadelphia, who the FDA has approved to clinically study the tamper-proof OxyContin tablet they say they have. That's the magic bullet that everyone is looking for.

You know, in my district it's, you know, we used to get calls for jobs and for housing, and those calls have been replaced by calls for detox centers and help, and these are families that have never been in the court system, they don't know—some of them don't even know where the juvenile court is, to be quite honest with you. I've got to go myself with these people who have no idea where the juvenile court was, but yet their son or daughter is in juvenile court for stealing, for credit card fraud, for possession of OxyContin or heroin.

Again, as Senator Tolman said, we had a hearing and I asked one of the kids who was in Meridian House, which is in east Boston, I said, "Son," I said, "Can you tell me, if you don't want to tell me you don't have to, but where did you get OxyContin?"

He said, "Representative, what I would do is, I would go to a pharmacy and I would wait there until I saw someone get it prescribed. I would follow him home, break in the house and steal it."

And, this is what's happening. This is what this drug has done to our communities, all across the country.

Purdue Pharma, I think the problem, the way I see it, is that if they had marketed this for cancer patients strictly, or for people with real serious pain, I think that would have been fine, but once they opened up Pandora's Box, and that's what it is, Madam Chairman, they opened up Pandora's Box, and they prescribed it for dentists, for people with sore shoulders, for sprained ankles, once they did that it became—it flooded the country, not only in Massachusetts, Virginia, Maine is probably the worst, Virginia is probably next, and these people started seeing this, as I mentioned it, in 1998, 3 years after the drug was introduced, and nothing was done about it.

So, I mean, it's a question now that Pandora's Box has been opened, now we have to deal with the generics, which are going to create all kinds of problems, because we don't know where they are coming from. At least Purdue Pharma, we had some sort of idea where they were coming from.

A doctor was arrested in Sandwich, and Sandwich is part of Cape Cod, recently. He prescribed one out of every three OxyContin tablets in the State, but yet he was allowed to do that for 6 to 7 years. There has to be some sort of enforcement. Someone has to know that this doctor is doing that.

Purdue said they have the mechanism to follow that, if they followed it why don't they tell the DEA? There's a doctor in Sandwich that's prescribing one out of every three OxyContin tablets in Massachusetts. That didn't happen, and that has to happen. The DEA, the FDA, they have to work in conjunction so that Purdue knows who is selling it, they have to tell the DEA, or otherwise what good is it? What good are all these mechanisms they have for following where their drugs go if they are not telling anyone? And, that's one of the problems I see, and again, thank you for—we appreciate you being here very much today.

Ms. MILLER. Yes, I appreciate that answer.

So, let me ask Doctor Abrahm, from a doctor's perspective, and I know you were in the audience, you heard the testimony from the FDA and the DEA witnesses that we had here who declined to answer both myself and Representative Lynch's question about what kind of things—tools the Congress could give them to assist in the scourges. Could you give me your observations from a doctor's perspective on what kinds of things the government could do to stop the abuse of this very powerful drug, as you stated so eloquently and articulated, in giving us some particulars there about a patient that you used to prescribe it to, and how important it is for pain management, but yet we see these problems. Could you give us any direction from your own observation in your own clinical practice?

Dr. ABRAHM. Well, it's hard to do it from my own clinical practice, since I prescribe the drug for people who need it for cancer pain and for sickle cell, severe sickle cell pain even, though I don't take care of sickle cell patients anymore.

I would say that from the American Cancer Society's perspective, and from the pain community's perspective, the importance of getting the FDA, and the DEA, and the pharmacists, and the doctors and nurses together, to be able to figure out, along with the pharmaceutical companies, ways to regulate the production of the medication. And again, we totally agree that in an abuse-free form that is how we would like this drug to appear.

And, if there are ways to be able to also get at the other causes, of course, of drug addiction, which are much bigger than a question that I could answer here, but the kind of suffering that an addict has, the kind of suffering that the people who aren't just experimenting once or twice, but really have suffering and are using these drugs to treat their suffering, the more support there is for that kind of work that you guys are doing, the more kind of understanding that there are societal causes of suffering, and the more attention there is to supporting those needs, I think for all the addictions we have, methamphetamine addictions, OxyContin addic-

tions, alcohol addictions, heroin addictions, this is one of the most dangerous addictions, but turning our society's spotlight on to how do we help those kids who are suffering and their parents, and what kind of supports do they need certainly would help solve this problem, too, form the position of a doctor, and that's what my business is, is to try to treat suffering.

Ms. MILLER. Thank you.

I'd like to recognize Representative Lynch at this time.

Mr. LYNCH. Thank you, Madam Chair.

Just to sort of get a sense of the scope of this problem. John McGahan and I have worked on this a while. John and I worked together to establish the Cushing House, along with Representative Wallace and Senator Tolman, and it houses 16 boys, 16 adolescent males.

Originally, the Cushing House was established because we had a suicide epidemic in the Boston area, and it was exclusively male, and some of those suicides were heroin related, drug related.

More recently, it has become a focus of our response to the OxyContin problem, and, John, you know, I know we talked last week, and you were telling me about the number of people—the number of boys in the Cushing House right now who had, I believe, heroin addictions now, but had come to that through a prior addiction to OxyContin. Out of the 16 boys that are now residing there, how many of them have been previously addicted to OxyContin?

Mr. MCGAHAN. All of them, every one of them.

Mr. LYNCH. OK, so 16 out of 16.

Mr. MCGAHAN. Right.

Mr. LYNCH. One of the things, the problem that has become so pervasive now that we are in the process of constructing, unfortunately, a home for girls right next door, that will have, I think, 10 beds to start, and was supported by my Republican colleagues in the Congress. This is one of those things where you see it as not being a partisan issue, and so I want to just give credit to my Republican colleagues for supporting me on that request, and also the President for signing it into law and to allow that money to go forward.

But, you said earlier in your testimony, John, that at that time there was no test for OxyContin. Is there a test now for OxyContin?

Mr. MCGAHAN. Yes, there is. We hate to discharge people, but we have to, if they are positive we need to know exactly what they are positive for and try to get them appropriate treatment, refer them back to detox if that's what's needed. There is a test specifically for OxyContin now.

Mr. LYNCH. OK.

But, what sort of struck me was, I know that Senator Tolman and Representative Wallace, you've got a bill regarding emergency room reports regarding, you know, drug interdiction and interventions. Is there some way that your legislation might actually require this test for OxyContin at the emergency room, when there's an overdose or, like I say, a medical intervention with an individual who, you know, has either overdosed on opiates? That would sort of give us the size of the problem within Massachusetts directly and specifically related to OxyContin, and/or if it's a chemi-

cal-based test, I think what it does, it tests for that time-release component that's only present in OxyContin, and it might give us a handle on how much of this stuff is going on.

Mr. MCGAHAN. Congressman, they are, the actual drug of overdose will be reported, but as we pointed out, this is not going to be like I got you or I can report you, it's going to protect identities.

Mr. LYNCH. No, no, it will be anonymous.

Mr. MCGAHAN. But, it will definitely, to the poison that is in the system, it will be identified.

Mr. LYNCH. OK, that's great.

Mr. WALLACE. Congressman, if I could just add something on that point.

Mr. LYNCH. Sure, go ahead.

Mr. WALLACE. One of the bills that I filed, and I never in my wildest dreams thought that I would have to file a bill like this, but one of the things we've seen is that young kids, teenagers, 14, 15, 16, were overdosing, non-fatal overdoses, and they were being brought to the emergency room by the EMTs, or the police, the fire, and they were being treated and released, and their parents had no knowledge of them even being in the hospital.

And, what happened is, one of my friends, his son got arrested for drinking a beer at Dorchester Heights, and he had to go down to the police station and bail him out and bring him to court the next day, and he knew where he was, but these parents, there's one individual that OD'd twice in the same day, twice in the same day, and his parents didn't even know about it.

So, the bill that I filed was that if a child is under 18, is brought to an emergency room, then his parents had to be notified. Again, never in my wildest dreams did I think I'd have to do that, but those are the depths that we have to go to, Congressman, at this point, and it's unfortunate.

Mr. LYNCH. Yes.

I know that this Weissman Institute, it may be Weissman, I don't know if I'm pronouncing that properly, but they are a fairly reputable rehab hospital, and according to their data 44 percent of their addicts, 44 percent of their addicts on OxyContin, were legally prescribed the drug. So, it's not someone out on a street corner somewhere looking for a fix, it's people who were legally and properly, according to the loose construction we have right now, they were just given the drug for a certain reason, and then its inherent addictive qualities, basically, dragged them down to the point where they are addicted.

And, that's the troubling part of this for me. I know that you are both, both Senator Tolman and Representative Wallace, you are working with a task force at the State level. Have you any, I know you've had, I think, seven, six or seven hearings, and you've got one coming up in Somerville that I'd love to come back, are there any things that we could help you with in terms of at the Federal level, just trying to get our arms around this thing.

I know that, I've got to be honest with you, the drug lobby is very, very powerful in Washington, DC. They tell me that there are 635 pharmaceutical lobbyists in Washington. There's only 535 Members of Congress, counting the Senate, and there are 635 lobbyists for the drug companies. They are extremely powerful, and

they have influence with both parties, let's be fair. And, you know, I have found it difficult to bring them to task, and believe me, if I could reasonably and cooperatively get them to reformulate this drug I wouldn't have a bill to ban it. If we could do it in a somehow reasonable way, but I just find they are so powerful and there's no incentive, quite frankly, for them to change, because I think their total take is $8 billion on this drug, $8 billion in profit on this drug. And, that's a powerful incentive for them not to change.

But again, my question, how do we help you? You've been doing great work on this, and we might have to attack it on a state-by-state basis, given the power of the lobby in Washington.

Mr. TOLMAN. Congressman, the Representative and I are very careful not to answer the way that DEA did, given that you are asking the question.

You are doing it, frankly. When you talked about the $300,000 that you, Congressman, with the Republican colleagues was to get for south Boston for that girls program that we just desperately needed, you are doing it.

The leadership that you've demonstrated throughout the State, most importantly, getting us to put in the extra $9 million to get the $13 to match the Federal funds, that's huge, but I think what we have to do, when we take detox in general, and you have a person maybe with alcohol and a 5 or 7 day detox may work, the problem that we are really facing here is, we are not equipped to deal with the opiate detox, because the opiate detox, as I refer to it as a spin cycle, it has to be far more extensive. It has to have the detox, but then it has to have the after care and the job training and, of course, the self-esteem building. That's not done in 3 to 5 days, and we are wasting our money to some extent when we are detoxing and then just letting them get out, or letting them get out because the programs that they need after that are just not available.

So, we need to continue the partnership with the Federal Government and the State funds, to make those programs that are going to have a much higher success rate at beating the addiction. I think that's a key component which we are trying to focus with the Bureau of Substance Abuse, the House, and the Senate, working together with the executive branch of Government, and, of course, you as well.

So, you are doing it. We have to keep vigilant. This hearing is a huge, in my opinion, positive benefit in the fight against this drug, because we have to let the public know how dangerous this is, do not touch it, do not go near it, and, you know, the way you've tried to do that in the general Massachusetts area has been terrific, Congressman. So, you are doing it, but we have to continue the partnership, I think.

And, Madam Chair, I can't thank you enough for this effort, because we have to get the message out. When you were young, and if you tried something, whether it was a can of beer or whatever it was, you knew you'd never touch heroin. The problem with this drug is, it's heroin, but you don't know you are touching it, and that's the difference, where you might have tried something that would be less potent or less addictive, and that's the key component, is that we have to let the public know, do not misuse this

drug, because it will ruin your life and it will kill you, and ruin everybody around you that loves you.

And so, you are doing it. We are going to continue partnership, but thank you.

Mr. LYNCH. Thank you.

Representative.

Mr. WALLACE. Yes, Madam Chair, one of the things that I think hasn't been mentioned is that we are hearing the word heroin a lot, and I mentioned that when I was doing my research I didn't even realize that it was legal in this country for 26 years, which kind of shocked me. But, a lot of things have shocked me lately, so that's just one of them.

But, one of the problems that we have is, any time that you can buy a bag of heroin for $4 a bag we are going to have problems in this country, and that's where it is right now. These kids can get a bag of heroin cheaper and easier than getting a six pack. To get a six pack they have to get someone to go in the liquor store to get it for them, to buy a bag of heroin for $4, you can go down the street and get it. So, I think that's one of the inherent problems that we have, is that it's available, and we have to do something along those lines.

Again, Congressman, thank you for what you've done for the Cushing House and for all of us, as far as your lead on this issue. It's been huge, and we appreciate it.

Mr. LYNCH. Thank you.

Madam Chair, I yield back.

Ms. MILLER. Thank you.

Well, I certainly want to tell you how much sincerely we appreciate, first of all, the gracious hospitality of the city of Boston for hosting this hearing, and all of our witnesses for coming here, and I certainly want to echo, as well, that if it hadn't been for Congressman Lynch this hearing would not have taken place. You know, quite frankly, it's much easier for us to have hearings in Washington, because everybody is there, but in this case I thought it was very, very important that he came to me and talked to the members of our committee about this terrible problem that we're having in his district, it is important for us to be here. I'm certain that there will be some legislation or certainly some changes as a result of all of the testimony that we've heard here today.

Congressman.

Mr. LYNCH. Madam Chair, I just have one question that I forgot to ask, and that was of John McGahan. I know you've got a 16 bed boys facility, I know you are doing the same for the girls. I'm trying to get a sense of the demand that's out there. How many beds, I know you've got a waiting list over there, how many beds do you think you could fill tomorrow if we had them available at your rehab facility?

Mr. MCGAHAN. We have 16 beds for boys, and we could fill 50. I mean we let the list only get so long, because we don't want parents to have to try to keep their kids safe for an extended period of time. I mean, the list can get, you know, four, five, six deep, and after that it's just too long, because the calls come every day. I mean, if we had a 50 bed facility, we could fill a 50 bed facility.

We are experiencing the same thing with the girls that we did with the boys. When we first opened it was going to be 10, 8 beds, then it went to 10, and then we snuck in another room to make it 12, and we are already up to putting in 12 at the girls side already, even though the original plan was 10, because the phone is ringing off the hook. So, I said, cut a couple of feet off of each room and jam in another room and make it 12 beds. So, I mean, we could fill 50 at the drop of a hat.

Mr. LYNCH. OK, thank you. That may become important testimony when we try to go for further funding for the girls home and for the boys as well in the future. I just wanted to get it on the record.

And then, just for a matter of housekeeping, I also would ask unanimous consent to enter into the record the GAO report that was conducted regarding OxyContin, and I would ask unanimous consent that be accepted as part of this record.

Ms. MILLER. Without objection.

[NOTE.—The GAO report entitled, "Prescription Drugs, Oxycontin Abuse and Diversion and Efforts to Address the Problem, GAO–04–110," may be found in subcommittee files.]

Mr. LYNCH. Thank you, Madam Chair, and again, thank you for your leadership and your kindness to myself and to my district in coming here. I really do appreciate working with you, and it's been a joy to serve on this committee.

Mr. MCGAHAN. Congressman, if I could just add one thing. In the story, one of the things that I think is important that you bring back and share with your colleagues is, it's not only about these teenagers when they are teenagers. These kids have no training, like the Senator said, no job skills, no education. They are contracting diseases. We need to think ahead of where they are going to be when they are 40 years old. They are not going to have an education. They are not going to have health insurance. They are going to have criminal involvement, and they are going to have kids. This isn't going to go away, it's going to get worse, and that's what we need to really share, is we need to say where are these 15 year old kids going to be 25 years from now. They are going to be parents, and that is scary, and that's what we should be sharing.

Mr. LYNCH. Right, and I know that you've got a high incidence of liver disease, and, you know, when you look at that in a 16 or a 17 year old young person, and you realize that person is going to be, you know, looking for a liver transplant in a matter of years, and you see the damage that's being done to these people over a lifetime, you realize what the huge, huge human cost is to this problem. So, it's another reason for us to get our arms around it and figure out a solution, if there is one.

Thank you, Madam Chair.

Ms. MILLER. Thanks very much again. We appreciate all of your attendance today, and the hearing is adjourned.

[Whereupon, at 1:35 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

September 12, 2005

The Honorable Candice Miller
Chairwoman
Subcommittee on Regulatory Affairs
House Government Reform Committee
US House of Representatives
Washington, DC 20515

Dear Chairwoman Miller:

On behalf of the Oncology Nursing Society (ONS) – the largest professional oncology group in the United States composed of more than 33,000 nurses and other health professionals which maintains a long-standing commitment to promoting excellence in oncology nursing, teaching, research, administration, education in the field of oncology, and the provision of quality care to individuals affected by cancer – we respectfully submit these written comments to your subcommittee to be part of the official record for the September 13th field hearing in Boston, *"OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers."*

As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, including initiatives that improve pain and symptom management and enhance quality-of-life. To that end, ONS commends you and your subcommittee colleagues for recognizing the importance of examining the role of the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) in regulating prescription painkillers. We thank you for the opportunity to submit these written comments and discuss the importance of appropriate regulation of, access to, and use of controlled substances for the treatment of cancer related pain.

Under-treated Pain - A Major Public Health Problem

Pain is a major health problem in the United States, especially the kind of pain that is often experienced by individuals with cancer. The treatment and management of pain and accompanying symptoms such as fear, anxiety, depression, weakness, nausea, and vomiting need to be improved significantly. When pain is severe, it interferes with activities and quality-of-life; diminishing physical, psychological, and interpersonal well-being. It is perhaps one of the more tragic realities in health care today that, despite the existence of many drugs and

techniques for treating pain, countless individuals continue to suffer needlessly from unrelieved pain.

Greater emphasis on quality-of-life for individuals at end-of-life and the growth of hospice care in this country have done much to validate the role of opiates in treating pain and suffering. Although considerable progress has been made to improve the adequate treatment of pain through efforts at educating health care professionals and the public, still less than half of patients with cancer get adequate relief of their pain and approximately one in four patients with cancer die with unrelieved pain. Much of the failure to relieve cancer-pain stems from patient, provider, and family misconceptions and fears. Moreover, recent controversies and negative media attention regarding the use of opiates have begun to erode much of the progress that has been achieved in this arena. It is, indeed, an unfortunate reality that the class of drugs that has the potential to alleviate pain and suffering also has the potential to be abused. Adequate pain control further is complicated by regulatory agencies that scrutinize professional licensure and restrictively regulate controlled substances – practices that are well-intended but unintentionally can obstruct legitimate use rather than stem diversion. However, while it is essential to strike a delicate balance between legitimate access and efforts to prevent diversion and abuse, it is critical to note that there is abundant evidence that the vast majority individuals – including people with cancer – who use these drugs for their legitimate and intended purposes, do not go on to abuse them.

Under-managed pain often results in emotional and economic consequences both of which have long term costs to affected individuals and their families. Therefore, it is essential that improved quality-of-life through expert pain control be available to all who experience pain, not just a select class of patients with specific diagnosis. More must be done to ensure that appropriate pain management is the standard of care for the young as well as the elderly, and for those with chronic illness or at end-of-life. ONS believes that the inadequate treatment of pain is a significant public health problem in the United States and requires the necessary public health response.

Cancer-related Pain

While we have made significant gains in cancer survival rates, unfortunately each year another 1.3 million Americans will receive a cancer diagnosis and more than 570,000 Americans will lose their battle with this terrible disease. For these individuals and their families, it is essential that we take all the steps necessary to ensure that throughout their treatment – and through survivorship or end-of-life, that their pain and other symptoms are managed appropriately. Moreover, as cancer risk increases with age, so do the risk and incidence of other chronic conditions. Therefore, many who develop cancer also suffer from other co-morbidities and underlying painful conditions associated with their other health problems such as arthritis, diabetes, or prior trauma.

Additionally, concurrent advances in the treatment of cancer have yielded a growing population of patients who are living longer with cancer as well as an increased number of people who are cured and transition to cancer "survivorship." Many of those patients who live

long-term continue to experience pain that may be related to their treatment rather than the malignancy itself. These patients often suffer moderate to severe pain on a daily basis which compromises their ability to function in various life activities. Therefore, this cohort has more in common with the non-malignant pain patient than the patient who has pain associated with advancing disease. For example, pain may be due to nerve injury or scar tissue formation from cancer-related surgical intervention. As such, ONS advocates increasing access to – and ensuring the availability of – quality, comprehensive pain and symptom management, psycho-social support, follow-up, and end-of-life care for people with cancer.

Opioid Treatment Essential to Managing Cancer-related Pain

Cancer patients typically have two types of pain – continuous, persistent pain that is always present and intermittent or breakthrough pain that occurs with activity. While surgery, radiation, and chemotherapy may be used to control the pain by shrinking the cancerous tumor, drugs such as non-opioids, opioids, and adjuvant medications are the mainstay of pain treatment. For years, morphine has been the standard opioid of comparison to treat severe pain in cancer patients. However, as knowledge about pain physiology and pharmacology translates into better analgesics or new formulations of opioids with fewer side effects, morphine has not remained the drug of choice. Morphine has several active metabolites including morphine 6-glucuronide and morphine 3-glucuronide that may accumulate in patients with renal disease, renal dysfunction, or elderly persons because of decreased clearance and prolonged elimination half-life. When this occurs, patients taking morphine may become confused, disoriented, sedated, and may experience other side effects. Because of these problems related to morphine's active metabolites, the trend has been to use semisynthetic opioids such as oxycodone, fentanyl, and hydromorphone.

People with cancer usually need to be treated with continuous release opioids (usually dosed twice a day) for the persistent pain and short acting opioids (usually dosed every two to four hours) for the breakthrough pain. At present the only continuous release opioids that are available are morphine (MS Contin®, Oramorph®, Kadian®), oxycodone (OxyContin®), and fentanyl (Duragesic patch® typically dosed every 72 hours). Some cancer patients cannot tolerate morphine because of side effects of nausea and vomiting while others need to take high doses of continuous release oxycodone because they are not able to use the fentanyl patch as they would need multiple patches to equal the OxyContin® dose they are taking. With the availability of controlled release oxycodone, cancer patients are able to have access to another analgesic for relief of persistent pain. If access to opioids, such as OxyContin®, were to be restricted severely, such a limitation could pose a major problem – and threat to health and well-being – not only for people with cancer but a multitude of patients with chronic nonmalignant pain who are enjoying an improved quality-of-life because of OxyContin®.

Risk Management, Diversion Control, Abuse Prevention, and Legitimate Access: A Delicate But Necessary Policy Balance

ONS maintains a long-standing commitment to ensuring that all people with cancer-related pain have access to the quality pain and symptom management care, services, and therapies

they need and deserve. Specifically, our organization believes that all people with legitimate need must be assured access to the medication and therapies that they and their health care providers deem most appropriate. We recognize and appreciate that with the potential for abuse, our nation must develop and implement appropriate, yet reasonable practices and regulations to ensure that these drugs do not fall into the wrong hands and are not abused.

As you may know, ONS is one of 21 national organizations that lent its support in 2001 for the "Joint Consensus Statement" on *"Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act"* articulating the need for balance between the treatment of pain and enforcement against diversion and abuse of prescription medications. This important document reflects a consensus among myriad health care providers, patient advocates, and law enforcement agencies that the prevention of drug abuse is an important public health and societal goal that can – and should – be pursued without impeding appropriate patient care.

As the Joint Consensus Statement asserts, "Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively." Moreover, the Joint Consensus Statement also recognizes that, "Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties."

Clearly, there are classes of drugs that should be regulated in an appropriate fashion so as to prevent and reduce diversion and abuse. However, in these important efforts, we must not increase the burden to patients or the health care professionals who are administering their pain-related care. Regulations that limit reliance on professional clinical judgment and unduly restrict access encumber the provision and delivery of appropriate pain management for patients with legitimate needs.

The percentage of the population who take prescription drugs for non-medical purposes has remained stable for the last decade at 1-1.5 percent as has the percentage of the population with an illicit drug problem (6-7 percent). This suggests that while periodic hotspots develop around a particular drug in certain communities, overall our nation's policies are working to minimize drug abuse. To that end, a study of opioid use and abuse published in the Journal of the American Medical Association concluded that the increase in medical use of opioid analgesics does not contribute to the increase in abuse.[1] However, we unfortunately always have had to be aware that an individual's request for a certain drug could be based in real need/response but also could be based on its street value. Yet, as noted above, we continue to see significant numbers of people with cancer dying in pain. This indicates that while our policies work to stem the tide of abuse they may be standing in the way of providing legitimate and necessary quality care for those in need. ONS agrees that drug abuse is a serious problem and that its prevention is an important societal goal; yet, ONS maintains – as stated in the Joint Consensus

[1] Data from 1990-96), Joransen DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. JAMA 2000; 283(13):1710-1714.

Statement – that [efforts to prevent drug abuse] "should not hinder patients' ability to receive the care they need and deserve."

ONS Recommendations

As part of our nation's ongoing effort to minimize diversion and abuse, nurses monitor the effects of controlled substances – including positive and negative effects, screen for drug use and abuse in daily practice, and make referrals when appropriate. Oncology nurses have been leaders in providing pain education and our organization provides education to our members through our journals, at conferences, and at special events. Nurses are experts in developing patient educational materials and work to teach patients how to manage their opioids, including safety issues. Moreover, nurses collaborate in teaching children in their community about drug abuse.

To augment and enhance these efforts, we feel strongly about the need for improved educational efforts that include how to stop drug diversion, how to keep records, and how to document proper assessment and prescription distribution. Specifically, health care professionals need access to education and training regarding pain control, especially with respect to the safe and appropriate use of opiates. Education and support are essential for health care professionals who prescribe and monitor patients using opiates in order to counter the intimidation that is often felt in the current climate where so much attention is focused on stemming diversion and abuse. Such education must include law enforcement, physicians, nurses, and pharmacists and should involve the national organizations representing these professionals (e.g. National Association of State Controlled Substance Authorities and National Association of Drug Diversion Investigators). These educational initiatives must focus equally on legitimate pain management and prevention of diversion and abuse. Unfortunately, many of the individuals and entities currently engaged in efforts relating to prescription drug abuse do not have a comprehensive understanding or perspective of the nature of pain and the associated therapies.

ONS believes that steps can be taken to prevent diversion and abuse while promoting access to opiates for legitimate pain relief. We respectfully encourage your subcommittee, the DEA, the FDA, and other relevant and appropriate federal agencies to address the critical issues of pain management and barriers to quality pain and symptom management as opposed to focusing solely on a particular therapeutic agent. Without a comprehensive understanding and evaluation of the status of the nation's current pain management delivery system, the potential unintended adverse repercussions of changing federal regulatory policy related to one drug could lead to fear and diminished access to care among those with legitimate needs. To that end, ONS recommends that the federal government:

1. Establish and maintain an ongoing dialogue between the DEA, the FDA, and health care professionals to encourage cooperation and mutual understanding in an effort to ensure a balanced and rational approach to effective symptom management and minimization of illicit drug use;

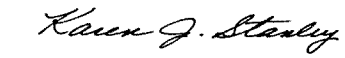
2. Work with health care professionals to develop guidelines for practice that will assure access to opiates based on sound clinical judgment and patient need, while increasing early recognition of problem behaviors;
3. Develop educational materials for patients and family members that will reassure them of the legitimacy of opiates in treating pain while giving them guidelines for safe use and the prevention of diversion or abuse;
4. Allocate resources to educate health professionals about the appropriate use of opiates and associated pain management techniques, both pharmacological and non-pharmacological;
5. Support projects aimed at identifying and eliminating system-level obstacles that preclude effective pain management in acute pain, cancer pain, and chronic pain; and
6. Assure that federal publications delineate clearly between substance abuse and legitimate pain management in acute pain, cancer pain, and chronic pain as the evidence that addiction is very rare in patients who have pain should be acknowledged more widely.

Summary

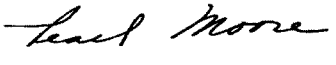
On behalf of ONS and our members who are involved in the provision of cancer-related pain and symptom management, we thank the Subcommittee for its consideration of our views on this important public health matter. ONS affirms its commitment to promoting the relief of cancer-related pain and suffering and urges the Subcommittee – as well as the FDA and the DEA – to consider first and foremost, the needs of those who suffer needlessly from unrelieved pain and to take steps to assure their continued access to the pain relief they need and deserve.

Please know that the Society stands ready to work with your subcommittee, the DEA, the FDA, and Congress to achieve our mutual goal of preventing diversion and abuse of pain therapies while also ensuring that patients with legitimate pain continue to have access to quality, appropriate, and legitimate relief. If we can be of any assistance to you, or if you have any questions, please feel free to contact us or our Washington, DC Health Policy Associate, Ilisa Halpern (202/230-5145, ihalpern@gcd.com).

Sincerely,



Karen Stanley, RN, MSN, AOCN®, FAAN
President



Pearl Moore, RN, MN, FAAN
Chief Executive Officer

Statement
of the

American Pharmacists Association

OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers

Submitted to the House Government Reform Committee Subcommittee on Regulatory Affairs

September 13, 2005
Boston, Massachusetts

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Statement of the American Pharmacists Association (APhA)
To the House Government Reform Committee Subcommittee on Regulatory Affairs

OxyContin and Beyond:
Examining the Role of FDA and DEA in Regulating Prescription Painkillers

September 13, 2005
Boston, Massachusetts

The American Pharmacists Association (APhA) welcomes the opportunity to present the pharmacist's perspective on the role of the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) in regulating prescription pain medications. As the medication experts on the health care team, and the health professionals dedicated to partnering with patients to improve medication use, we appreciate the opportunity to discuss the importance of striking a balance between providing effective health care and preventing prescription drug abuse and diversion. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession

APhA agrees that the diversion and abuse of prescription medications is a significant public health problem. Everyday, pharmacists work collaboratively with prescribers and other health care providers to prevent the diversion of prescription medications and to identify incidents of abuse or addiction. Because activities of the FDA and DEA impact the ability of pharmacists to provide patients access to prescription pain medications and therefore appropriate pain care, APhA and its members are committed to working with Congress, the FDA, the DEA, other health care providers, and patients to find the appropriate balance between appropriate medication use and measures to curb the abuse and diversion of prescription drugs. However, APhA is very concerned with recent proposals to circumvent the FDA's authority to determine which drugs should be in the market and recent DEA activities that may result in a 'chilling effect' on effective pain care — creating barriers to reign in 'bad actors' should not limit access to legitimate medications.

FDA: Step One

What drugs should be available in the market are critical decisions that impact the workings of our health care system. These decisions are best conducted by the FDA. The FDA reviews data provided by drug manufacturers to determine whether a drug may be marketed safely. APhA opposes efforts to circumvent this review process, such as through the legislative process. Using the legislative process to set clinical policy circumvents the thoughtful, scientific-based dialogue that supports the Food and Drug Administration's decisions. What may appear to be a simple decision to a legislator is to a clinician an intrusion on their ability to provide their patients necessary and appropriate care.

APhA is particularly concerned with legislative efforts to remove specific drugs, such as pain medications, from the market. Opiate analgesics like OxyContin® are a valuable tool in the management of pain. Opiate analgesics have significant therapeutic value for the millions of patients who suffer from chronic pain due to disease, injury, or surgery – pain that other medications will not alleviate. The legislative process is an inappropriate way to remove a drug from the market; legislative proposals to remove FDA-approved pain medications from the market ignore the value these products provide to patients who suffer from pain. APhA supports continued use of the FDA as the Agency that should make these types of decisions.

DEA: Step Two
Once a drug is approved for marketing by the FDA, the next step is determining whether restrictions should be placed on the access to the drug because of the drug's level of potential for abuse and dependency. The Drug Enforcement Administration (DEA) plays a role in managing the accessibility of addictive drugs through enforcing the U.S. controlled substances laws and regulations and supporting programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

While limiting illicit trafficking of prescription medications is very important, we must provide a balanced approach to enforcement efforts. It is imperative that we balance the need to regulate the 'bad actors' with the need to address the health care needs of patients who have legitimate medical conditions that require access to prescription pain medications. Without an appropriate balance of law enforcement and health care, patients suffer unnecessarily.

Pharmacists: Step Three
Determining whether a drug is available on the market and determining how tightly to control these products are just the first steps of providing patients access to appropriate medication therapy. The final decision of whether an individual patient should receive a specific medication should be a decision that involves the patient, the prescriber, and the pharmacist. Involvement of pharmacists is an appropriate and effective way of mitigating abuse and diversion.

Pharmacists work with patients to help them use their medications appropriately. Prescription drug abuse is one type of medication misuse that pharmacists try to prevent. Working collaboratively with prescribers and other health care providers, pharmacists prevent the diversion of prescription medications and identify incidents of abuse or dependency. As part of this process, pharmacists assess the appropriateness of every prescription order they review or dispense. Every day, pharmacists assess the validity of prescriptions, watching for errors in the content or format of the communications. They also watch for individuals who attempt to fill fraudulent prescriptions, visit multiple prescribers, or present prescriptions for unusually large quantities of medication. However, it is not always easy to determine if a prescription is legitimate – no simple algorithm determines appropriate use. And importantly, pharmacists cannot view every patient as a potential drug abuser without compromising their responsibilities as a health care professional.

Chilling Effect on Care
Although APhA agrees that some action is necessary to address the diversion and abuse of prescription medications, we know that some well-intentioned interventions can actually create new problems. Every effort to prevent diversion and abuse has the potential to diminish appropriate prescribing and dispensing exponentially. Any additional stigma attached to the drugs will have a significant impact on health care providers' willingness to prescribe and dispense appropriate pain medication and patients' interest in using the medications. While decreasing the number of controlled substance prescriptions written and dispensed may be seen as a way to decrease the opportunity for diversion and abuse, it is not an appropriate solution. Law enforcement efforts to reduce abuse and diversion can negatively impact care to thousands of patients living in pain who could be helped by appropriate use of controlled substances.

A recent example of the DEA going one step too far is its recent withdrawal of support for the pain management guidance "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel" (FAQ) and its release of an interim policy statement on the dispensing of controlled substances for the treatment of

pain. APhA is troubled that these actions signal a change in the Agency's direction. The Agency appears to be shifting away from striking a balance between appropriate pain management and strategies to reduce diversion and abuse, to an increased emphasis on investigation and prosecution.

Specifically, the Agency's interim policy statement contains a list of nine factors that the DEA believes may indicate diversion or abuse of controlled substances. While several of the factors may help the Agency distinguish between legitimate medical use and diversion or abuse, a pattern of diversion or abuse will only be evident if multiple factors are considered in concert with one another, and the Agency examines the unique situation of the prescriber and patients involved. The FAQ implies that the Agency may launch an investigation and/or prosecution of a health care professional because the individual appears to meet one of the factors listed. According to the DEA, just one of these factors – the number of patients, the quantity of controlled substances prescribed, or the length of therapy – may indicate that a health care professional is involved in diversion or abuse. APhA strongly disagrees with this conclusion.

The number of patients prescribed controlled substances, the quantity prescribed to each patient, and the duration of the drug therapy are not good indicators of diversion and abuse when considered by themselves. There are a number of legitimate medical reasons why a prescriber might prescribe controlled substances to a large number of his/her patients, prescribe significant quantities, and keep a patient on therapy for long periods of time. Physicians who specialize in pain management, because of the very nature of their practice, may have a large number of patients who require opiate analgesics to manage their pain. Patients who grow tolerant to a medication or experience break-through pain may need increasingly larger quantities of the drug to manage their pain. And patients who have chronic pain due to disease, illness, or surgery may need to remain on the drug therapy for extended periods of time.

APhA is also troubled by how the DEA's interim policy statement addresses the preparation of multiple prescriptions. The DEA takes issue with a statement from the Prescription Pain Medications FAQ which states, "Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different days."[1] According to the Agency's most recent interpretation of the Controlled Substances Act (CSA), however, the second half of the statement, "a physician may prepare multiple prescriptions on the same day with instructions to fill on different days," is incorrect. The DEA argues that this practice is tantamount to writing a prescription authorizing refills of a Schedule II controlled substance, which is prohibited.

APhA does not dispute the fact that prescriptions for Schedule II controlled substances may not be refilled. This is an established and settled matter of statutory, regulatory, and case law. However, we disagree that the scenario in question here – the preparation of multiple prescriptions on the same day with instructions to fill on different days – is equivalent to the authorization of refills. In this case, each prescription is prepared on a separate prescription blank or form and each prescription bears the date the prescription was issued and signed, the name and address of the patient, the drug name, strength, dosage form, quantity prescribed, and directions for use, and the name, address, and DEA registration number of the prescriber. Each prescription

[1] Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel. Supported by the Drug Enforcement Administration, Last Acts Partnership, and Pain & Policy Studies Group of the University of Wisconsin. 2004; pg. 39.

meets the requirements for a controlled substance prescription under the CSA.[2] Each prescription stands as a separate, new prescription for the medication prescribed.

The preparation of multiple prescriptions on the same day with instructions to fill on different days, is also a long-standing accepted medical practice – a practice the DEA itself has recognized and encouraged several times in the past. In a 1995 letter from the DEA to MEIJER, Inc., the Agency described a situation in which a prescriber "signs and dates as many as six prescriptions on the day of issuance…the prescriptions are noted that the pharmacist is not to dispense the prescription for 30, 60, 90 or 120 days." The letter continues to state that "there appears to be no violation of current federal laws or regulations in the prescribing manner you have described."[3] The letter clearly illustrates that the Agency had no objection to this practice, and that the issuance of multiple prescriptions with instructions to fill on future dates is not in violation of the CSA or subsequent regulations. The DEA has reiterated this stance on several other occasions including official Agency correspondence dated January 31, 2003. In that letter, the DEA clearly stated its approval of the practice:

> The DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time. If, in keeping with the practitioner's professional medical judgment, multiple prescriptions are issued at one time, each must bear the actual date that the prescriptions were issued and signed as well as the directions for dispensing. For example, if three prescriptions, each for a 30-day supply, are issued on January 9, 2003, each prescription must be dated January 9, 2003. In addition, the prescriptions to be filled at later dates must include directions for the dispensing pharmacist such as, "do not dispense before February 9, 2003." Although Title 21 of the Code of Federal Regulations, Section 1306.12 (21 CFR 1306.12) prohibits the refilling of a prescription for a Schedule II controlled substance, the DEA does not consider multiple prescriptions in the scenario outlined above as refills, and has authorized this practice provided that it is not in violation of the laws of the state in which the practitioner is licensed.[4]

The Agency's decision to reverse its position on this practice in the interim policy statement is confusing, inappropriate, and jeopardizes patient care. Prescribers have been issuing multiple prescriptions in this manner for years with the Agency's approval. There is no new law or regulation that serves as the basis of the Agency's new position. Similar to the Agency's change in position regarding the factors that may indicate diversion or abuse, the DEA's sudden change in position regarding multiple prescriptions will confuse health care professionals and dramatically affect patient care. This confusion will be compounded by the fact that many state boards of medicine and pharmacy continue to endorse the practice.

It is important that prescribers continue to be allowed to issue multiple prescriptions in this manner. Prescribers issue multiple prescriptions at one time to help improve patient compliance with drug therapy, decrease inconvenience for the patient and the provider, as well as decrease the quantity of controlled substances dispensed at one time. Prohibiting prescribers from issuing multiple prescriptions at one time will significantly impact patient access to these needed medications. Patients will be required to visit their physician for each new prescription – even if the patient has successfully been treated on the medication for some period of time. In most situations, patients will have to visit their physician or other prescriber on a monthly basis to

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[2] 21 CFR Section 1306.05.
[3] Letter from G. Thomas Gitchel, DEA to Patrick Gavin, MEIJER, Inc. Dated June 8, 1995.
[4] Letter from Patricia Good, DEA to Howard Heit, physician. Dated January 31, 2003.

obtain a new prescription. Although prescribers could prescribe higher quantities of a medication to eliminate the need for frequent physician visits, the cost of a large supply may be cost prohibitive for cash paying patients and most insurance companies restrict patients to a 30-day medication supply. If patients are capable of securing the larger supplies of medications, it is unclear how introducing *higher* quantities of medications into patients' hands at one time is preferable to an approach that facilitates periodic patient/pharmacist interaction and the provision of smaller supplies and dispensed more frequently.

The need for frequent physician visits will decrease access for some patients. It will especially disadvantage the disabled, those in lower socioeconomic classes, those who may rely on other means for transportation, and those who are unable to travel. And while the Agency's interim policy statement is specific to controlled substance use in the treatment of pain, it is important to note that this change in policy will also affect all patients using controlled substances. For example, patients with attention-deficit hyperactivity disorder (ADHD) may be treated with a Schedule II controlled substance such as Ritalin® (methylphenidate). Once these individuals are stabilized on a medication, there may not be a specific medical reason for the patient to see a prescriber every thirty days; however, under the Agency's new interpretation of the CSA, ADHD patients would be required to see their physician monthly to obtain a new prescription. This will greatly inconvenience parents and caregivers who must take off time from work and, often, remove their children from school for monthly physician visits.

Prohibiting the issuance of multiple prescriptions at one time will also affect prescribers. While more frequent physician visits may produce higher incomes for prescribers (and higher health care costs for patients and insurance companies), it will also increase the prescriber's workload. It may be difficult for prescribers to see every patient on a Schedule II medication every month. Physicians may be hesitant to prescribe a Schedule II drug – even when medically necessary – when doing so will require the patient to visit the prescriber every month for a new prescription. This may have a chilling effect on health care providers' willingness to prescribe and dispense controlled substances.

The DEA's recent FAQ has led health care professionals to feel uncertain about their risk of investigation. This legitimate fear is further compounded by the fact that the DEA has reserved the right to "investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not."[5] As it stands now, the Agency is sending the message to providers that they may be investigated for any reason or for no reason at all. This increased fear of DEA investigation and/or prosecution among the medical and pharmacy communities – even though the vast majority of prescribers and pharmacists are appropriate in their use of pain medications and other controlled substances – will have a "chilling effect" on the prescribing and dispensing of medically necessary controlled substances.

Education – Not Restricted Distribution – is the Answer

During a December 2001 U.S. House of Representatives Appropriations' Commerce, Justice, State, and Judiciary Subcommittee hearing on OxyContin®, both then-DEA Administrator Asa Hutchinson and Subcommittee Chairman Frank Wolf stated that they do not want or intend to restrict legitimate use of the drug. According to Hutchinson, the "DEA recognizes that the best means of preventing the diversion of controlled substances, including OxyContin® and all other drugs, is to increase awareness of the proper use and potential dangers of the products." The

[5] 69 FR at 67,171.

Association agrees, and notes that pharmacists can be an excellent communicator of that information.

APhA fully supports efforts to examine possible strategies to reduce the abuse and diversion of opiate analgesics without restricting access to drugs for patients with legitimate medical need. In October, 2001, APhA in collaboration with 20 other health care organizations and the DEA, released a joint consensus statement on the need to prevent abuse of prescription medications while ensuring that they remain available for patients in need. The groups recognized that for many patients, opiate analgesics are the only treatment option to provide effective and significant pain relief. However, a narrow focus on the abuse potential of a drug could erroneously lead to the conclusion that these medications should be avoided when medically indicated—generating a sense of fear rather than respect for their legitimate purpose.[6]

Striking a Balance

APhA generally supports the FDA's and the DEA's efforts to ensure that legitimate users of prescription medications maintain the ability to continue using these products, while reducing their diversion and abuse. However, we caution against efforts to restrict the distribution of certain medications or arbitrarily limit health care providers' ability to prescribe or dispense appropriate medications. With every barrier erected to limit diversion, the potential for those barriers to diminish appropriate prescribing increases exponentially. Restrictions in the drug distribution process can disrupt patient care by delaying access to medication therapy, disrupt existing patient-pharmacist-prescriber relationships, and potentially create an increase in the cost of medications. Also, any additional stigma attached to the drugs will have a significant chilling effect on health care providers' willingness to prescribe and dispense appropriate medication and patients' interest in using the medications. Decreasing the number of patients using a medication may be seen as a "success" in managing risk. But this "success" is tempered by the accompanying "failure" of patients with legitimate need to access the same medication.

Federal enforcement agencies, such as the DEA, should continue to be a law enforcement agency fighting the illegal diversion of drugs. But the DEA should not be turned into a medical oversight body – a task for which it is unsuited. Providing a government agency the explicit authority to question the intent of any physician or medical practitioner who authorized the use of a medication for a patient could increase doctors' reluctance to prescribe drugs resulting in more patients suffering, especially at the end of life. Drug therapy should be managed by healthcare professionals – physicians, nurses, and pharmacists – not by federal law enforcement officers. The very threat of regulatory intervention and oversight – and the fear of having their intentions misconstrued – could dissuade physicians from using aggressive efforts that are often needed to use medications effectively.

APhA encourages Congress to work with physicians, pharmacists, state and federal regulatory and law enforcement agencies, and representatives of pain management and other consumer organizations to examine possible strategies to reduce the abuse and diversion of controlled substances without decreasing patient access. It is imperative that the Agency strike an appropriate balance between providing adequate pain treatment and maintaining proper controls to prevent diversion and abuse. Despite assurances that the DEA's new policy statement does not

[6] A Joint Statement From 21 Health Organizations and the Drug Enforcement Administration. *"Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act."* Oct. 2001.

represent any change in the Agency's investigative emphasis or approach,[7] prescribers, pharmacists, and others perceive (appropriately) the Agency's withdrawal of support for the Prescription Pain Medications FAQ and the release of the interim policy statement as indicators that the DEA is placing a greater emphasis on investigation and prosecution. The chilling effect this perception will have on legitimate medical and pharmacy practice will be significant.

Thank you for your consideration of the views of the nation's pharmacists. APhA looks forward to working with the Committee to develop a safer and more effective system of providing prescription medications to all Americans.

[7] Letter from William Walker, DEA to William Winsley, Ohio State Board of Pharmacy. Dated January 27, 2005.

STATEMENT OF

J. DAVID HADDOX, DDS, MD
Vice President, Risk Management & Health Policy, Purdue Pharma L.P.

ON BEHALF OF

PURDUE PHARMA L.P.

BEFORE THE

SUBCOMMITTEE ON REGULATORY AFFAIRS
OF THE COMMITTEE ON GOVERNMENT REFORM

U. S. HOUSE OF REPRESENTATIVES

September 13, 2005

MADAM CHAIRMAN:

Thank you for giving me the opportunity to submit testimony for this hearing on behalf of Purdue Pharma L.P., the distributor of OxyContin® (oxycodone HCl controlled-release) Tablets. For almost five years, addressing the diversion and abuse of OxyContin has been one of Purdue's top priorities. The FDA has approved OxyContin for a medical purpose for those patients who need it (see attached professional prescribing information). Tragically, there also has been illegal trafficking and abuse of OxyContin in some regions of the country where it has become part of the much larger, historical problem of the abuse of prescription medicines. For example, much of Massachusetts, Kentucky, West Virginia and Florida lie within federally designated High Intensity Drug Trafficking Areas, with HIDTA designation dates ranging from 1990 to 2001. While there is no easy solution that will prevent the abuse of prescription medications while still ensuring their availability to patients with legitimate medical need, Purdue Pharma, more than any other pharmaceutical company, is working on solutions to this complex problem.

I would like to address allegations that Purdue's marketing of OxyContin has contributed to the illegal trafficking and abuse of the medication. I would also like to highlight some of the Company's efforts to combat this problem.

On December 23, 2003, the General Accountability Office (GAO) issued a report titled "PRESCRIPTION DRUGS: Factors That May Have Contributed to OxyContin Abuse and Diversion and Efforts to Address the Problem." After a lengthy and comprehensive investigation, the GAO confirmed that there is no easy solution to, and that no one factor can be blamed for, the abuse and illegal trafficking of OxyContin. The GAO report made some important findings:

- One of the primary questions posed to the GAO was: *"Is there a direct correlation between the marketing strategies of the drug [OxyContin] and its excessive abuse?"* Following an in-depth investigation over a two-year period, the GAO was unable to establish such a correlation.

- The GAO pointed out that the Food and Drug Administration (FDA) approved OxyContin in 1995 amid heightened awareness that many people were suffering from undertreated pain. It was in that context that Purdue's marketing efforts contributed to rapidly increasing sales. According to the GAO, "Fortuitous timing may have contributed to this growth." (p. 9)

- The GAO recognized that when it was approved, both Purdue and the FDA knew the abuse potential of OxyContin, but could not anticipate the extent of diversion and abuse that was to emerge. The GAO noted that, although OxyContin was classified by the federal government as a Schedule II controlled substance with a high potential for abuse, "FDA officials said when OxyContin was approved the agency believed that the controlled-release formulation would result in less abuse potential because, when taken properly, the drug would be absorbed slowly, without an immediate rush or high." (p. 29). According to the GAO, "FDA officials stated that neither they nor other experts anticipated that crushing the controlled-release tablet and intravenously injecting or snorting the drug would become widespread and lead to a high level of abuse." (p. 30)

- The GAO identified several factors that may have made OxyContin an attractive target for abuse and diversion:

    - OxyContin's controlled-release formulation, which made the drug beneficial to patients, enabled the drug to contain more of the active ingredient oxycodone than non-controlled-release opioid products.
    - The safety warning on the OxyContin label directed to health care professionals about taking the tablets intact could have unintentionally provided abusers with information on how to obtain the rapid release of oxycodone by crushing or chewing the tablet.
    - While the GAO noted that the increased availability of OxyContin in the marketplace may have increased the opportunities for diversion and abuse, the GAO specifically noted that the historic predisposition of certain areas to prescription drug abuse may have contributed to OxyContin diversion and abuse, particularly when coupled with the profit potential resulting from the illicit sale of OxyContin. (p. 32).
    - The GAO report also states that, according to the Drug Enforcement Administration, while OxyContin is "a drug of choice among abusers, OxyContin has not been and is not now considered the most highly abused and diverted prescription drug nationally" (p.33). More current federal data from the Substance Abuse and Mental Health Services Administration indicate that, while OxyContin continues to be abused, it is not the number one opioid-containing medication that is abused, nor are the opioid medications as a group the only drugs abused with any frequency.

- The GAO acknowledged Purdue's efforts to combat the problem: "After learning about the initial reports of abuse and diversion of OxyContin in Maine in 2000, Purdue formed a response team made up of its top executives and physicians to initiate meetings with federal and state officials in Maine to gain an understanding of the scope of the problem and to devise strategies for preventing abuse and diversion." (p. 10).

Having identified some factors that, in retrospect, may have contributed to diversion and abuse, but recognizing that they had not been a primary concern at the time of approval because the FDA and Purdue were focusing on the legitimate use of OxyContin as a pain medication, the GAO reached this conclusion: "Addressing abuse and diversion problems requires the collaborative efforts of pharmaceutical manufacturers; the federal and state agencies that oversee the approval and use of prescription drugs, particularly controlled substances; the health care providers who prescribe and dispense them; and law enforcement." (p. 42)

Purdue has been working to establish this type of collaborative approach ever since it became aware of the problem. Testifying on August 28, 2001 before a field hearing of the House Commerce Committee's Subcommittee on Oversight and Investigations, Michael Friedman, who is now Chief Executive Officer and President of Purdue Pharma, confirmed Purdue's commitment to addressing the problem through a collaborative effort, as follows:

> "Solving the problem of drug abuse requires the cooperation of many elements in our community: law enforcement, the schools, religious institutions, parents and family, the courts, the medical community, the press, federal and state legislators, government agencies, social services providers, and the pharmaceutical industry. Purdue is trying to help through our specific programs and our cooperation with the other elements in the community. Prescription Monitoring Programs can reduce doctor shopping and diversion from medical practices. Tamper resistant prescriptions can reduce copying or alteration. Education of responsible doctors can arm them with the tools they need to stop diversion from their practices. A better information system can allow us to know where abuse and diversion is cropping up and allow medical education and law enforcement to act earlier to "nip these problems in the bud." Development of abuse resistant products can reduce the incidence of abuse. What is needed is cooperation and common purpose. This is a long-standing societal problem that requires a reasoned solution."

The extent of the abuse and diversion of OxyContin, although unanticipated, is a matter of serious and special concern to Purdue. Once Purdue recognized the problem; it launched a comprehensive program to combat the abuse and diversion of OxyContin, much of which is part of its risk management program. To date, these initiatives include:

- Distributing approximately a quarter of a million free, tamper-resistant prescription pads to more than 16,000 doctors;
- Working with federal, state and local law enforcement to support and enhance their drug diversion investigations;
- Educating teens and parents about the dangers of prescription abuse through the Painfully Obvious® awareness and education program;

- Supporting community based anti-drug programs in numerous communities, in conjunction with "Communities That Care® and the Community Anti-Drug Coalitions of America;
- Creating RxPATROL™, a shared database to assist law enforcement in apprehending pharmacy robbers;
- Intensifying efforts to help healthcare professionals recognize and reduce abuse and diversion;
- Implementing the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System, a national surveillance program that tracks the incidence of abuse and diversion of selected opioid analgesics; and
- Working with state legislators and members of Congress to develop legislation that would help states implement prescription monitoring programs that can help reduce diversion by doctor shopping. Purdue's efforts have led to several states adopting PMP legislation and the company was instrumental in helping the federal NASPER legislation become law, which will provide for federal support for the purpose of creating or improving state PMPs.
- Investing more than $200 million in research to develop more abuse-resistant opioid analgesics that offer patients safe and effective pain control, while being undesirable to those who would abuse them.

I will take this opportunity to address the mistaken perception that developing an abuse-resistant opioid pain medication can be easily accomplished and that Purdue is not committed to this effort. On the contrary, the development of a pain medication that is safe and effective for patients with pain and also resistant to tampering by drug abusers is extremely challenging work. According to an article in the Washington Post, more than 450 patent applications have been filed relating to processes to develop abuse-resistant pain medications and at least 19 companies are engaged in this type of research. However, to date, no company has successfully brought an abuse-resistant medication to market. The Post article includes a statement from Martin Adler, Executive Director of the College on Problems of Drug Dependence, who puts this matter into proper perspective: "If this was easy to do, it would have been done long ago."

The GAO recognized that in response to concerns about diversion and abuse of OxyContin, the FDA and Purdue collaborated in developing a risk management program to help detect and prevent diversion and abuse. The report recommends that FDA guidance to the pharmaceutical industry include such programs to manage risk with New Drug Applications for Schedule II controlled substances. Purdue strongly endorses that recommendation. At least four companies now marketing generic forms of OxyContin have captured 70 percent of the controlled-release oxycodone market with their products, and other companies are marketing other Schedule II opioid analgesic products. The elements of the risk management programs for many of these Schedule II analgesics, if they exist at all, are not publicly available.

Purdue Pharma voluntarily designed what we believe is one of the most comprehensive Risk Management Programs (RMP) put forth by the industry for a medication of this type. This RMP is intended to facilitate proper patient selection, reduce abuse, minimize diversion, and avoid other improper uses of OxyContin Tablets. The RMP includes extensive medical education, sales force training, detailed prescribing information, epidemiological surveillance of

opioid analgesic diversion and abuse, and provisions for intervening in areas where diversion or abuse of opioid analgesics has been identified as occurring . Specifically:

- The professional prescribing information contains clear and strong warnings, including a prominent boxed warning, for prescribers, pharmacists, and other healthcare professionals.
- Educational programs are provided to healthcare professionals regarding assessment, treatment, and evaluation of patients suffering from persistent pain. These programs have been provided on an ongoing basis, particularly in areas with high levels of abuse of prescription medicines.
- Surveillance of the rates of diversion and abuse is being conducted through the company's RADARS® System.
- When surveillance reveals abuse, appropriate interventions are initiated. Interventions may include, but is not limited to, notification of health care professionals and law enforcement in the affected area, with offers of what our company has available to mitigate the problems, as outlined above.
- The company has implemented a state of the art supply chain security systems to combat diversion from the distribution chain and pharmaceutical counterfeiting.
- Additionally, Purdue supports efforts to regulate Internet pharmacies in an effort to curb diversion and abuse of controlled substances

It must be noted that no RMP will be able to completely eliminate abuse, diversion, pediatric use, improper patient selection or other unintended uses of OxyContin or any other medicine.

Purdue believes that the GAO report should put to rest the often-repeated assertion that Purdue's marketing is somehow responsible for the illegal diversion and the abuse of OxyContin. At a hearing of the Senate's Health, Education, Labor and Pensions Committee on February 12, 2002, Senator Dodd insightfully asked: "How do you address illicit use by going after targeting and promotion of a product that is supposed to be used legally?" He continued, "I do not understand the connection between illegal use and marketing and promotion. I do not see the connection." (Hearing transcript, p. 93) As noted in the GAO report, some prescription drugs, hydrocodone combinations, for example, are more abused than OxyContin, notwithstanding the fact that most companies that sell them do virtually no promotion. The prescription drug increasingly mentioned in the press and highlighted in the Senate Government Affairs hearing in the summer of 2003 as a drug of abuse, methadone, is also not actively promoted.

In fact, in the lawsuits where Purdue has been accused of "aggressive" marketing, we have to date had 365 such suits dismissed or decided in our favor, and none have been lost or settled. In a Kentucky case, the United States District Judge wrote in her opinion (Foister et al. vs. Purdue Pharma L. P., et al):

> "The plaintiffs' theory...appears to be based on the argument that additional restrictions on the marketing, promotion, and prescription of OxyContin will (i) reduce the overall quantity of OxyContin prescribed, which in turn will (ii) reduce the overall quantity of OxyContin available for illegal diversion, which in turn will (iii) reduce the likelihood that purported class members, or the general public, will illegally obtain OxyContin. As a matter of law, this theory is too speculative, hypothetical, and devoid of record proof...."

The court further stated:

> "The plaintiffs have failed to produce any evidence showing that the defendants' marketing, promotional, or distribution practices have ever caused even one tablet of OxyContin to be inappropriately prescribed or diverted."

Despite considerable litigation since then, no court has found otherwise.

No one can seriously think that Purdue is marketing OxyContin to criminal traffickers and drug abusers. The company does not engage in direct-to-consumer marketing for OxyContin. Purdue only markets OxyContin to health care professionals. By and large, the patients being treated by those health care professionals are not abusing this medicine -- iatrogenic addiction to opioids, although not well studied, is rare. It is not Purdue's marketing to doctors who treat patients with pain that creates the problem we are all concerned about. It is the illegal trafficking of these medications and the societal problem of substance abuse.

Since this hearing is being held in Boston where the media has written extensively about the abuse of OxyContin, I would like to join with local health care professionals who have raised concerns that sensational and inaccurate media coverage has jeopardized the availability of OxyContin and similar prescription drugs to patients who need them. Certainly there is an important and appropriate role for news reports that bring attention to illegal trafficking and abuse of prescription medications. But care must be taken to recognize that the very same medications are absolutely indispensable to many patients with pain.

I hope that this testimony demonstrates Purdue's commitment to combating the illegal trafficking and abuse of prescription medications and our concern that patients with pain continue to have access to appropriate treatment, including when medically necessary, prescription pain medications like OxyContin Tablets.

The professional product labeling for OxyContin® Tablets contains the following **boxed warning:**

WARNING:

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

Full prescribing information for OxyContin is attached as Exhibit B-4.

TOM DAVIS, VIRGINIA,
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INDEPENDENT

September 15, 2005

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Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Crawford:

On Tuesday, September 13, 2005, a representative from your agency, Dr. Robert Meyer, testified before the Government Reform Subcommittee on Regulatory Affairs at a field hearing in Boston, Massachusetts, on FDA and DEA regulation of Schedule II prescription pain relievers.

During the hearing, we asked Dr. Meyer what Congress could do to help FDA accomplish its mission of assuring the safety and effectiveness of drugs and more specifically, how Congress could help FDA in its efforts to address Schedule II prescription pain reliever addiction and abuse. Dr. Meyer responded that he was not prepared to answer these questions and that he would have to consult agency staff.

While Dr. Meyer's testimony was generally informative, we were disappointed that FDA would come to a Congressional hearing on FDA's regulatory process unprepared to answer questions about how Congress could help your agency better do its job. We would like to provide you an opportunity to provide us with a written response to these questions by October 3, 2005.

Thank you for your attention to this request.

Sincerely,

Candice S. Miller
Chairman

Stephen F. Lynch
Ranking Minority Member

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BERNARD SANDERS, VERMONT,
INDEPENDENT

September 15, 2005

Karen P. Tandy
Administrator
Drug Enforcement Administration
U.S. Department of Justice
700 Army Navy Drive
Arlington, VA 22202

Dear Ms. Tandy:

On Tuesday, September 13, 2005, a representative from your agency, Mr. Joseph Rannazzisi, testified before the Government Reform Subcommittee on Regulatory Affairs at a field hearing in Boston, Massachusetts, on FDA and DEA regulation of Schedule II prescription pain relievers.

During the hearing, we asked Mr. Rannazzisi what Congress could do to help DEA accomplish its mission of assuring the safety and effectiveness of drugs and more specifically, how Congress could help DEA in its efforts to address Schedule II prescription pain reliever addiction and abuse. Mr. Rannazzisi responded that he was not prepared to answer these questions and that he would have to consult agency staff.

While Mr. Rannazzisi's testimony was generally informative, we were disappointed that DEA would come to a Congressional hearing on DEA's regulatory process unprepared to answer questions about how Congress could help your agency better do its job. We would like to provide you an opportunity to provide us with a written response to these questions by October 3, 2005.

Thank you for your immediate attention to this request.

Sincerely,

Candice S. Miller
Chairman

Stephen F. Lynch
Ranking Minority Member

Congressman John F. Tierney
Additional Questions for the Record
Government Reform Committee Hearing
"OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers"
September 13, 2005

Additional Questions for Dr. Robert Meyer

1. What, if any, Risk Management Plans were filed by Purdue with respect to OxyContin either before or after approval of the application? Additionally, I am seeking to know whether the Food and Drug Administration would find useful, as a matter of policy, the ability to require Risk Management Plans as a condition of approval, and if so, in what circumstances.

2. The "Indication and Uses" on OxyContin reads, "OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time." What steps does the Food and Drug Administration take to ensure that physicians prescribe OxyContin only for the limited use indicated? Would federal guidelines for prescribing pain management be useful to the Food and Drug Administration?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Stephen F. Lynch
Ranking Minority Member
Subcommittee on Regulatory Affairs
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

NOV 9 2005

Dear Mr. Lynch:

Thank you for your letter of September 26, 2005, in follow-up to the September 13, 2005, field hearing of the Subcommittee on Regulatory Affairs entitled, "Oxycontin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers." Enclosed are the answers to the questions for the record that were submitted by Representative John Tierney. We apologize for the delay. We have restated the question in bold text followed by our response.

> **Question: What, if any, Risk Management Plans (RMP) were filed by Purdue with respect to OxyContin either before or after approval of the application? Additionally, I am seeking to know whether the Food and Drug Administration would find useful, as a matter of policy, the ability to require Risk Management Plans as a condition of approval, and if so, in what circumstances.**

Response: The original approval for OxyContin did not have an RMP. The RMP was developed by FDA and the sponsor in response to reports of abuse that surfaced in 2000 and beyond. The RMP evolved over time through discussions between FDA and Purdue and as more information was learned about the nature and extent of the abuse.

We would look forward to discussing with Congress whether statutory authority to require a risk management plan would be necessary.

> **Question: The "Indication and Uses" on OxyContin reads, "OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time." What steps does the Food and Drug Administration take to ensure that physicians prescribe OxyContin only for the limited use indicated? Would federal guidelines for prescribing pain management be useful to the Food and Drug Administration?**

Response: Because FDA does not regulate the practice of medicine, the prescribing practice of a physician regarding opiates is not so much an FDA issue as it is a State Medical Board and DEA issue. Nonetheless, FDA considers appropriate prescribing as an important issue and considers it in writing labeling, in reviewing promotions, and in developing RMPs where physician educational efforts by the sponsor concerning the appropriate prescribing of opiates is a key element.

While Federal practice guidelines informing the use of opiates might be a useful endeavor, for FDA's purposes they would not necessarily be directly useful, as the practice of medicine is not strictly within our purview. However, were such guidelines to be developed, they would be duly considered in FDA's regulatory responsibilities surrounding the potent opiates, including informing labeling and the RMPs.

Thank you for your interest in this important public health issue. If you have further questions, please let us know.

Sincerely,

Karen G. Meister for

Patrick Rohan
Associate Commissioner
for Legislation

cc: The Honorable Candice Miller
Chairman
Subcommittee on Regulatory Affairs
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

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INDEPENDENT

September 26, 2005

Dr. Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

This letter is being sent in follow-up to the September 13, 2005, field hearing of the Subcommittee on Regulatory Affairs, entitled "OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers." Enclosed with this letter are questions for the record that have been submitted by Representative John Tierney.

I look forward to receiving your response to these questions by October 10, 2005. Please send your response by mail to the Subcommittee majority staff in B-373B Rayburn House Office Building and to the minority staff in B-350A Rayburn House Office Building and by fax to the minority staff at (202) 226-2508. If you have any questions, please call my staff contact, Krista Boyd, at (202) 225-5420. Thank you for your attention to this request.

Sincerely,

Stephen F. Lynch
Ranking Minority Member

Enclosure

cc: The Honorable Candice Miller

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Candice Miller
Chairman
Subcommittee on Regulatory Affairs
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

NOV 17 2005

Dear Chairman Miller:

Thank you for your letter of September 15, 2005, in follow-up to the September 13, 2005, field hearing of the Subcommittee on Regulatory Affairs entitled, "Oxycontin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers."

The Food and Drug Administration's (FDA or the Agency) mission is to review and approve drugs. FDA is committed to ensuring safe and effective drugs for all Americans. Before any drug is approved for marketing in the United States, FDA must decide whether the studies and other information submitted by the drug's sponsor have adequately demonstrated that the drug is safe and effective when used according to the drug's labeling. Since no drug is without risk, FDA's approval decisions always involve an assessment of the benefits and the risks for a particular product and its proposed use. When the benefits of a drug are found to outweigh the risks and the labeling instructions allow for safe and effective use, FDA approves the drug for marketing.

At the time of approval, and sometimes after approval, FDA may develop, in cooperation with the drug's sponsor, a plan of interventions beyond labeling to help assure the safe and effective use of a drug. This has recently been referred to as a "risk management plan" (or RMP), but this practice dates back many years. In the recent past, FDA has worked with drug sponsors of other products to implement RMPs. These interventions making up an RMP may be varied, but all are aimed at assuring that some known or potential issues regarding the proper use of the drug are addressed by prescribers and patients using the drug. FDA will continue to work with drug sponsors in the future to implement RMPs for prescription medications that warrant such approaches to ensuring drug safety for American consumers.

The fiscal year (FY) 2006 Agriculture, Rural Development, FDA Appropriations bill for FY 2006 contains a $5,000,000 increase for the Office of Drug Safety as requested. In addition, the bill provides an increase of $5,000,000 for drug safety activities within FDA's

Center for Drug Evaluation and Research. These increases will be used for FDA's highest priority drug safety needs that were not funded in FY 2005, such as hiring of additional scientists or the acquisition of databases to which FDA does not now have access to help track adverse drug events. FDA is required to provide a report to the Committees on Appropriations within 30 days of enactment, setting forth its proposed use of these funds in detail, including an object class breakout for the $10,000,000 increase. FDA is working to prepare this report.

Thank you for your interest in this important public health issue. If you have further questions, please let us know.

Sincerely,

Patrick Ronan

Patrick Ronan
Associate Commissioner
for Legislation

cc: The Honorable Stephen F. Lynch
Ranking Minority Member
Subcommittee on Regulatory Affairs
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143