TO DO NO HARM: STRATEGIES FOR PREVENTING PRESCRIPTION DRUG ABUSE

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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TO DO NO HARM: STRATEGIES FOR PREVENTING PRESCRIPTION DRUG ABUSE

MONDAY, FEBRUARY 9, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Winter Park, FL.

The subcommittee met, pursuant to notice, at 9:07 a.m., in the Winter Park City Hall, 401 Park Avenue South, Winter Park, FL, Hon. Mark Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Mica, Norwood and Keller.

Staff present: Nick Coleman, professinal staff member and counsel; and Nicole Garrett, clerk.

Mr. SOUDER. Good morning, and thank you all for coming. This hearing focuses on a very old and very widespread problem, the abuse of prescription drugs. Prescription drug abuse itself is nothing new, but recently a new generation of morphine-based pain killers has caused a wave of addiction in overdoses throughout the United States. The drug OxyContin has produced the greatest amount of publicity, but numerous similar drugs such as, Percocet, Percodan, and Tylox have also been abused.

Prescription drug abuse presents special problems for the government, the medical community, and the pharmaceutical industry. On the one hand, these are powerful and dangerous drugs, with as great a capacity for addiction and abuse as heroin and cocaine. There are many ways for these drugs for to fall into the wrong hands. Supplies of the drugs can be stolen from pharmacies and manufacturers, and then sold on the black market. Doctors may intentionally or unintentionally over-prescribe the drugs to patients leading to addiction and abuse. Or patients themselves may obtain illegal quantities of the drug by shopping for multiple prescriptions and filling them at multiple pharmacies.

On the other hand, these drugs have legitimate medical uses, and may give the only possibility of relief for patients suffering from chronic pain. Many cancer patients for example, rely on OxyContin and similar drugs to combat crippling pain, while other individuals suffering from severe injuries may need similar treatment. Any regulatory plan must balance these completing concerns. Two Federal agencies are primarily responsible for the regulation of prescription drugs. The U.S. Food Administration and the Drug Enforcement Administration.

The FDA has the job of testing new drugs, and specifying how the drug may be marketed, prescribed and used, while DEA is re-

sponsible for monitoring the distribution and prescription of these drugs to prevent their illegal use. In addition to investigating illegal trafficking of prescription drugs, DEA also, controls the licenses that every physician must have in order to prescribe controlled substances. FDA and DEA have been criticized both for being too lenient and for being too strict in the regulation of prescription drugs.

Former addicts, relatives of those who have died of overdoses and many media commentators have argued that FDA has failed to safeguard the public from dangerous drugs by sufficiently regulating their marketing and distribution. These critics, some of whom it must be noted have filed lawsuits, have accused manufacturers of over-marketing pain killers and failing to warn doctors of the real risks of addiction and abuse.

By contrast, some doctors, patients, and other advocates for pain treatment have accused DEA of carrying out a virtual war against physicians by aggressively prosecuting those who willfully over-prescribe pain killers. While the specific actions of FDA and DEA and the pharmaceutical companies may be debated, it is clear that the Federal Government needs to explore new approaches to these problems. Congress and the executive branch need to reexamine the approval and marketing process, and determine how best to monitor the distribution and state of pain killers.

Several new proposals are already being debated. For example a number of States are exploring the concept of setting up computerized data bases that would track the sale and prescription of controlled substances to enable law enforcement officials to determine when a doctor is prescribing, a pharmacist is dispensing, or an individual is receiving suspiciously large amounts of a drug. Many States are also attempting to combat the illegal distribution of these drugs over the Internet, an issue that Government Reform Committee Chairman Tom Davis is working to address.

Other proposals focus on what warnings pharmaceutical manufacturers are required to give doctors and patients in providing information on addiction and how to treat it.

This hearing will allow the subcommittee to hear from governmental, medical, and other witnesses to testify about the cost of prescription drug abuse, the benefits afforded by those drugs, and how to best balance between these two.

I first want to thank Congressman Mica for proposing this hearing, and for the assistance that he and his staff have provided in setting it up. Congressman Mica, was chairman of this subcommittee before myself, and both of us have been active on this committee since the Republicans took over Congress. In fact Congressman Mica, used to be, in his first term, a critic of this subcommittee for not focusing on drug abuse and when we took over Congress this committee changed from having I think maybe one hearing on the issue on illegal drug use to becoming the focal committee in Congress. Then, now Speaker Hastert, chaired the committee with Congressman Mica being a very active member, and then Congressman Mica chaired it, and it has been my honor to chair it since then. And he has been vigilant from the time he was a staffer for Senator Hawkins as I was for Senator Coats and we worked on these issues in 1989 and 1990, to coming over as we became the

majority in the House and making sure we have both the best health care system in the United States, but also go after the illegal drugs in the United States. I appreciate his coming to me on the House floor saying we need to focus on this and I really would like you to do this in Florida, and for his leadership in the House on this issue.

We also have been joined by two of my colleagues, Congressman Charlie Norwood who also came in with our class in 1994 and we have been good friends for a long time, and Congressman Keller from Florida who is a more recent Member of Congress who we served on the Education Committee together, and have since moved over, and who has been another leader in Congress.

We also welcome three witnesses who joined us to discuss the Federal Government's response to this problem. Mr. William T. Fernandez, Director of the Central Florida High Intensify Drug Trafficking Area or HIDTA, a program administrated by the White House Office of National Drug Control Policy; Dr. Robert J. Meyer, Director of the U.S. Food and Drug Administration's Office of Drug Evaluation at the Center for Drug Evaluation and Research; and Mr. Tom Raffanello, Special Agent in Charge of the Drug Enforcement Administration's Miami Office.

We are also pleased to be joined by two representatives of the Florida State government who have taken a lead role in fighting against prescription drug abuse, Mr. James R. McDonough, director of the Florida Office of Drug Control; State Senator Bert Saunders, who has just called in and has had an emergency and cannot be here.

We also welcome Dr. Stacy Berckes, Board member of the Lake Sumter Medical Society; Mr. Jack E, Henningfield, of Pinney Associates who is testifying on behalf of Purdue Pharma; Ms. Theresa Tolle, president of the Florida Pharmacy Association.

We also, welcome several witnesses who can discuss the importance of these issues to patients and individuals. In particular, we welcome Mr. Frederick Pauzar, who lost a son to an OxyContin overdose, and who has taken a leadership role in addressing the problem of prescription drug abuse. We are especially pleased to be joined by a specialist in the treatment of prescription drug addiction, Dr. Douglas Davies, medical director of the Stewart-Marchman Center. We also, welcome Professor Paul L. Doering of the University of Florida College of Pharmacy; Ms. Karen O. Kaplan, president and CEO, of Last Acts Partnership, and Dr. Chad D. Kollas, medical director of the palliative medicine at M.D. Anderson Cancer Center of Orlando.

We thank everyone for taking the time to join us this morning, look forward to your testimony, and now I would like to yield to my friend and colleague Mr. John Mica.

Mr. MICA. Thank you, Mr. Chairman. I am pleased that the Subcommittee on Criminal Justice, Drug Policy and Human Resources has agreed to conduct this first oversight hearing on the problem that we face not only in our community and our State but also our Nation, the problem of misuse and abuse of certain prescription drugs, particular today we are going to focus on the problem of OxyContin abuse and misuse. I think this is a very important hearing, and I appreciate your responding to my request.

I want to also thank and welcome Charlie Norwood, from Georgia. A gentleman from Georgia, he is a key player in this. Our committee is investigative and oversight. Dr. Norwood—and he has a medical background, a dentist—he serves on a committee that can actually move legislation forward and I know in my discussions with him last evening he is anticipating putting together some legislative fixes to this problem. He does so not just from a legislative standpoint, he is not an attorney, but he has been an expert in medical practice here in dentistry, so he knows a lot of what he is talking about, has a very great deal of experience that we can draw upon.

And I am also, pleased that Rick Keller—there are four Members of Congress that share Winter Park. It is a great community to share, but I am pleased that he came out. He shares my concern about what is happening in our community, again across the State, and Nation with abuse of prescription medication, so this is an important area.

I was sitting here thinking, as we convened the hearing, back to I think it was December 1980, Senator Paula Hawkins was sworn in this room in advance actually of her term. It was a prearranged swearing in so she could gain a little bit of seniority, and she really began some of the fight to address the problem of illegal narcotics, bring it the attention of the U.S. Senate, the Congress, the problems we had back in the 1980's. At that time it was cocaine and other drugs.

And so, it is ironic that we are back here.

When I took over chairing this subcommittee—but before that when I was on the committee, Mr. Hastert—Mr. Souder served with and got to know the current Speaker very well in service. He was very dedicated to addressing the problem of illegal narcotics, and we conducted back in the late 1990's a hearing in Lake Mary on the problem of heroin addiction. I point that out because we continue to be challenged as a community, State, and Nation on the problem of illegal narcotics. Some of that now has shifted to abuse of prescription medication, and particular, again the focus of this hearing is OxyContin.

For the record, Mr. Chairman, we did a little review of some of the statistics, back in 1999, we had in central Florida 80 heroin deaths, and that was considered an epidemic. In 2000—and actually we had zero according to the figures I have of OxyContin deaths, overdose or deaths from OxyContin. In 2002, we had 68 deaths in central Florida. If we look at it statewide, in 1999, we had 198 heroin deaths, had zero that I have a record of for OxyContin. In 2002 we had 589 OxyContin deaths, as opposed to 326 statewide for heroin. So, if we had a serious problem or epidemic then, we certainly have a situation that deserves our attention as an oversight committee, today.

Finally, I want to say that the purpose of this hearing is to find some positive solutions to deal not only with one particular drug, but any drugs, whether they are illegal or legal, find means and ways of keeping them out of the hands of people who abuse them, misuse them. In some cases we find they are stealing, robbing, pillaging to obtain those narcotics. It is our responsibility in Congress to make certain that we have adequate legislative and law enforce-

ment and agency rules, regulations and laws, to deal with a problem of this magnitude. So, I am hopeful that this hearing will help us find some positive solutions.

I look forward to my colleague, Mr. Norwood, Dr. Norwood's legislative proposal. I look forward to hearing the testimony today from, of course, members of the community who have been affected by the ravages of misuse of prescription medication. We look forward to hearing from some of the national experts, that have been assembled here in Winter Park. And I think that we will also, hear from our law enforcement folks who had to deal with some of the problems created by misuse, abuse, addiction to prescription medication.

So, again I welcome Chairman Souder, I thank you, and again I hope we can have some positive results from this oversight hearing. I yield back.

Mr. SOUDER. Thank you, I would now like to recognize my friend, Congressman Norwood. When we first ran in 1994, both of us, I as a small businessman, and he as a dentist, we never thought we were going to be Congressmen. And then we came in this big wave and all of a sudden over the years it has been developed that we are in the majority, and we not only have the Senate and the Presidency, and it is a whole lot different now actually with the responsibility of having to figure out how to do these things and work them out. But, it has been a great opportunity to work together and join our other colleagues, and it is great that you could be here today.

Dr. NORWOOD. Thank you, Chairman Souder, for allowing me to join you today. As you know we have great interest in this subject in the Health and Environment Subcommittee out of the Commerce Committee, and I am grateful for the opportunity to listen and learn today.

I also want to thank my host Mr. Mica, for the hospitality that he has shown me during this visit. I will tell you it is unusual for Georgians to say nice things about Floridians this close to football season, but I do appreciate the warm welcome and I have enjoyed being in your hometown.

The use of drugs to relieve pain is a subject which I have had significant experience in my life. I have experienced it when I was in Vietnam treating wounded soldiers. I have experienced it as a practicing dentist for 25 years. I have experienced it with family and friends through difficulties they may have faced in life, and I have experience a little bit of it personally after a car wreck in 2000.

I feel pretty strongly that we do not do a good enough job to alleviate pain when we can, and morally and ethically we should. I will say I think we are doing a much better job of that today, then we did in the 1970's and 1980's. I also know that drugs that relieve the most severe pain can be those drugs that are must dangerous. The value of drugs in relieving pain is obviously a double-edged sword. These drugs can create a dependency that makes it difficult for sufferers to wean themselves off those pain killers, and these pain-killing drugs can be diverted for recreational use by abusers. That is actually why we have the Controlled Substance Act, that

is why we hold certain drugs to be in a higher regulatory standard, because we are concerned about how they might be used or abused.

I come to this subject knowing that OxyContin has been controversial because of abuse and misuse and diversions of the drug, and I strongly believe we should work to eliminate the abuse of OxyContin and we will. But, I also believe we should work to eliminate the abuse of all controlled substances, it is not the only one that is addicting, and it is not the only one that is dangerous. But how we do this is critical. If we come up with solutions that discourage our physicians from prescribing appropriate pain killers, pain care in this country will take a serious step backward. And we all must remember unless you have been there, unless you have had that pain and can hardly live with it, you do not understand personally the importance of what these drugs can do for you.

I believe there are several areas we need to address if we are going to attack prescription drug abuse and Lord knows we need to. I support the use of state-based prescription monitoring programs. My friend Congressman Chairman Harold Rogers has been funding an appropriation that allows States to set up these monitoring programs, and they are out there in 18 States. With a monitoring program, a State could then catch a person who is running from pharmacy to pharmacy getting a prescription filled. The State could also raise questions about doctors who appear to be illegitimately writing controlled substance prescriptions and my view is that if they are and they are caught, they ought to be put under the jail. That is where one of the problems is.

Today, there is little in place in this country to stop either of these abuses. I come from the time even in the 1980's where we had to keep our prescription pads under lock and key, because people actually would come into the office for bogus reasons hoping that I would walk out of the room where they could grab a pad. I believe we need to reign in Internet pharmacies. That may be the greatest danger. Right now I could go on the Internet and buy a controlled substance just by pointing and clicking two things, I need the drug and I am not lying. So could my 13 year old granddaughter. There are legitimate Internet pharmacists, but those that do not require prescription from a treating provider are going to have to change the way they do business. That loophole must be closed.

When a drug leaves a manufacturer, where does it go? The more I learn, the more concerns I have that our systems have giant holes that allow counterfeit drugs to enter the system. Last year, there was a counterfeit Lipitor scare right here in Florida. That made it much more difficult for wholesalers in this State to sell drugs without knowing where they came from, and it should be done. Right now, you can go back and forth across the borders of this country with 50 doses of a prescription. It is called the personal use exemption. However, the law allows you to cross the borders as many times as you want to a day with 50 doses. That loophole has to be closed.

Finally, I want to say a word about OxyContin. OxyContin has a legitimate use for patients in severe pain that I believe must be preserved. And there are other drugs out there that may work just as well. If we banned OxyContin tomorrow, and forbade every drug

manufacturer from marketing to doctors, does anybody in this room really believe that prescription drug abuse will go away? It will not, it was there before OxyContin ever came on the market. Prescription drug abuse is bigger than any drug, and it is not caused necessarily by marketing practices. I have an hour's worth of reasoning behind that, but I will not do it, Mr. Chairman, right now. What we need to do is close the loopholes that are in our system.

I thank the chairman and Congressman Mica for allowing me to be here today. I really look forward to hearing the testimony of the witnesses. This is a real learning effort for my subcommittee, and I am grateful to both of you. Thank you and I yield back.

Mr. SOUDER. Thank you. And right now I would like to recognize Congressman Keller, many of us were very thrilled to see him win his first primary and get elected and become an active Member of Congress, and it is great to be here in central Florida.

Mr. KELLER. Well, thank you very much, Mr. Chairman. First and foremost, I would like to thank my colleague from Winter Park, Congressman Mica, for his leadership on this issue, and bringing this congressional field hearing right here to Winter Park, FL. It would not have happened without his leadership, and we certainly thank him.

Also, because of our lax immigration laws here in Florida, a couple of out-of-state Congressman were able to slip through our porous borders and come here today. Chairman Norwood and Chairman Souder, traveled hundreds of miles to be here and that is just a testament to how important this issue is to them. We are very lucky, actually we have three subcommittee chairman up here so some powerful Members of Congress with the ability not only to listen today and learn what the challenges are but, to go back to Washington and do something about it. So, I am just thrilled that they are here in person in our community.

As a member of the Crime Subcommittee in Congress, national drug control policy is something that is near and dear to my heart, and I have to tell you in the interest of straight talk, the abuse of prescription drugs like OxyContin presents some very special problems for Members of Congress like me. On the one hand, these are very powerful and dangerous drugs with as high a capacity for addiction as heroin and crack cocaine. On the other hand, these drugs have legitimate medical uses and may give the only possibility for relief for millions of patients suffering from chronic pain, especially those with terminal cancer, and so we have to listen today, and try to get it in the strike zone and do what is appropriate, and that is why we are here.

And I want to thank you all so much for being here as well. Mr. Chairman, with that I will yield back.

Mr. SOUDER. I thank each of you for your statements.

A couple of orders of business first. I ask unanimous consent that all Members have 5 legislative days which is basically a week to submit written statements and questions for the hearing record and any answers to written questions provided by the witnesses also be included in the record. Without objection, so ordered.

Second, I ask unanimous consent that all Members present be permitted to participate in the hearing. Without objection, so ordered.

Let me explain a little bit first about how we conduct our hearings. This is a Federal oversight hearing, it is not a town meeting and it is not like a State hearing where people can testify. It is only invited witnesses, and that others may submit written testimony. So you can submit any written testimony either to Congressman Mica's office or Congressman Keller. And when I asked unanimous consent that all Members have 5 legislative days to submit written statements, which is effectively a week, that means it can go through their office. We do not take testimony from the floor. As has been explained several times this is an oversight committee.

In 1994, when we first took over Congress this committee was probably the most high profile in Congress. We did every thing from the Waco hearings to the White House investigations on who hired who, the travel office, China, the FBI files and so on. And so, all witnesses are sworn in. It is one of the only—this is not an intimidation but it is a fact—it is the only committee in Congress where people who have testified have been prosecuted for perjury. Because it is an oversight committee, the statements are presumed to be accurate, so we encourage you to qualify if you are not absolutely certain, because this is an investigative committee.

The name of this Subcommittee is Criminal Justice, Drug Policy and Human Resources. We have jurisdiction over any drug policy and we do authorizing on narcotics issues as well, but because of the nature of how Congressman Mica and Congressman Hastert pulled together these agencies, we also have jurisdiction over HHS and FDA. And we do hearings as well on those subjects and the Department of Justice which includes DEA. And so we are, for example the only committee in Congress, that in addition to drug policy has oversight over both of those different areas, and so we can blend and do followup with both levels of agencies unlike a health committee that can only deal with FDA, or a judiciary committee that can only deal with the Justice Department.

We do different field hearings like this as well in Washington. This subject is not unrelated to others that we have held on illegal narcotics and the difficulty of sorting these things through, but is actually the first one I believe on OxyContin directly. And it is obviously being very closely watched and it is a great privilege to be here in Florida with this hearing. I would like to yield to Mr. Mica.

Mr. MICA. Mr. Chairman, just a housekeeping point. I think Members are aware last week of the ricin scare that we had. They did come and collect our mail and also some of the mail delivery has been suspended. I have had an extraordinary number of request to submit testimony for the record and the chairman is leaving the record open for 5 days. However, I would advise those who want testimony submitted either to get it to Congressman Keller's office, hand carried to Congressman Keller's district office, or my district office. We will be glad to make certain that it gets to the subcommittee within the required amount of time. And I am not sure how you are accepting mail, whether we need an offsite location. Maybe by the end of the hearing, we can make certain that we have a location. There may be some delay in the subcommittee or Members of Congress receiving that testimony and that does give me some concerns, so we can look into that and, also I think

the chairman is going to announce a fax number if you want to submit for the record.

While everyone cannot be a witnesses in these formal congressional hearings, they do have an opportunity to submit for the record testimony.

Mr. SOUDER. I thank the chairman, that was a good point over the mail. We do not know how much mail, it is not the first time and the procedures sometimes take forever to get to us. The best way is not to send written materials to our offices. Either our fax number for the committee is 202–225–1154. The safest thing is to get it to a Member's district office here in Florida.

With that, we would like the first panel to come forward. Mr. Terry Fernandez of the Central Florida HIDTA; Dr. Robert Meyer, of FDA; and Mr. Tom Raffanello, of the DEA. If you could come forward and remain standing. Will you raise your right hands.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

For those who are not familiar we have a 5-minute clock, so we have time for questioning. It will turn yellow after 4 minutes. We will be a little flexible with that, but to make sure we have time for questioning and get all our panels in, we ask you that all written statements will be submitted. Any additional material be submitted. So if you want to summarize—however you want to do this is fine. Mr. Fernandez, you are recognized first.

STATEMENTS OF WILLIAM T. FERNANDEZ, DIRECTOR OF CENTRAL FLORIDA HIGH INTENSITY DRUG TRAFFICKING AREA, OFFICE OF NATIONAL DRUG CONTROL POLICY; ROBERT J. MEYER, M.D., DIRECTOR, OFFICE OF DRUG EVALUATION II, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; AND TOM RAFFFANELLO, SPECIAL AGENT IN CHARGE, MIAMI DIVISION, DRUG ENFORCEMENT ADMINISTRATION

Mr. FERNANDEZ. I would like thank the Chair and the committee for the ability to be here today, and I would like to thank you for your efforts in this effort—and in this field.

The State of Florida has seen an alarming increase in the abuse of pharmaceutical drugs in recent years. Most specifically OxyContin, and others that contain its active ingredient, Oxycodone. The Controlled Substances Act has placed Oxycodone under Schedule II due to its highly addictive potential.

OxyContin is a drug with two identities—an FDA approved schedule II drug developed for treatment of long term moderate to severe pain, and a substance that can be used by the heroin addict due to its similar euphoric effect. OxyContin also provides the heroin user with the security of a predictable potency in a regulated dosage unit. There are instances of the OxyContin abuser switching to heroin in some parts of the State.

Abusing an OxyContin tablet is easily accomplished by chewing the tablet thereby voiding its controlled-release feature. The tablet can be crushed and snorted, or made soluble and injected. It is often mixed with other licit and illicit drugs which can prove very deadly.

In 2002, there were 589 drug deaths in the State of Florida in which Oxycodone was found in the system. Oxycodone was found in lethal amounts in 256 of these. During the first 6 months of 2003, there were 292 deaths involving Oxycodone. It was found in fatal amounts in 136 persons, 48 of whom were central Florida residents. Of the 136 Oxycodone fatalities in the first half of 2003, 67 percent were over the age of 35 and 16 percent were over the age of 50.

Intelligence indicates doctor shopping, prescription fraud, and robbery, are the three most common means of obtaining OxyContin.

The heroin problem in central Florida has certainly contributed to the abuse of OxyContin and other drugs containing Oxycodone. Further, the lack of availability or increase in price of one, motivates the abuser to seek the other.

I cannot recall a substance so diversely abused, crossing all age groups, ethnicities and social statuses, with such a devastating effect. We know the source of this drug, the retail price, the illicit price, the distribution routes, and very much about the end user and his supplier.

I refer to the November 2003 article in the South Florida Sun-Sentinel which lists the top 12 OxyContin prescribers for Medicaid during the period 2000 to 2002. These 12 doctors wrote prescriptions totaling $15,645,745.00. This figure represents 1,689,605 80-milligram tablets of OxyContin or 9,540,000 10-milligram tablets. Should our efforts to bring this abuse under control not start here?

The Florida Prescription Validation Program utilizing an electronic data base containing prescription history and counterfeit-proof prescription forms will certainly assist in curbing doctor shopping and forged prescriptions.

The validation program in cooperation with the Drug Enforcement Administration's Office of Diversion Control and its registry of physicians prescribing controlled substances, should be a natural alliance.

Thank you.

Mr. SOUDER. Thank you, and I should have repeated that Mr. Fernandez is the director of the Central Florida High Intensity Drug Trafficking Area, Office of National Drug Control Policy, which coordinates State, local and Federal anti-drug efforts in central Florida.

Now we are going to hear from Dr. Robert Meyer, Director of Office of Drug Evaluation II, I should have said earlier, the Center for Drug Evaluation and Research, of the U.S. Food and Drug Administration, FDA. Thank you for coming.

[The prepared statement of Mr. Fernandez follows:]

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Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human resources

"To Do No Harm: Strategies For Preventing Prescription Drug Abuse"

Statement by: William T. Fernandez
Director
Central Florida HIDTA

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Abusing an OxyContin tablet is easily accomplished by chewing the tablet thereby voiding its controlled-release feature. The tablet can be crushed and snorted, or made soluble and injected. It is often mixed with other licit and illicit drugs which can prove very deadly.

In 2002 there were 589 drug deaths in the state of Florida in which Oxycodone was found in the system. Oxycodone was found in lethal amounts in 256 of these.

During the first six months of 2003 there were 292 deaths involving Oxycodone. It was found in fatal amounts in 136 persons 48 of whom were central Florida residents.

Of the 136 Oxycodone fatalities in the first half of 2003 67% were over the age of 35 and 16% were over the age of 50.

Intelligence indicates doctor shopping, prescription fraud, and robbery, are the three most common means of obtaining OxyContin.

The heroin problem in central Florida has certainly contributed to the abuse of OxyContin and other drugs containing Oxycodone. Further, the lack of availability or increase in price of one, motivates the abuser to seek the other.

I cannot recall a substance so diversely abused, crossing all age groups, ethnicities, and social statuses, with such a devastating effect. We know the source of this drug, the retail price, the illicit price, the distribution routes, and very much about the end user and his supplier.

I refer to the November 2003 article in the South Florida Sun-Sentinel which lists the top twelve (12) OxyContin prescribers for Medicaid during 2000 to 2002. These twelve doctors wrote prescriptions totaling $15,645,745.00. This figure represents 1,689,605 80 mg. tablets of OxyContin or 9,540,000 10 mg. tablets.

Should our efforts to bring this abuse under control not start here?

The Florida Prescription Validation Program utilizing an electronic database containing prescription history and counterfeit-proof prescription forms will certainly assist in curbing doctor shopping and forged prescriptions.

The validation program in cooperation with the Drug Enforcement Administrations Office of Diversion Control, and its registry of physicians prescribing controlled substances, should be a natural alliance.

Dr. MEYER. Thank you. Good morning Mr. Chairman and members of the subcommittee. I oversee the review division that has regulatory responsibility for the high dose of opiate analgesic products. And I appreciate the opportunity to talk about FDA's drug approval process and our role in preventing prescription drug abuse.

FDA is a public health agency that is strongly committed to promoting and protecting the public health by assuring that safe and effective drugs are available to the public. FDA is aware of and is concerned about reports of the growing problem with prescription drug abuse. We understand the seriousness of this issue and sympathize with the families and friends of individuals who tragically lost their lives or otherwise have been harmed, as a result of prescription drug abuse and misuse, including OxyContin.

We also sympathize with the many pain patients who suffer needlessly due to under treatment or substandard treatment. In taking actions on these matters, FDA must strike a critical balance.

Let me turn for a moment to one of the issues upon which I was asked to speak, the FDA 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 drug's sponsors have adequately demonstrated that the drug is safe and effective when used according to the drug's labeling. When the benefits of a drug are found to outweigh the risk, and the labeling instructions allow for safe and effective use, FDA approves the drug for marketing.

There are instances where FDA may develop, in cooperation with the drug sponsor, a plan of intervention beyond just labeling to help assure the safe and effective use of a drug. This has recently been referred to as risk management plans [RMP], but the 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 issue regarding the proper issue of the drug is addressed when the drug is used.

During the approval process, FDA assesses a drug product's potential for abuse. If a potential for abuse is found to exist, the product's sponsor is required to provide FDA with all data pertinent to the abuse of the drug, a proposal for scheduling the drug under the Controlled Substances Act and data on overdoses. Under the Controlled Substances Act, FDA must notify DEA if a new drug application is submitted for any drug that is assumed to have abuse potential, and that includes depressants, hallucinogenics, or stimulants.

Finally, it is important to state that FDA's job is not over when the drug is approved. The FDA conducts post-marketing surveillance that monitors drugs post-approval for their safety, allowing for reassessments of drug risk based on new data learned after marketing. When needed, we then recommend ways to most appropriately manage these newly identified risks. In part prompted by our experience with OxyContin post-marketing, FDA has undertaken a number of actions to help prevent prescription drug abuse.

First amongst these is FDA's actions and planned actions with the regard to drug labeling of the high dose opiates, particularly the extended release products. Labeling not only serves as an important means of informing prescribers and patients about the proper use of a drug, but also importantly defines the bounds of marketing and advertising for that drug. Labeling to these opiate products should emphasize that drug treatment for pain should be initiated at a lever appropriate to the pain and condition of the patient.

Additionally, labeling should help prescribers properly assess potential patients for the likelihood of abuse. In particular, patients with a personal history of substance abuse or a strong family history of abuse should be considered as being at higher risk for drug abuse. It should be noted that when significant changes are made to a drug's labeling, FDA encourages the drug sponsors to notify health care professionals, and to educate them about the serious risks. And FDA helps in the dessimination of this information via its Med Watch program and its Web page, amongst other means.

A second important means by which FDA addresses issues of drug abuse is through the regulation of prescription drug marketing.

A third way that FDA can use to address these problems is through the development of risk management plans as I mentioned earlier.

A fourth means that FDA uses to meet this challenge is by working with other involved entities, such as government agencies, industry and professional groups. We work with them to share information and insights needed to address this broad problem. For instance, FDA and DEA meet regularly to discuss ways to prevent prescription drug abuse and diversion, and we are working on the following areas with DEA: physician education, State prescription drug monitoring programs, a joint task force participation focused on illegal sale of controlled substances, and the assessment of new products with abuse potential.

In conclusion, FDA recognizes the serious problem of prescription drug abuse. The agency has taken many steps to address this serious problem and will continue to act to curb abuse, misuse, and diversion. Since this problem is broad in its scope and implications, we are committed to working with our partners. We share the subcommittee's interest and concerns regarding prescription drug abuse and would be happy to answer any questions.

Thank you.

Mr. SOUDER. Thank you. We will now hear from Mr. Tom Raffanello, Special Agent in Charge, Miami Division, Drug Enforcement Administration. Thank you for coming today.

[The prepared statement of Dr. Meyer follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

STATEMENT BY

ROBERT J. MEYER, M.D.

DIRECTOR, OFFICE OF DRUG EVALUATION II

CENTER FOR DRUG EVALUATION AND RESEARCH

U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

FEBRUARY 9, 2004

RELEASE ONLY UPON DELIVERY

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. I appreciate the opportunity to talk about FDA's drug approval process and role in preventing prescription drug abuse.

Recognized worldwide as the regulatory gold standard for food and drug safety and effectiveness, the mission of FDA is to protect and advance the public health. FDA is strongly committed to promoting and protecting the public health by assuring that safe and effective products reach the market in a timely way and monitoring products for continued safety after they are in use.

FDA is aware of and is concerned about reports of prescription drug abuse, misuse, and diversion. We understand 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.

BACKGROUND

The Need for Effective Pain Relief

Millions of Americans suffer from chronic pain. The medical and lay literature has documented 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."[1] 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."[2] 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."[3]

Pain of moderate to severe intensity impacts many aspects of patients' lives, including enjoyment, work, mood, activity level, and ability to sleep or even walk. While a variety of drugs are available for the treatment of moderate to severe pain, opiates are an effective class of

[1] National Cancer Institute, 1990.

[2] Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. Panel Co-chairs: Daniel B. Carr, M.D., Massachusetts General Hospital's Division of Pain Management, and Ada Jacox, Ph.D., R.N., Johns Hopkins University School of Nursing. Guideline Release Date: March 5, 1992.

[3] Joint Commission Focuses on Pain Management, Press Release, Joint Commission on Accreditation of Healthcare Organizations, August 3, 1999.

medications that is recommended by numerous guidelines and statements for the treatment of pain. For many patients, adequate pain relief will only occur through the proper, informed use of opiates as a part of their treatment.

FDA must assure that patients who require narcotics for pain control maintain full, appropriate access to them through informed providers, while limiting misuse, abuse and diversion of these products. FDA takes its responsibility in meeting this challenge very seriously. Given the broad scope of factors at issue, it is essential that FDA work in concert with other government agencies, professional societies, patient advocacy groups, industry, and others to share information to take steps to prevent abuse and misuse while ensuring that these products are available for patients who need them.

The Problem of Prescription Drug Abuse

FDA is concerned about the rising abuse of prescription drugs. Abuse of opioid analgesics (substances with an addiction potential similar to that of morphine), in particular, has risen steadily over the past five years. By contrast, rates of abuse of illicit drugs have been relatively stable over the same time period.

The Substance Abuse and Mental Health Services Administration (SAMHSA) conducts the National Survey on Drug Use and Health annually on a random sample of U.S. households to determine the prevalence of non-medical use of illicit and prescription drugs. In 2002, an estimated 6.2 million persons in the U.S. over the age of 12 reported having used one or more

psychotherapeutic drugs (stimulants, sedatives, tranquilizers, and analgesics available through prescription) for non-medical purposes at some time in their lives. This represents 2.6 percent of the population aged 12 or older. Stimulants, analgesics, and tranquilizers were the most widely used drugs that fit this category. This is a significant annual increase from 2001 when 3.5 million persons reported non-medical prescription drug use, and from 2000 with an estimate of 1.6 million users.

The consequences of this dramatic rise of prescription drug abuse are great. SAMHSA's Drug Abuse Warning Network (DAWN) surveys a national sample of emergency departments. DAWN captures drug-related visits to emergency departments (ED) contacts for non-medical use of substances for psychic effects, dependence, or suicide attempt. 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 (single and combination products) show that ED contacts increased from 6,429 in 1999 to 22,397 in 2002. Sustained release oxycodone (OxyContin is the sole approved sustained release oxycodone product) contributed to most of the observed increase, with ED mentions increasing from 1,178 in 1999 to 14,087 in 2002.

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 in the drug's labeling. It is important to realize, however, that there is always 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 if 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 (HHS) to notify the Attorney General through the Drug Enforcement Administration (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 management program (RMP) 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 most appropriately manage that risk.

OxyContin (oxycodone HCl)

OxyContin is a narcotic drug that was approved by FDA for the treatment of moderate to severe pain on December 12, 1995. OxyContin contains 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. OxyContin is the only currently marketed FDA approved controlled-release formulation of oxycodone. 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 and combination dosage forms.

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 were already 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 that has been reported over the past few years was not predicted. In fact, at the time of its approval, FDA believed that the controlled-release characteristics of the OxyContin formulation would result in less abuse potential since, when taken properly, 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 had been 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, that crushing the controlled-release capsule followed by intravenous injection or snorting would become 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 RMP. The program included strengthening OxyContin's warning label, educating healthcare professionals and Purdue Pharma'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 ACTIONS TO PREVENT PRESCRIPTION DRUG ABUSE

Labeling changes

FDA is responsible for ensuring that drug products are safe and effective for use as directed in the labeling. Part of the labeling for all drugs is the recommended prescribing information derived from the clinical trial data and approved by the scientists who review the products at the Agency. This prescribing information is essential for physicians who will be recommending products to their patients. Labeling can serve as a useful education tool for both physicians and patients. It also importantly serves to define the content of advertising and promotional materials about a drug. Establishing effective, consistent labeling of potent and long-acting opiate products will help assure that their marketing will be appropriate.

Most approved controlled-release, high-strength opiates contain a "black box" warning. Generally, when a serious risk is identified FDA works with the drug's sponsor to identify methods to manage that risk. The black box warning is one of these methods. FDA works with the sponsor on the specific language to be included in the warning. Boxed warnings are used in labeling to convey serious risks associated with the use of a drug product. The promotional materials of drug products with boxed warnings must present these serious risks in a prominent manner.

Labeling is helping prescribers properly identify patients for whom these products are appropriate. For the extended release products that contain high concentrations of an opioid drug, appropriate patients would have moderate to severe pain (i.e., pain that impacts on a person's ability to function) that requires continuous, around-the-clock therapy for adequate control over an extended period of time. While this description clearly would apply to many patients with cancer pain, it also properly includes many patients with chronic, non-cancer pain, such as those with severe osteoarthritis or many patients with neuropathic pain. Long-acting, controlled-release products are not suitable for patients who only need intermittent analgesia, nor patients for whom only a few days of therapy is thought to be needed (e.g., for wisdom tooth extraction). Such patients can be satisfactorily treated with immediate release opiates, if opiates are even needed. While current labeling for some drugs already stresses this indication (e.g., OxyContin), FDA will work to ensure consistent labeling across agents and that this message is clear and prominent.

Labeling should emphasize that drug treatment for pain should be initiated at a level appropriate to the pain and condition of the patient. Non-steroidal anti-inflammatory drugs are appropriate therapies for patients with lesser degrees of pain and even in more moderate pain, may be a reasonable first-line therapy. If opiates are needed for acute pain, initially or due to inadequate response to non-opiate analgesics, short-acting opiate formulations should be administered. The higher dosage forms (concentrations) of the extended release opiates are only safe and should only be used in patients already undergoing long-term treatment with high dose opiates and who are opiate-tolerant. FDA will work to assure the rational evaluation of pain and analgesia is more clearly delineated and stressed in the labeling of these products.

Finally, labeling should help prescribers properly assess potential patients for the likelihood of abuse. In particular, patients with a personal history of substance abuse or a strong family history of substance abuse should be considered as being at higher risk of abuse. While use of opiates may still be appropriate in such patients when they have conditions requiring effective pain control, these patients deserve even more careful assessment in follow-up for signs of abuse.

Monitor Drug Advertising and Promotion

FDA has regulated the advertising of prescription drugs since 1962, under the FD&C Act and its implementing regulations. The 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 accurately communicated. 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 regulates prescription drug advertisements and other promotional materials (called "promotional labeling") disseminated by or on behalf of the advertised product's manufacturer, packer, or distributor to health care professionals and consumers.

FDA continues to monitor promotional materials for controlled substances, particularly for sustained release products, to ensure that false and potentially misleading claims are not tolerated. To date, advertising and marketing for these products has been directed only to health care professionals, although direct-to-consumer marketing is not prohibited by the FD&C Act.

FDA will continue to encourage sponsors, as part of their RMPs, to voluntarily refrain from advertising directly to consumers as a means to avoid excessive or unnecessary use. Also, FDA regulations require that all product promotional materials prominently feature any information in "black box" warnings of a label. 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 could be considered false or misleading. Purdue Pharma, the sponsor of OxyContin, was cited in May 2000 and January 2003 for advertisements that promoted OxyContin in a manner that was false or misleading. In response, Purdue Pharma agreed to correct the 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 have good medicines available, but are not subjected to false or misleading claims.

Strong Risk Management Programs (RMPs)

FDA's September 2003 Anesthetic and Life Support Drugs Advisory Committee and a recent General Accounting Office report[4] recommended that the Agency encourage pharmaceutical manufacturers with new drug applications to submit plans for a RMP that contain a strategy for addressing abuse and diversion. The Agency agrees with these recommendations and believes that it is highly desirable for all extended release or high concentration Schedule II opiate drug products to have RMPs in place at the time of approval. FDA defines a RMP as a strategic safety program designed to decrease product risk by using one or more interventions or tools

[4] GAO Report (GAO-01-110) to Congressional Requesters entitled, *"Prescription Drugs – OxyContin Abuse and Diversion and Efforts to Address the Problem."*

beyond the package insert. RMPs across individual products would likely vary, depending on the approved indications and product-specific considerations, including the product's safety profiles. However, each RMP would appropriately address such elements as: 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, overdose, abuse, and diversion. Manufacturers have access to tools that help them effectively monitor for adverse outcomes including: access to drug utilization, distribution, and prescribing data; reports from physicians (manufacturers are required to provide safety reports to FDA); and access to various databases. The development of such programs would provide an added measure of safety in the drug approval process. FDA plans to provide more specific guidance to the pharmaceutical industry on the development, implementation, and evaluation of RMPs this year.

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 reports of OxyContin abuse and diversion, resulting in serious consequences including death were received, Purdue Pharma warned health care providers in the form of a "Dear Healthcare Professional" letter (issued July 18, 2001). The letter was issued to educate health care providers about these serious risks. The "Dear Healthcare Professional" letter was distributed widely 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 Page on FDA Web Site

An important component of FDA's strategic plan is to enable consumers to make smarter decisions by getting them 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 safely use their drug products. In an effort to educate health care providers and consumers about the risks associated with OxyContin, FDA has 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.

Advisory Committee Meetings

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 will more likely reflect a balanced evaluation. Committee recommendations are not binding on FDA, but the Agency considers them carefully when deciding drug issues.

FDA's Anesthetic and Life Support Drugs Advisory Committee has met twice within the last two years[5] 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.

Committee members agreed that opioids are essential for relieving pain. Members suggested that a balanced approach should be taken to relieve pain for patients and to prevent diversion. They noted that imposing restrictions on use of opioids could have substantial likelihood of hurting legitimate patients and reversing the tremendous progress that has been achieved in the appropriate treatment of pain.

Collaboration with Other Government Agencies, Professional Groups, and Industry

FDA has met and continues 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.

FDA and DEA meet regularly to discuss new ways to prevent prescription drug abuse and diversion. A description of joint investigative efforts is discussed later in the enforcement

[5] Meeting of FDA's Anesthetic and Life Support Drugs Advisory Committee, September 9-10, 2003, Bethesda, Maryland. Transcript located at: *http://www.fda.gov/ohrms/dockets/ac/cder03.html#AnestheticLifeSupport*; Meeting of FDA's Anesthetic and Life Support Drugs Advisory Committee, January 30-31, 2002, Gaithersburg, Maryland. Transcript located at: *http://www.fda.gov/ohrms/dockets/ac/cder02.htm#AnestheticandLifeSupport.*

section of this testimony. In addition to assisting one another with criminal investigations, both agencies are currently working together on the following initiatives:

- *Physician Education* - In order to prescribe controlled substances, including opiate analgesics, physicians must maintain a registration with the DEA, which is renewed on a periodic basis. Currently, there is no requirement for demonstration or attestation of knowledge or training in order to maintain DEA registration. FDA supports linking renewal of DEA registration to up-to-date training and education in the appropriate prescribing of opiate analgesics in some appropriate manner.

- *State Prescription Drug Monitoring Programs* – States that have monitoring programs have shown lower levels of abuse and misuse of scheduled drugs compared to 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. FDA strongly supports state-based prescription drug monitoring programs.

- *Task Force Participation* – FDA Office of Criminal Investigations (OCI) agents 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. Examples of

some of the working groups both agencies are members of are: 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, NIDA, SAMHSA, National Institutes of Health), DEA, ONDCP and other agencies to address issues of drug abuse and control under the CSA.

- *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 FDA's regulatory issues involving 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 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.

Enforcement

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 OCI is working closely with DEA on criminal investigations involving the illegal sale, use, and diversion of controlled substances, including illegal sales 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, which have been taken. FDA, DEA, FBI, and Main Justice have worked together to pursue other significant Internet pharmacy cases involving prescription drugs, and these enforcement efforts will continue.

A subset of the criminal cases investigated by FDA has involved the drug OxyContin. Since 1998, OCI has opened 46 criminal investigations relating to OxyContin. Twenty-four of these cases have successfully been adjudicated, resulting in a variety of criminal penalties. 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 those individuals involved in such activities criminally responsible. This relationship will continue to be important as the Federal government addresses the increasing number of websites that offer controlled substances.

CONCLUSION

FDA recognizes the serious problem of prescription drug abuse. The Agency will continue to take steps to curb abuse, misuse, and diversion 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.

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

Mr. RAFFANELLO. I am here before you today to discuss the challenge of prescription drug abuse, and the efforts of the DEA to combat it. My name is Tom Raffanello, I am the Special Agent in Charge of DEA's Miami Field Division, which is the entire State of Florida.

I would like to thank this subcommittee on behalf of Administrator Tandy for your unwavering support of the men and women of the Drug Enforcement Administration and its mission.

Opiates in pill form have historically been among the most abused prescription drug, especially hydrocodone, hydromorphone and oxycodone. Diverted from legitimate channels these drugs can substitute for illegal narcotics and are frequently trafficked on the street by individuals or structured organizations. As far back as the 1970's, hydromorphone based Dilaudid was known on the street as drugstore heroin. Prescription drug abuse has recently escalated to a new level of concern with the development of opiate-based pain killers designed for controlled or sustained release. These products pose special challenges to law enforcement. It is easy to see why when you consider OxyContin contains 2 to 16 times the dosage of oxycodone as its well known predecessor Precodan.

OxyContin is also the most widely known example of an abused prescription drug, and its diversion has increased dramatically since its introduction into the market. OxyContin is a valuable and efficient pain management drug when properly prescribed and used. At the same time, however, its popularity for abuse sky-rocketed when word made its way to the street that manipulating this powerful drug can bring heroin-like effects. DEA has never witnessed such a rapid increase in the abuse and diversion of a pharmaceutical drug product.

The popularity of OxyContin and other drugs of abuse have also inspired a wide range of diversion methods, some new and some old. Practitioners and pharmacists illegally or indiscriminately prescribe or dispense OxyContin for profit. Addicts and dealers steal drugs through pharmacy thefts and in-transit highjacking. Forged or fraudulent prescriptions are common occurrences as are patients who claim false medical needs. Doctor shopping abusers travel from doctor to doctor to find an easy mark who will readily write prescriptions or who can be duped.

Foreign diversion and smuggling of contraband drugs into the United States continues to be a problem. Perhaps the greatest concern, the Internet, has become a virtual wild west bazaar for spam e-mails and Web site advertisement that sell controlled substances with little or no oversight that the drugs are sold for legitimate medical reasons.

At times, multiple methods of diversions occur simultaneously. In Sarasota, FL, a physician recently was arrested for writing prescriptions for controlled substances to known drug dealers and abusers including Dilaudid and OxyContin. The doctor saw as many as 80 patients daily, charged $250 for an initial office visit and $150 for followup appointments. During the search of the physician's office, DEA and local law enforcement seized approximately 25,000 dosages of controlled substances including large quantities of oxycodone, methodone, and hydrocodone.

In response to growing concern among Federal, State, and local officials about the dramatic increase in the illicit availability and abuse of OxyContin, the DEA initiated an OxyContin action plan in May 2001 as a comprehensive effort to prevent diversion and abuse of the drug. This is the first time the DEA has taken such a comprehensive approach to a particular brand name prescription drug. The initiative is not intended to impact the availability of OxyContin for legitimate medical use.

The plan has four main goals: First, to enhance the coordination of enforcement and intelligence programs with other Federal, State, and local agencies to target individuals and organizations involved in the illegal sale and abuse of OxyContin.

Second, to use the full range of regulatory and administrative authorities to make it more difficult for abusers to obtain OxyContin. The DEA does this by closely monitoring the quota of oxycodone available to manufacturers, continue to work with the FDA to reduce the abuse of reformulated OxyContin by injection, and to continue our efforts to improve physician education on treatment of pain and recognition of addiction.

Third, increase the cooperative efforts with the pharmaceutical industry.

Fourth, advanced national outreach to educate the public, the health care industry, the schools, and the State, and local governments on the dangers related to abuse and diversion of OxyContin.

DEA is also, working with States on prescription monitoring programs, to prevent diversion at the State level. PMPs capture information regarding prescriptions electronically at the point of sale, usually the pharmacy. The information is transmitted to a State agency to identify the doctor shoppers, and/or other evidence of diversion. Sixteen States have activated PMPs and another five States have partial or pending programs. The General Accounting Office concluded in a 2002 study that PMPs have aided investigators and helped to reduce doctor shopping.

For the past 2 years, Congress has appropriated funds for States to initiate and expand PMPs. Florida has applied for an enhance grant of $350,000 to augment an initial grant beginning in January 2005.

Mr. SOUDER. Mr. Raffanello, if you could kind of summarize.

Mr. RAFFANELLO. Surely.

The DEA is committed to protecting the American public's health and safety from the serious consequences of abuse of legal pain relief for life destroying illegal purposes.

Initiatives like the OxyContin action plan, PMPs and additional diversion investigators to be able to work on the Internet abuse that we have will help the enforcement effort that we feel is the key into slowing down and doing with the problem.

I thank you very much, and I will answer any questions that you gentlemen have.

[The prepared statement of Mr. Raffanello follows:]

Statement of
Thomas W. Raffanello
Special Agent In Charge, Miami Division
U.S. Drug Enforcement Administration

Before the

U.S. House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
February 9, 2004

"To Do No Harm: Strategies For Preventing Prescription Drug Abuse"

Executive Summary

The rapid rise and widespread abuse of new generation high potency prescription drugs like OxyContin® presents new strategic challenges in controlling the longstanding problem of prescription abuse. In addition to traditional methods of diversion such as forged and fraudulent prescriptions, pharmacy theft, and doctor shopping, new technology has facilitated increased diversion of drugs through "rogue" Internet pharmacies. In response, DEA is creating a sophisticated infrastructure that will use an encryption system known as Public Key Infrastructure (PKI) to protect against fraudulent prescriptions as well as an advanced system that will search the online public domain for illicit drug activity. In addition, the 2001 DEA OxyContin® Action Plan has spurred a flurry of joint enforcement operations with state and local agencies to combat traditional methods of diversion. We also continue to work with state officials on Prescription Monitoring Programs (PMP) to prevent diversion at the point of sale and participate in numerous Joint Task Forces nationwide to combat the abuse of pharmaceutical controlled substances and health care fraud. Our approach to illicit diversion of prescription drugs is reasonable and ensures adequate supplies of pain medications are available for those with legitimate needs while protecting the public from the consequences of abuse.

Chairman Souder and distinguished members of the Subcommittee, it is a pleasure to appear before you today to discuss the challenge of prescription drug abuse and the efforts of the Drug Enforcement Administration to combat it. My name is Thomas Raffanello, and I am the Special Agent In Charge of the Miami Division. Mr. Chairman, on behalf of Administrator Karen P. Tandy, I would like to thank this subcommittee for its unwavering support of the men and women of the DEA and its mission.

Introduction

DEA has primary authority to prevent and prohibit the diversion and improper use of controlled substances under the Controlled Substances Act (CSA), as well as the duty to ensure their availability for legitimate medical and scientific needs. While the problem of prescription drug abuse unfortunately is not a new one, its urgency has been heightened by a new generation of high dose, extended release, opioid pain medications. Along with greatly increased effectiveness to treat pain, these drugs also offer equally increased risk of abuse and diversion that force a delicate balance for medical and health professionals and law enforcement personnel. OxyContin®, Duragesic® and Actiq® are examples of this type of licit drug. The potency, purity and quantity of their active ingredients are stronger and more dangerous than ever before, tempting addiction by legitimate patients and offering a high potential for deliberate abuse by those seeking narcotic drugs. In addition, these powerful drugs provide strong incentives for diversion by both new means such as "rogue" Internet pharmacies and older challenges such as improper prescriptions written for profit. The DEA is committed to aggressively address and counter the risks posed solely by this new generation of prescription drugs and their abuse.

Personifying a Different Type of Drug Abuser

Prescription drugs can be an easy and insidious form of abuse for a variety of reasons. Abusers know that prescription drugs are not adulterated and have standardized, precise dosages. Abusers believe that "If my doctor can prescribe it for me, it can't be bad." Many think that if the user does not inject the drug, he or she is not truly a drug abuser. Controlled substances obtained via prescriptions are frequently covered by health insurance or Medicaid. Finally, prescription drugs are readily available through open commercial markets.

Opiates in pill form have historically been among the most abused prescription drugs, especially hydrocodone, hydromorphone, and oxycodone. Diverted from legitimate channels, these drugs can substitute for illicit narcotics and are frequently trafficked on the street by individuals or structured organizations. As far back as the 1970s, hydromorphone-based Dilaudid® was known on the street as "drug store heroin."

Increasing Abuse of Controlled Release and Sustained Release Opiates

Prescription drug abuse has recently escalated to a new level of concern with the development of opiate-based pain killers designed for controlled or sustained release. These products pose special challenges to law enforcement. It is easy to see why when you consider that OxyContin® contains two to sixteen times the dosage of oxycodone as its well known predecessor Percodan®.

OxyContin® is also the most widely known example of an abused prescription drug, and its diversion has increased dramatically since its introduction to the market. OxyContin® is a valuable and efficient pain management drug when properly prescribed and used. At the same time, however, its popularity for abuse skyrocketed when word made its way to the street that manipulating this powerful drug can bring heroin-like effects. DEA has never witnessed such a rapid increase in the abuse and diversion of a pharmaceutical drug product.

Problems with OxyContin® diversion occurred relatively soon after its initial marketing. By 2000, DEA had noted a dramatic increase in its illicit availability and abuse. Available data for the following year indicated that OxyContin® reached record levels of diversion and abuse never before seen. In 2001, the DEA's National Forensic Laboratory Information System (NFLIS) reported double the amount of drug exhibits analyzed by state and local forensic laboratories contained oxycodone in comparison to 2000. OxyContin® diversion first emerged as an issue in rural areas of the eastern United States, particularly in parts of Appalachia and New England, and became so prevalent it is known as "hillbilly heroin." Its popularity among prescription drug abusers spread quickly, and it was not long before OxyContin® abuse and diversion widened to other parts of the country, including Florida.

OxyContin® abuse has been so prevalent in the Florida Panhandle and the Jacksonville area that DEA, the Federal Bureau of Investigation (FBI), the Defense Criminal Investigative Service, the Florida Attorney General's Medicaid Fraud Control Unit, the Florida Department of Financial Services and the Bay County Sheriff's Office formed the North Florida Health Care Task Force (HCTF) in 2001. The Task Force combats abuse of pharmaceutical controlled substances and health care fraud. HCTF recently created an OxyContin® focus group to concentrate on the diversion of OxyContin® in the Florida Panhandle area.

Investigative successes are having an impact, but also highlight the extent of the problem of prescription drug abuse. In September 2002, the Citrus County Sheriff's Office arrested the owner and pharmacist of an Inverness, Florida pharmacy for diverting several hundred OxyContin® pills from his pharmacy each week. A subsequent DEA investigation and audit revealed shortages of approximately 90,000 pills of diverted drugs in just ten months, including approximately 36,000 tablets of oxycodone products and 54,000 tablets of hydrocodone products. The pharmacist was recently sentenced to five years imprisonment. More recently, the HCTF apprehended a Panama City, Florida physician on several counts of illegal distribution of controlled substances, including distribution resulting in death. Our enforcement operations have also had a positive effect on public awareness. The DEA Tallahassee Resident Office has responded to numerous telephone calls, ranging from inquiries as to where to obtain substance abuse treatment to physicians asking how to handle the influx of patients requesting OxyContin® prescriptions.

Methods of Diversion

The popularity of OxyContin® and other drugs of abuse have also inspired a wide range of diversion methods, some new and some old. Practitioners and pharmacists illegally or indiscriminately prescribe or dispense OxyContin® for a profit. Addicts and dealers steal drugs through pharmacy thefts and in-transit hijackings. Forged or fraudulent prescriptions are common occurrences, as are patients who claim false medical needs. "Doctor Shopping" abusers travel from doctor to doctor to find an easy mark who will readily write prescriptions or who can be duped. Foreign diversion and smuggling of contraband drugs into the United States contributes to the problem. And perhaps of the greatest concern, the Internet has become a virtual wild west bazaar for "spam" emails and website advertisements that sell controlled substances with little or no oversight that the drugs are sold for legitimate medical reasons. At times, multiple methods of diversion occur simultaneously. In Sarasota, Florida, a physician recently was arrested for writing prescriptions for controlled substances to known drug dealers and abusers including Dilaudid® and OxyContin®. The doctor saw as many as 80 patients daily and charged $250.00 for an initial office visit and $150.00 for follow-up appointments. During the search of the physician's office, DEA and local law enforcement seized approximately 25,000 doses of controlled substances including large quantities of oxycodone, methadone and hydrocodone.

Preventing Diversion

The OxyContin® Action Plan

In response to growing concern among federal, state and local officials about the dramatic increase in the illicit availability and abuse of OxyContin®, the DEA initiated an OxyContin® Action Plan in May 2001 as a comprehensive effort to prevent diversion and abuse of the drug. The initiative is not intended to impact the availability of OxyContin® for legitimate medical use.

The OxyContin® Action Plan has four main goals: First, enhance coordination of enforcement and intelligence programs with other federal, state, and local agencies to target individuals and organizations involved in the illegal sale and abuse of OxyContin®. Second, use the full range of regulatory and administrative authorities to make it more difficult for abusers to obtain OxyContin®. The DEA does this by closely monitoring the quota of oxycodone available to manufacturers, continuing to work closely with the Department of Health and Human Services to reduce the abuse of reformulated OxyContin® by injection, and continuing our efforts to improve physician education on treatment of pain and recognition of addiction. Third, increase cooperative efforts with the pharmaceutical industry. Fourth, advance national outreach to educate

the public, the healthcare industry, schools and state and local governments on the dangers related to the abuse and diversion of OxyContin®.

Since implementation of the OxyContin® Action Plan, DEA has initiated over 400 OxyContin® investigations, resulting in the arrest of approximately 600 individuals. Sixty percent of the cases initiated involved professionals such as doctors and pharmacists. Doctor shoppers, forgers, and individuals arrested for armed robberies and burglaries accounted for the remaining forty percent of the investigations.

The plan's impact locally is best illustrated by the recent arrest of a physician in Melbourne, Florida who was charged in state court with eleven counts related to trafficking large quantities of OxyContin® and other controlled substances. The investigation further revealed that office employees were operating a drug ring using the physician's prescriptions. To date, forty people have been arrested for illegal drug trafficking as a result of this investigation.

Prescription Drug Monitoring

The DEA is also working with states on Prescription Monitoring Programs (PMP) to prevent diversion at the state level. PMPs capture information regarding prescriptions electronically at the "point of sale," usually the pharmacy. The information is transmitted to a state agency to identify doctor shoppers and/or other evidence of diversion. Sixteen states have active PMPs and another five states have partial or pending programs. The General Accounting Office concluded in a 2002 study that PMPs "... have aided investigators and helped to reduce doctor shopping ..." For the past two years, Congress has appropriated funds for states to initiate and expand PMPs. Florida has applied for an enhancement grant of $350,000 to augment an initial grant beginning in January 2005. Use of these funds is contingent upon the passage of legislation during Florida's current legislative session.

Internet Initiatives

Although the Internet has fostered the diversion of controlled substances and the inappropriate use of other drugs, it can also be used as a tool to reduce prescription fraud. As part of an overall modernization effort, DEA is developing regulations that will allow physicians to use the Internet to securely transmit prescriptions from their offices to the patient's pharmacy. These regulations will specify standards to electronically transmit prescriptions to foil prescriptions from being altered and prevent office staff from making fraudulent telephone authorizations on behalf of physicians. DEA anticipates that the regulations will be finalized this year with procedures being implemented in 2005.

DEA is also examining ways to deal with the recent rapid proliferation of "rogue" Internet pharmacies. During 2004, DEA intends to improve our capacity to identify illicit operations and better restrict internet sales of controlled substances through the use of a new and advanced system that will search the online public domain for illicit drug activity. We anticipate receiving $2.1 million and more than 60 diversion and support positions dedicated to the Internet diversion problem under DEA's Fiscal Year 2004 budget. We also plan to work with the Food and Drug Administration (FDA) and other agencies to better educate the public and work with those companies that facilitate the illegal sale of controlled substances including commercial freight carriers, credit card companies and Internet search engines.

Understanding Pain Management

As I mentioned earlier, high-dose opiates can be an important and legitimate means of pain relief. In striking the delicate balance between preventing abuse and facilitating patient care, the DEA believes that physician education and cooperation with medical groups is essential. The DEA agrees with 21 health care organizations who endorsed a balanced approach to the use of pain medications like OxyContin®. We are continuing to work with organizations such as Last Acts and the University of Wisconsin Pain and Policy Studies Group to formulate Frequently Asked Questions (FAQs) for physicians and investigators alike to clarify appropriate prescribing issues. These FAQs will be made available to interested parties through DEA's website and other media. The DEA is also exploring continuing medical education opportunities for physicians that will become electronically available when a physician applies for, or renews, a DEA registration.

Conclusion

The DEA is committed to protecting the American public's health and safety from the serious consequences of abuse of legal pain relief for life destroying illegal purposes. Initiatives like the OxyContin® Action Plan, PMPs, additional funding and positions for DEA diversion investigations, and our new Internet search system will enhance the DEA's enforcement efforts to stop the flow of prescription drugs from reaching our streets illegally.

I would be happy to answer any questions the Subcommittee may have.

Mr. SOUDER. Thank you.

Let me start with Dr. Meyer. You said in your testimony that the FDA did not anticipate what was going to happen when you first cleared this OxyContin. Do you seek input from DEA and all the anti-narcotic agencies when you are clearing it?

Dr. MEYER. We notify DEA, of the fact that we have the NDA in house and we work with DEA on establishing a quota for the drug substance that goes into the drug product.

Mr. SOUDER. Do you believe that the actions, because you gave me a list of actions that you have done since then because, according to your testimony, as the abuse spread, FDA then changed labeling, and you have been trying to catch up. Do you believe had you done all those things at the beginning, we would not have this problem or do you believe that the things that you are doing are not effective in stopping the problem unless something else is done?

Dr. MEYER. I think that the things that we have done will have an effect and I think if we had put them in place at the beginning, that we would have less of a problem than what we have now, but I think the problem goes beyond the means available to the FDA, or beyond this particular drug.

Mr. SOUDER. Mr. Raffanello, you stated that there has not been another prescription drug abused at this level?

Mr. RAFFANELLO. That is correct.

Mr. SOUDER. Anything even approximating?

Mr. RAFFANELLO. I believe Dilaudid for many, many years has been used as a heroin substitute, and very effective.

Mr. SOUDER. What would you have done differently at the beginning, and as we look at other similar things possibly coming on the market, because at this point if OxyContin went off something else would likely come on. What would you do different at the very beginning in addition to some of the things I think we are trying to address now, because once it starts to explode, it is just so hard to control it?

Mr. RAFFANELLO. Being a career law enforcement officer, I would make sure that practitioners and pharmacists knew that there would be a penalty to pay for over-prescribing or for doing anything that even smites of going against the law. I think strong law enforcement would be a key.

Mr. SOUDER. Mr. Fernandez, you stated in your testimony that you would first look at—which is kind of a logical business approach—at the top 10 people who are currently prescribing it. Is that not being done? It does not mean that they are doing it illegally, but why would that not be the first place you would look? I think your testimony said that there were the top 12 OxyContin prescribers for Medicaid, the 12 doctors that wrote prescriptions this figure represents so much, should our efforts to bring this abuse under control not start here? Why would it not start here, what is keeping it from starting there?

Mr. FERNANDEZ. I do not know that anything is keeping it from being started. I think I made the statement basically to show you—I mean, to me it is just inconceivable that 12 doctors wrote prescriptions totaling that much. And that is just Medicaid. I do not know how many more they wrote that had nothing to do with Medicaid.

Mr. SOUDER. You coordinate the Central Florida HIDTA, Mr. Raffanello is the Miami DEA person, we have the representative from FDA. I would like to know why would it not start there, and why has nobody started there?

Mr. FERNANDEZ. I do not think it is—and I could be wrong here, but I do not believe anyone knows when they are writing it until after the fact, and then it is too late. That is why at the end of mine, I recommended this the Florida——

Mr. SOUDER. Who has jurisdiction to start that? Would that be an FDA responsibility to look at that currently, and say we have 12 doctors who wrote this many? Here is what it seems like. I am a Member of Congress, and this is still what it seems like. I thought it would be different after I got out of the private sector into the public sector, that when we go after hospitals in the United States for Medicaid or Medicare or whatever, it seems like we take the ones that are easy pickings off the tree who are filing all the stuff and we get somebody who has 2 percent of the market and skip the people who have 90 percent of the market. It does not mean that these 12 doctors are doing anything wrong, but why would that not be the first place you look to check and see what the failures of the system are? Have those people been looked at and who would be responsible for that, I do not understand here?

Mr. RAFFANELLO. Maybe I can help. The Drug Enforcement Administration has a diversion responsibility, and in that responsibility we monitor practitioners and doctors. I would—unfortunately I would like to go back to the times that Congressman Norwood said, when they were kept under lock and key. It is one thing to be able to look and see a pattern, it is another thing to effect an arrest, and get someone to prosecute the case. It is very, very difficult to prosecute and convict a doctor or a prescriber for one of these types of offenses initially. But in my opinion, that is where the work really needs to be done. If people that prescribe this knew there was a severe penalty to pay, you would have less people doing it. And that is where we should start.

Mr. SOUDER. Mr. Mica.

Mr. MICA. Let me just continue along the line of questioning of Chairman Souder. It is difficult to convict—where is the flaw, is it in the Federal law, is it in the FDA regulations of the narcotic? What is the problem?

Mr. RAFFANELLO. I think it is a fairly new phenomenon. I think that the States may in some cases not have the law. We have—in Federal statutes, we can take the doctor's license away. Criminal statutes are always the last resort. I would like to see prosecutors more energized to pursue criminal statutes, I would like to see the States work through their legislation to have severe criminal penalties for doctors, for pharmacists, and for people that prescribe it. I think that the groundwork is there, I just do not think we have them to the level that we need to have them to make the impact that we want to have.

Mr. MICA. Is this something we need to do from a Federal level or State by State? I mean, it does not sound like we can get a handle on it if we rely on 50 legislatures to act.

Mr. RAFFANELLO. Speaking from the Florida situation, we are very fortunate here. I work with Jim McDonough, the director of

the Florida Office for Drug Control, and they aggressively pursue this in the State of Florida.

Mr. MICA. But, again, OK that is a State agency, we have the HIDTA which does the combination State, Federal, all efforts, you are DEA, Federal. Do you have enough laws and tools to deal with this? You also testified and we heard similar testimony about diversion, about Internet access. Chairman Norwood said that his young 13 year old could get this stuff in quantities. We need to know where the gaps are and if they are Federal gaps we need to know that, and particularly from you. So you are recommending tightening one, two, three, tell us?

Mr. RAFFANELLO. At first I would look—the Internet has been a tremendous source for drug distribution. I would go back and see what we have. If someone in Oklahoma, took applications and prescribed drugs in Florida, they should be able to be tried in whatever district is affected. I believe that the law on that is very vague right now.

Mr. MICA. Right. Now, the other thing you have is people becoming addicted to a legal source of the prescription and then the second part is illegal availability through prescription fraud. You described prescription fraud. How do we address that from a Federal standpoint? Those two.

Mr. RAFFANELLO. I would go back to more inspections on doctors and pharmacists, and tighter reins on just what they are doing. I think the prescription program that we are now trying to work with Congressman Rogers' help would be something that I would like to see supported, so we can automatically see who is being prescribed. I think we have mechanisms that need to be tightened up there, and need to be applied across more States.

Mr. MICA. All right. FDA.

Dr. MEYER. Yes, sir.

Mr. MICA. Abuse of narcotics as we have heard, I gave this historical sequencing, starting in this room with election of Senator Hawkins, the cocaine problem, the heroin problem. Of course, we have cited here a different prescription drug problem and this is now a prescription drug of choice that we found being diverted. Has FDA adequately changed its rules, its regulations regarding abuse and misuse of this substance?

Dr. MEYER. I think that a lot of the abuse and misuse is occurring in circumstances where FDA does not actually have strict purview. I think our main——

Mr. MICA. So does the law need to be tightened to give you that purview?

Dr. MEYER. I think I would defer to DEA, since DEA has the jurisdiction on this, whether they would need something, but, FDA does not regulate the practice of medicine. Much of this is occurring in the setting of——

Mr. MICA. Well, you discovered a drug where we have deaths off the chart here that doctors are—and we have had testimony here of 12 doctors on Medicaid issuing incredible volumes of this stuff and people are dying in an unprecedented numbers. So you either you change the rules or we change the laws, and if we need to change the law, do we have enough laws directing FDA to deal with this or do you already have that authority?

Dr. MEYER. Again, I do not believe we have the authority to act with regard to how these drugs are used in the practice of medicine.

Mr. MICA. All right, I want you to submit to me a written statement. You can do it through the committee of what it would take for you to have the authority under the law to more aggressively pursue this matter, can you do that?

Dr. MEYER. We can do that, be happy to do that.

Mr. MICA. As an agency—and I would like you to submit the same thing to me as far as any loopholes or changes that DEA sees—our enforcement agency—so we have a better handle on how we can change the law. You have the ability to change regulations already within the law, so I need to know specifically what we can do.

Mr. Fernandez, you talked a little bit about electronic data validation, the problem with getting a handle on people who are prescription shopping and I was interested in that. Could you elaborate a little bit more how we get a handle on medications, not just OxyContin, but drugs that can be used, prescription drugs that can be used and abused, and how do we get a better handle on all of this?

Mr. FERNANDEZ. Yes, sir. I think there is a gap between the doctor writing the prescription and the people that give that doctor the ability to write that prescription. I do not think the Federal level gets the information as rapidly. I do not know if they get it at all in some cases, but I certainly do not think they get it in a timely manner. That was one reason I referred to the Florida prescription validation program. And I do not claim to be an expert on that. Mr. McDonough can certainly tell you more about that then I could. But, as I understand it, a prescription would be written and it would be computerized and State officials would know. I would assume then they would see a doctor writing more than he should be.

Mr. MICA. It disturbs me when we have a Federal program and you cited, right, 12 Medicaid doctors?

Mr. FERNANDEZ. I got that from a newspaper article; yes, sir; 12 doctors wrote prescriptions totaling over $15 million.

Mr. MICA. So, a Federal program they are gaming to bring on the market, a substance of which hundreds of our people are dying. Well, I would like to—Mr. Chairman, I did have an opportunity to meet with some folks I believe that are involved in this electronic data validation program under Medicaid, which I believe the feds and also, the State is supporting. I would like to ask unanimous consent to submit for the record testimony by Jim Kragh who is the president of Good Health Networking. He demonstrated to me I guess this is just a little type of a Palm Pilot. But the software does electronically validate prescriptions, gives us a better handle on what prescriptions and what amounts, and who the users are.

So, I would like Mr. Kragh's testimony to be submitted as part of the record, describing what I understand in central Florida we have over 800 physicians participating in this demo to get a handle on where these prescriptions are written. So I ask unanimous consent for that submission.

Mr. SOUDER. Without objection, so ordered.

[The information referred to follows:]

Statement by
James F. Kragh
President and Chief Executive Officer
Good Health Network

Before the

U.S. House of Representatives
Committee on Government reform
Subcommittee on Criminal Justice, Drug Policy
And Human Resources
February 9, 2004

Executive Summary

More than a year and a half ago the Florida Department of Medicaid understood that there were numerous problems and issues with the ability to track the specific reasons for the enormously high costs for the drugs dispensed under the Medicaid Program. The Program knew the potential existed for fraud and abuse, for duplication of prescriptions, and for waste within the system. Previously the Department had developed a Preferred Drug List (PDL) in an effort to reduce the number of drugs that needed to be monitored and to take advantage of better pricing through volume purchasing. The PDL was provided to physicians in paper format and through extensive monitoring the Department ultimately gained a major improvement in compliance with ordering drugs only from the PDL unless prior authorization was received for ordering non-PDL drugs. This helped in controlling some of the cost side of the equation.

The second step in a vigilant effort to address the issues occurred last year with the development of a partnership between Gold Standard MultiMedia, Inc, an online pharmacology company and Sprint United Management Company, a wireless service provider. This partnership brought together the Florida Medicaid PDL, the Florida Medicaid database of patient drug history (most recent 60-day prescription history), and the Gold Standard Pharmacology system onto a hand-held wireless PDA (Pocket PC). Each of the Pocket PCs included a PKI-based digital certificate to authenticate the user and provide for secure transmission of the data to and from the state database and the end user. GHN has deployed a sophisticated infrastructure that will use an encryption system known as Public Key Infrastructure that will provide secure and identifiable role-based access into the Medicaid database. Note: the PKI-based digital certificate is currently in place, but is not being utilized at the present time, pending the E-prescribing function. An SSL-based certificate is being used.

This pilot program will enable the 1000 participating physicians to access a 60-day drug history for all of their Medicaid patients, once the patient's Medicaid number is entered. This function has already demonstrated the ability to discover numerous drug shoppers. It also has allowed physicians to discover the patients who do not get their scripts filled after the physician writes the prescription. This helps the physician identify the non-compliant patient. This portion of the program will help reduce the duplication of services (drug shoppers) and reduce some of the fraud and abuse (both drug shoppers and stolen, forged prescriptions). As an example, a doctor in the Orlando area discovered that prescriptions were still being filled under his name for patients that he had not seen in more than a year.

The physicians also now have access to the State PDL online which means they don't have to deal with hundreds of pages of computer print-out that was, at best, cumbersome to use. While compliance with the PDL was quite high, the PDA (which is also a 'Smart' cell phone with Internet access) has provided a better method for requesting prior authorization, thereby making the physician more efficient. The cell phone portion of the PDA includes a speed dial function to contact the prior authorization section of the Medicaid Department.

The pharmacology program that resides on the PDA provides the physician access to basically any drug on the market today and includes the drug-to-drug interactions, IV alerts (interactions for IVs), and food to drug interactions. The physician now has immediate access to information that has the potential to reduce medication errors.

While the actual outcomes study of this pilot program will not be completed until mid-year the results in identifying drug shoppers, lost, stolen, forged prescriptions, and improved compliance with the PDL have convinced the Medicaid Department that expansion of the project should be considered for the coming fiscal year. The initial thought is to add approximately 2000 physicians treating Medicaid patients.

However, in addition to the proposed increase in the number of physicians participating in the program, other functionality should be considered. The present system is a re-active system in that the data is only available after the fact. The sixty-day drug history is gathered from paid claims. This leaves a number of potential areas where fraud and abuse could continue. Adding an E-prescribing ability would include the pharmacy in the entire process. Linking the E-prescribing function to the Department's patient drug history would provide Medicaid with the ability to track what was dispensed against what was actually prescribed by the physician.

Including E-prescribing and the pharmacy in the network would provide the additional benefit of including the drugs that were dispensed in a cash environment, thereby eliminating another method of drug shopping. With the proper security built into the network the E-prescribing function can eliminate the potential of lost, stolen and forged prescriptions. The Drug Enforcement Administration (DEA) has defined the security requirements (Public Key Infrastructure Analysis DEA Division Control E-Commerce PKI Certificate and CRL Profile, Draft 1.2, dated June 5, 2003) for controlled substances; however, these same requirements should be the standard used for the entire E-prescribing process. It will be imperative that the network used for the dissemination of health care data is foolproof when it comes to security. It may be required for the State to mandate the security access protocol that will be used going forward.

The benefits of this program demonstrate the value to other public programs, including Medicare and the Uninsured sectors. By expanding the same infrastructure to complement the President's National Health Information Infrastructure to be designed around standards, the financial return to government at the local, state and federal levels can be substantial.

eMPOWERx

PRODUCT INFORMATION

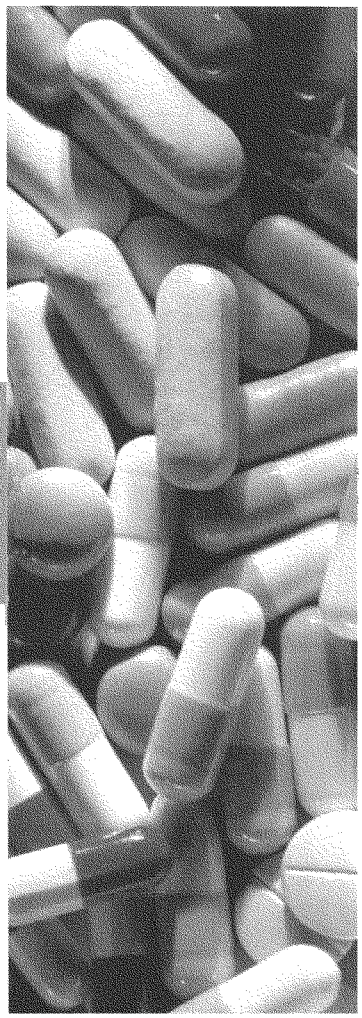

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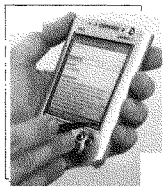
Table of Contents

Introduction to the eMPOWERx System

About the Product

The eMPOWERx system is designed to provide you with the most current and comprehensive drug information available today. Written *by* healthcare professionals *for* healthcare professionals, the eMPOWERx system ensures that you always have clinically-relevant information and clinically-important medication management tools at hand when and where they're needed. Look up timely drug information, check for potentially dangerous drug interactions and identify patient-specific compliance issues quickly and effectively at the office, during hospital rounds, in the ER, during patient consults, at the point-of-care, from home or on the road.



Leveraging wireless technology, wherever you go, eMPOWERx goes, too, empowering you with a clinical solution you can rely on to help you make informed decisions like never before. Because we understand firsthand the demands placed on busy healthcare professionals, we have made it *our* job to arm you with the right content and tools critical to performing *your* job—and performing it well— enabling you to take both your practice and patient care to the next level:

COMPREHENSIVE DRUG INFORMATION

eMPOWERx has redefined comprehensive drug information by applying patient-specific elements to traditional drug information queries

eMPOWERx provides patient information, including refill compliance, active drug interactions and complete prescription drug histories, irrespective of prescriber or pharmacy

eMPOWERx provides the most complete and concise clinical monographs currently available on handheld devices

eMPOWERx enables you to review drug descriptions, indications, interactions, contraindications/precautions, classifications, adverse reactions, administration, pregnancy/ lactation information and preferred drug list (PDL) status

eMPOWERx provides pediatric, adult, geriatric, renal and hepatic dosing and dosage limits, specific to indication, including off-label uses

eMPOWERx allows you to look up drugs by generic or brand name, indication, classification, precaution or adverse reaction

POWERFUL CLINICAL REPORTS

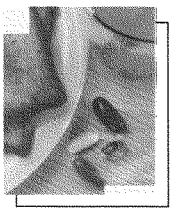
Drug Interactions Report—Screen combinations of prescription drugs, over-the-counter medications, herbal and nutritional products for interactions

Preferred Drug List Alternatives—Identify therapeutic alternatives on Florida Medicaid's Preferred Drug List alphabetically or by therapeutic class

IV Compatibility Report—Check the compatibility of two or more intravenous products and/or solutions when mixed in solution or a syringe, or via Y-site administration

System Requirements

The eMPOWERx system has been verified to run on the Compaq iPAQ H3600 models or higher (with at least 64 Mb Ram) and the Toshiba 2032SP (with at least 64 Mb Ram). Other PPC models designed to run the latest OS should work, but have not been tested. The PDA must have at least 25 Mb of RAM free to install and use the program.



Contact Us

For more information about the eMPOWERx system or to order, please contact us:

Gold Standard Multimedia
320 W. Kennedy Blvd., Suite 400, Tampa, FL 33606
Phone: (800) 375-0943 or (813) 258-4747
Fax: (813) 259-1585
Office Hours: Monday-Friday, 8:30 a.m. - 5:30 p.m. EST

Visit our websites:

The eMPOWERx System – empowerx.gsm.com
Gold Standard Multimedia – gsm.com

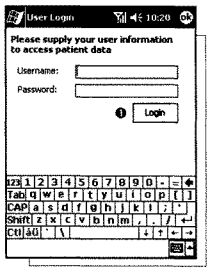
GETTING STARTED

ACCESSING THE PROGRAM

Running the eMPOWERx program can be done easily by tapping the Windows "Start" icon located in the top left corner of the screen. From the options listed in the drop down menu, select "EmpoweRx". The first screen you will see when the eMPOWERx system is operating is the user login screen.

LOGGING IN

Before you can gain access to the program, you will be prompted to provide a username and password. Use the digital keypad to enter your unique login information. Once your information has been entered, tap the "login" button to gain access to the eMPOWERx system.❶ If the user name or password does not match your registered information, you will be prompted to re-enter the information. The "Clear Current User" button may be used when another provider will be using the same device. This ensures that patient-specific information is secured from one user to another.

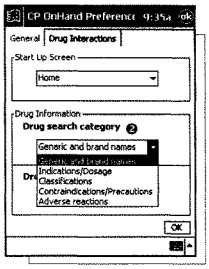


How to Use the eMPOWERx System

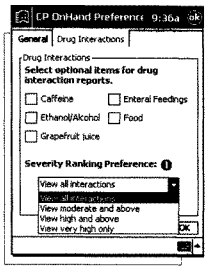
SETTING YOUR PREFERENCES

eMPOWERx allows you to set your own preferences according to how you like to use the program. Save time by defaulting to the options you use most.

For your Drug Information searches, you can default to look up by generic and brand names, indications, classifications, precautions, or adverse reactions.❷ When reading information about a drug (Drug details), you can choose to start with the description, indications/dosage, precautions, interactions, adverse reactions, classifications or a listing of similar PDL drugs.



When running drug interactions, you may select to include specific drug-food interactions including caffeine, enteral feedings, ethanol/alcohol, food in general and grapefruit juice. Additionally, you can select what drug interaction severity levels you wish to see ranging from very high to low.❶



Viewing Your Patient Manifest

Use the Patient Manifest to glean information about your patient's medication history. Identify drug therapies initiated by other providers and better understand your patient's refill frequency for maintenance medications. With one simple daily download, a new dimension in drug information is seamlessly integrated into a valuable clinical tool.

MANIFEST LAYOUT

Update Manifest – Updates entire patient manifest❷

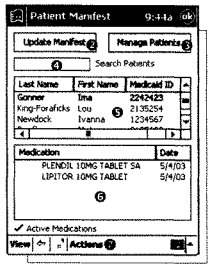
Manage Patient – Enables you to add/delete patient records❸

Search Patients – Allows you to search for your patient within the table by Medicaid ID number or name❹

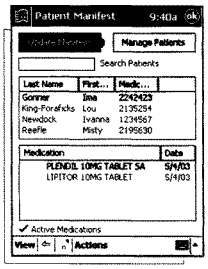
Patient Table – Displays a listing of all your patients downloaded in last update❺

Medication History Table – Gives you a 60-day medication history for the patient selected in the Patient Table❻

Actions – Provides you with access to medication details, monographs, and a link to interaction reports❼

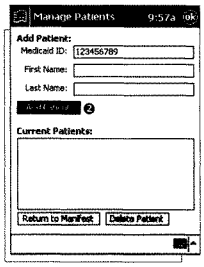


UPDATING THE MANIFEST



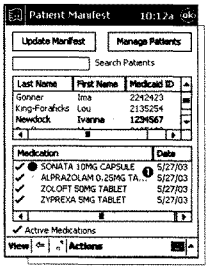
It is recommended that the Patient Manifest be updated once a day, ideally before or after office hours or at a time that is convenient to your practice. The Patient Manifest can be easily updated by tapping the "Update Manifest" box. ❶

Once selected, you will be asked, "Are you sure you want to update?" By tapping "Yes," a secure wireless connection is created and your patients' sixty-day medication histories are downloaded directly to your PDA. Manifests can also be downloaded to your PDA by using a desktop computer that has an internet connection. By placing your PDA in its cradle and following the steps listed above (for wireless updates), your PDA will use your desktop computer's modem to download patient information directly to your PDA. If your desktop computer utilizes a high-speed internet connection, you may find this option will save you time. Please note that if an error occurs during transmission, you will be asked to download the manifest again. If this problem persists, it is advised that you contact the Help Desk at 877-629-0304.



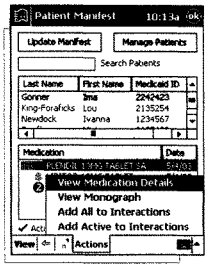
The Patient Manifest page can also be used to obtain a sixty-day drug history for a new patient to your practice. The "Manage Patient" button will enable you to input your new patient's Medicaid ID number. Use the key pad at the bottom of the screen to input the Medicaid number and then select the "Add Patient" button. ❷ You may then close this window by selecting the "Return to Manifest" button at the bottom of the screen. You are now ready to retrieve your new patient's drug history by selecting the "Update Manifest" button in the top left corner of the screen.

New patients may also be added using a desktop computer and the "Patient Manager" program. First, be sure to cradle your PDA and connect it to your computer. Then click on the "Shortcut to Patient Manager" icon on your desktop screen. The user name and password will be identical to the user name and password used to access the eMPOWERx system. Once you have entered your user name and password, you can add new patients to the Patient Manager by inputting the appropriate Medicaid ID numbers and selecting "Add Patient". When you have completed inputting all of the patients you wish to add to your next manifest query, select the "Save list to Pocket PC" button located in the lower left-hand corner of the program. You are now ready to update your manifest following the steps outlined above.



VIEWING DRUG HISTORY

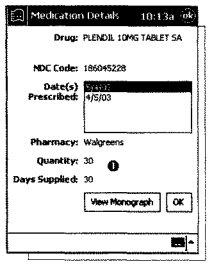
By tapping the desired patient name in the Patient Table (name will be highlighted in blue), the Medication History Table will display all of the medications dispensed to that patient during the past 60-days. ❶ If there is a check mark to the far left of the drug name, this drug is active and the patient should still be taking the medication (based on the quantity dispensed and the days supply as determined by the pharmacy). If the medication is calculated to be finished and it has not been refilled, then this field will be left blank. Directly next to the status indicator is a red or green circle. This is the Preferred Drug Indicator and provides information on the Medicaid Preferred Drug List status of the medication; green is a preferred drug and red indicates a prior authorization was required. Continuing to the right, the next field labeled as "Medication" is the name and strength of the drug dispensed. Moving to the far right, the last field entitled "Date" displays the last refill date on record for that particular medication.



VIEWING MEDICATION DETAILS

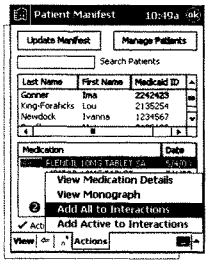
"Medication Details" provides information about a specific drug within the medication history. By first selecting the desired drug and then accessing Medication Details via the "Actions" button, information concerning the drug, refill dates, dispensing pharmacy, quantity and calculated days supply will be provided.❷

Specific information about the dispensing pharmacy, quantity and days supply are also available by selecting the refill date in question. From this screen, direct access is available to the relevant clinical monograph or you may return to the manifest by selecting "OK".❶



AUTO-POPULATING DRUG INTERACTION REPORTS

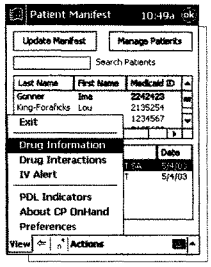
The "Actions" button also provides two options for auto-populating the drug interaction reporting feature. This tool is useful when either determining possible drug interactions that exist in the patient's current regimen or when selecting a new therapy to add. If the patient is taking particular medications PRN (as needed), the user may choose to "Add All to Interactions," regardless if the medication is calculated to be active or not.❷ If it is determined the patient is only taking active medications, "Add Active to Interactions" is also available. Functionality of the drug interaction reporting feature will be outlined in the Drug Interaction section of this User Manual.



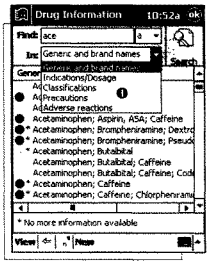
DRUG INFORMATION

Use the eMPOWERx Drug Information module to perform versatile searches in just seconds, and to review concise and clinically-relevant drug information at the point-of-care. The module can be accessed directly by either selecting the "Clinical Pharmacology OnHand" icon on the home page or by tapping the "View" button located in the bottom left-hand corner of the screen and selecting "Drug Information".❸

A unique feature of the drug list provided within this module is the green and red circles located to the left of each medication. These circles are indicative of the Preferred Drug List status for that particular medication. Green circles are preferred medications and do not require a prior authorization, whereas red circles indicate the medication requires a prior authorization. To assist in identifying medications that do not require prior authorization, the user is given an option to view a list of similar medications that do not require prior authorization when a drug with a red circle is selected.



SEARCHING



You can search by: ❶

- Generic and brand names
- Indications/Dosage
- Classifications
- Precautions
- Adverse reactions

The generic and brand name search allows you to find information about a specific drug, nutritional product or herbal supplement.

The classifications search brings up a menu of drug classes; from there, you can go to a list of drugs contained within each class.

The indications/dosage search results in a list of drugs used to treat the indication you specified. Select a drug to go directly to its dosage for that indication.

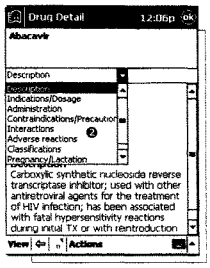
Searches by precautions or adverse reactions result in a list of drugs associated with the precaution or adverse reaction you entered. Click on the drug you are interested in to get more information.

SEARCH OPTIONS

If you are unsure of how to spell a drug name, or want to save time on your drug look ups, enter just a few letters. The partial word search feature will find all matches for you and display a list of drugs containing those letters.

Using the drop-down menu beside the "Find" box, you can also search by first letter to see the entire list of drugs that begin with that letter.

DRUG DETAILS

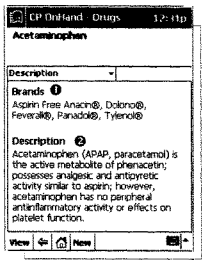


***eMPOWER*Rx** supplies a wealth of need-to-know information for more than 1,100 drug monographs, and continues to add to its growing database on a consistent basis. Learn about each drug's: ❷

- Description
- Indications/Dosage
- Administration
- Contraindications/Precautions
- Interactions
- Adverse reactions
- Classification
- Pregnancy/Lactation
- PDL Status

GENERIC AND BRAND NAMES

The drug's generic name and major brand names are displayed. ❶

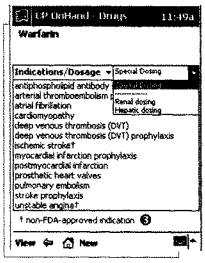


DESCRIPTION

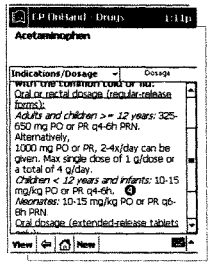
Read a concise paragraph of descriptive information about each drug, specifically written for the PDA format from a clinician's perspective. ❷

INDICATIONS/DOSAGE

See a list of indications for the drug you are reviewing, including non-FDA-approved (off-label) uses. ❸



Non-FDA-approved uses are included when the use represents current practice and a dosage regimen has been established and documented for the indication.

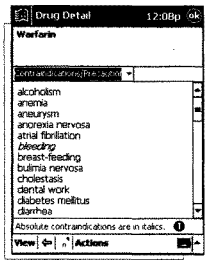


Select an indication to view dosage information for that indication, including pediatrics ❹, adults, geriatrics, dosage limits and special dosing for patients with renal or hepatic impairment.

CONTRAINDICATIONS/PRECAUTIONS

To help you make the safest medication decisions for your patients and to determine whether another option may be preferable, eMPOWERx distinguishes between contraindications—absolute conditions where a drug should not be used, and precautions—conditions where a drug can be used, albeit with caution.

See a list of precautions for the drug you have looked up, including contraindications, designated in italics. ❶

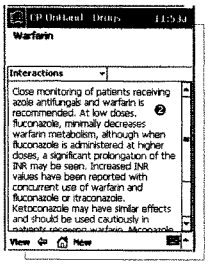


INTERACTIONS

Interactions listed in eMPOWERx drug information module are based on clinically-important data and not limited to only those described in the package insert. These more complete listings are included to help you check for, and avoid, dangerous interactions at the point of care.

Classes of drugs are also included in the interactions list, and are indicated with a "*" symbol.

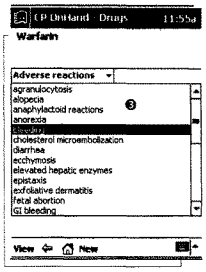
Select a drug or class of drugs to view interaction information, written in clear, concise language for quick comprehension on a PDA. ❷



ADVERSE REACTIONS

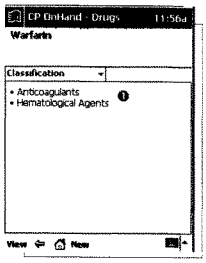
View a list of adverse reactions that may be caused by the drug you are reviewing. ❸

This feature enables you and your patient to be fully informed about potential side effects that may occur BEFORE the patient starts taking the medication.



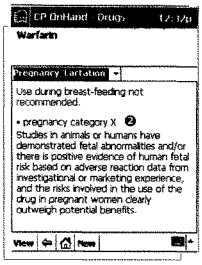
CLASSIFICATION

Examine the list of classifications in which the drug you are reviewing is contained. This feature is useful both as a reference and to help guide you toward appropriate alternatives when needed.❶



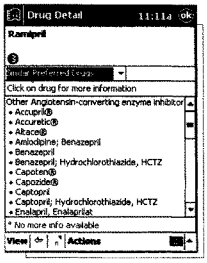
PREGNANCY/LACTATION

This section includes a recommendation for usage or avoidance of the drug during breast-feeding, as well as the drug's FDA pregnancy category classification, and a discussion of its use during pregnancy.❷



SIMILAR PREFERRED DRUGS

This section lists all drugs within the therapeutic category that do not require a prior authorization by Florida Medicaid. By selecting a medication on this list, you will be linked directly to its monograph.❸



Clinical Reports

Avoid patient adverse drug events by using the Clinical Reports module of eMPOWERx, where you can run powerful reports on Drug Interactions and IV Compatibility.

DRUG INTERACTIONS

Written for you, the healthcare professional, the purpose of the Drug Interactions Report is to identify clinically-important interactions found within a patient's medication regimen. To auto-populate the drug interaction reporting screen with a specific patient's medication profile, see the Patient Manifest section. The reporting module can be accessed directly by either selecting the "Drug Interactions" icon on the home page, or by tapping the "View" button located in the bottom left-hand corner of the Patient Manifest screen and selecting "Drug Interactions".

RUNNING REPORTS

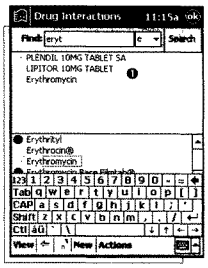
In the "Find" box, type the name (or partial name) of any drug/product you would like added to the interactions report. Matches will appear in the lower part of the screen. Simply tap on your selection to add it to the report. To remove a drug from the report, tap the medication you wish to remove listed on the top half of the screen. The drug name should no longer appear in the list of drugs to be reported.

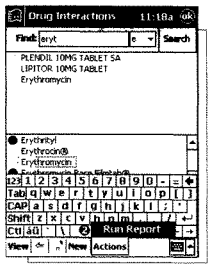
Continue with this process until you have added all drugs/products that you want to include in your interactions report.❶

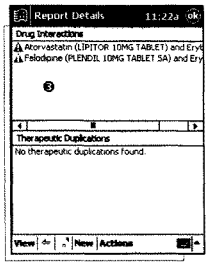
To run the report, tap on the "Run Report" button at the bottom of your screen.❷

REPORT CONTENT

The program will quickly generate an easy-to-read list of interactions among each drug/product you have entered.❸ The report will summarize interactions for prescription drugs, herbal supplements, and over-the-counter and nutritional products. Interactions for an entire medication regimen can be assessed simultaneously.







Interactions are listed by the severity of the clinical impact of the interaction. The highest severity is listed at the top of the screen and color coded in red, with the least severe interactions at the bottom and coded in blue. Select a listed interaction to read clinical, need-to-know data about that interaction. ❶ Drug combinations that contain medications within the same therapeutic class will be listed in the "Therapeutic Duplications" section on the Report Details screen.

To run another interaction report for a different patient, select the "New" button at the bottom of the screen and all listed drugs will be removed.

IV COMPATIBILITY

The IV Compatibility report enables you to check the compatibility of two or more intravenous products and/or solutions when mixed in solution or a syringe, or via Y-site. The reporting module can be accessed directly by selecting the "IV Alerts" icon on the home page, or by tapping the "View" button located in the bottom left-hand corner of the Patient Manifest screen and selecting "IV Alerts".

RUNNING REPORTS

In the "Find" box, type the name (or partial name) of any drug/product you would like to include in the IV compatibility report. ❷ Matches will appear in the lower part of the screen. Simply tap on your selection to add it to the report.

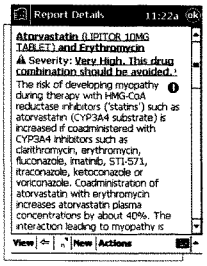
Continue with this method until you have added all drugs that you want to include in your IV compatibility report. ❸

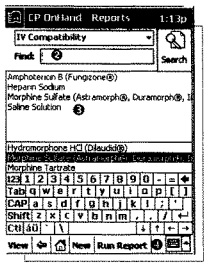
To run the report, tap on the "Run Report" button. ❹

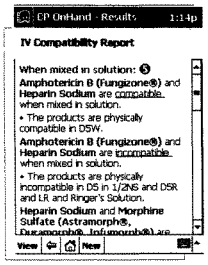
REPORT CONTENT

In just seconds, the program will create a report showing the compatibility of IV drugs when mixed: in a solution ❺, in a syringe, or via Y-site—and clearly state whether the mixtures are compatible or incompatible.

Enhance patient care, reduce medication errors, and improve compliance with the mobile eMPOWERx drug information and medication management system. For more information, please call 800-375-0943 or visit empowerx.gsm.com.







FLORIDA MEDICAID

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Dear Medicaid Provider,

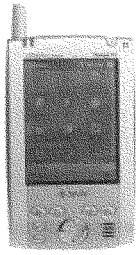
Florida Medicaid is offering a new program to help you streamline your practice, reduce phone calls and improve your ability to provide top quality clinical care.

Working with Gold Standard Multimedia and Sprint PCS, Medicaid has developed a fully integrated drug information system providing you timely access to your patients' drug history and current Preferred Drug List (PDL) information. All of this information will be at your fingertips with a Pocket PC/PCS phone.

Understanding the value this information can have in assisting you with informed drug therapy selection, Medicaid has fully funded the eMPOWERx application with no cost to you.

This program will enable you to:

- Minimize incoming pharmacy calls due to non-PDL prescriptions;
- Coordinate care with other physicians, decreasing the potential for duplicate therapies;
- Identify and dissuade doctor shoppers;
- Analyze and avoid potential drug-drug and drug-food interactions; and
- Remain up to date with the latest in drug information including many popular herbal and over-the-counter products



Features of this program include:

- A Toshiba 2032 Integrated Pocket PC/PCS phone;
- Unlimited PCS data minutes including wireless internet, 300 minutes peak talk time, and 1000 minutes on nights and weekends;
- A comprehensive drug information database readily identifying the medications covered by Florida Medicaid without a prior authorization;
- A current 60- day prescription history for your Medicaid patients that is updated daily over a secure wireless connection. This information includes all medications dispensed to your patients assisting you in identifying medications written by other providers; and
- One of the most robust drug interaction tools available, fully integrated with your patients' drug history.

This program will initially be made available only in Orlando, the Tampa Bay Area, Miami, Jacksonville, Tallahassee and Pensacola. Due to the limited supply of Pocket PCs, only the first 1000 physicians that sign up to participate will be enrolled. If you would like to reserve a unit today, you may do so by registering online at http://www.empowerx.gsm.com or by calling 800.375.0943 ext. 0. After you have registered, a team member from the Good Health Network will be contacting your office to schedule an appointment.

We thank you for your commitment to Medicaid recipients.

Bob Sharpe
Deputy Secretary for Medicaid AHCA

2727 Mahan Drive • Mail Stop #38
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CEO, GSM

320 West Kennedy Blvd, Suite 400
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Mr. SOUDER. Mr. Norwood.

Dr. NORWOOD. Thank you, Mr. Chairman, I appreciate it. Let me, I would be remiss if I did not introduce you to our court reporter, Bill Warren. He is my only voter in this room, and I am glad Bill is here from Monroe, GA.

Mr. Fernandez, you said in your report, intelligence indicates doctor shopping, prescription fraud and robbery are the three most common means. Just so you and I are on the same page, define doctor shopping?

Mr. FERNANDEZ. Going to one doctor and getting as much as you could on a script, claiming to have pain, going to a second doctor within probably a short period of time, getting another prescription written for the same.

Dr. NORWOOD. I would define it the same way, I just was trying to see if you meant by that going to 1 of the 12 who the underground knows is writing bogus prescriptions. Is that doctor shopping, too?

Mr. FERNANDEZ. Yes, sir.

Dr. NORWOOD. Just to make the record clear there are thousands and thousands of physicians in Florida that take Medicaid, and the fact that we are talking about 12 makes me wonder why we could not deal with that 12. You obviously have information, do you have that information, on those 12?

Mr. RAFFANELLO. I am unfamiliar with it.

Dr. NORWOOD. Why would you know that, and he not, because any time 12 physicians are writing $15 million worth of Schedule II drugs, my dander goes up a little bit. Something does not smell right about that immediately, and I would think somebody ought to be asking those people some questions. What is going on with that 12? Recognizing what you said is so true, this is very difficult, I will get into that in a minute.

Mr. FERNANDEZ. I got the information from a newspaper article that I referred to earlier, but they named the doctors, there were 12 doctors.

Dr. NORWOOD. So we know who perhaps—through Medicaid records, who these people are?

Mr. FERNANDEZ. Oh, without a doubt, and all of these doctors had prior problems, would probably be a good word. I think they have had some run-ins with different medical boards and what-have-you.

Dr. NORWOOD. Just to make this point too, taking the license is not the solution. Frequently that drives the physicians underground. They do not have a way to make a living, it just gets worse in my opinion. There needs to be criminal activity, as you pointed out, involved in this and the penalty for this needs to be very, very steep. That does not mean maybe the license is not taken and they can practice in prison, but my view is we do not take it seriously enough. I do not know the percentage. I do not know the number of doctors that see Medicaid, but that is a low percentage. At least that 12 ought to be visited on a pretty regular basis.

One of you were pointing out earlier, all of this, these prescriptions, you do not know about it frequently, until after it the fact. And that is what we are looking at in our committee is how you could know it a little sooner. Because there are patterns that occur.

I mean, just like this 12, you can know who they are pretty easily. This 12 do not just see Medicaid patients, incidentally.

So you do not really know the numbers until you go in, until this is a criminal problem rather than just a problem with the ethics committee or the State board of dental examiners.

I am glad to hear you talking about the Internet. I wonder—and we are thinking about this too—if we outlawed in this country the purchase of Schedule IIs over the Internet, do any of you know how much might be available out of this country, to buy over the Internet from India? And we do not know how to fix that. We do not know how in the world we would keep it from coming across the Internet if we closed down every Internet prescription shop in America. Any comments, any thoughts?

Mr. FERNANDEZ. I cannot answer that question, but I would ask the good doctor here, we do know who produces OxyContin. Is it just one company?

Dr. MEYER. OxyContin is only produced by one company, but oxycodone has many sources and I do not, as the U.S. regulator of drugs, we do not have a good handle on, say who might produce it in India, unless it is for a U.S. manufacturer.

Dr. NORWOOD. Well, this is so profitable even though I do not know where the company is that produces OxyContin, but it is so profitable, if we shut that company, or control them tight, it is going to pop up somewhere else.

Which is part of my point of this hearing. The Dilaudid, look I remember when people were trying to come in and get Dilaudid. Now they want OxyContin. Though I never prescribed OxyContin it seems to work really well for pain relief, which means it also works really well for the people who would abuse it. That is why they want that today, that is the popular one today. It used to be Percocet, Percodan. You guys have been around long enough to remember when that was. But we have to—I think it ought to be a State program, Congressman Mica, maybe under a Federal umbrella, because we have to cross State lines. You have to be able to—if you are going to stop doctor shopping they cannot come to three doctors in Augusta, GA, cross the Savannah River and go to three in Aiken, SC, without us having some handle on that.

Part of the difficulty is how do you do this with privacy. But somewhere, somebody, has to collect this information and it has to be electronic and automatic, they do it now anyway. They immediately send out electronic messages to get paid from the pharmacist. That same message could go to some collecting point, so that we do know and you could know in the State of Florida. You pick up abuses on that in 2 minutes. Do you need more—you need the penalties to be greater, do you not?

Mr. RAFFANELLO. Yes, absolutely. I have just two points I would like to make in response to your question——

Dr. NORWOOD. Please.

Mr. RAFFANELLO [continuing]. About out-of-the country sources. If past be prologue, in the past when we had problems with Qualudes—and we did a very efficient job in the United States banning them—Mexican traffickers took to taking the precursor chemicals, took to using the pill presses, and did exactly that in Mexico. The Mexican and Colombian traffickers are very, very ingenious.

They will fill a void. If there is a need, they will fill a void. I think that eventually they would probably use the Internet or use 2,200 miles of border. They will use whatever they perceive is a weakness to be able to do it. And that is something that could happen in the future and that is something that DEA, intelligence-wise, is looking at.

Second, on 12 doctors with Medicaid, primarily Medicaid fraud is—I believe there are several other Federal agencies that have that initial responsibility. What happens in those scenarios is when they get to the point where they want to pursue a Title 21 offense, then they will call DEA and bring DEA in. But the vast majority of the time, the offense is initially discovered by the agency with the oversight of the doctor on the Medicaid program.

So it is not—I do not have the manpower to be able to cover every doctor in Florida, and DEA does not have that kind of manpower, but the people with Medicaid oversight, if they see something that does not look good, they will often call us. And if it is another Federal agency, they may have Title 21 authority, and they may do it themselves.

Dr. NORWOOD. Have they called you about these 12 doctors?

Mr. RAFFANELLO. Not at this point.

Dr. NORWOOD. Then they are not doing their job.

Mr. RAFFANELLO. If it were the Federal Bureau of Investigation, they have concurrent jurisdiction to Title 21. So they may decide to enforce that themselves, that is a possibility. I promise you that I will find out more about it.

Dr. NORWOOD. Well, in conclusion, Mr. Chairman if I may, we can stop I believe immediately—not immediately but pretty quickly—the three problems you are talking about. Maybe robbery is a different subject. I know one time I caught a fellow trying to abuse the Percodan deal and we took care of that real quick. We had your folks over there immediately, and of course they tried to burn our office down after that, in a few weeks. I am just telling you how bad these people want these drugs, and they will do anything for it.

But I think we can probably stop the problem of doctor shopping, I think we can stop prescription fraud, maybe we can never stop robbery. In the long term, at the end of the day, the real problem for us about people abusing and getting too many Schedule II drugs, is going to be just what we are talking about—it is going to be the Internet, and it is going to be foreign sources. And you guys are really smart and need to help me figure out how to do that.

Thank you, Mr. Chairman.

Mr. SOUDER. I think this Georgian is downplaying his own smartness. That is, I take it, a southern trait. A very smart man. Mr. Keller.

Mr. KELLER. Thank you, Mr. Chairman. Just to followup on something Congressman Norwood was hitting on. Mr. Fernandez we know from your testimony we have 12 physicians who have written over $15 million worth of Medicaid prescriptions for OxyContin, that is 9.5 million tablets. As of this morning anyway, the south Florida newspaper Sun-Sentinel, has known for 4 months who these people are, but as three Federal experts sit here today,

we do not have a clue if they have even been interviewed, any of these doctors by the DEA or FBI.

Mr. Raffanello, what can you tell us about the future prospects with respect to these 12 doctors who have now been identified through public records, and a newspaper; will they at least be interviewed by some law enforcement agency?

Mr. RAFFANELLO. Let me say this, I have 22 officers in the State of Florida, and because I do not know about it, I am assuming the DEA is not part of it. I very well may find out that we are. I have not read the article, I am not familiar with it, I am not familiar with that incident, but all that aside I take responsibility for it, and I assure you that I will find out who has the investigation and they will be talked to.

Mr. KELLER. OK, I will tell you, that reminds me, you know, September 11, we had 15 of the 19 highjackers came here from Saudi Arabia. We had one guy at the State Department that issued 10 of those visas. Afterwards nobody talked to him. And I look at this situation—I do not know if we need new laws right now, maybe just some enforcement of the existing ones, and maybe they are being enforced and we just do not know. We have to get to the bottom of that.

Let me ask you a question, Dr. Meyer, are there any specific marketing practices by the distributors of pharmaceuticals that you would like to see stopped with respect to OxyContin?

Dr. MEYER. The FDA has actually found that the vast majority of the marketing of OxyContin specifically has been within our legal bounds. We have in two incidences cited them for deviating from acceptable practices, going beyond the labeling or not giving sufficient warnings about the misuse and abuse of the drug.

I would say that the company itself has voluntarily elected not to directly market to consumers, and we wholeheartily agree with that.

Mr. KELLER. Does that mean they have not done any TV ads for OxyContin.

Dr. MEYER. They have not done any TV ads.

Mr. KELLER. OK.

Dr. MEYER. Right.

Dr. NORWOOD. Would the gentleman yield?

Mr. KELLER. Yes, I will yield, Mr. Norwood.

Dr. NORWOOD. As long as they do not market to the public, which I would be 100 percent against, and so I understand they are, too. We need to remember who they are marketing to. Actually they are talking to people and trying to encourage them to, and explain their new drug, who should know the pharmacology inside out, who should know the ill effects and particularly the addictive effects, and my view on that is that shame on the doctor who does not explain that to their patient. It is not like they are being talked into using something they do not understand, they do understand, they understand the pharmacology of it.

That is why I said earlier in my opening statement, the marketing to a physician is not abnormal. Most drug companies do want you to use their particular product over another product, but they are not talking to people who totally do not know what they are being asked to use. So, I blame it on the doctor who does not ex-

plain it to their patient that we need to be very careful here and monitor that patient.

Dr. MEYER. I would point out, Dr. Norwood, that I think I agree with a lot of what you are saying, pain management has changed greatly in the last 10 to 15 years. When I was licensed in the State of Oregon, we had a mandatary training in pain management prior to getting our license. That was about 12 years ago. A lot of what I was taught then is no longer believed to be true now, so the FDA——

Dr. NORWOOD. Thank goodness.

Dr. MEYER. Pardon.

Dr. NORWOOD. Thank goodness.

Dr. MEYER. Thank goodness. I think the FDA in conjunction with DEA and others is supporting better education, because I believe that part of this is education. There is a need for physicians to better understand both the good points of these medicines, how to effectively treat pain, how to screen for abuse and how to help prevent abuse as well. While I think a lot of physicians are very well educated in basic pharmacology, these are specialties or special skills that are not necessarily effectively taught in medical school. So it is really incumbent on us to continue the education efforts.

Mr. KELLER. Thank you, Dr. Meyer.

I have one final question for Mr. Fernandez and Mr. Raffanello. The one common denominator from all the questioning from the various Congressman today seems to be that they are very interested in having the Federal Government crack down on the practice of selling OxyContin in similar drugs over the Internet. You seem to have a sympathetic Congress on this issue. Mr. Raffanello, let me start with you. Do you have any specific steps that you would like the Federal Government to take to crack down on this practice of selling OxyContin over the Internet?

Mr. RAFFANELLO. Yes, and thank you. I would like to do a review and find out what the existing laws are. As I explained before, you will run in to venue problems, prosecutorial venue problems.

Second, that a condition of prescribing some controlled substances that a physical exam be given, you cannot give a physical exam over the Internet. I think we can dispense with a lot of that if we review what we have and let it evolve to take in the fact that it is being exploited by crooks on the Internet.

Mr. KELLER. That sounds great, especially a physical exam requirement there. Mr. Fernandez, do you have anything to add to that?

Mr. FERNANDEZ. No, sir, I do not. I think that covers it pretty well.

Mr. KELLER. OK, Mr. Chairman, I will yield back.

Mr. SOUDER. Thanks.

I want to do a couple of followup things to make sure we have these in the record, because we kind of plunged right in with certain implied things. Mr. Fernandez, it seemed from the chart I have heard some of the information that there are more OxyContin deaths than heroin deaths in Florida, at least there were in 2002?

Mr. FERNANDEZ. In central Florida, there were not, there were more heroin deaths. I really cannot speak well for the whole State. I kind of concentrate my efforts for seven counties.

Mr. SOUDER. OK, let us talk about central Florida for a second. The OxyContin deaths were approximating heroin or far behind? What is the extent of the OxyContin problem here in central Florida?

Mr. FERNANDEZ. It is very bad and growing. And I think Congressman Mica mentioned it earlier, it has happened rapidly and I would like to think that it has peaked, but I do not think it has. Heroin is continuing to grow.

Mr. SOUDER. Would you compare this to the other threats in the community here from the other narcotics? Is OxyContin, when you get addicted, there are more overdoses and it does not have as much violent crime related to it? Is there a tendency if you get this stolen OxyContin to peddle it, and do you have a dealer network? Or are the doctors in effect who are illegally doing this—give us the social consequence in the community and in hierarchy of trying to decide what your HIDTA focuses on where you see OxyContin?

Mr. FERNANDEZ. My HIDTA is not a good sounding board to be very honest with you. We concentrate on heroin, and we have a DEA led heroin task force that looks at strictly heroin. We have seen surprisingly little OxyContin tablets, we have not seized very many at all. I think it is for a couple of reasons. One I think it is because they come through doctors and the people that we put on the street, our task force do not look there. And I think it has moved in relatively small amounts. And we are constantly encouraging our people to look at organizations and, you know, just bigger distributors.

So far as the addictive abilities and what have you, certainly it is on par with heroin.

Mr. SOUDER. Let me ask you something, Mr. Raffanello, do you see OxyContin as a greater problem in other parts of Florida, other than central Florida? I am trying to get a handle on—let me get to my end point here. Why is there not a HIDTA sub-task force on OxyContin, or a DEA task force on OxyContin in Florida that is pursuing this?

Mr. RAFFANELLO. Because, OxyContin—our biggest threat in the State of Florida is heroin, and the heroin deaths exceed the OxyContin deaths. Our second biggest threat is methamphetamine. We have gone from 25 methamphetamine labs several years ago to over 250 this year. We have a different client that uses OxyContin and oxycodone. Unfortunately, sometimes a student or someone will cocktail, will take OxyContin with something else. Most of these oxycodone deaths are not based on oxycodone alone, it is part of what else is in their system.

In the big scheme of things for us, it comes in third in this particular area. And working with the same amount of people we have worked with as agents over the last 10 years, we have to prioritize to our biggest threat. It is not our biggest threat.

Mr. SOUDER. I cannot remember where I saw it in the materials I was reading for the hearing that I thought it was in Florida that the OxyContin deaths exceeded the heroin. You are saying there are poly drugs?

Mr. RAFFANELLO. That is correct.

Mr. SOUDER. Are you saying deaths exceed it?

Mr. RAFFANELLO. No, it is not deaths, it is addiction, it is people in emergency rooms. If you just looking for the deaths, I believe my theory is correct, that it is still heroin deaths that, unfortunately, are the No. 1 here. But methamphetamine, because of the endangered children—we are trying to cover all three; oxycodone, at this point is not in their league.

Mr. SOUDER. So you are saying basically that oxycodone is a danger to the user predominantly?

Mr. RAFFANELLO. Yes.

Mr. SOUDER. Whereas the difference with meth, even though as many people may not be dying, it is impacting the others in the home more?

Mr. RAFFANELLO. Communities, children, we do not even know what some of those chemicals do to the environment.

Mr. SOUDER. How many people have to die and at what level does OxyContin have to become a problem here in central Florida, and Florida, before it becomes a part of a HIDTA request or a DEA request?

Mr. RAFFANELLO. Well, that is not our criteria. If we see an emerging trend, and we have, I only have somewhere in the vicinity of 25 diversion investigators for the entire State. And that also includes regulatory functions and that also includes inspection functions. So, quite frankly I am trying to cover a large State with a relatively small amount of people.

Mr. SOUDER. One of the things, however, it does not prohibit either the HIDTA or the DEA from requesting to headquarters, and then the headquarters can request to Congress and put the blame on us, if we have not funded, which is part of the problem. We have not necessarily funded—we rail against all the different problems and then do not necessarily adequately fund them.

But, in trying to sort through, it has clearly been an emerging problem, and I am trying to figure out why there has not been a focus or it seems to—but I have some problems similar in Indiana. We just did a meth hearing on Friday, but we also just had a major arrest of somebody who—the biggest series of bank robberies in the tri-State area I cannot remember if it was 20 banks or 30 banks. Some violent bank robbers were stealing money to buy OxyContin.

Also, some of that was not just banks—a few were banks, most of them were pharmacies. And they were very violent robberies of pharmacies related to OxyContin, which is another side thing that is happening if we cannot get doctors to prescribe it. But we need to look at this, because clearly this has been a big focus. And we have to have focus which I do not believe is the case in the law enforcement side, but let us just say there is not. I am going to say this as a Member of Congress who is perceived correctly as being friendly to the pharmaceutical industry, who is friendly to the medical industry, who believes that malpractice insurance is already driving doctors out of business and unwilling to cover certain people, and we have to figure out how to deal with medical malpractice.

But, there is a general perception in the public that to some degree the pharmaceutical companies are keeping us from correctly and aggressively addressing the subject when it comes with a legal drug. And when we are hearing in places like Florida, where this

is exploded, that we do not even have a request on the table for a task force. It is a little troubling. Because somewhere in the country—you said you had a national task force, but I do not understand it. Some Members—there is a rumbling in Congress about the concerns about this too. And some internal arguing among Members.

Mr. RAFFANELLO. I believe that in 2004, we do have a significant plus something diversion investigators, and what we have learned and what we try and do in the field is to try and use State and local partners as force multipliers, and we have been fairly successful. And that is the reality of it, we do not have nor could we ask you for the amount of agents that it is truly going to take. So we have formed alliances with our police partners and with our State people, the FDLE here.

The chief in Lake Mary sits on the narcotics and dangerous drugs of the International Chiefs of Police. We have been working with them to roll these things out. But it takes manpower, and it takes a little bit of money, and it takes time.

Mr. SOUDER. Congressman Mica had the subcommittee in here, he mentioned and I mentioned back when we believe it was now Speaker Hastert, chaired this subcommittee, because there has been a string of heroin overdoses in the school systems in this area, like there was in Plano, TX. And at that time there was not much focus on heroin. So part of our goal through this is to help us focus on this, but it is kind of frustrating. I want two other quick things.

One, to followup on Mr. Keller's question on advertising, and marketing, which many of us who are free market are very concerned about having restrictions placed on companies and their abilities to market. And it is—I am greatly relieved to hear about public advertising. But I am unclear a little bit on even marketing to doctors and pharmacies. Should there be and are there different standards in Schedule II, or is there any kind of mechanism internally in FDA that would have DEA and law enforcement agencies saying this drug is being abused at X level? And what we heard today was no drug has been abused at this level, and this is a primary problem. So do we have any kind of trigger or should we have a trigger internally that says when that happens that there is now a further restriction on internal promotion and how that promotion is done? Because the inherent conflict in the free market is that somebody wants to increase their sales, not decrease their sales.

Now if there is medical malpractice problems and it is going to push up doctors' liability cost if they prescribe this drug, and then other patients are paying for it all over the place. So, you could even have a contradiction where you have a company pushing something that is driving up everybody's total health cost, because somebody is promoting something that has a higher level of risk. Do we have any current systems that restrict or put hard warnings on that are mandatory on the company? You mentioned a little black box on the thing, but frankly, a little black box on the bottle is not going to deter an addict.

Dr. MEYER. Right. Let me answer that, and I think it is a several part answer. First of all, there is no difference in the FD&C Act between how we regulate the promotion of Schedule IIs versus any

other drug, so I think that was part of your question there, there is currently no difference.

Mr. SOUDER. And even after abuse if there is additional warnings, then there is no legal thing we would all be.

Dr. MEYER. There is no legal; right. We do internally of course, especially with knowing what we know about these, but even with other Schedule II drugs, we do pay closer attention to those in our survey of the marketing practices, than we would for drugs with less potential harm if they are misused, for instance.

With regard to the black box warning it is absolutely essential, and I made the point during my testimony, that labeling informs the marketing, and one of the things that is necessary in marketing a drug with a box warning is that box warning be prominently displayed in any marketing of it. So it is not just on the bottle, it is not just in the package insert that the pharmacist throws away, but it is actually a part of labeling. And in fact one of the enforcement actions we took against the manufacturer back in I believe in 2001, they ran a JAMA ad in the Journal of American Medical Association where we felt they had not properly displayed those warnings and we took action against them and they had to do a corrective advertisement to rectify that situation.

Mr. SOUDER. We clearly have a new problem in society and that is our labeling which is correct in trying to run on TV ads and other things. Now you see these TV ads that basically say this drug will make you smile more, by the way you can get liver cancer or heart disease, die of lung cancer, this and this, but you will smile more. And people are becoming immune to the labeling, let alone hard addicts, and we are going to have to deal with something beyond the labeling because we are kind of now not able to distinguish the levels of risk and the intensity of risk. And it is a new challenge for Congress.

Mr. Mica, did you have any additional questions?

Mr. MICA. Yes, just a couple of quick questions.

Mr. Souder and I participated in the development of a billion dollar drug education program that is now in effect, we have had some problems with it and we still are trying to work that out.

Dr. Meyer, you testified that education is important in this process. I am wondering, Chairman Souder, if we have a disconnect between this program that we helped create and what is happening on the streets and in our communities. Do you report in any way or recommend to the Office of National Drug Control Policy any—do you provide any recommendations in the education program based on what you are seeing happening and problems out there, because you said education is an important part—do you have any working relationship with that program, or the director?

Dr. MEYER. I would have to check to answer that, I personally do not know the answer to that. I would be happy to get you an answer.

Mr. MICA. And then the other thing would be from law enforcement. Now, you are only within the State and Miami, but DEA also, do you know any mechanism they have with ONDCP on getting information on what is currently happening to our education program, and those that are developing the educational message that we are paying a lot of taxpayer bucks to get out?

Mr. RAFFANELLO. We do have an executive DEA agent who sits on Director Walters' staff, at ONDCP.

Mr. MICA. And you feel you are getting adequate information, but it does not sound like you are staying up with the information if you are from south Florida and we have 12 doctors on our Medicaid program that are milking the hell out of a Federal system, actually participating in the abuse problem, that gives me great concern. I have sat on this subcommittee longer than anybody. I think when Ed Towns was one of the predecessors—we have changed the title slightly—people went bananas when we had overbilling of patient's taxi service in south Florida, they were milking the billing of the taxi service for Medicaid patients. And here we actually have the program being used to produce and divert, what is it, Schedule II narcotics and our three panelists and it is sort of que paso; nobody knows what is going on.

I am going, when we get to McDonough, our State drug czar, head of ONDCP, we will have some more questions, but we need to get a little bit better coordination between the agencies and also focus on sort of the bad apples in this process. And I look forward to the recommendation I have asked for.

Mr. RAFFANELLO. I am very happy to report I was just told by one of my people here that we are a part of the 12 doctor investigation. That fact that we were not mentioned in the paper really does not surprise me.

Mr. MICA. Well, what surprises me is that you do not know and we do need a better connect. Again, if we can go after people who are overbilling for patient taxi service, we sure as heck can go after them if they are diverting illegal narcotics that are killing our young men and women in the State and across the country.

I yield back, Mr. Chairman.

Mr. SOUDER. Mr. Norwood, do you have anything more?

Dr. NORWOOD. Just very briefly, Mr. Chairman. And I would recommend to you that you see the JAMA ad that Dr. Meyer is referring to. My personal opinion was they were—the FDA was stretching it just a little bit, but I think it would be valuable to you to see, so you can see exactly what they were considering a major mistake.

I have just one statement and I would like to know if you guys agree with it. Heroin is illegal in Florida, but heroin is your No. 1 problem. If we were to make the manufacture of OxyContin illegal, it would still be a problem, it would only be a problem at the borders more so than in the pharmacies. It would be a problem still on the Internet.

If we were some way able to stop OxyContin from ever coming into this country, then we would again be back to dealing with Dilaudid, Percocet, Percodan and things like that. And I want to first see if you agree with that statement. Do you believe what I just said would be correct? Yes, sir.

Mr. RAFFANELLO. If we outvote it, I believe it would come from outside the country or through the Internet from other countries, absolutely, someone would fill the void with all of the above. If you could not get it internally, than you see other drugs you could get, abused to a higher level to make up the difference.

Dr. NORWOOD. As it use to be prior to OxyContin.

Mr. RAFFANELLO. This is not a new phenomenon, people have been abusing prescription drugs since we instituted prescription drugs. It is just that now there is a lot more information out there on it.

Dr. NORWOOD. And my concern is that we be very, very careful and not take away this, particularly I guess for cancer patients in the country. And if you outlaw it totally then the patients who actually need it and are using it correctly no longer have it available; only those who are abusing it will have it available. So all I am saying, Mr. Chairman, is we have to be very careful how we handle this problem.

And I yield back.

Mr. SOUDER. I appreciate that, and as we tackle a couple of things, it is just like what we had on our meth hearing on Friday, and some of our meth hearings are emerging drugs. In Indiana, for example, meth has doubled each of the last 4 years in a row. And there are ones that are growing, there are some that are relatively stable. I think it is fairly safe to say we do not have control of the south border yet, and the Carribean or the south border.

But as we think more progress, particularly on things coming through airports and through UPS, FEDEX searches and we get better control of our borders, which if we are going to have homeland security we have to do. Than we have to watch for things that we are doing internally as well, that they do not become a replacement. So if in fact we are successful in pushing Afghanistan and Colombia on the heroin question, that we do not have methamphetamine and then OxyContin replace those drugs of choice. And think ahead 3 to 5 years or 10 years. We also ought to at least have the social stigma on something that is dangerous and make sure, because part of what happened, like what is happening on so-called medical marijuana which is a substance inside marijuana that if you get something that is an illegal drug labeled as a good drug it becomes much harder. And what we have to do is separate it in the case of some of these things, that they are controlled, that only under managed use can you get them.

And what we are debating here is something that was widely spread that is now becoming more tightly managed and how, as a society, do we rein it, when at the very beginning we did not understand the nature of the risk, as I understood. That still has a huge benefit in this case and in high risk case, and we are going to face this and more. But if we are successful in border control, we have to watch about the replacement.

I thank each of you for your testimony. We will have some additional written questions. If you want to submit anything else for the record, feel free to do so.

If the second panel could now come forward. The second is the Honorable James R. McDonough, director of the Florida Office of Drug Control; Dr. Stacy Berckes, Board Memeber, Lake Sumter Medical Society; Mr. Jack E. Henningfield, Ph.D., Pinney Associates, on behalf of Purdue Pharma; Ms. Theresa Tolle, president of Florida Pharmacy Association. Mr. Mica.

Mr. MICA. Mr. Chairman, while the next panel of witnesses are being seated, unfortunately the Honorable Burt Saunders, the State Senator, District 37, and chairman of the Florida Senate

Committee on Health, Aging and Long Term Care, because of another emergency situation is not able to be with us today. He has notified the subcommittee. So I ask unanimous consent that his entire statement be made part of the record.

Mr. SOUDER. Without objection, so ordered.

[The prepared statement of Mr. Saunders follows:]

TESTIMONY OF FLORIDA STATE SENATOR BURT L. SAUNDERS[1] BEFORE THE GOVERNMENT REFORM COMMITTEE SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

Monday February 9, 2004
Winter Park, Florida

Good Morning Chairman Souder and Members. It is a privilege to appear before the Subcommittee on Criminal Justice, Drug Policy and Human Resources today to discuss prescription drug abuse. Thank you for devoting the time to understand and contend with these complex issues, and for holding a hearing in this state to gain the Florida perspective. Florida, like many other states, is facing adverse consequences from drug over-prescribing – the consequences being shattered and lost lives, as well as lost fiscal resources. Your subcommittee's efforts to tackle the difficult and oftentimes tragic problem of prescription drug abuse are of paramount importance to Florida. I am here today to specifically address how these issues relate to Medicaid prescription drug fraud that costs the federal and state governments hundreds of millions of dollars annually.

Immoral or illegal acts by a handful of providers, patients, drug addicts and profiteers cause serious, sometimes deadly, consequences. Prescription drug abuse is part of an insidious cycle. Data suggest that 1/3 of all illicit drug use in America involves the improper use of prescription medications. There are literally millions of Americans abusing prescription drugs. Many of these drugs are available through state and federal programs. In the realm of Medicaid prescription drug fraud, we find overzealous pharmaceutical companies, pill-pushing doctors, illegal practices by pharmacists, and fraudulent behavior by Medicaid recipients. Florida's commitment to battle these practices is strong and unwavering. However, without federal attention and action, no state can meet these challenges effectively.

I. BACKGROUND

Medicaid is a federal entitlement program that has both mandatory and optional components for states to follow. Currently, Florida's Medicaid budget is $12.5 billion. The Prescribed Drug portion of this budget is $2.3 billion. The Federal government currently contributes 61.88% of this total for Florida (58.93% Federal Medicaid Assistance Percentage plus a 2.95% supplemental through June 2004). Florida's general revenue contribution to the Medicaid Prescribed Drug program will be approximately $877 million for our fiscal year ending June 30, 2004.

Medicaid fraud has been a high profile problem for many years. Dollars are drained off through fraud which should be used to benefit those people the program was designed to

[1] Senator Saunders serves the 37th District in southwestern Florida. He is the Chair of the Florida Senate Committee on Health, Aging, and Long-Term Care. He also is the Chair of the Florida Senate Select Subcommittee on Medicaid Prescription Drug Over-Prescribing.

benefit. Fraud can be perpetuated by Medicaid providers, non-Medicaid providers, clinics, pharmacists, drug companies, Medicaid recipients and industrious entrepreneurs.

Recognizing the high costs associated with Medicaid fraud, a select subcommittee of the Health, Aging, and Long-Term Care Committee in the Florida Senate investigated Medicaid fraud two years ago, which resulted in significant statutory changes and a major commitment of state resources to prevent and to prosecute Medicaid provider fraud in general. Florida continues to refine and implement initiatives arising from that select committee's work. The 2003 Florida Legislature enacted groundbreaking legislation to clean up the drug wholesaler industry.[2] In the coming months we anticipate enacting legislation to establish an electronic monitoring system for the prescription of controlled substances.[3]

In early December 2003, the South Florida Sun-Sentinel ran a series of news articles regarding the over-prescribing of narcotics. The series was multi-faceted and offered segments about all participants in the fraud – doctors, clinics, pharmacists, patients, addicts and pharmaceutical companies. About the same time those articles ran, the Seventeenth Statewide Grand Jury issued its Second Interim Report, entitled "Report on Recipient Fraud in Florida's Medicaid Program" (Case Number SC02-2645). This report also examined the problem from many angles – the providers, the recipients, the buyers, and the pharmaceutical companies. The Statewide Grand Jury made a series of findings and put forth many recommendations for action by the Florida Legislature and for the Florida Agency for Health Care Administration.

II. Florida Senate Select Subcommittee on Medicaid Prescription Drug Over-Prescribing

The Statewide Grand Jury Report and the media highlighted that prescription drug over-prescribing presents unique problems in the context of the Medicaid system. As Chairman of the Florida Senate Committee on Health, Aging, and Long Term Care, I asked Senators David Aronberg and Mike Fasano to serve with me on a new Select Subcommittee on Medicaid Prescription Drug Over-prescribing and Fraud. This select subcommittee is investigating issues raised by the Sun-Sentinel and other media sources, as well as the findings and recommendations contained in the Statewide Grand Jury Report.

The select subcommittee has conducted three public hearings in Tallahassee and one in Orlando on the topic of Medicaid over-prescribing and fraud, with the goal of identifying the problems and solutions to be recommended to the full Senate Health, Aging, and Long-Term Care Committee. Public testimony at these hearings was offered by persons who felt drugs such as Oxycontin must be made available for legitimate health care needs, while others proposed that the lack of controls on doctors who prescribe the drugs and inadequate labeling can lead to more tragic deaths.

In addition, representatives from several state agencies including the Department of Health, the Agency for Health Care Administration, the Office of the Attorney General, the Department of Law Enforcement and the Office of Drug Control have testified before the

[2] CS/CS/SB 2312, "Prescription Drug Protection Act", Ch. 2003-155, L.O.F.
[3] CS/SB 580, "Controlled Substances", 2004.

select subcommittee. These agencies discussed which areas of the Medicaid program fall under their jurisdiction and their individual and collective efforts to combat Medicaid fraud. We have heard also from spokespersons for the Florida Medical Association, pharmacists, the pharmaceutical industry, and other private entities. These representatives presented testimony on the various components of the Medicaid drug over-prescription fraud cycle, from the role of the pill-pushing doctor, to the unscrupulous pharmacist, to the overzealous drug marketers, to the AIDS patient without hope selling his or her expensive drugs on the street for fast cash rather than more time.

As a result of this testimony and the reports cited below, legislation designed to address some of these issues at the state level has already been filed for consideration by the Legislature. Other state legislation is being developed, too.

III. FINDINGS AND RECOMMENDATIONS BY THE STATEWIDE GRAND JURY

The Statewide Grand Jury studied the diversion of tens of millions of Medicaid dollars worth of prescription drugs by large numbers of Medicaid recipients. The Statewide Grand Jury found that there are few, if any, consequences to Medicaid recipients who sell their expensive medications to illegal drug wholesalers.

According to the report, "efforts to deal with the problem of recipient fraud have been hampered by the lack of effective state statutes, federal limitations that restrict Florida's attempt to control this fraud, and a lack of awareness by some state and federal officials of the extent of the problem of recipient fraud. The result is the waste of hundreds of millions of dollars, exploitation of Medicaid recipients, and the tainting of our supply of critical lifesaving medication."[4] Accordingly, the Statewide Grand Jury further found that "the societal cost of this illicit trade in pharmaceuticals cannot be overstated."[5]

Testimony was presented concerning Medicaid recipients selling large quantities of medicine on the streets. According to the report, one illegal wholesaler bought and sold approximately $2.4 million in Procrit, Epogen, and Panglobulin[6], most of which came from Medicaid recipients, in just three months.

The Statewide Grand Jury discussed the fact that the proliferation of infusion clinics has provided another way for Medicaid recipients to sell their drugs. Some infusion clinics recruit Medicaid recipients by offering them a small payment. The recipient is directed to a particular pharmacy, which then delivers the drugs in smaller doses (rather than one dose) directly to the clinic. The clinic turns around and sells the remaining doses on the black market. The pharmacy, however, bills Medicaid for all of the doses of drugs. The clinic then infuses perhaps one dose of the diluted drugs or in some instances, unbeknownst to the patient, simply infuses saline solutions into the Medicaid recipient. The clinic profits from the re-sale of the diverted drugs; and while the Medicaid recipient receives a small bribe for

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[4] Second Interim Report, Seventeenth Statewide Grand Jury, "Report on Recipient Fraud in Florida's Medicaid Program" (Case Number SC02-2645), p. 2

[5] *Id.* at p. 3.

[6] These drugs are used to treat anemia associated with chronic renal failure, kidney disease, cancer or HIV/AIDS.

his or her participation, the patient is oftentimes not receiving any of the drugs that are medically appropriate. Thus, the losses are two-fold. First, some of our Medicaid recipients are receiving bad health care. Second, tax dollars that could be used elsewhere are being used to pay providers and recipients for drugs that are prescribed, bought, sold, and used fraudulently.

The Statewide Grand Jury reviewed how some criminals have recruited Medicaid recipients to pretend to have AIDS by using imposters to take blood tests for them. One such Medicaid recipient received over $600,000 in AIDS medications by falsely claiming to have AIDS. In some instances, corrupt labs either exaggerate a Medicaid recipient's illness or completely falsify lab reports to come up with a phony AIDS diagnosis. Though these are often not Medicaid approved labs, Medicaid does accept lab reports from non-Medicaid labs to document the diagnosis. The Florida Agency for Health Care Administration does not require a second opinion or follow-up lab work to verify the initial diagnosis.

The Florida Agency Health Care Administration has made efforts to curtail the abuse of some drugs by restricting the uses for which they can be prescribed. Often one step ahead, some providers will just change the diagnosis to fit the desired drug. For example, the Statewide Grand Jury found instances where some doctors have falsely diagnosed AIDS patients with chronic inflammatory demyelinating polyneuropathy[7] (CIDP) as a means to avoid regulatory restrictions on expensive drugs.

One Miami-Dade clinic claims to have treated 132 patients with CIDP, and billed Medicaid for over $2.3 million in 10 months. Most of these phony claims, according to the Statewide Grand Jury report, could have been avoided if Medicaid simply required a second opinion, as does the Veterans Administration.[8]

The Statewide Grand Jury concluded, "while drug diversion is only part of that fraud, the other societal costs of diversion - dollars lost to the system, the exploitation of recipients, the tainting of our pharmaceuticals – leaves too much at stake for Florida taxpayers to be content to chase after the fraud. [The] Agency for Health Care Administration must make greater efforts to get ahead of this fraud and stop it before it starts. We are confident that the Legislature will recognize the seriousness of the problems that we have identified and will be supportive of Agency for Health Care Administration's efforts to address this fraud with renewed vigor."[9]

At the conclusion of the report, the Statewide Grand Jury issued a series of recommendations to the Florida Legislature and to the Agency for Health Care Administration. Many of these proposals can be accomplished under current state and federal law. Some, however, require changes to state law, while others could be realized after changes to federal law.

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[7] CIDP is a neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms, diagnosed more often in young male adults than other groups. Treatment for CIDP includes corticosteroids such as prednisone, which may be prescribed alone or in combination with immunosuppressant drugs. Plasmapheresis (plasma exchange) and intravenous immunoglobulin (IVIg) therapy are effective.

[8] This requirement may contribute, however, to long waits for medical care in order to get prescriptions filled in high volume facilities or rural areas.

[9] Statewide Grand Jury Report, p. 39.

IV. Media Reports

As mentioned, the South Florida Sun-Sentinel ran a series of investigative reports entitled "Drugging the Poor". According to the news articles, some very unscrupulous physicians are writing prescriptions for literally millions of dollars worth of dangerous narcotics for a few patients that are selling these drugs to street addicts and drug dealers for resale. Many Medicaid recipients go from doctor to doctor and pharmacy to pharmacy collecting incredible amounts of narcotics for this illicit trade. The tragic results of this illegal provider and recipient activity have been highlighted recently by reports of numerous deaths resulting from drug overdoses.

Investigations focusing on pharmaceutical companies' roles, rather than provider or recipient fraud, have also been ongoing. These inquiries tend to be handled in multijurisdictional, judicial forums and are often centered on fraudulent marketing practices or illegal pricing activities. Certain fraudulent practices by pharmaceutical companies fall under the jurisdiction of the Office of the Attorney General, Medicaid Fraud Control Unit, and are subsequently addressed in their proposals below.

V. Proposals for Federal Action

The need for coordination and cooperation among state and federal agencies, as well as providers, pharmacists and the drug companies, cannot be overemphasized if society is genuinely determined to stop this cycle of abuse. State agencies, while committed to do their part in combating the perils of drug abuse, have ascertained that their efforts could be vastly enhanced if certain federal barriers were removed. Below is a listing of proposals offered by the Agency for Health Care Administration and the Office of the Attorney General that would require revision of federal laws or regulations.

A. Florida Agency for Health Care Administration

The Agency for Health Care Administration administers the Medicaid program in Florida. It does not determine eligibility for Medicaid nor does it prosecute fraud claims. It does, however, have several internal controls and practices that guard against and detect fraudulent activities relating to the Medicaid program.

1. Recipient Fraud

To combat recipient fraud, Congress should amend 42 U.S.C. 1320a-7b to include that the administrator of a Federal health care program may limit, restrict, or suspend the Medicaid eligibility of individuals convicted of offenses under state law for acts involving federal health care programs, including the following: drug trafficking; trafficking in other goods and supplies paid for by Medicaid; illegal use of a Medicaid identification card; illegal transfer of a Medicaid identification card; doctor shopping for the purpose of illegally obtaining controlled substances; altering a prescription; intentionally receiving duplicative, excessive, contraindicated or conflicting health care services for personal gain; and misrepresenting symptoms or conditions to receive unnecessary medical care, goods or supplies.

In addition, Congress should authorize the imposition of fines, longer periods of suspension, and termination of Medicaid benefits for individuals convicted of offenses set forth in 42 U.S.C. 1320a-7b.

Congress should also authorize the administrator of a Federal health care program to impose fines and penalties (including restriction/suspension/termination of benefits) upon the conviction in state or federal court of an individual for acts involving federal public assistance programs.

Through federal legislation or state rulemaking, types of convictions that affect Medicaid eligibility should be defined, and penalties applied as appropriate. For example, a conviction for altering a prescription could be considered a "Level 3" conviction affecting eligibility, the penalty being a restriction of benefits for a period of time deemed reasonable according to the nature of the offense. Restrictions could include denial of payment for certain classes of drugs. A conviction for illegal use of a Medicaid identification card could be considered a "Level 2" conviction affecting eligibility, the penalty being suspension of all Medicaid benefits for a reasonable period of time.

Another method of combating recipient fraud would be to amend federal legislation to authorize an administrative remedy process for Medicaid, which would allow for more coordinated action between the Agencies in taking action for beneficiary fraud and abuse, and would allow for a less costly and complex process for levying sanctions than the criminal process. Through federal legislation or state rulemaking, the restriction, suspension or termination of benefits, restitution or imposition of fines would be allowed.

2. Lock-In Programs

Congress should amend federal legislation to grant broader authority to states to limit Medicaid beneficiaries' freedom of choice of providers to preferred/enrolled providers, and to expand a state's ability to limit provider networks through expedition or elimination of the 1915(b) waiver process.

Under Section 1915(a) of the Social Security Act, and 42 C.F.R. 431.54, states are permitted to enroll beneficiaries suspected of fraud/abuse/misuse of benefits into a pharmacy or physician lock-in program. However, 1902(a)(23) of the Social Security Act provides that Medicaid eligible beneficiaries must be allowed to obtain benefits from any willing and qualified provider. Notwithstanding the provisions in 1915(a), waiver of this section is permitted through 1915(b) of the Social Security Act; however, the waiver process is burdensome, both on time and resources.

3. Provider Networks

Congress could ensure clarity and consistency in this matter by modifying 1902(a)(23) "Any Willing, Qualified Provider" provisions, and other pertinent provisions of the Social Security Act, to set forth states' rights in the area of provider network controls. This process would be further streamlined by expanding states' ability to limit provider networks through expedition or elimination of the 1915(b) waiver process.

Section 1902(a)(23) of the Social Security Act provides that beneficiaries may obtain services from any qualified Medicaid provider that undertakes to provide the services to them. There appears to be an exception to the general freedom of choice rule in 42 U.S.C. 1396n, which provides that a State may impose certain specified allowable restrictions on freedom of

choice; however, the federal law is not clear on exactly what restrictions may be imposed. In addition, although federal regulations, specifically 42 C.F.R. 431.51(c)(2), provide that states may interfere with a beneficiary's freedom of choice by "[s]etting reasonable standards relating to the qualifications of providers, " it has been left up to courts to determine what are "reasonable standards."Some of the reasons for restricting provider enrollment that have been deemed reasonable by courts include (1) the protection of beneficiaries by allowing the state to exercise some degree of control over providers, (2) assisting the state in properly allocating scarce public resources, (3) preventing fraud, and (4) promoting good service.

Although courts have interpreted federal "any willing provider" provisions in various ways, the language of the current federal statutes limits states' options in restricting willing and qualified providers from participating in Medicaid. Section 1915(b) of the Social Security Act allows for waiver of 1902(a)(23) through a formal application process, which is often burdensome and costly to states.

4. Provider Over-Payments

The state is at a fiscal disadvantage because it must refund the federal portion of the provider overpayment before the collection process has been completed. Upon discovering that it has overpaid a provider, the state Medicaid agency must report the overpayment to the Centers for Medicare and Medicaid Services (CMS). Under 42 C.F.R. 433.316(d), the state must refund to CMS the federal portion of the amount owed by the provider at the same time the overpayment is reported. This occurs at the time a state Medicaid official determines that an overpayment has been made. However, because of provider appeal rights and the hearing process, the amount refunded to the CMS may not be recouped from the provider by the state Medicaid agency.

Collecting debts owed to the state is a difficult process. For various reasons (bankruptcy, refusal to pay, imprisonment of debtor) the amount billed on the Final Audit letter may not be collected. Additionally, the amount due may be reduced by the Appellate process. This dilemma could be avoided by revising federal law to allow for the recording and refunding of the overpayment at the time all appellate and collection efforts are exhausted. This would require changing the CFR reporting requirements from "date of final written notice" to "the date of the final notice of amount due that a Medicaid agency or other State official sends to the provider in which no appeal is pending or after resolution of the appellate proceeding."

5. Bankruptcy

Oftentimes, when agencies pursue sophisticated perpetrators of fraud, the party will declare bankruptcy under federal bankruptcy laws to shelter his or her assets. Under federal law, Medicaid overpayment claims are unsecured claims in the bankruptcy of a provider. [11 U.S.C. §§ 101(5), 506]

- Medicaid overpayment claims are not granted a priority over the claims of other creditors. [11 U.S.C. § 507]
- Whether the case is a Chapter 7 liquidation, Chapter 11 reorganization, or Chapter 13 individual payment plan, Medicaid only receives a pro rata share of the distribution to general unsecured creditors. [11 U.S.C. §§ 726, 1129, 1325]

- In bankruptcies under Chapters 7 or 11, a bankrupt Medicaid provider may not discharge liability for Medicaid overpayments obtained by fraud, false pretenses, false representation, or larceny. [11 U.S.C. §523(a)(2), (4)] However, to enforce these exceptions to discharge the State would have to bring a separate suit against the debtor in the bankruptcy court, waiving the State's sovereign immunity on these issues.
- Debtors may discharge liability for Medicaid overpayments obtained by fraud in Chapter 13 individual payment plans, except for those restitution liabilities imposed by a criminal conviction. [11 U.S.C. §1328]

By making the following changes to federal bankruptcy laws, states would improve their ability to collect overpayments:

- Create an exception to discharge under 11 U.S.C. §523 providing that Medicaid overpayments determined in State civil, criminal, or administrative proceedings may not be discharged under 11 U.S.C. §§ 727 and 1141, and must be paid in full for a debtor to receive a discharge in a Chapter 13 case.
- Modify the automatic stay under 11 U.S.C. §362 to allow the State to pursue proceedings to adjudicate the amount of a Medicaid overpayment but not permitting collection of the overpayment other than by State law recoupment.
- Modify the automatic stay under 11 U.S.C. §362 to acknowledge the rights of Medicare and the state Medicaid programs to recoup overpayments against current and future payments.
- Modify 11 U.S.C. §507 by giving state Medicaid overpayments at least an eighth priority (above unpaid taxes) in payment. This will require payment in full or satisfactory treatment of all Medicaid overpayments claims prior to any payment to general unsecured creditors.

6. Data Sharing

Any efforts to identify and combat fraud must be served by accurate and valuable data. The role of technology in locating fraud sources is critical. An agreement is currently in place under which CMS will conduct a computer matching program with the Agency for Health Care Administration to study claims, billing, and eligibility information to detect suspected instances of Medicare and Medicaid fraud and abuse in Florida. CMS and the Agency for Health Care Administration will provide TriCenturion, a CMS contractor for the Medicare and Medicaid programs, records pertaining to eligibility, claims, and billing which TriCenturion will match in order to merge the information into a single database. Utilizing fraud detection software, the information will then be used to identify patterns of aberrant practices requiring further investigation.

Although Florida is one of six states to participate in this matching program, this contract is only in effect for 18 months after the contract execution, expected to be in April 2004. The Agency believes that this national project should be made permanent and extended to all states to assist in identifying duplicate payments, duplicate services and much more.

7. Federal Funding

Currently, Medicaid Program Integrity (MPI) functions receive approximately 50% federal matching funds. The Medicaid Fraud Control Unit (MFCU) in the Office of the Attorney

General currently receives an enhanced federal match (75-90%) for its fraud functions. Federal matching for MPI functions should be increased to 90% federal matching for MPI system and other development activities, and 75% federal matching for MPI operations. By increasing the federal matching funds to align with that of MFCU, MPI would be able to increase its investigative abilities and resources to monitor aberrant billings and look at possible fraud and abuse in more detail.

B. Office of the Attorney General

The Office of the Attorney General (OAG) houses the Medicaid Fraud Control Unit (MFCU) and prosecutes provider and corporate fraud. This office has suggested the following changes in federal law that would greatly enhance its efforts to pursue and combat Medicaid prescription drug fraud.

1. "Average Sales Price" definition

A definition of "Average Sales Price" should be added to federal law analogous to the definitions of ASP provided in several current DOJ Corporate Integrity Agreements with manufacturers that arose from settlement negotiations (e.g., the recent Bayer and GlaxoSmithKline CIAs). The newly enacted Medicare pharmacy bill has a definition of "Average Wholesale Price" but it is not particularly helpful for anti-fraud purposes. Perhaps an amendment to that new AWP definition would be helpful.

2. Price Certification

Congress should formulate a federal requirement for manufacturer certification of the prices that they report to First DataBank. The State of Texas has required certification under state law for many years, and California is considering the same. A federal law requiring price certification would be very helpful.

3. Identifier Codes of pharmaceuticals

There appears to be some conflict between the legal requirements of the Food & Drug Administration and the Centers for Medicare and Medicaid Services (CMS) as to whether the unique identifier code of individual pharmaceuticals (the National Drug Code, or NDC) should be changed in the event the pharmaceutical is "rebottled" or "relabeled" after the manufacturer sells the drug. This is the process whereby very large containers of drugs are broken down into many, small, retail-distribution size containers. The FDA law appears to require the NDC to stay the same in the event of rebottling. Conversely, the CMS regulations seem to indicate that anytime a drug is rebottled, it need be assigned a new unique NDC. The significance of the matter centers in the federal/state Medicaid drug rebate program administered by CMS under 42 USC s. 1396r-8 (manufacturers pay a percentage of Medicaid's initial cost back to the states as a rebate). Rebottling increases the ultimate cost of the drugs, which increases the amount of drug rebate paid to the states. Manufacturers ignore the CMS law and hide behind the FDA law when paying rebate on rebottled drugs because it allows them to pay a lower rebate on an unchanged NDC. Thus, Medicaid pays for high-priced "small-bottle" dispensing, but the manufacturers pay lower-cost "big-bottle" Medicaid rebates. These inconsistencies should be addressed at the federal level.

VI. CONSEQUENCES OF FAILING TO ACT

The findings by the Statewide Grand Jury, the Sun-Sentinel and other media reports, the live testimony heard before the Florida Senate select subcommittee all depict a tragic state of affairs plaguing our public health care system. Unscrupulous people are profiting at the expense of other people's misery. Failure to address these problems head-on will result in more dollars diverted from the poor and needy, and will result in more deaths. Efforts to meet these challenges forcefully yet fairly, while ensuring that the legitimate activities of providers, patients and others are not hindered, must be Herculean in their scope.

In our search to develop solutions to Medicaid fraud, there is no desire to add unneeded regulations, impede the delivery of legitimate health care or inhibit the caring provision of pain management to those patients who genuinely need it. The state has made its commitment to accomplish this task by implementing policy changes, improving interagency coordination and communication, and enacting legislation where appropriate. However, our efforts will be magnified significantly if federal barriers to our goals are removed.

VII. CONCLUSION

Again, I very much appreciate this Subcommittee being here, focusing on these and related issues and listening to our concerns. It gives me great hope that we are on our way in dealing with the insidiousness of Medicaid fraud and prescription drug over-prescribing. As the Florida Legislature continues to seek ways to provide the necessary tools and resources to all entities having a role in this fight against illicit drug trafficking, we may identify additional federal barriers that we will ask you to examine.

We welcome all opportunities to continue to partner with the federal government, and with other states, in identifying ways to attack these issues through legislation, policy decisions and continuing education.

Thank you again for providing this invaluable opportunity to share with you the Florida experience on this very vexing issue. Please let me know if there is anything we can do to assist you in this important work. I appreciate being able to participate in this dialogue today, and look forward to additional communications in the coming months.

Mr. SOUDER. If each of the witnesses will raise their right hands.
[Witnesses sworn.]

Mr. SOUDER. Thank you, let the record show that each of the panelists replied in the affirmative.

Thank you for coming today, we really appreciate you helping us clarify this issue. We are going to start with Mr. McDonough, I keep wanting to say the regional drug czar, so I thank you for coming today.

STATEMENTS OF JAMES R. MCDONOUGH, DIRECTOR, FLORIDA OFFICE OF DRUG CONTROL; DR. STACY BERCKES, M.D., BOARD MEMBER, LAKE SUMTER MEDICAL SOCIETY; JACK E. HENNINGFIELD, PH.D., PINNEY ASSOCIATES, ON BEHALF OF PURDUE PHARMA; AND THERESA TOLLE, R.PH., PRESIDENT, FLORIDA PHARMACY ASSOCIATION

Mr. MCDONOUGH. Mr. Chairman, thank you very much for having me and for holding this hearing. On behalf of Jeb Bush, the Governor of the State of Florida, he extends his greetings and his appreciation for what you are doing.

And to Mr. Mica, sir, thank you very much for your suggestion that the hearing be held, it is always an honor to appear before you.

And sir, welcome from Georgia, very good to have you down here. I live only about 12 miles from your State and I love it because I can go up there and get my gas at about 20 cents a gallon cheaper.

I have submitted a statement for the record, I would like to sum up that statement, in just a very few minutes if I might, Mr. Chairman.

I think there has been adequate discussion of the scope of the problem. I would just add a couple of things that we have noted. In addition to the theft of prescriptions through the thefts of the pharmaceuticals themselves in resale, in addition to the Internet sales which we think is a major problem and to the doctor shopping, what I call pharmacy hopping, and finally in addition to the corruption we have a small amount but some in the system itself. We also have uncovered a great deal of recipient fraud in the State of Florida, and diversion at the far end, such as in nursing homes for those for whom the drugs are intended. They do not get them, and are often unaware of that and unable to report it.

Florida does have a large problem with this, I do have oversight on the extent of the problem and the problem I am talking about specifically is prescription drugs, the abuse of them and that is all of them. Much has been said this morning on OxyContin. As we are able to track this it is oxycodone the chemical compound in OxyContin and other drugs that we really keep track on, but when we combine them with the hydrocodone and the methadone, we come up with an aggregate that led to a greater death rate than heroin and cocaine.

So from my perspective, prescription drug abuse has become the greatest killer in the drug world in this State, and that is an enormous amount. There are, as you know, and you will hear later from the mothers and fathers of some of those who have died in this room. I hear from them and count the total loss as 10 a day. If we look only at the abuse of prescription drugs, devoid of any other il-

legal drug abuse, it is five killed per day. Unacceptable, an epidemic of first proportion. I might add what is really unnerving about this in addition to that grotesque death rate is the rate at which it is rising. So we only began tracking them in Florida in 2001, and every year we saw it go up 25 to 30 percent. I do believe we have the rise in the death rate stopped this year but it is still far too high. We are on track in 2003, to come in slightly above the numbers that we had in 2002.

So the scope of the problem is vast, it is steep, and very complex. Governor Bush had directed a series of very aggressive actions that will address it. I would just like lay out the breadth of that briefly.

First of all, we would appreciate, all the help we can get from our friends at Federal level, and I know all the people that testified before, admire them all, but I think we have to work harder on this particular problem.

ONDCP and the National Institute on Drug Abuse points out that the second most abused drugs in the United States now after marijuana are prescription drugs. That is an enormous event, it tells me it is the new wave of drug abuse. In the history of drug abuse in the United States, there is always a new way: it is cocaine, it is crack cocaine, it is methamphetamine. Today it is prescription drug abuse, and by the way, methamphetamines have not gone away so we still have a problem with that. But it is a serious problem.

We are looking at law enforcement as a way to get at this problem, and although it did not come out clearly from our Federal friends, who are helping us, I will tell you the State of Florida is getting very aggressive in going after any corruption in the system. So, all of the doctors and I do not know the names of the ones specifically referred to in that article, but I do know that we are looking at where we believe there is an element of corruption and we are going after that. Not just for doctors, but for the pharmacies as well.

We also have, as I said, a major recipient fraud problem, which is not a light problem. A recent statewide grand jury investigation indicated that it could be a significant percent of the Medicaid system in the State and the Medicaid system in the State is something like $13.5 billion. But law enforcement I have to point out is not enough by itself, it comes in after the fact, after people have died. So we are looking at early warning systems that will allow us to detect early through Medicaid and other data mining sources that we have a problem.

And we are also looking at process, the process that allows the administrator that oversees the system, whether it be the distribution of pharmaceuticals, the use of Medicaid, passes that off to the appropriate investigative authority when we believe we could have an instance of fraud and abuse and diversion. It is also the education of doctors. We find that many doctors do not have adequate identification capability of addiction, as well as the pharmaceuticals themselves. So, we are looking at requiring a greater effort to educate our doctors. And certainly we need to inform the public of the risk of prescription drug abuse.

So, it is the entire process that we will get at early warning, law enforcement, training, and education, and finally a legislative pack-

et within the State that will allow us to deter the event for the most part before it happens. I will tell you that the prescription drug validation system we are looking at all by itself will go a long way to stopping the grotesque death rate we are going under. It will not completely stop it, but it is the single most important thing we can do. It is that package of events in combination with what the Federal authorities can do that I think would help us bring this problem under control.

Thank you, sir.

Mr. SOUDER. Thank you, very much. Doctor, is that Berckes, next.

[The prepared statement of Mr. McDonough follows:]

TESTIMONY OF JAMES R. MCDONOUGH BEFORE THE GOVERNMENT REFORM COMMITTEE SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

JAMES R. MCDONOUGH
Director, Florida Office of Drug Control
Executive Office of the Governor
Monday February 9, 2004
Winter Park, Florida

Good morning, and thank you for the honor of testifying today before Chairman Mark Souder of the Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy and Human Resources. On behalf of Florida Governor Jeb Bush and the many state and community leaders and citizens involved in our combined efforts to bring down the abuse of prescription drugs in Florida, I am appreciative of the national leadership Congressman Souder and the members of the Subcommittee have given to the matter. I thank you for your time and attention to this most important issue and also for the opportunity to meet with you to discuss the urgency of the growing problem of illicit diversion of prescription drugs.

INTRODUCTION

Florida has a serious problem with illegal prescription drug diversion and abuse. Pharmaceutical drug diversion hurts Florida significantly in terms of lost lives, increased crime, human misery from addiction, and substantial costs connected to treatment, medical expenses and Medicaid fraud.

Prescription drug diversion is the channeling of licit pharmaceuticals for illegal purposes or abuse, a practice that far too many have participated in, from addicts seeking a quick high to (unfortunately) children seeking adventure and (sadly) some doctors, pharmacists, and patients in pursuit of ill-gotten income. Much of illegal prescription drug diversion in Florida begins with a stolen, forged, counterfeit, or altered prescription form. Equally as harmful, individuals often seek out multiple doctors (doctor shopping) to prescribe drugs for imaginary or even bogus ailments, and then fill the prescriptions at multiple pharmacies (pharmacy shopping) in order to conceal the sum total of the prescriptions being filled. Contributing to the problem,

doctors may unwittingly over-prescribe powerful drugs not realizing their potential for abuse, or they may simply sell prescriptions and the related doctor office visits knowing full-well that the "patient" is a substance abuser. Likewise, pharmacies can contribute to the problem by failing to recognize when over-prescription and/or fraud is taking place, or by failing to meet their legal and ethical obligations to operate within the law and accepted industry standards.

Across the board, Florida has seen prescription drugs diverted through fraudulent means, outright theft, phony "pharmacy" fronts, loose internet "medical evaluations," and inappropriate importation. Prescription drug abuse accounts for 30% of the nation's illicit or illegal drug problem. Scheduled drugs that are prescribed by physicians are diverted from their intended use and then abused or illegally sold. Drugs diverted include Schedule II, III, and IV controlled substances, and nationwide constitutes a multi-billion dollar criminal industry.

The National Household Survey on Drug Abuse ("NHSDA") reports that 11.1 million Americans used prescription drugs "non-medically" during 2001. Of these, 5.4 million were ages 12-25. In Florida over the past two years, we have seen a 120% increase in admissions to treatment centers for prescription opiates, and steady increases for the past two years in treatment center admissions, especially for children, due to Schedule IV benzodiazepines, such as Xanax and Valium.

In 2002, Florida experienced 9,116 drug overdose deaths. Of these, prescription drugs caused some 3,324 deaths, or 36% of the total. For the year 2002, Florida suffered more deaths from prescription Schedule IV benzodiazepines (such as Xanax and Valium) than from cocaine. This tragic trend has continued in 2003 to the point where now five Floridians die per day solely from prescription drug overdoses. If we include medical examiner autopsy reports that cite prescription drugs used in conjunction with other illegal drugs, the casualty rate is ten killed a day. For the past few years overdose deaths in Florida from prescription drugs have surpassed the combined death rate from heroin and cocaine. Florida urgently needs an effective and comprehensive set of tools to arrest this deadly epidemic.

THE SCOPE OF THE PROBLEM

The intricacies of illicit diversion of prescription drugs are complex. I do not for a minute believe, however, that these problems are germane only to Florida. The problems we have seen here, I suggest, exist elsewhere in the United States. If anything, we may have a lead in addressing the extent of the problem since we have been investigating its reach and its consequences for the last several years. Simultaneously, we attempted to mitigate the harm done by prescription drug diversion and abuse without detracting from the sanctity of the doctor-patient relationship, privacy rights, and the benefits that pharmaceuticals – properly prescribed, dispensed and taken – can bring to the afflicted.

What we have been able to do in Florida is categorize the scope of the problem in its many parts. Beginning with a review of provider (e.g., treatment center) phenomena and trend-lines, we ascertained several years ago that addicts were shifting their focus from the traditional drugs of abuse (i.e., cocaine, heroin, etc.) to man-made drugs, some completely illegal (such as "home-cooked" methamphetamines) and some perfectly legal – and beneficial – when used properly. These include benzodiazepines and pharmaceuticals containing hydrocodone, oxycodone, and methadone. The reasons for this shift by addicts appear to have been three-fold. First, addicts believe that such drugs are safer (which they are not when abused) because they are pharmaceutically produced and obtainable through the medical system. Second, they are readily available through the legitimate free-market system. And, third, they produce a quicker, longer and deeper high.

Aware of such trends by addicts, Florida officials turned to law enforcement officers and state medical examiners for their insights as to the depth of the problem. All reports confirmed our worst fears – diversion of illicit drugs to feed (and also fuel) addiction was rife. Law enforcement revealed whole patterns of abuse, from outright theft of pharmaceuticals (at the pharmacy, at outlets such as nursing homes, in transient to market, etc.), to black-marketeering, doctor/pharmacy complicity, and even organized crime. Medical examiner reports – now mandated to record benzodiazepines, oxycodone, hydrocodone, and methadone – indicated an alarming number of overdose deaths (with corroboration from emergency room interviews) and an alarming rise in the rate of deaths over time, in some cases rising at more than one hundred percent a year. Simultaneously, extensive newspaper articles began to cover stories of this new wave of drug abuse. By every measure, it was apparent that a new phenomenon of drug abuse had come upon the scene, with devastating effect.

Doctor shopping and pharmacy hopping, clearly, was only one part of the trend. Greatly exacerbating the problem was fraud, and, in particular, Medicaid fraud. In 2003 Florida initiated a Statewide Grand Jury investigation looking into what was called "recipient" fraud. The "Report on Recipient Fraud in Florida's Medicaid Program" defines a professional recipient as an individual who routinely defrauds one or more entitlement program. Florida is plagued by recipient fraud because, as the report lays out,"...Florida is hampered by a lack of state statutes, federal limitations that restrict Florida's attempts to control this fraud, and a lack of awareness by some state and federal officials of the extent of the problem of recipient fraud." (*Report,* Page 2)

As the Grand Jury *Report* describes, so-called "street sales" are the most commonly encountered form of recipient fraud. Quite simply, Medicaid recipients sell their Medicaid-bought drugs to criminal wholesalers, who, in turn, repackage the pharmaceuticals for resale to regional wholesalers or to local pharmacies. According to the *Report*, one illegal wholesaler bought and sold approximately $2.4 million worth of three specific prescription drugs in just the first three months of 2002, the drugs coming largely from Medicaid recipients reselling their own drugs. (*Report*, Page 4)

Indeed, the diversion and abuse of pharmaceutical controlled substances is already a well-established multi-billion dollar illicit market operating in the United States. The National Household Survey of Drug Abuse indicates that approximately 13 million Americans are current illicit drug users, meaning they had used an illicit drug in the month prior to their interview. This represents over 6% of the population 12 years old and older. The Survey also indicates that the non-medical use of prescription drugs exceeds that of all illicit substances except marijuana and hashish.

Even though Drug Enforcement Administration statistics have consistently identified pharmaceuticals as almost 30% of the overall drug problem in the United States, to date there is no nation-wide reporting system in effect that might mitigate the harm from such abuses. As the Grand Jury *Report* surmised, it is almost impossible to know the true extent of the prescription drug abuse problem because so much of the problem goes unreported. We can only rely on drug abuse indicators and the information that is available from health regulatory authorities and state and local law enforcement officials.

Yet another area of abuse is internet access with little or no scrutiny by qualified medical professionals. Florida law requires a physical examination by a doctor for the proper prescription of Schedule drugs, (Fla. Statute 465 and Chapter 64F-12). Many internet sites offer in lieu of that physical examination a questionnaire, allegedly reviewed by a doctor on site. Far too often, the questionnaires are so general and cursory in nature as to be farcical. Whether or not a doctor ever reviews them, or is even available to review them, is unknown. Either way, internet questionnaires do not suffice under Florida law as a physical examination. Nonetheless, prescriptions are filed and filled, much of it, we believe, for illicit purpose.

Nor can we be certain where internet purchased drugs come from or even what is actually in them. An earlier Florida Statewide Grand Jury Report, The First Interim Report of the Seventeenth Statewide Grand Jury, revealed an extensive system of adulteration of drugs. Subsequently, the Florida legislature passed, and Governor Bush signed, legislation that would guard against adulteration. Internet sales, however, too often bypass normal systemic safeguards. Some of the drugs provided come in from abroad – a further manifestation of the scope of the problem – circumventing not only local statutory constraints but U.S. Customs procedures as well. Clearly, internet sales are a whole category of complexity that must be adequately addressed.

Indeed, the potency of the modern genre of pharmaceuticals and the lack of understanding of that very potency and its relationship to addiction by inadequately trained and educated medical professionals contributes greatly to the problem. As a general observation, too many doctors do not recognize the signs of addiction. Even when treating a legitimate patient, they may not recognize when the line between medical benefit and debilitating addiction has been crossed. Lacking such recognition, they may inadvertently feed an addiction and miss the underlying diagnosis.

So too do law enforcement officials lack adequate training to deal with the complexity of illegal diversion of pharmaceuticals. Criminal activity has gravitated to this sector because of the vast amounts of money to be made in both primary and secondary markets. Drug traffickers, corrupt officials, and other criminal elements have been drawn to illicit diversion because, in the words of the famous bank robber Willie Sutton, "...that's where the money is." We will need to improve and specialize the training of law enforcement officers in this area if we are to reduce the crime we are seeing there.

Law enforcement operations, however, are not enough in and of themselves to stop the hemorrhaging of lost lives and criminally diverted money. Even should better training and greatly enhanced commitment of resources be available to this particular field of criminal activity, law enforcement necessarily comes in only after the fact, when the damage has already been done. The law is broken only when an act is committed, and by then it may be too late to save lives. A number of newspaper articles in Florida have documented just how horrific some of that damage can be, most notably a series done by Doris Bloodsworth in the Orlando Sentinel (submitted herewith) and Fred Schulte in the Fort Lauderdale Sun-Sentinel (also submitted). Among many examples of egregious findings, they include reports of 61 deaths associated with the top 16 Medicaid prescribers in Florida, 23 of the top 24 prescribers having either criminal or administrative charges against them, a doctor long-since dead having recently billed million of dollars worth of prescriptions to Medicaid, and a criminally charged doctor having the charges dropped in exchange for ethics training, only to subsequently see eleven deaths associated with her prescriptions. Their accounts, and the reports of many others, make for shocking reading.

To be sure, Florida has taken aggressive action against criminal practices. Dr. James Graves of Pensacola was convicted of 4 counts of manslaughter for prescribing excessive amounts of oxycodone to his patients. In 2003, Dr. Sarfraz Mirza of Melbourne was arrested for the fraudulent prescription of over $500,000 in prescription drugs and 11 counts of trafficking in OxyContin. Dr. Mitchell Wick of Plantation was barred in April 2003 from prescribing narcotics because the Medical Examiner's Office discovered 16 overdose deaths among his patients. Dr. Asuncion Luyao of Port St Lucie has recently been charged with six counts of manslaughter for overdose deaths due to medications she prescribed. Many phony and/or corrupt pharmacies have been busted. We will continue to go after criminal activity. But we need other systems in place that can help to deter such activities and prevent the unacceptable damages before they are done.

Part of the problem may stem from such issues as the classification of pain medications themselves. Medication that is appropriate for severe pain may not be appropriate for moderate pain. Doctors and their patients make that decision, but the Food and Drug Administration classification of the appropriate categories of pain must guide them. The Doris Bloodworth articles, referred to above, suggest that this is a major area of concern. Focusing on only one of the many prescription drugs containing

oxycodone, OxyContin, she reviewed several hundred autopsy reports in Florida and narrowed in on 247 of them. Her findings were that OxyContin was found to be the drug of use in 205 (83%) of them. In her words: "Of those who died from oxycodone, 52% were white men between the ages of 30 and 60, many of whom suffered from back pain. When health histories were specified in oxycodone overdoses, autopsy and police reports mention pain-related medical problems much more frequently than recreational-drug abuse. The Sentinel furthermore determined health histories in 303 of the 500 cases studied. Back pain or injuries accounted for 87 cases, while drug abuse accounted for 38 cases."

What this suggests is that it may not be illegal diversion alone that contributes to the extent of the problem. It may also be fed by inappropriate degrees of classification and education. If so, no solution would be complete unless these considerations were also taken into account.

SOLUTIONS TO THE PROBLEM

Florida has already taken a number of strong steps to address these challenges. Governor Bush, immediately upon his election to a first term of office in 1999, prioritized bringing down drug abuse in Florida. Now deep into his second term, that goal remains a priority.

He has directed a number of administrative, policy, and legislative initiatives to deal specifically with the problem of prescription drug abuse. In 2003 he reinforced this determination by directing that a Principals' Group form to develop an action agenda to address the breadth and the depth of the problem, while ensuring the sanctity of the doctor-patient relationship, privacy rights, and appropriate access to pain medication. The Principals' Group consists of the Florida Attorney General, the Secretaries of the Department of Health, Agency for Health Care Administration, and Department of Children and Families, the Commissioner of the Florida Department of Law Enforcement and myself as the Chair.

Assisting this group is a Deputies' Committee (composed of principle staff leadership from each of the involved agencies) that is exploring the administrative, technological and analytical steps necessary to ensure a smoothly operating process for early warning of possible diversion, appropriate education and training of all involved professionals, interagency and intergovernmental coordination and appropriate board reviews, and when necessary, criminal investigation of suspicious practices. These recent initiatives follow three years of efforts that have included involvement by all pertinent parties, legislators, interest groups, medical professionals, pain-management experts, law enforcement officials, private industry, parents, and the public in general.

Legislation

Government leaders, lawmakers, and professional groups have considered three salient points when addressing the problems of illicit drug use. First and foremost, modern medications, when used appropriately, help alleviate the pain of thousands of Floridians who otherwise would suffer needlessly. Second, it is the abuse and misuse of these medications, not the medications themselves, that is the cause of the problem. Third, according to the Florida Medical Examiners reports, the majority of drug-related fatalities occur from a lethal cocktail of several drugs. (Notwithstanding the sad statistic of five dead a day in Florida from lethal doses of prescription drug alone.)

Armed with this insight, the Principals' Group's considerations for reducing drug diversion recommends a number of effective and properly focused statutes. Foremost among them is a system for prescription validation, a method to preclude doctor-shopping/pharmacy-hopping, fraud and corruption.

The proposed Florida prescription validation program will, if fully implemented, go a long way toward easing Florida's prescription drug diversion problem. Administered by the Florida Department of Health (DOH), it will consist of two major components – an electronic database in the DOH containing patient prescription history, and the voluntary use of counterfeit-proof prescription forms by prescribing physicians. The primary purpose of this system is to assist physicians in the proper treatment of their patients. The secondary purpose is to assist law enforcement, once properly activated, during investigations. The use of counterfeit-proof prescription forms for Schedule II-IV controlled substances will serve as a deterrent to those who would forge or copy ordinary doctor scrip pads.

The validation program is a streamlined operation. Once a prescription is presented at the pharmacy, the pharmacy retains the original scrip and enters the data electronically. The system will assist doctors by providing them with a record of prescriptions previously received by the patient so that the physician can appropriately treat the patient. The physician can then see exactly what the patient has been prescribed in the past by other physicians. This will quickly identify a patient who visits many physicians for the same medications. Pharmacies who suspect that a patient is presenting an invalid prescription can check to insure the prescription they are filling is legitimate.

In this proposed program, the Florida Department of Health will maintain strict confidentiality ensuring that both patient and doctor privacy rights are protected. Queries will only be accepted from physicians (concerning their own patients), pharmacies (only access to recent history to validate prescription permitted), Agency for Health Care Administration (access only for ongoing investigation of practitioner/Medicaid fraud), the Department of Health, and the Florida Department of Law Enforcement (access permitted for active criminal investigations only). To enforce the confidentiality of patient and physician information, a companion bill will make it a 3rd degree felony crime for knowing disclosure of data to non-authorized persons.

A patient may withhold access to prescription history by his or her doctor. Children of a certain age will be excluded from the system. We believe that privacy will be adequately protected. We note that in more than 20 years of other states operating prescription validation systems similar to the one being proposed here in Florida - with over 65 million prescriptions processed - not a single breach of patient confidentiality has been identified.

Nor do we believe that a prescription validation system would detract from a doctor's willingness to prescribe medicine. Indeed, all the states that operate serialized prescription systems report no evidence of any decrease in prescription for legitimate patients. Nor have they had complaints from either practitioners or patients that would indicate a lessening of necessary prescriptions. In fact, states that have analyzed prescribing data have found that the drugs that have decreased in being prescribed are limited to the drugs that were being heavily abused, and that other controlled substances stayed the same or increased consistent with national treatment patterns.

The benefits of a prescription validation program for Florida are numerous. First, the electronic system assists patient treatment. The physician will be able to query the system concerning his patient and quickly receive the patients' prescription information. The use of this system will greatly reduce doctor and pharmacy shopping as well as the over-prescribing of prescription drugs. Secondly, the use of counterfeit -proof pads will help eliminate the forgery and counterfeiting of prescription forms, thereby greatly reducing the illegal diversion of prescription drugs. Additionally, this will improve law enforcement's ability to investigate, prosecute, and stop criminal activity. The benefit to both physicians and pharmacies will be the reduction of doctor and pharmacy shopping by unscrupulous patients. In short, the establishment of this system in Florida will prevent a great number of deaths from the illegal diversion and subsequent abuse and overdose of prescription drugs in our state.

The prescription drug validation system is not the only piece of legislation needed to address the scope of the diversion challenge. We are also advocating a Florida law that would require that internet pharmacies obtain a permit in order to operate. It further provides for disciplinary action when a pharmacist knows or has reason to believe a prescription is invalid and fills it anyway. During the 2001 legislative session, the Florida Legislature passed Florida Law 2002-81 making it a crime (3rd degree felony) for doctors to write prescriptions for fictitious persons, write prescriptions solely to make money, and knowingly assist patients in fraudulently obtaining controlled substances. It also encompasses a patient who withholds information regarding previous receipt of a prescription for a controlled substance (doctor shopping).

Other key legislative initiatives address:

- Internet Pharmacies – Requires internet pharmacies to obtain a permit to operate. Also provide for disciplinary action of dispensing

medicinal drug when pharmacist knows or has reason to believe prescription is not valid. This statue provides a penalty of a second-degree felony for distribution of medicinal drugs without a permit (aimed at the illegal distribution of drugs via internet pharmacies).

- Prescription Drug Protection – Based on findings from Seventeenth Statewide Grand Jury this bill requires high end/high cost drugs to have pedigree papers from manufacture to dispensing to prevent unauthorized adulteration and dilution of drugs. This bill will also prohibit purchase or sale of Rx drugs in wholesale distribution in exchange for currency.

- Medicaid Fraud and Abuse – Authorizes the Agency for Health Care Administration to impose mandatory enrollment in drug-therapy-management or disease-management programs for certain categories of recipients; provides specified conditions for providers to meet in order to submit claims to Medicaid program; provides that claims may be denied if not properly submitted; and, finally, provides that agency may seek any remedy under law if provider submits specified false or erroneous claims, etc.

- Protection Against Use of False Identification – Creates third degree felony for using false or stolen driver's license or ID to obtain a prescription drug or controlled substance from a pharmacist and for dispensing prescriptions without first being furnished photo identification.

- Early Warning – An amendment to existing statute would require medical examiners to report multiple suspicious deaths by overdose tied to a single practitioner.

Aggressive Response

Aggressiveness characterizes Florida's approach to the epidemic of prescription drug abuse and diversion. We will move rapidly to curtail the many manifestations of the overall problem. The scope of that includes: illegal diversion of prescription drugs; doctor shopping/pharmacy hopping; Medicaid fraud; adulteration; criminal organizations; licensing; data screening; nursing home diversion; internet prescriptions, and a host of other concerns. Our approach will be a combined interagency effort coordinating the actions of respective agencies, partnership between public and private concerns, better education and training, and law enforcement. Professional board and law enforcement efforts will, for example, continue to focus especially on the small class of over-prescribing -- and in some instances criminally culpable -- doctors and pharmacists. Florida law enforcement will be augmented with both a greater degree of trained

professionals and new procedures for joint cooperation and intelligence connectivity between state, local and federal fraud diversion investigators. Indeed, we will use the criminal justice system as appropriate, from investigation through arrest and prosecution, to deter criminal activity that would mar our very proficient medical system.

Early Warning

Florida will also develop an aggressive early warning screening system that will flag possible problems (such as operating without a license, suspicious volume of prescriptions by single sources, multiple sources of prescription to a single individual, records' discrepancies, medical examiner observations, etc.). Key elements of Florida's early warning system will include, in addition to the prescription validation program:

- Medical Examiners Early Warning System – Medical examiners will be required to report to both law enforcement and health officials suspicious circumstances surrounding overdose deaths involving prescription drugs. The intent of this process is to identify the origins of the drugs involved in the deaths and prevent future deaths from the same source.

- Medicaid Early Warning – (1) Drug Utilization Review (DUR): Quarterly macro review by physicians and pharmacists to detect fraud and abuse in the system (2) Prescribing Pattern Preview Panel: Quarterly in-depth review of practitioners identified by the DUR to specifically identify practitioners whose prescribing patterns are suspicious. (3) ACS Web Profile: Allows physicians to access up to 90 days of prescription records on Medicaid recipients to identify potential abuse (4) Gold Standard Program – Allows 1,000 physicians to review prescription history of Medicaid patients before issuing prescription. AHCA is seeking to expand this to 3,000 physicians that would include total of 80% of all Medicaid prescriptions (5) Pharmacy Auditing – Under the Heritage program, AHCA reviews pharmacy records to identify suspicious prescribing patterns among Medicaid pharmacies.

- Information Sharing – Florida Department of Law Enforcement (FDLE) will improve information sharing concerning cases on physicians and pharmacists. FDLE will also fold this new type of prescription drug criminal investigation information into its currently existing FDLE regional task force structure. The new effort be well-defined, well-scheduled, and well-executed in order to be both effective and promote the interagency communication required to respond to the problems of prescription drug abuse. Additionally, FDLE will share information concerning those physicians, pharmacists, and patients under investigation with other law enforcement authorities across the state as part of the early warning system.

Education and Training

We will also aggressively develop comprehensive education and training opportunities for medical specialists, appropriate people. Doctors need more information on the potency of what they are prescribing, the possible effects of various drugs in combination. Pharmacists need to be aware of fraud and imposter techniques. Law enforcement needs instruction on how to identify likely cases, track the prescription and money trails, and integrate their efforts with other officials. We will also provide public information messaging to protect the user.

There are many aspects to Florida's campaign to provide education and training to health care professionals and the public. For instance, the Department of Health will conduct workshops throughout the state on addiction, as well as on standards for pain management clinics throughout the state. DOH will also work closely with the state's medical schools to incorporate training on prescription drugs and addiction into the curriculum. A key to the effort to expand physician training is a new Department of Health "continuing education" requirement mandating up to two hours of training every two years for all physicians on recognition of addiction. Florida is also working with the U.S. Department of Health's Substance Abuse and Mental Health Services Administration (SAMHSA) to provide resources and opportunities for more doctor education on substance abuse addiction. Florida will develop a model program that should prove instructive and beneficial to the rest of the nation.

The Department of Health will also use the media to provide appropriate anti-diversion education by rolling out television messages reminding physicians about the dangers of over prescribing. DOH will also publicize the "800" telephone number for doctors to call when in question about a possible patient addiction. Furthermore, DOH will work with the Florida Board of Medicine to craft language making the addiction training mentioned above mandatory. Finally, DOH will mandate that physicians must monitor patients receiving Schedule II, III, or IV drugs every 30 days to check how well medications work to relieve symptoms, adverse reactions, and evaluating need to continue the medication.

Partnership

We are also encouraging pharmaceutical companies to analyze and anticipate the problems leading to over prescribing, addiction and abuse and to develop strategies for combating these problems. Proactive strategies implemented simultaneously with the introduction of powerful new opioid pain relievers will forestall many of the problems associated with over prescription and illegal diversion. Board procedures will also be strengthened to guard against abuse, either intentional or unintentional. Doctor training in pain management must be stressed. The failure to properly set effective guidelines in no small way facilitates a permissive environment where damage might be done.

Interagency Coordination

Florida will also aggressively pursue interagency cooperation at every juncture. Some key breakthroughs here will be a clean hand-off and sharing of responsibilities when criminal activity is suspected, continuous, cross-talk on identification of new and emerging problems with an eye to early resolution, focus on problem areas at the local level, and so on. Florida will develop formal processes, both inter- and intra- agency wide, for establishing routines for data mining and other carefully developed standard operating procedures thereby focusing the search for irregular patterns that signal illegal drug diversion and abuse.

Closely aligned with their effort to establish within their pre-existing regional information network the sharing of criminal information regarding drug diversion, the Florida Department of Law Enforcement will further act to craft legislative language establishing an interagency prescription drug council in statute. This Council will establish a formal process for information sharing involving the Principals' Groups agencies and departments. The concept here is for review, evaluation, and sharing of information to occur at the regional level every month with the same procedure conducted at a statewide level every quarter. The intent of this process is to use the early warning systems to prevent fraud, abuse, and diversion. Secondly, the process would facilitate investigations required by violations of law and regulation.

This communication among the agencies is key to identifying patients, pharmacists and physicians who are in violation of regulations and laws with regard to prescription drugs. The passing of key information as to which physicians have suspended or revoked licenses is a prime example of information that each agency can use to enforce standards. There are many other types of information that can and should be shared in order to reduce diversion and abuse prescription drugs.

Resourcing

Finally, thanks to the leadership of Governor Jeb Bush, we will provide sufficient resources at the appropriate levels. That means that we will develop greater prescription drug abuse expertise within the agencies, appoint adequate numbers of fraud investigators dedicated to prescription drug abuse, employ state-of-the-art technological systems, and commit adequate staff oversight. All agencies involved will submit requirements for additional resources base on immediate needs and long-term needs to be incorporated into future budget requests.

CONCLUSION

Florida recognizes the opportunities for better medical care that today's pharmaceuticals have brought to the market. And we are protective of both the special relationship that exists between doctor and patient and the privacy rights of the patient. But we also recognize the vast amount of damage caused by the illegal diversion of prescription drugs, and are determined to lessen it.

Florida is not alone in experiencing this problem. What may be unique is the manner in which we have identified the scope of the problem in its many parts and in devising a detailed strategy to deal with it. In so doing we have highlighted the issue for the rest of the country.

We, therefore, are appreciative of what you the Committee can do to bring further relief to the issue. Because of its national and international parameters, there is only so much a single state can do alone. Nonetheless, we have adopted an aggressive, holistic approach – one informed by the ethical requirements of sound medical practice and good law enforcement – to stop the criminal practices that have led to so many deaths and wasted resources.

Dr. BERCKES. Mr. Chairman, I would just like to clarify my credentials, in addition to on the witness I am identified as a member of the Board of Governors of the Medical Society, and indeed it is via that mechanism that I was invited, but, I think it is important before I give my testimony that it is understood that I am also a Board certified anesthesiologist and pain medicine practitioner. My practice is in Florida Pain Management Center, and additionally that I am the chief of staff at Florida Hosptial, Waterman.

Since there was not an opportunity, and if you thought it was beneficial for the record I will certainly attach my CV to the written testimony if you thought that was useful.

Mr. SOUDER. It is always helpful to have any extra information about the witnesses.

Dr. BERCKES. Thank you for allowing me to clarify that.

"First do no harm." Those words, from the Hippocratic Oath, take on special meaning when discussing the topic of drug use and abuse. I speak to you today with almost 20 years of experience practicing medicine, the majority of those years treating acute and chronic pain. I agreed to testify because I feel strongly that being on the front line of an issue offers a unique perspective to those interested in directing substantive public policy.

These proceedings are being followed by many that have been touched in one way or another by this issue. To those that have lost loved ones, I extend condolences. As painful as it may be we must learn what we can from each and every failure to best serve those with needs in the future. Simply banning a drug that has demonstrated usefulness is not an option.

To the pharmaceutical companies that may have an interest in these proceedings, let me say, keep your science pure. Continue efforts to provide true continuing education so we can best serve our patients. Attempts to manipulate data and words for the sole purpose of creating demand and increasing sales will ultimately fail. Do not promote the mindset that there is a pill for every ill.

To the patients that suffer chronic pain, please know that efforts continue to increase the quality of your lives. We understand now more than ever before about the neurophysiology of pain, the pain signal, pain generators and the pain process. This understanding has resulted in many more treatment options than ever before. The use of narcotic analgesics is just one of the tools that may be useful.

In my practice lifetime, I have seen the pendulum swing from one end of the spectrum to the other with respect to the use of narcotics. In the 1980's, I had to regularly defend this practice and now I am having to recommend against it with almost the same regularity. Every patient deserves to be evaluated and treated as an individual in a way to be determined by his or her physician. Many things cannot be cured. Pain as a symptom is handled differently from pain as the disease State, which often, at best, is managed. True pain management is a dynamic process that demands continuous communication between a patient and the doctor.

To the pharmacists who fill prescriptions, I urge you to adhere to the highest level of your profession's ethics, and do not hesitate to question prescriptions that appear irregular. The system of

checks and balances only works when active 100 percent of the time.

To my colleagues, you know that you are responsible for knowing the possible consequences, benefits, risks, and complications of any prescription you write. There is no substitute for the history and physical examination. The issue of diversion of legitimate prescriptions is an area in which we are not formally trained, but one in which we always must maintain a high level of suspicion when we are prescribing drugs with known street value. The judicious use of urine or serum screening to document compliance of a treatment regimen probably needs to be increased. Additionally, understanding the differences in abuse, addiction, tolerance and dependence is required for appropriate communications with patients, caregivers, as well as other colleagues and law enforcement individuals and officials.

With respect to public policy, I can only say that there is no way to legislate judgment. This is particularly true to the problem at hand. There are already laws that cover inappropriate obtaining, use, and possession of controlled substances. There are already laws that cover the inappropriate practice of medicine and pharmacy. There are already laws that cover what a drug company can say or do. Additional laws in these areas will probably not result in any substantive change in the status quo. Additional funding in specific areas to enforce laws already on the books may help.

The data base that has been discussed may have merit but the details about the design, construction, implementation, and ongoing costs have not been forthcoming. Anything that makes it more difficult for doctors to take care of patients is unacceptable. The availability of controlled substances via the Internet is one frontier which probably deserves additional legislation.

Finally, the unfortunate truth is that there are, always have been, and always will be people with the genetic makeup that fosters drug abuse and the black market that feeds it. Any system that man creates will be circumvented by man. So let us be cognizant of the law of unintended consequences when we try to make anything better.

Perhaps our greatest hope lies in the continued discoveries of the human genome project, that will let us understand the more complex areas of opiate receptors, and why people react in such varied ways to the same drug. Meanwhile, there is no better cure for the present situation, than a true understanding of the existing science, and an ongoing doctor/patient relationship.

Thank you.

Mr. SOUDER. Thank you for your testimony. Next we go to Dr. Henningfield.

[The prepared statement of Dr. Berckes follows:]

"First do no harm..."- Those words, from the Hippocratic oath, take on special meaning when discussing the topic of drug use and abuse. I speak to you today with almost 20 years of experience practicing medicine, the majority of those treating acute and chronic pain. I agreed to testify because I feel strongly that being on the "front line" of an issue offers a unique perspective to those interested in directing substantive public policy.

These proceedings are being followed by many that have been touched in one way or another by this issue. To those that have lost loved ones, I extend condolences – for you, my profession's edict to "first do no harm" obviously failed. As painful as it may be, we must learn what we can from each and every failure, to best serve those with need in the future. Simply banning a drug that has demonstrated usefulness is not an option.

To those of you that have had bad experiences with a medication, be generous with all the facts so that my profession can learn how to do better the next time. Again, simply banning a drug that has demonstrated usefulness is not an option.

To the pharmaceutical companies that may have an interest in these proceedings, let me say that I am thankful for investments in research and development that result in "miracle drugs" that help my profession reach those that were previously unreachable. Keep your science pure so we will not lose faith in your work. Continue efforts to provide true continuing education to my colleagues and me, so that we can best serve our patients. Attempts to manipulate data and words for the sole purpose of creating demand and increasing sales will ultimately fail. Do not promote the mindset that there is a "pill for every ill".

To the patients that suffer chronic pain, know that efforts continue to increase the quality of your lives. We understand now, more than ever before, about the neurophysiology of pain, the pain signal, pain generators and the pain process. This understanding has resulted in many more treatment options than have been previously available. The use of narcotic analgesics is just one tool that we have that may be useful.

In my practice lifetime I have seen the pendulum swing from one end of the spectrum to the other with respect to the use of narcotics to treat non-cancer pain. In the mid 1980's I had to regularly defend this practice and now I'm having to recommend against it with almost the same regularity. "First do no harm..." Every patient deserves to be evaluated and treated as an individual in a way to be determined by his or her physician. Many things cannot be "cured". Pain as a symptom is handled differently from pain as the disease state, which often, at best, is "managed". True pain management is a dynamic process that demands continuous communication between a patient and the doctor. This is the only way the pain state can be evaluated, the only way better treatments can be attempted. The notion that a pain clinic is a place you visit to get drugs, and a pain management doctor is someone you need to convince you need narcotics is one that must be dispelled. Only continuous monitoring and interest in the patient will result in the highest quality care. I have many patients that were on narcotic pain medications for years, that have been able to totally discontinue these drugs without withdrawal, and without a decrease in the quality of their lives. These successes can only come about with the true practice of the science and art of medicine, which unfortunately today is coming under increasing attack from all sides.

To the pharmacists who fill prescriptions, I urge you to adhere to the highest level of your profession's ethics, and don't hesitate to question prescriptions that fall out of the norm. The system of checks and balances only works when active 100% of the time.

To my colleagues, you know that you are responsible for knowing the possible consequences, benefits, risks, and complications of any prescription you write. It is not acceptable or defensible to blame a drug company or their representatives if the facts do not add up, especially with respect to the complicated area of narcotics and opiate receptors. There is no substitute for the history and physical exam. The issue of diversion of legitimate prescriptions is an area in which we are not formally trained, but one in which we must always maintain a high level of suspicion when drugs with known street value are prescribed. The judicious use of urine or serum screening to document compliance of a regimen probably needs to be increased. Additionally, understanding the differences in abuse, addiction, tolerance and dependence is required for appropriate communications with patients, caregivers, as well as other colleagues and law enforcement officials.

With respect to public policy, I can only say that there is no way to legislate judgement. This is particularly true to the problem at hand. There are already laws that cover inappropriate obtaining, use, and possession of controlled substances. There are already laws that cover inappropriate practice of medicine and pharmacy. There are already laws that cover what a drug company can do or say. Additional laws in these areas will probably not result in any substantive change in the status quo. Additional funding in specific areas to enforce laws already on the books may help.

The database that has been discussed may have merit but the details about the construction, implementation, and ongoing costs have not been forthcoming. Anything that makes it more difficult for doctors to take care of patients is not acceptable.
The availability of controlled substances via the internet is one frontier which probably deserves additional legislation.

Finally, the unfortunate truth is that there always have been, are, and always will be people with the genetic makeup that fosters drug abuse and the black market that feeds it. Any system that man creates will be circumvented by man. So let us be cognizant of the law of unintended consequences when we try to make things "better".
Perhaps our greatest hope lies in the continued discoveries of the human genome project, that will let us understand more the complex areas of opiate receptors, and why people react in such varied ways to the same drug. Meanwhile, there is no better cure for the present situation, than a true understanding of existing science, and an ongoing dynamic doctor-patient relationship.

Respectfully submitted,
Stacy J. Berckes, M.D.
Lake-Sumter Medical Society
Written testimony for the Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources in Winter Park, FL on February 9, 2004.

Mr. HENNINGFIELD. Thank you for the opportunity to testify on the challenges posed by prescription drug abuse. I am a professor at the Johns Hopkins Medical School where I direct the Innovators Combatting Substance Abuse Awards Program. I am also, vice president for research and health policy at Pinney Associates, which is a science and health policy consulting firm.

We assist Purdue Pharma and other companies seeking help in identifying factors contributing to prescription drug misuse, abuse, diversion and addiction. We help develop strategies to reduce such unintended consequences while enabling appropriate medication use and access. I am representing Purdue Pharma to offer recommendations on this topic. The issue is important to me and it is to Purdue Pharma. The consequences of abuse and diversion of medications are serious for the people who abuse drugs, and the consequences are serious for the million of people living with pain. I have several observations and recommendations that I hope will help you. My written testimony provides these in much greater detail. There are no simple solutions, I think we have all said that, and I agree heartily.

Prescription drug abuse is a complex historic and evolving public health problem. The modern history of pain reliever abuse in America may be traced to the Civil War when the syringe revolutionized the treatment of pain, but also led some to develop addiction to the opioid drug morphine. It was than called "soldier's disease." Our Nation has struggled to find the right balance between medication access and control ever since. The history of substance abuse also reveals that the cycles are rarely anticipated and not readily controlled. For example, cocaine went from a small blip on our radar screen in the 1970's to our Nation's major drug of concern in the 1980's. Opioids such as heroin increased in the 1980's, in the 1990's prescription opioid abuse increased undoubtedly due in part to the perception that they were safer and less addictive than street drugs.

It is clear that drug abuse and diversion go far beyond the chemistry of the drug. My first chart shows data from the major Federal survey that measured non-medical use of opioid pain relievers by brand names. The short bar on the left side represents OxyContin. I show these data to illustrate the diversity of drugs that are abused and the complexity of the challenges facing us. As you may surmise and has been stated several times today, drug abusers have lots of choices and history tells us that when they are denied one drug they quickly turn to another.

Such surveys provide a general picture of the substance abuse landscape, but they have many shortcomings compared to the data that we rely upon to track outbreaks such as influenza, West Nile virus, and hepatitis. In fact the December GAO report on prescription drug abuse acknowledged these limitations concluding, "Current Federal surveys do not provide reliable, complete or timely information that could be used to identify abuse and diversion of a specific drug." Accurately estimating the numbers of deaths, and correctly attributing their cause is also critical to developing efforts to prevent future such deaths.

I would like to show a second chart from the 2003 Florida Medical Examiners Interim Report of drugs identified in deceased per-

sons. Some of these data have been discussed today. This chart shows the frequency of association of various drugs with deceased persons. Alcohol was associated with the greatest number at 31.7 percent, then benzodiazepines at 16.1 percent and cocaine at 14.6 percent. All oxycodone medications combined were associated with 5.6 percent. While this chart implies straight forward relationships between drugs and deaths, the reality is not so clear, as evidenced if you look at the report in detail. Determining the actual cause of death for any of these drugs is complicated and in many cases multiple drugs were evident.

Another study found that 97 percent of drug abuse deaths contributed to oxycodone drugs actually involved several drugs. In discussing these statistics I must state that any death from drug abuse is tragic, but as we seek solutions we must understand the problems well enough to develop solutions that will actually work to prevent such tragedies in the future.

Another complication in understanding drug abuse trends is that abuse of single drugs by individuals is rare. For example the overwhelming majority of persons who used OxyContin non-medically in a Federal survey had abused at least two other analgesics and/or illicit drugs of abuse, such as heroin, cocaine, and marijuana.

Let me wrap up by mentioning six key recommendations that I believe could contribute to a comprehensive solution: First, address deficiencies in our drug abuse monitoring system that were describe in the GAO report. We need accurate and timely information. Second, provide education at all levels of society about the dangers of prescription drug abuse. Third, nurture community partnerships as advocated by President Bush in his State of the Union Address. Fourth, strengthen our drug abuse treatment system so that people who develop addictions can get treatment that matches their needs when they need it. Fifth, encourage the development of comprehensive risk management programs for controlled medicines as recommended in the GAO report as well as by FDA and DEA. Finally, we need to address gaps in the drug control effort opened by unregulated Internet sales.

So, in conclusion, let me emphasize that prescription drug abuse and diversion is an important public health problem that warrants increased attention. There are no simple answers. As we move forward in search of strategies to deter abuse and reduce diversion we need to recognize the needs of people in pain as well as the health care professionals who treat them. I believe that these actions need to be part of a comprehensive solution to the problems of prescription drug abuse.

Thank you for the opportunity to testify.

Mr. SOUDER. Thank you for your testimony, and we will make sure your entire written testimony appears in the record, and if you have additional materials too.

Ms. Theresa Tolle, is it Tolle.

Ms. TOLLE. Tolle, it is Tolle, yes.

Mr. SOUDER. President of the Florida Pharmacy Association.

[The prepared statement of Dr. Henningfield follows:]

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Testimony on behalf of Purdue Pharma

By

Jack E. Henningfield, Ph.D.

Vice President, Research and Health Policy
Pinney Associates, Bethesda, Maryland
And
Professor of Behavioral Biology
Director of the Innovators Awards Program
Sponsored by the Robert Wood Johnson Foundation
Department of Psychiatry and Behavioral Science
The Johns Hopkins University School of Medicine

Before the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
United States House of Representatives

Investigative Hearing:

To Do No Harm: Strategies for Preventing Prescription Drug Abuse

February 9, 2004
Winter Park, Florida

On behalf of Purdue Pharma, I am pleased to appear at this hearing today on strategies for preventing prescription drug abuse. I am Dr. Jack Henningfield, Professor of Behavioral Biology, Department of Psychiatry, The Johns Hopkins University School of Medicine, where I direct the Robert Wood Johnson Foundation, Innovators Combating Substance Abuse Awards Program. I am also Vice President, Research and Health Policy at Pinney Associates, a science and health policy consulting firm.

Pinney Associates is a science and health policy consulting firm specializing on issues emerging at the convergence of science, health and policy, always with a goal of contributing to the improvement of public health. In this capacity we serve many organizations and agencies, public and private, including pharmaceutical companies, large and small. These include Abbott Laboratories, Bayer, GlaxoSmithKline, Jannsen, Pfizer, Purdue Pharma, Shire, and Women's Capital Corporation. Such companies seek the expertise of myself and my colleagues at Pinney associates to help to identify potential factors contributing to drug misuse, abuse, diversion, and addiction, and then to assist in the development of strategies for minimizing such unintended consequences while enabling appropriate medication use and access. Pinney Associates has assisted Purdue Pharma in its efforts to understand the factors that lead to abuse and diversion of OxyContin® (oxycodone HCl controlled-release) Tablets (hereinafter, "OxyContin") and similar drugs and to assist in developing more effective strategies for reducing abuse and diversion.

I was trained in behavioral science, pharmacology, and other disciplines relevant to understanding drug addiction and have been actively engaged in addiction research for more than 30 years. From 1980 to 1996, I was a scientist at the National Institute on Drug Abuse (NIDA), where I also headed the Biology of Dependence and Abuse Potential Assessment Laboratory and Clinical Pharmacology Research Branch. My studies at NIDA included assessment of a variety of prescription drugs for abuse potential and the development of treatments for addiction. I was also actively engaged in drug policy issues and public health, contributing to the first four of NIDA's Triennial Reports to Congress, serving on FDA and other governmental committees, and contributing addiction expertise to numerous reports to the Surgeon General on Smoking and Health. I have published over 300 scientific articles as well as several books and monographs pertaining to drug addiction.

I should also note that I am not a medical doctor and do not treat pain patients, rather I am here as an expert in addiction to provide information that I hope will be relevant to the consideration of policies to reduce prescription drug abuse and addiction, while ensuring access to these life saving drugs for those who need them. I have been invited by Purdue Pharma and the Subcommittee to offer my recommendations on the topic, "to do no harm: strategies for preventing prescription drug abuse." I recognize that there is a myriad of issues to address and recommendations to consider, however, my focus and recommendations will be on those pertaining to drug abuse and addiction. There are no simple solutions and in few areas of public health are the words of H.L. Mencken so apropos. He said: "*For every complex problem there is a solution that is simple, neat, and wrong.*"

Use of Terminology

Before I begin I would like to define a few of the terms that are key to my testimony, but that are often used inconsistently or inappropriately. The term "addiction" is generally used synonymously with "drug dependence," "chemical dependence," or "substance dependence" and refers to a chronic disease characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. See Exhibit A. In the case of opioid analgesics, that is, morphine-like pain medicines, the body will generally develop a level of "physical dependence," such that abrupt abstinence will precipitate a 'withdrawal syndrome,' also called the 'abstinence syndrome.' Medically managed analgesic use includes strategies for gradual discontinuance, if the patient no longer needs a medicine, to avoid withdrawal. "Tolerance" describes the diminishing of some effect of a drug when a person has taken it repeatedly. In the case of opioid abuse, tolerance to the euphoria or "high" develops predictably and relative quickly, leading the abuser to consume more of the substance, or mix it with other substances, trying to achieve the same degree of euphoria. In the case of a patient taking an opioid analgesic in a proper manner, tolerance to the respiratory depression effects occurs quickly, adding a margin of safety that the occasional abuser may not have. Tolerance to the constipating effects of opioid analgesic virtually never occurs, however. Tolerance to the analgesia may occur, but clinical experience shows that what is initially thought to be tolerance to analgesia is often due to disease progression, in the case of pain from cancer, or causes other than analgesic tolerance in cases not related to cancer, such as disease progression, over-exertion in the face of deconditioning related to chronic pain, etc. In the setting of medical care, taking an opioid analgesic on a repeated basis can be expected to produce physical dependence. In the medical setting, neither physical dependence nor tolerance is synonymous with addiction.

The term "misuse" is generally employed when a drug is used to treat a symptom, but not under supervision of a health care professional. For example, a person with pain might take an extra dose of medication at bedtime hoping it will help them sleep better, or a person who did not obtain a prescription for an analgesic might use the prescribed analgesic of a spouse to self treat his or her acute back pain.

"Drug abuse" is nonmedical use of a drug, e.g., abusing a drug at a party. Abuse of opioid analgesics often leads to addiction and can be especially deadly because of the inexperience and low levels of tolerance to respiratory depression of the abusers. This risk is especially enhanced when drugs with different mechanisms of action are abused simultaneously, e.g., intoxication with alcoholic beverages followed by abuse of a prescription sedative or an opioid analgesic. The term "drug abuse" or its variant, "substance abuse" is often used as a broad umbrella term to cover both addiction and abuse, based on the notion that every active addict is, by definition, abusing drugs. Unfortunately, most national surveys provide little basis for distinguishing among these various categories of drug misuse, drug abuse and addiction. For example, misuse is generically identified as abuse ("nonmedical use") in the National Household Survey of Drug Abuse because it does not distinguish between such medication misuse and abuse.

The term "iatrogenic addiction" to opioids is addiction that develops in a person, without a prior history of substance abuse or addiction, who is using opioids as intended for a legitimate medical purpose – that is, the treatment of pain. It should not be confused with the development of tolerance or physical dependence, as described above. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However data

are not available to establish the true incidence of addiction in chronic pain patients. This phenomenon was reviewed in detail by a special taskforce of the College on Problems of Drug Dependence (CPDD) and at an FDA advisory committee meeting that occurred this past September.[1] Both the CPDD taskforce and the FDA advisory committee noted that there is a need for study of the rates of new onset, or iatrogenic addiction among patients treated for pain, in different clinical settings, with and without histories of substance abuse.

Prescription Drug Abuse: Brief History of an Evolving Problem

Prescription drug abuse is a complex and evolving public health problem in which life saving medicines are sometimes misused, abused, or associated with addiction. The modern history of analgesic abuse and addiction in America may be traced to the introduction of the hypodermic syringe used to deliver morphine as a means of providing effective pain relief to thousands of suffering soldiers during and following the Civil War. The treatment was considered by many to be a "Godsend" to many thousands who were injured and disabled with pain. While pain relief drugs such as morphine provided much needed relief to the injured, they also had downsides. For example, a new disease emerged, referred to by some as "soldiers' disease." This term referred to the use of pain relieving drugs by soldiers who did not appear to need them for medical purposes, as well as those who appeared to suffer psychologically and socially from taking such medication. Of course, at that time in our history, the concept of ongoing, chronic pain was just forming in the medical literature. In fact, one of the first treatises on a family of chronic pain conditions emerged from the medical experience of Dr. Silas Weir Mitchell during and immediately following the Civil War. In this era, the presence of physical dependence or tolerance alone was equated with addiction, unlike modern thinking. Thus, the questions that have never been fully answered about "soldiers' disease" is this: How many were addicted, how many were merely physically dependent and using the morphine to stave off the withdrawal syndrome, and how many were, in fact, suffering from unrecognized chronic pain and using the morphine in a manner that would be considered appropriate today? It is interesting in the context of today's hearing to remind ourselves that, at that time, morphine, heroin, and other drugs could be obtained over the counter and even ordered from the Sears, Roebuck and Company.

By the early 20th century, it was recognized that certain drugs warranted more stringent control with access sufficiently restricted to reduce inappropriate use, abuse, and addiction. One piece of legislation from the early 20th century worthy of noting is the **Harrison Narcotic Act of 1914.** This legislation was a well-intended effort to allow for medical access to "narcotic drugs," predominately derivatives of coca and opium, through regulation of their distribution and dispensing via taxation. However, within a year of passage it was evident that serious problems were emerging, including the jailing of innocent doctors, which led to reluctance to use of opioids to treat patients suffering from debilitating pain. In addition, a black market of drugs was emerging to supply the needs and desires of abusers and addicted persons.

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[1] Zacny J, Bigelow G, Compton P, et al. College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: Position statement. Drug and Alcohol Dependence 2003;69:215-232; Meeting of the Anesthetic and Life Support Drugs Advisory Committee, September 9-10, 2003.

From a legislative perspective, the Harrison Narcotic Act was only the beginning, but it is important to note in light of today's hearing because it illustrates the problem that we are still struggling with today – a way to ensure that people with legitimate medical needs get the medicine they deserve, while curtailing diversion, trafficking, abuse and addiction. The regulatory struggles we are faced with today in terms of finding the right balance of access and control have been with us for over a century and most likely will be with us for the foreseeable future.

The **Controlled Substances Act (CSA)**, of the Comprehensive Drug Abuse Prevention and Control Act of 1970, laid the legal foundation for efforts by the Department of Justice to reduce drug abuse. The legislation placed restrictions on the manufacture and distribution of several categories of drugs with a potential to produce abuse and addiction, as well as certain chemicals used in the illicit production of controlled substances. Controlled substances are those drugs designated by the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) on the basis of definitions and criteria described in the Act.

Controlled substances are regulated into one of five schedules. Schedule I is reserved for highly addictive drugs with no recognized medicinal value and thus are not permitted for sale (e.g., heroin, LSD, marijuana). Schedules II through V are used to classify drugs that are approved for medicinal use and marketing, but also have addiction or abuse potential and, thus, have varying levels of control over manufacturing, distribution, and prescribing, depending on the schedule. Cough medicines requiring a prescription are placed in schedule V, many sedatives are placed in schedule IV or III, and schedule II is reserved for morphine-like opioid analgesics and amphetamine-based stimulants. Recommendations for drug scheduling are jointly developed by the FDA, DEA and NIDA.

Since passage of the CSA, new challenges have emerged that were not anticipated by the Act. For example, the Internet provides a virtually instantaneous means of enabling drug abusers to learn of new ways to obtain and abuse drugs as well as to purchase drugs without prescriptions. In addition, the way a drug is formulated can make it a target for abuse and diversion but virtually all morphine-like opioids are abused. These and other factors have required that the CSA be increasingly supplemented by what the FDA now terms risk management programs to provide additional controls on a drug specific basis. I will provide greater detail on this later in my testimony.

The struggle to find the right balance will unfortunately not end in the near term because the continuing push for ever more effective medicines will undoubtedly be matched by creative entrepreneurial illicit drug sellers whose interest is in creating and feeding abuse and addiction. In fact, it may be appropriate to view the problem in much the same way that the Centers for Disease Control and Prevention (CDC) views infectious diseases, such as influenza. From a public health perspective, there are many similarities in measuring, documenting, and responding to the challenges posed by potentially addictive drugs, both licit and illicit, as are posed by the endless cycles of influenza and other infectious diseases.

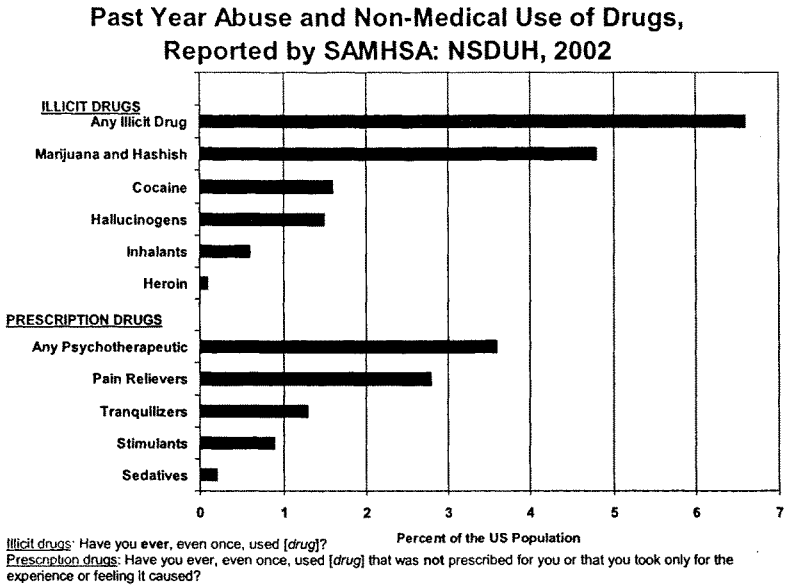
Trends in Substance Abuse

The various cycles of substance abuse are not entirely controllable nor readily anticipated. For example, cocaine went from a small blip on the tracking surveys to our nation's major drug of concern from the 1970s to the 1980s; and that was before the advent of the crack formulation in the mid-1980s that fostered further expansion of the illicit market. Opioids including heroin also saw resurgence in the 1980s as depicted in a 1981 Newsweek article entitled, "Middle-Class Junkies."

The 1990s witnessed an increase in prescription opioid abuse as these drugs were considered to be identifiable, purer, and, erroneously, safer and less addictive when abused. This may have been further fostered by widely reported interviews with popular icons such as Courtney Love who claimed she didn't abuse "street narcotics," but did abuse prescription opioids. The ability of the Internet to enable drug abusers and sellers to share information has undoubtedly complicated efforts to control abuse and to limit "outbreaks."

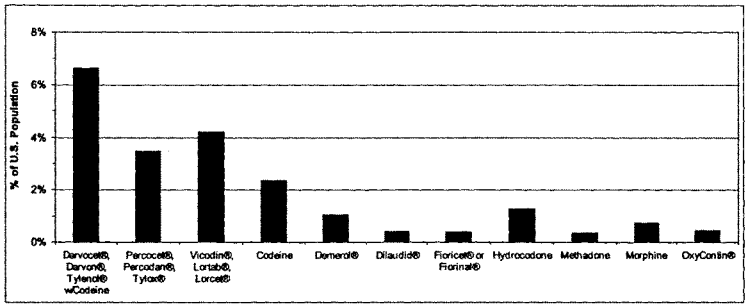
Increased prescription drug abuse in the 1990s has been particularly noteworthy among the stimulants and opioid analgesics as well as anabolic steroids. Among opioid analgesics, national figures indicate that the hydrocodone-containing cough and analgesic medicines are abused most frequently, with the oxycodone drugs currently in second place.

The chart below shows rates of non-medical use for a number of drugs and drug classes, including illicit drugs and prescription medications, for the year 2002. It is important to keep the overall substance abuse problem, illicit and prescription, in perspective.



The next chart focuses specifically on prescription analgesics, showing rates of non-medical use for a number of different medication brands. I show it to illustrate the diversity of analgesics that are abused and the complexity of the challenges facing us: drug abusers have lots of choices and history tells us that if they are denied one source they will turn to another, particularly when they have not been thoroughly educated regarding the dangers of abusing prescription medications.

Lifetime Non-Medical Use of Specific Prescription Analgesics in the U.S. population, Reported by SAMHSA: NHSDA, 2001



Source: SAMHSA, Office of Applied Studies, National Household Survey on Drug Abuse, 2001.

Limitations of Available Data

While hindsight provides a clear picture of trends in substance abuse, current limitations on tracking such trends is a problem that warrants greater attention. Tracking prescription drug abuse raises challenges that go beyond those that exist for tracking illicit drug abuse trends. For example, while any use of an illicit drug might be considered abuse in a general sense, it appears likely that at least some nonmedical use of prescription analgesics is more appropriately termed misuse. However, available surveys do not always distinguish between use by a person for whom the medication was not prescribed, even if it were taken only once and for a reasonable medical need, and a pattern that might more accurately be considered "abuse," such as "recreational" abuse of an illicitly procured medication. In addition, with respect to prescription drug abuse and diversion, brand names can be highly relevant. In fact, various brands of oxycodone-containing medications differ widely in their content and formulation, which can alter their affect and appeal. However, the surveys were not designed to collect valid brand-specific data. Rather, they were developed with a focus on illicit drugs, in which various types are identified in some surveys (e.g., injection cocaine versus smoked cocaine), but there has been no apparent historical need for the equivalent of "brand" specific information. The December 2003 General Accounting Office (GAO) report on prescription drugs, entitled "Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem", acknowledged these limitations

concluding that current federal surveys do not provide reliable, complete, or timely information that could be used to identify abuse and diversion of a specific drug.[2]

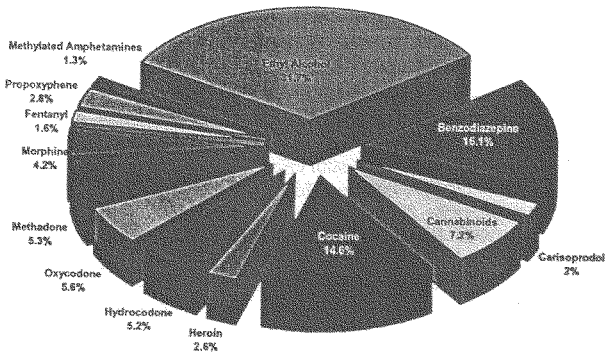
This represents an important gap in our nation's drug abuse surveillance infrastructure that needs to be remedied in order to provide the data needed to guide effective responses to trends and apparent "outbreaks." To put it into perspective, imagine if the CDC did not receive reliable data until 1-2 years after an outbreak began of an infectious disease, such as SARS, West Nile Virus, or a new influenza, and if the data provided little specific information as to the nature of the newly emergent strain. Although hard to imagine, this is the current situation in terms of surveillance data for prescription drug abuse. A more timely, reliable and efficient means for tracking such abuse is warranted.

Another important aspect of any public health effort is accurately estimating the numbers of deaths and correctly attributing their cause. This is critical in the development of efforts to prevent future deaths; otherwise, time, effort, and resources can be diverted into ineffective efforts. While this may seem basic, in the area of substance abuse, the science of estimating and attributing deaths has lagged far behind that in other areas of public health. This was starkly evident at SAMHSA's important hearing last May to address the rising deaths attributed to methadone, which I will discuss in greater detail shortly. That hearing made clear that the numbers of deaths appropriately attributed to methadone has probably been greatly overestimated because it appears that most of the deaths involved the simultaneous abuse of more than one drug, often including alcohol, so-called "polydrug abuse." Second, although some news stories attributed the rise to lax procedures in methadone treatment clinics for heroin addicted persons, in fact, it appeared that increased use of methadone as a analgesic – its original indication -- was a major factor. The need for substantial improvements in our ability to estimate and appropriately attribute cause of death was also discussed in detail.

The chart below is reproduced *in toto* from the 2003 Interim Report of Drugs Identified in Deceased Persons by Florida Medical Examiners. The chart shows the frequency of association of various drugs with deceased persons. Cases in which multiple drugs were in evidence were multiply counted, and the specific cause of death may not have been clear, or may have been accurately attributed to a lethal cocktail of several drugs, each one of which is counted as a causative agent in the tally. Nonetheless, the chart reflects the many drugs that are associated with drug deaths and thus indicates the scope and complexity of preventing deaths from drug abuse. Alcohol was associated with the greatest number of deaths at 31.7%, then benzodiazepines, cocaine and so forth. All oxycodone medications were associated with 5.6%, although I remind you that in some of these cases other drugs were also found and considered causative by the originating medical examiner.

[2] United States General Accounting Office (GAO). Report to Congressional Requesters. Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem. GAO-04-110. December, 2003.

Frequency of Occurrence of Drugs in Decedents January – June 2003



Note: GHB, Ketamine, Freon, N2O, Hydromorphone, Meperidine, and Tramadol constituted less than 1% of the drug frequencies.

Source: Interim Report by Florida Medical Examiners Commission on Drugs Identified in Deceased Person, October 2003.

While this chart appears to illustrate a simple, straightforward story, in reality, the story is not so simple. A recent study, done at the request of Purdue Pharma, sheds further light on this issue. The study was conducted by two of our nation's leading forensic experts, Dr. Edward Cone, former chief of the chemistry laboratory at the NIDA and presently at Pinney Associates, and Dr. Yale Caplan, former chief toxicologist of the Maryland Medical Examiner's Office. The purpose of the study was to help better understand actual causes of death involving one oxycodone drug, OxyContin. This analysis was published last year as the lead article in the March edition of the *Journal of Analytical Toxicology*.[3] One of the major findings of the study was that the vast majority of deaths that were attributed to OxyContin were, in fact, polydrug abuse deaths, frequently involving alcohol.

In pointing out these statistics, I must state that any death from drug abuse is tragic. But in order to seek solutions, one must first understand the problems.

[3] Cone EJ, Fant RV, Rohay JM, et al. Oxycodone involvement in drug abuse deaths: A DAWN-based classification scheme applied to an oxycodone postmortem database containing over 1000 cases. Journal of Analytical Toxicology 2003;27:57-67.

Single Entity Drug Abuse is Rare

A further complication in identifying and understanding prescription drug abuse trends is that single entity abuse (i.e., abuse involving just one drug) is rare. At a general level this has been well understood for decades. With respect to prescription drug abuse, the relationships appear even more complex as brands within a category and across categories are interchanged as a function of such factors as availability, price, current media hype, and what, in the realm of product marketing, is termed "buzz" marketing. That is to say, the "buzz" or "hype" or reputation developed for a particular product may be short or long lived and may have little to do with its actual physical performance.

In the case of analgesics, Pinney Associates has analyzed data from the 1999, 2000, and 2001 National Survey on Drug Use and Health (NSDUH, which was formerly known as the National Household Survey on Drug Abuse or NHSDA) to examine rates of non-medical drug use in the U.S. population (12 years of age and older) and examine the demographic and drug abuse profiles of those reporting such use.

Although the focus of our analysis was specific to OxyContin, the findings are not unique to oxycodone drugs but certainly apply to other classes of analgesics, as well as other categories of prescription drugs. Specifically, the analysis shows that the overwhelming majority of persons who had abused OxyContin non-medically during their lifetime had abused at least two other analgesics and/or nonprescription drugs of abuse such as heroin, cocaine and marijuana. Alcohol and marijuana abuse, along with cigarette smoking, are prominent in this survey and generally precede abuse of opioid analgesics.

For each of the three years examined, non-medical OxyContin users were, on average, approximately twice as likely to report non-medical use of at least two additional prescription analgesics, 1.7 times as likely to report having abused cocaine, 2.8 times as likely to report having abused heroin, and 3.6 times as likely to report having used needles to inject drugs of abuse as compared to non-medical users of other prescription analgesics. Furthermore, the initial non-medical use of prescription analgesics was typically preceded by abuse of other drugs: over 80% of those reporting non-medical use of OxyContin reported having abused illicit drugs or engaged in non-medical use of other prescription medications (i.e., tranquilizers, sedatives, stimulants) prior to their first non-medical use of prescription analgesics. These data are also consistent with those from a NIDA-supported Kentucky Youth Survey in 2001 that found that most youth who had abused OxyContin had prior experience with several drugs of abuse.

Such findings are consistent with decades of data indicating that abusers of drugs within a given class (e.g., sedatives, stimulants, or opioids) are very likely to try new drugs that come along and that their actual abuse patterns will be substantially influenced by a range of factors including cost, availability, and reputation. The challenge to reducing drug diversion, abuse, and addiction is to respond appropriately to the "drug of the day" without simply shifting abusers to other drugs, which in some cases may be even more risky.

The complexity of the problem is made even more difficult by the fact that the solution to one problem may precipitate or exacerbate another. For example, concerns about overdose led the

FDA to approve the following warning for inclusion in the OxyContin labeling: "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." As noted in the GAO Report discussed above, this "safety warning... may have also contributed to the drug's potential for abuse and diversion, by inadvertently providing abusers with information on how the drug could be misused."

None of the examples provided are intended to fully explain prescription drug abuse trends and consequences. Rather, they are an attempt to illustrate the complexity of the challenges before us and the need to minimize unintended consequences. For example, as a result of media attention on the dangers of oxycodone drugs, some doctors are turning to alternative analgesics to treat their patients with pain. One such analgesic is methadone, a strong analgesic also used to treat opioid addicted persons, such as those addicted to heroin. However, methadone requires close monitoring of dosing, particularly when it is used in the treatment of pain, as the doses that are effective for relieving pain can produce severe respiratory depression for many people if it is not dosed and titrated appropriately. Unlike most other opioid analgesics, methadone demonstrates great variability between patients with regard to duration of action, accumulation and excretion, making its safe use more challenging than other opioid analgesics.

This issue is generally well understood by health care professionals with experience in treating addiction and pain with methadone. However, for doctors without such experience, turning to methadone as an alternative to oxycodone and hydrocodone medicines could prove dangerous to their patients. According to Dr. Edward C. Covington of Ohio's Cleveland Clinic, who was quoted in the *New York Times* (February 9, 2003), "Methadone is probably one of the very few drugs that I've seen doctors almost kill patients with. It's that hard to use when you first start to use it."

Use of methadone as an alternate analgesic is being increasingly viewed as a major contributor to the sharp increase in methadone related deaths over the past few years. Unfortunately, the media portrayal of the increase in methadone use has often been attributed to other things, such as liberal use of methadone and methadone dosing take home privileges in heroin treatment clinics.[4] As a result, some states took actions to restrict how methadone is used in the treatment of heroin addiction.

Last May, the U.S. Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA, CSAT) convened the conference referenced previously to examine the extent, nature, and cause of methadone-related deaths in the US. Specifically, deaths initially attributed to methadone had increased substantially in Washington D.C., Maine, and Florida. The conference included representatives of the CDC, DEA, FDA, NIDA, other organizations, and many experts. Although not intended as a consensus conference per se, strong agreement emerged around several points. First, the increase in deaths attributable to methadone were largely polydrug related and included many people apparently medicated for

[4] "Methadone, Once the Way Out, Suddenly Grows as a Killer Drug", The New York Times, February 9, 2003.

pain. Second, there is little evidence that there has been an increase in appropriate use of methadone treatment for addiction nor is there a basis for new national restrictions on the use of methadone in substance abuse treatment clinics. Third, concern was expressed that fear of prescribing oxycodone, in particular OxyContin, and other opioid analgesics among health care professionals, along with the substantially lower cost of methadone, was driving physicians, managed care plans, or state Medicaid programs to switch to methadone as an alternative analgesic. This was considered a potentially dangerous switch for doctors without extensive experience with methadone dosing for analgesia.

The methadone example is important because it illustrates a larger point. As we consider policies to reduce abuse and diversion of any given class of drugs, or any specific drug, it is important to study all potential consequences and make every effort to avoid harmful unintended consequences.

Potential Solutions

If there was a simple straightforward solution to the issue of prescription drug abuse, there would be no need for this hearing. If you took the extreme action to ban the top 10 prescription opioids that are associated with the highest rates of diversion and abuse, they would be quickly replaced by 10 other drugs. In addition, you would disrupt the lives of the many patients with pain whose well-being depends upon those drugs.

Although there remain many unknowns, there are many things that can be done to reduce prescription drug abuse without discouraging legitimate and medically appropriate use of medications by patients. However, severely limiting access of analgesics with new burdens on doctors and pharmacists would surely result in reduced utilization by patients and almost certainly increase pain and suffering in our country. It is also not clear that such action would have any effect on opioid abuse and addiction because there are so many alternatives to opioids that could be obtained on the street and through the Internet. It is important that in our zeal to reduce abuse and diversion, we do not forget that we continue to have a significant problem of under treatment of pain and its attendant suffering, in part due to fears surrounding the use of opioid analgesics. Ideally, in our efforts to devise strategies to reduce abuse and addiction, we should be simultaneously devising strategies to improve the treatment of pain.

Surveillance. There are deficits in our nation's infrastructure for understanding prescription drug abuse and diversion that need to be remedied. We need a surveillance system that is geographically sensitive, responsive to emerging trends and timely. Our system for identifying drug abuse outbreaks and trends should be no less effective or comprehensive than is our nation's system for tracking infectious disease such as influenza by the CDC. Many of our current surveys will continue to have an important place and have been undergoing improvements in recent years, yet GAO's conclusion that "data on abuse and diversion are not reliable, comprehensive, or timely" is a sad reminder of the challenge that lies ahead in this area.

Education. Among the many challenges our nation faces in reducing prescription drug abuse is the need to better educate our children. The concept that abuse of an opioid analgesic can be as deadly is the abuse of street heroin is apparently not a readily known fact. It is plausible that by

focusing anti-drug messages on illicit drugs, we have created the impression that prescription drugs are not a major concern. Yet, most children have far easier access to potentially harmful medicines than they do street drugs – in the family medicine cabinet. We clearly need better balance in education and anti-drug information to teach our young about the dangers of prescription drug abuse, while helping them to understand the vast difference in safety between appropriately supervised medical use and the abuse of the same medicine. While children today receive more education about the dangers of illicit drug abuse, smoking and drinking, than in decades gone by, prescription drug abuse has not received the equivalent degree of attention.

Education also needs to include health care professionals (doctors, pharmacists, nurses, etc.), policy makers, medical licensing boards, other regulators, law enforcement and the public on the appropriate use of pain medications and what constitutes misuse, abuse and addiction. Education needs to include such basics as proper disposal of prescription medicines that are no longer needed. The educational needs are broad, real, and important.

Community Partnerships. During his State of the Union address, President Bush emphasized the importance of community-based strategies in preventing drug abuse and other problems of our young. Substance abuse community partnerships are recognized as a cornerstone of building awareness, providing guidance, and fostering alternatives to destructive behaviors, yet they are too often underappreciated, underutilized and under-funded.

NIDA, other federal agencies, and private organizations, have supported many of these efforts and helped to develop their science base so that we are learning more and more about what works, what doesn't work, and the important considerations in transferring success from one community to another. This is vital if we are to reduce prescription drug abuse in both the short and long-term.

One such program is the **Communities That Care®** (CTC) program, which emerged in part with funding from the NIDA, and is sponsored in 10 communities in seven states by Purdue Pharma. CTC is a community mobilization and prevention effort that is based on over 20 years of careful social science research. Program professionals collaborate with local community leaders to develop long-term strategies to reduce the occurrence of a number of different problems facing youth in communities today. One of the important nurturing grounds for CTC was the State of Pennsylvania, where the program had strong support from then Governor Tom Ridge and benefited from the active involvement of Mrs. Ridge, who is today a national spokesperson for CTC. Today, the program is in place in over 500 communities in the U.S. and is also in place in the United Kingdom, Australia and the Netherlands. Such partnerships of government, community, and corporate America should be encouraged. All have a stake; all stand to benefit.

Drug Addiction Treatment Needs. There is also a considerable need to strengthen our treatment infrastructure. More treatment is needed today and will undoubtedly be needed in the future, despite our many efforts to curb addiction. Former Surgeon General, Dr. C. Everett Koop, has summarized the treatment situation most elegantly. He said, "It is easy to get the drugs, hard to get treatment. Our challenge as a nation is to reverse this."

It is evident from the streets of America to the White House that formidable challenges must be overcome to achieve Dr. Koop's vision. According to the Office of National Drug Control Policy (www.whitehousedrugpolicy.gov/publications/factsht/methadone), less than 165,000 methadone treatment slots are available for the more than 800,000 heroin users in apparent need of such treatment. Moreover, while heroin abuse is dispersed throughout the nation, most treatment centers are concentrated in major cities.

Today, those abusers who become addicted to prescription drugs are in much the same situation as those who become addicted to illicit drugs. The addictive drugs are accessible through channels that they know how to use. If they seek treatment, they typically face a discouraging patchwork quilt system that would challenge many of us to negotiate. In some respects, the plight of many prescription drug abusers is even worse, in that many of them live in regions of the country without opioid addiction treatment clinics. They may have to travel hours to reach one. Only a few clinics are prepared to address the needs of adolescents who become addicted to opioids, a growing trend according the NSDUH. Our nation has taken some steps to address this. The Drug Abuse Treatment Act of 2000 was an important one. This Act enables certified doctors to offer certain treatments to opioid addicts in an general medical office setting. However, many barriers to the success of this Act exist and it needs refinement to have a significant impact on the national problem of opioid addiciton.

Risk Management. We have a system of categorizing and regulating drugs based on their addictive potential, and that system is codified by the Controlled Substances Act (CSA). Although developed in a simpler day, when drug formulation was not so prominently on the radar screen of concern, the CSA and its provisions are the backbone of the system for regulating drugs with a potential for abuse and addiction. The CSA primarily addresses the pharmacology of the chemical entity, providing a basis for differentially scheduling and regulating drugs based on their pharmacology. This is a science-based mechanism of fundamental importance. For a number of years it was my honor to head the laboratory at NIDA that developed many of the scientific methods used to categorize drugs and I am well aware of the strengths and weaknesses of the methods. I have worked with the College on Problems of Drug Dependence and other organizations to continue to refine these methods. Refinement of the methods and evolution of strategies is critical and with continuing support from NIDA and other federal agencies this important area of science will continue to progress and keep pace. Again, one can think of this as the equivalent to what we expect of CDC in its ability to refine its methods and keep pace with evolution of disease types and the surprise emergence of new diseases.

On the other hand, the CSA has limitations, in that abuse and diversion are modulated by factors that go far beyond the chemistry and pharmacology of the drug. Such factors include the formulation of the drug, its dosing characteristics and capability, its liability to tampering, its indication, the nature of the intended patient population, how it is labeled and advertised, "buzz" about it in the media and on the street, and potential effects that are incidental to its intended effects. These factors and more can influence how a drug is properly used, its liability for abuse and diversion, and the consequences of abuse and diversion. Attempting to address this broad range of complex factors with any simple strategy will not work. It would be like attempting to manage a computer software glitch with a hammer – not that that isn't tempting at times. Here

the answer may be best summarized by another GAO conclusion that bolsters one of FDA's major strategic initiatives, namely, risk management.

Risk management is both a concept and a process. The concept is simple: On a drug by drug basis, identify all plausible risks of marketing the drug and take actions to mitigate those risks while fostering beneficial drug use. The process is more complex and is as varied as the drugs themselves, the indications, and other factors. Nonetheless, it is this process, which has enabled the approval and marketing of drugs for which there were serious concerns by providing mechanisms to mitigate risks [examples include Acutane®, thalidomide, OTC nicotine, tramadol, Actiq®]. The process, with respect to drugs with potential for abuse and controlled substances, is largely guided by FDA, but in practice has input from DEA. This makes sense and continued collaboration should be encouraged. For these types of drugs, risk management programs contemplate not only the intended patient class, but exposure to people who would voluntarily abuse them. I would be remiss, however, if I did not encourage a third party in controlled substance scheduling issues to be given a more active role and that is the National Institute on Drug Abuse or NIDA. NIDA is not a regulatory agency and should not be turned into one, but NIDA is the closest thing our nation has to being the keeper of science in this field and NIDA's role in helping to keep the process guided to the greatest possible extent by science is important.

Implementation of the risk management process occurs via what is now referred to as the Risk Management Program. The GAO report concluded as follows: "FDA's risk management plan guidance should encourage pharmaceutical manufacturers with new drug applications to submit plans that contain a strategy for identifying potential problems with abuse and diversion." Risk management plans can be relatively simple or they can be very complex. In some cases they may include mechanisms for supplementing federal surveillance efforts with surveillance to address potential concerns that appear specific to the drug [examples include Tramadol, OTC nicotine gum, Purdue's RADARS® System]. In virtually all cases, they include attention to labeling, marketing, and formulation.

Moreover, risk management plans provide a mechanism to address the limitations of provisions of the Controlled Substance Act (CSA) on a drug-by-drug basis, taking into account the diverse range of factors that can contribute to benefit and risk.

Risk management plans enable drugs to realize their potential to provide benefits while endeavoring to address all plausible risks with strategies to reduce those risks. This concept inherently recognizes the importance of finding the right balance in drug access to enable realization of benefits, with controls to minimize risks. The concept makes sense for virtually all categories of drugs, but I believe it is particularly useful with respect to all controlled substances, which, by definition, have abuse and addiction potential.

Of course, risk management plans are no panacea or simple road to reducing abuse and diversion, and important issues remain to be addressed in the nature and process of risk management program development. For example, should the process be systematically extended to all drugs in a category or just to new drugs? Should the marketing and promotion of generic equivalents of a branded drug be accompanied by a risk management program similar to that of the branded medicine? How does the process of risk management interact with the scheduling

process? In other words, might the scheduling of a drug be influenced by its risk management program? It will also be helpful for FDA to develop further guidance on risk management program development procedures and expectations. By nature, the risk management program process will be evolutionary. My main plea for the process is that it strives to maintain the balance necessary to maximizing the benefits of drugs while minimizing their risks. That is the way to optimize the risk benefit ratio of a drug. That is the course to improving medicine, patient care, public health, and the lives of individuals in need of care.

Drug Monitoring and Internet Sales Restrictions. An apparently growing problem that needs to be addressed is that of distribution and sales that escapes regulation such as Internet sales. Some of you may have read the *Washington Post* series that began October 19, 2003. This series highlighted an investigation undertaken by *Post* reporters into the growing shadow market of prescription drugs. The yearlong investigation by the *Post* revealed networks of "middlemen, felons and opportunists" operating out of storefronts and garages, and rogue merchants setting up Internet pharmacies that serve as "pipelines for narcotics." While the U.S. system for the distribution of prescription medicines has been arguably the best in the world for a half century or more, that system, according to the *Post* investigation, is being undercut by a growing illegal trade in pharmaceuticals. Increasing recalls of tainted medicines and cross-border pharmaceutical trade are all a part of a larger pattern according to *Post* investigators. This larger pattern is threatening public health, and leaving victims in its wake. The result of this growing trade is "pharmaceutical roulette for millions of unsuspecting Americans."[5]

The *Post*'s analysis of one Internet pharmacy, prescriptiononline.com, showed that nearly 90 percent of the orders were for controlled substances, including hydrocodone. In some cases, orders went to multiple customers using the same address. For example, over the course of five months, 2,030 pills were shipped to five customers at one home in Baileyton, Alabama. Of those pills, 80 percent were for hydrocodone. When confronted with the *Post* analysis, the physician who wrote the prescriptions stated, "I didn't have that data at that time." The physician called the information "very disturbing. You've presented some information that certainly gives me some pause how this whole system can be blatantly abused and easily abused."

While some have argued that there have been no deaths related to importation, unfortunately they are wrong. The *Post* series identified multiple victims, including: James Lewis, 47, a former triathlete who suffered from aches and pains. Lewis turned to the Internet pharmacies in South Africa, Thailand and Spain to purchase painkillers. Lewis' wife found her husband dead of an overdose from a drug he bought online. Ryan Haight was an 18-year old who died in his bedroom from an overdose after taking narcotics obtained on the Internet. Todd Rode, 38, was a skilled musician and computer whiz, who battled depression from the time he was a teenager. As an adult, he had bouts of drinking and argued with his doctors about his treatment. In 1999, Rode overdosed on medications he bought from a South African online pharmacy. These stories illustrate the real dangers that exist from online "consultations" and Internet sales of controlled substances. No matter what restrictions we put in place in the U.S., to the extent that we allow

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[5] *See* Washington Post Five-Part Series, "U.S. Prescription Drug System Under Attack" (October 19-23, 2003).

this practice to continue, it will undoubtedly impact our ability to curb abuse and diversion of prescription medicines in the U.S.

Now my expertise is not on prescription monitoring and controlling Internet sales, but as a drug abuse expert it is clear to me that these unregulated sales are a hemorrhage in our system. For the record, I would like to append the testimony of Dr. J. David Haddox, Vice President, Health Policy, Purdue Pharma, as Exhibit B. On behalf of Purdue Pharma, Dr. Haddox recommended the following:

Additionally, Purdue supports the concepts in federal legislation that it understands is being considered by Members of Congress that, among other things, would promote the development of effective state prescription monitoring programs to identify and reduce "doctor shopping"; regulate Internet pharmacies in an effort to curb diversion and abuse of controlled substances; establish a working group to address pharmaceutical counterfeiting; and call for baseline research on prescription drug abuse, more comprehensive and accurate reporting, and grants for drug abuse education programs for healthcare professionals, teachers, and parents. Purdue also strongly supports efforts like the Dime Out a Dealer program being sponsored by Congressman Weldon from Pennsylvania. This program is aimed at finding and arresting "dealers" who are illegally selling prescription drugs on the streets and campuses.

Although this is not my area of expertise, the concepts he espoused make sense as strategies for addressing important gaps in our system of drug control.

Conclusion

Prescription drug abuse and diversion are an important public health problem and warrant increased attention. Unfortunately, there are no easy answers. As I stated earlier, H.L. Mencken once said, "For every complex problem there is a solution that is simple, neat, and wrong." As we move forward in search for solutions to deter abuse and reduce diversion, we should be cognizant of the needs of pain patients, as well as the healthcare professionals who care for them. We need to recognize that efforts to reduce abuse and addiction by nonmedical users, and reduce diversion require finely tuned efforts as part of the risk management process to supplement national policies. Better surveillance is vital to enable responsive and appropriate actions and community partnerships need to be companions in the process.

Thank you for the opportunity to testify. I will be pleased to contribute to this important process in any way.

Exhibit A

Definitions Related to the Use of Opioids for the Treatment of Pain

A consensus document from the **American Academy of Pain Medicine,** *the* **American Pain Society,** *and the* **American Society of Addiction Medicine.**

BACKGROUND

Clear terminology is necessary for effective communication regarding medical issues. Scientists, clinicians, regulators, and the lay public use disparate definitions of terms related to addiction. These disparities contribute to a misunderstanding of the nature of addiction and the risk of addiction, especially in situations in which opioids are used, or are being considered for use, to manage pain. Confusion regarding the treatment of pain results in unnecessary suffering, economic burdens to society, and inappropriate adverse actions against patients and professionals.

Many medications, including opioids, play important roles in the treatment of pain. Opioids, however, often have their utilization limited by concerns regarding misuse, addiction, and possible diversion for non-medical uses.

Many medications used in medical practice produce dependence, and some may lead to addiction in vulnerable individuals. The latter medications appear to stimulate brain reward mechanisms; these include opioids, sedatives, stimulants, anxiolytics, some muscle relaxants, and cannabinoids.

Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused. Since their clinical implications and management differ markedly, it is important that uniform definitions, based on current scientific and clinical understanding, be established in order to promote better care of patients with pain and other conditions where the use of dependence-producing drugs is appropriate, and to encourage appropriate regulatory policies and enforcement strategies.

RECOMMENDATIONS

The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine recognize the following definitions and recommend their use

---

I. **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 one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

II. **Physical Dependence**
Physical dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

III. **Tolerance**
Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

DISCUSSION

Most specialists in pain medicine and addiction medicine agree that patients treated with prolonged opioid therapy usually do develop physical dependence and sometimes develop tolerance, but do not usually develop addictive disorders. However, the actual risk is not known and probably varies with genetic predisposition, among other factors. Addiction, unlike tolerance and physical dependence, is not a predictable drug effect, but represents an idiosyncratic adverse reaction in biologically and psychosocially vulnerable individuals. Most exposures to drugs that can stimulate the brain's reward center do not produce addiction. Addiction is a primary chronic disease and exposure to drugs is only one of the etiologic factors in its development.

Addiction in the course of opioid therapy of pain can best be assessed after the pain has been brought under adequate control, though this is not always possible. Addiction is recognized by the observation of one or more of its characteristic features: impaired control, craving and compulsive use, and continued use despite negative physical, mental, and/or social consequences. An individual's behaviors that may suggest addiction sometimes are simply a reflection of unrelieved pain or other problems unrelated to addiction. Therefore, good clinical judgment must be used in determining whether the pattern of behaviors signals the presence of addiction or reflects a different issue.

Behaviors suggestive of addiction may include: inability to take medications according to an agreed upon schedule, taking multiple doses together, frequent reports of lost or stolen prescriptions, doctor shopping, isolation from family and friends, and/or use of non-prescribed psychoactive drugs in addition to prescribed medications. Other behaviors which may raise concern are the use of analgesic medications for other than analgesic effects, such as sedation, an increase in energy, a decrease in anxiety, or intoxication; non-compliance with recommended non-opioid treatments or evaluations; insistence on rapid-onset formulations/routes of administration; or reports of no relief whatsoever by any non-opioid treatments.

Adverse consequences of addictive use of medications may include persistent sedation or intoxication due to overuse, increasing functional impairment and other medical complications, psychological manifestations such as irritability, apathy, anxiety, or depression; or adverse legal, economic or social consequences. Common and expected side effects of the medications, such as constipation or sedation due to use of prescribed doses, are not viewed as adverse consequences in this context. It should be emphasized that no single event is diagnostic of addictive disorder. Rather, the diagnosis is made in response to a pattern of behavior that usually becomes obvious over time.

Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.

Physical dependence on and tolerance to prescribed drugs do not constitute sufficient evidence of psychoactive substance use disorder or addiction. They are normal responses that often occur with the persistent use of certain medications. Physical dependence may develop with chronic use of many classes of medications. These include beta blockers, alpha-2 adrenergic agents, corticosteroids, antidepressants, and other medications that are not associated with addictive disorders. When drugs that induce physical dependence are no longer needed, they should be carefully tapered while monitoring clinical symptoms to avoid withdrawal phenomena and such effects as rebound hyperalgesia. Such tapering, or withdrawal, of medication should not be termed detoxification. At times, anxiety and sweating can be seen in patients who are dependent on sedative drugs, such as alcohol or benzodiazepines, and who continue taking these drugs. This is usually an indication of development of tolerance, though the symptoms may be due to a return of the symptoms of an underlying anxiety disorder, due to the development of a new anxiety disorder related to drug use, or due to true withdrawal symptoms.

A patient who is physically dependent on opioids may sometimes continue to use these despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects. For example, in the case of opioids, tolerance usually develops more slowly to analgesia than to respiratory depression, and tolerance to the constipating effects may not occur at all. Tolerance to the analgesic effects of opioids is variable in occurrence but is never absolute; thus, no upper limit to dosage of pure opioid agonists can be established.

Universal agreement on definitions of addiction, physical dependence, and tolerance is critical to the optimization of pain treatment and the management of addictive disorders. While the definitions offered here do not constitute formal diagnostic criteria, it is hoped that they may serve as a basis for the future development of more specific, universally accepted diagnostic guidelines. The definitions and concepts that are offered here have been developed through a consensus process of the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.

This document was prepared by the following committee members: Sedion Savage, MD (Chair) - APS; Edward C. Covington, MD - AAPM; Howard A. Heit, MD - ASAM; John Hunt, MD - AAPM; David Jorgenson, MSSW - APS; and Stanley H. Schnoll, MD, PhD - ASAM.

Approved by the AAPM Board of Directors on February 13, 2001

Approved by the APS Board of Directors on February 14, 2001

Approved by the ASAM Board of Directors on February 21, 2001

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Exhibit B

STATEMENT OF

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

ON BEHALF OF

PURDUE PHARMA L.P.

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES
OF THE COMMITTEE ON GOVERNMENT REFORM

U. S. HOUSE OF REPRESENTATIVES

FEBRUARY 9, 2004

MR. 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 four 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. Tragically, there also has been extensive abuse of OxyContin in some regions of the country where it has been a part of the much larger problem of prescription drug abuse. Florida is one of those regions. We welcome a fresh look at this problem by your Subcommittee, and we pledge our support for your effort.

Purdue is doing everything it can to be a part of the solution to the growing public health problem of prescription drug abuse. For example, here in Florida in November 2002, Purdue worked collaboratively with then Attorney General Butterworth, and with other law enforcement officials and healthcare professionals, to bring important new resources to the medical and law enforcement communities. Let me quote Attorney General Butterworth:

> "Our agreement with Purdue consists of two unique components: first, Purdue has agreed to provide 2 million dollars to create the nation's first real time software program that will enable doctors to check a patient's prescription history while the patient is still there in their office. Second, Purdue has agreed to fund the nation's first comprehensive and statewide training for law enforcement agencies seeking to stem the growing illegal use and abuse of prescription drugs. In addition, what makes this agreement so unique is that it was not lawyer driven. Rather, it was the product of a partnership between the medical profession, law enforcement, pharmacists, physicians and a pharmaceutical company. All working together to

create the best and most practical way to make sure that the growing number of potentially dangerous drugs are used to ease a patient's suffering and pain, as opposed to feeding a street addict's habit or a drug dealer's greed-driven gang."

On January 21, 2004 in a hearing before the Florida Select Subcommittee on Medicaid Prescription Drug Over-Prescribing, Alan Must, Purdue's Vice President of State Government and Legislative Affairs, described additional initiatives being undertaken by Purdue to reduce abuse and diversion of prescription drugs in Florida. A copy of his testimony is attached to my statement as Exhibit B-1.

Since this hearing is being held in Orlando where the Orlando Sentinel has written extensively about 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 the tragedy of prescription drug abuse. But care must be taken to recognize that the very same prescription drugs that are being abused by some are absolutely indispensable to the patients who need them. OxyContin is not an illegal drug, such as heroin or crack cocaine, that serves no medical purpose. There is no easy solution that will end the abuse of prescription medications while still ensuring their availability to patients with legitimate medical need. Purdue Pharma is massively assisting in this effort to contribute to a solution, more than any other pharmaceutical company, and any suggestions for additional assistance will be entertained.

This is the first hearing held by a congressional committee or subcommittee since the issuance of a relevant report by the General Accounting Office on December 23, 2003: "PRESCRIPTION DRUGS: Factors That May Have Contributed to OxyContin Abuse and Diversion and Efforts to Address the Problem." That report is particularly important in that the GAO also recognized that there is no easy solution, and that no one factor can be blamed for the abuse and diversion of OxyContin. In December 2001, the GAO was asked to answer this question: "Is there a direct correlation between the marketing strategies of the drug [OxyContin] and its excessive abuse?" The GAO's lengthy and comprehensive investigation was unable to establish that correlation and the report clearly says so.

The GAO put the issue into perspective, pointing out that the Food and Drug Administration approved OxyContin in 1995 amid heightened awareness that many people were suffering from undertreated pain. It was in that context that Purdue's extensive 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 abuse and diversion that was to emerge. OxyContin was classified by the federal government as a Schedule II controlled substance because of its high potential for abuse. Even so, according to the GAO, "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).

What neither Purdue nor the FDA anticipated was the extent to which OxyContin would come to be used improperly. The GAO identified several factors that may have made OxyContin an attractive target for abuse and diversion. The GAO noted that the

controlled-release formulation, which made the drug beneficial to patients, enabled the drug to contain more active ingredient oxycodone than non-controlled-release products. The GAO even acknowledged that the common safety warning on the OxyContin label could have unintentionally provided abusers with information on how to obtain the rapid release of oxycodone by crushing or chewing the tablet. 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)

While the GAO noted that the increased availability of OxyContin in the marketplace may have increased the opportunities for abuse and diversion, the GAO specifically noted that the historic predisposition of certain areas to prescription drug abuse may have contributed to OxyContin abuse and diversion, particularly when coupled with the profit potential resulting from the illicit sale of OxyContin. (p. 32). The report states that ".... the Appalachian region, which encompasses parts of Kentucky, Tennessee, Virginia, and West Virginia, has been severely impacted by prescription drug abuse, particularly pain relievers, including oxycodone, for many years. Three of the four states – Kentucky, Virginia and West Virginia - were among the initial states to report OxyContin abuse and diversion. Historically, oxycodone, manufactured under brand names Percocet, Percodan and Tylox, was among the most diverted prescription drugs in Appalachia." (pp.31,32). It is interesting to note that, because there have been many generic alternatives; these branded products have not been heavily promoted for years. 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).

Having identified some factors that, in retrospect, may have contributed to abuse and diversion, 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)

We couldn't agree more. 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."

Purdue is committed to meeting this challenge as part of a collaborative effort, and as Attorney General Butterworth acknowledged in November 2002, we are trying our best to do our part in Florida as part of "a partnership between the medical profession, law enforcement, pharmacists, physicians and a pharmaceutical company [Purdue]."

The GAO recognized that in response to concerns about abuse and diversion of OxyContin, the FDA and Purdue collaborated in developing a risk management program to help detect and prevent abuse and diversion. The report recommends that guidance being developed by FDA to the pharmaceutical industry include such programs with New Drug Applications for schedule II controlled substances. We endorse that recommendation.

The abuse and diversion of OxyContin, although unanticipated, is a matter of serious and special concern to Purdue. We are firmly committed to combating the abuse of our product, and we appreciate the GAO's acknowledgment of our efforts in this regard: "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) 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 nearly a quarter of a million free, tamper-resistant prescription pads to more than 15,000 doctors;
- Supporting law enforcement with more than $1 million in grants for special equipment, education, tip lines, and other assistance;
- Educating teens and pre-teens about the dangers of prescription abuse through the Painfully Obvious® awareness and education program;
- Creating RxPATROL™, a shared database to assist law enforcement in apprehending pharmacy robbers;
- Supporting community based anti-drug programs in 10 communities, in conjunction with "Communities That Care®;
- Intensifying efforts to educate healthcare professionals about abuse and diversion;
- Serving as the catalyst for the Rx Action Alliance, chaired by Former New York City Mayor Rudolph Giuliani – a consortium of stakeholders from the public, corporate, and nonprofit sectors with a shared interest in improving patient access to medicines and combating prescription drug abuse;
- Implementing the "Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System," an unprecedented, research-based initiative to study the prevalence and nature of abuse and diversion of seven controlled opioid medications; and
- Investing more than $200 million on research into more abuse-resistant medications that will provide patients with safe and effective pain control, while being undesirable to those who would abuse them.

- Adding language to its promotional materials to healthcare professionals (Purdue has never advertised OxyContin directly to patients) to address criticism about the use of the word "moderate" in the indication for OxyContin. 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. The language that was added emphasizes that "moderate" and "moderate to severe" pain as used in the indication do not include commonplace and ordinary aches and pains, pulled muscles, cramps, sprains, or similar discomfort.

A more extensive description of Purdue's efforts to fight the abuse and diversion of prescription drugs is attached as Exhibit B-2.

Additionally, Purdue supports the concepts in federal legislation that it understands is being considered by Members of Congress that, among other things, would promote the development of effective state prescription monitoring programs to identify and reduce "doctor shopping"; regulate Internet pharmacies in an effort to curb diversion and abuse of controlled substances; establish a working group to address pharmaceutical counterfeiting; and call for baseline research on prescription drug abuse, more comprehensive and accurate reporting, and grants for drug abuse education programs for healthcare professionals, teachers, and parents. Purdue also strongly supports efforts like the Dime Out a Dealer program being sponsored by Congressman Weldon from Pennsylvania. This program is aimed at finding and arresting "dealers" who are illegally selling prescription drugs on the streets and campuses.

Purdue hopes that the GAO report will put to rest the often-repeated assertion that Purdue's marketing is somehow responsible for the tragic abuse and diversion of OxyContin. At a hearing of the Senate's Health, 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 the companies that sell them do virtually no promotion. The prescription drug now most frequently mentioned in the press and highlighted in the Senate Government Affairs hearing in Maine last summer as a drug of abuse, methadone, also is not promoted. In fact, in the lawsuits where Purdue has been accused of "aggressive" marketing, we have to date had 70 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. Purdue only markets OxyContin to health care professionals with no direct to consumer marketing. 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. See Exhibit B-3. Consider for a moment that Purdue has spent over $200 million in efforts to develop more abuse resistant pain medications. If an ideal abuse-resistant form of OxyContin existed today, the very same patients would be receiving the very same doses of oxycodone without anyone being concerned about Purdue's marketing. It is not Purdue's marketing to doctors who treat pain patients that creates the problem we are all concerned about. What Purdue, the law enforcement and the health care communities, and Congress collaboratively must address is the illegal secondary market that is run by criminal diverters. Purdue is trying to do its part, and stands ready to work with this Subcommittee and anyone else to do more.

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

POTENTIALLY FATAL DOSE OF OXYCODONE.

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

Exhibit B-1

TESTIMONY

Florida Select Subcommittee on Medicaid Prescription Drug Over-Prescribing

January 20, 2004

Chairman Saunders, Members of the Florida Select Subcommittee on Medicaid Prescription Drug Over- Prescribing, Thank you for the opportunity to speak with you today concerning prescription drug abuse and diversion in the Florida Medicaid program and statewide. My name is Alan Must. I am the Vice President of State Government and Legislative Affairs for Purdue Pharma L.P. located in Stamford, CT. Purdue and its associated U.S. companies specialize in research on persistent pain and associated treatments. Purdue is engaged in research, development, production, and distribution of both prescription and over the counter medications and hospital products. I have come today prepared to speak with you concerning the issue of prescription drug abuse and diversion and what Purdue is doing to address this very important problem in Florida.

The issue of prescription drug abuse and diversion is a complex problem that requires the collaborative efforts of pharmaceutical manufacturers, the federal and state agencies that oversee the approval and use of prescription drugs, the health care providers that prescribe and dispense them and law enforcement. Purdue Pharma hopes all the named parties – as well as local government, community groups and parents – will heed this important rallying cry.

Purdue is committed to addressing the issue of prescription drug abuse in Florida and across the country and has done so with a variety of initiatives to identify, educate, and attempt to reduce prescription drug abuse and diversion while assuring that patients with a legitimate medical need for pain medication have access to these important medications. The following are some of the initiative that Purdue has initiated in Florida to address this problem:

Healthcare Professionals

- **Medical Education Programs**

Since January 2001, Purdue has sponsored 500 Continuing Medical Education and Lecture Programs with roughly 135,058 participants. These programs consist of educational seminars and lecture programs that focus on appropriate prescribing of pain medications. Currently there are 30 approved programs for 2004.

- **Tamper Resistant Prescription Pads**

Purdue provides tamper resistant prescription pads to healthcare professionals. Since the launch of this program on May 31,2001 Purdue has distributed 34,770 pads in the state free of charge to 2,220 prescribers. Florida leads the nation in adoption of this program, which is now being utilized by over 15,000 doctors nationally.

- **Pharmacy Education Materials**

Purdue provides educational materials on how to protect pharmacies from abuse and diversion. Purdue partnered with National Consumer Pharmacists Association to provide the 2002 NCPA Drug Safety Award. As of November 24, 2003, there are 1077 registered users, 391 resource requestors and 999 requests for resources from Florida recipients.

Law Enforcement

We have provided many resources to law enforcement to combat prescription drug abuse and diversion. Purdue has hired a staff of former law enforcement personnel with expertise in prescription drug diversion and has assisted the law enforcement community by providing training in this area. This group of professionals not only provide training for law enforcement but also provide training to healthcare professionals on how to protect themselves from doctor shoppers and educate them on the latest scams to obtain prescription drugs through fraudulent means.

In 2003 - Training sessions in Florida for law enforcement officers reached 680 officers and 170 health care professionals.

5,536 NADDI drug identification charts were distributed statewide. These charts allow the street level officers to identify the most widely diverted drugs when they are uncovered.

1,867 Anti-Diversion Brochures were distributed statewide (Protect Pharmacy, Practice, Institution). These brochures offer education on how to identify and protect yourself from prescription drug diversion.
213 Tamper Resistant Rx Advertorials and 432 CDs of Regulations and Responsible Use of Controlled Substances were distributed statewide.

- **Grants to Law Enforcement**

Purdue has assisted law enforcement in addressing prescription drug abuse & diversion by providing grants to three local police departments in 2003 :
4/01//03 Plantation Police Department
5/15/03 Palm Bay Police Department
12/11/03 Ft. Myers Police Department

These grants are provided with no strings attached, to enable local law enforcement to pursue criminals engaged in the trafficking of prescription drugs.

- **Pharmaceutical Drug Diversion Training Conferences**

In early 2003 Purdue provided for statewide law enforcement training on prescription drug diversion in collaboration with the Office of the Florida Attorney General, FDLE, and the National Association of Drug Diversion Investigators (NADDI). At these training conferences, drug identification bibles were distributed to all attendees as well as membership in NADDI at Purdue's expense.

Consumers

- **Public Service Advertising**

Through an advertising campaign that consists of print, radio and television, Purdue has communicated messages on the danger of abusing prescription medication to the citizens of Florida. These messages target all members of society including Medicaid recipients and have been broadcast in the Tallahassee, St. Petersburg, Palm Beach and Pensacola markets to name a few. These ads specifically address prescription drug abuse and diversion and do not promote the use of our products. Purdue does not do any "direct to consumer" advertising of our prescription medications.

Communities That Care / Painfully Obvious

"Communities That Care"- A nationally recognized community outreach program, has three Purdue sponsored CTC sites in Florida: Tampa (launched April 14th, 2003), Tallahassee (launched May 6th, 2003), and Palm Beach county (launched, June 6th 2003) - each site is underwritten by Purdue with a grant of $25,000 per community. Purdue is the only corporate sponsor of these programs.

One day Community Forums on Prescription Drug Abuse - funded by Purdue and sponsored by CADCA, Community AntiDrug Coalitions of America will be held in each CTC site during 2004.

Purdue has been an annual sponsor of the Florida Prevention Conference in 2002 and 2003. We have provided Clay Yeager, Director of Community Partnerships, as the speaker at the Annual Conference of Safe Schools Coordinators sponsored by the Mendez Foundation in Tampa - January 2003.

In reference to the Painfully Obvious materials, the following items have been shipped to recipients in FL as of the 4th quarter of 2003:

67 CD ROMs
1,424 Folder Kits
2,859 Parent Brochures
21,953 Brain Boxes

Medicaid and State Legislative Remedies

Purdue supports appropriately designed state operated electronic prescription monitoring programs. Through an agreement with the Florida Office of Attorney General, Purdue has pledged $2 Million for the development of a state of the art electronic prescription-monitoring program to be developed in Florida and made available to all states at no cost. We would encourage the Florida legislature to pass this proposed legislation in this session.

We support the newly enacted pedigree paper statute that was passed by the Florida legislature last year as a good first step and would encourage the legislature to expand the coverage beyond the top 30 prescribed products and include all prescription medications.

Purdue has reviewed the Second Interim Report Of The Seventeenth Statewide Grand Jury " Report On Recipient Fraud in Florida's Medicaid Program " and support the recommendations. Of note, is recommendation # 13 which states, " Survey other states' program integrity units and determine what steps they have taken that have been successful in curbing recipient fraud such as software applications for detecting over-utilization" Purdue has developed a software program (CS PURE) that identifies potential areas of abuse within managed populations such as Medicaid and has entered into discussions with the agency on their interest in piloting such a program. In 2002, Purdue offered a similar application to the Florida Medicaid program but that offer was rejected by the agency at that time. We are hopeful that we may be able to work cooperatively on this project.

All of these initiatives are extremely important to decrease prescription drug abuse and diversion statewide as well as within the Medicaid program. We all need to be ever mindful to ensure that the needs of the great majority of legitimate patients are not compromised when attempting to address the abuses of a few.

Thank you for again for the opportunity to address you this afternoon.

Exhibit B-2

EFFORTS BY PURDUE PHARMA TO ADDRESS ABUSE AND DIVERSION OF PRESCRIPTION DRUGS

While there are limits to what an individual company can do to prevent the social and criminal activities associated with prescription drug abuse, some highlights of the efforts made by Purdue Pharma L.P. to address abuse and diversion of OxyContin® (oxycodone HCl controlled-release) Tablets and other prescription drugs are as follows:

- After learning about the initial reports of problems relating to OxyContin abuse and diversion in Maine in March of 2000, Purdue immediately formed a response team made up of our top executives and physicians who immersed themselves in this problem and made it a key corporate priority. The initial efforts resulting from the team's plan included: (1) initiating meetings with public officials, including U.S. Attorneys, State Attorneys General, state legislators, regulators, administrative personnel, Secretaries of Public Safety, law enforcement personnel, and community leaders in more than 12 states where abuse was reported; (2) collecting as much information as possible on the methods by which OxyContin was diverted and abused; (3) working with federal, state, and local officials on measures to reduce abuse and diversion; and (4) immediately developing and distributing brochures educating pharmacists and physicians on the various actions they could take to prevent diversion of prescription medicines and reduce abuse. More than 770,000 of these brochures have been distributed to physicians and 546,000 have been distributed to pharmacists nationwide.

- As Terry Woodworth, then Deputy Director of DEA's Office of Diversion Control, testified at a Congressional hearing, "The best means of preventing the diversion of OxyContin is to increase awareness of the proper use of this product, as well as its high potential for abuse." Beginning in late April of 2000 and continuing to the present, Purdue has sponsored or provided educational programs on prevention and investigation of pharmaceutical drug diversion, proper pain management, and recognizing addiction for more than 5,800 law enforcement officers in 30 states.

- In addition to providing training to healthcare professionals on abuse and diversion issues, Purdue has contributed more than $1 million to numerous drug abuse prevention organizations to help combat prescription medicine abuse. Recipients include Community Anti-Drug Coalitions of America (CADCA) and the National Center on Addiction and Substance Abuse (CASA) at Columbia University.

- With funding and active involvement from Purdue, CADCA developed a "Strategizer" and "Tool Kit" to help its constituent community organizations address prescription drug abuse. These resources have been distributed to 5,000 CACDA member organizations around the country. Purdue also provided funding for five CADCA community forums on prescription drug abuse in a number of states. These forums are intended to raise public awareness of prescription drug abuse and engage the community in finding ways to address this societal problem.

- Purdue has prepared numerous informational bulletins and training programs for our Professional Sales Representatives and their management in an effort to communicate the importance of the appropriate use of OxyContin to our employees, and to emphasize the need to ensure that healthcare professionals understand the abuse potential of our medication. Our representatives were told that in the 100 counties where abuse potential was highest, their goal was to provide physicians with additional information regarding abuse and diversion as well as tools (including opioid therapy documentation kits) for proper pain assessment. If physicians were not willing to use these tools, our representatives were instructed to ask them to **stop** prescribing OxyContin.

- Purdue established a toll-free number and notified physicians and pharmacists that they should call us if they had questions or concerns regarding Purdue's sales representatives or its advertising and promotional activities. This toll-free number now appears on all promotional materials used in the distribution for OxyContin, and it will appear on all materials as they are reprinted. All advertising for Purdue prescription products is restricted to medical journals and directed at professionals; Purdue has never advertised its prescription products directly to patients.

- Purdue initiated meetings with the FDA at which we proposed revisions to the OxyContin labeling that ultimately resulted in a Boxed Warning highlighting the appropriate indications for the use of OxyContin tablets as well as the abuse potential and dangers of the medication. Purdue also initiated and developed a Patient Information Sheet, intended to accompany each prescription, which alerts patients to the risk of misuse and abuse of the medication.

- Purdue mailed a "Dear Healthcare Professional" letter to more than 500,000 healthcare professionals, informing them of the new Boxed Warning and prescribing information. Purdue also ran an advertisement featuring the Boxed Warning in medical journal for six months. In addition, our representatives were instructed to review the Boxed Warning with all doctors and pharmacists upon whom they called.

- While Purdue does not think the distribution of OxyContin "conversion chart scroll pens" was inappropriate, we nonetheless discontinued distribution of this item in July 2001.

- In response to a suggestion by an Assistant U.S. Attorney who expressed concern that Purdue's sales representatives should not benefit inordinately from prescriptions written by an individual doctor, Purdue revised its Sales Representative compensation plan to cap sales commissions from prescriptions by any single physician.

- Purdue has provided more than 230,000 free tamper-resistant prescription pads to over 15,000 physicians in 32 states and the District of Columbia to aid in combating prescription fraud

- Purdue voluntarily – and without request by any governmental agency – suspended shipment of the 160 mg. OxyContin tablets.

- When alerted by the staff of a Congressional committee to the problem of diversion of OxyContin from Mexico into the United States, Purdue voluntarily took escalating steps to prevent such diversion. First we changed the markings on the tablets to allow law enforcement to identify product crossing the border from Mexico. This was in response to a suggestion made by the staff of that committee, who told us that major pharmaceutical companies had refused to comply with their request to do the same. Subsequently, we imposed limitations and restrictions on sales to Mexico. Finally, upon learning of a significant theft of OxyContin in Mexico in December 2001, Purdue discontinued all sales to Mexico. While such action resulted in a costly lawsuit by the Mexican licensee, Purdue refused to resume shipments to Mexico.

- Purdue has spent more than $175 million to date in an effort to develop new formulations of pain medicines that would be more resistant to abuse while providing safe and effective pain relief to patients who use the medicines as intended. Patents on new formulations have been filed, and Purdue is actively working with the FDA in an attempt to expedite appropriate clinical trials and regulatory review.

- Purdue has actively participated at the state level to support enactment and funding of well-designed Prescription Monitoring Programs (PMPs). We feel that if structured properly, PMPs will provide an early warning system for physicians and pharmacists to prevent "doctor shopping", identify individuals who are abusing prescription medicines so they can be treated, and assist law enforcement in minimizing abuse and diversion. Purdue also supports efforts in Congress to provide grants to the states for funding their PMPs.

- To support state efforts to implement PMPs, Purdue has agreed to contribute up to $2 million toward the efforts of the State of Florida to design and acquire the software necessary to support the most sophisticated PMPs. When developed, this software will be available to any state at no cost.

- Purdue hired the State of Pennsylvania's former Executive Director of Community Partnerships to head our Community Partnerships program, which is developing community-based anti-drug abuse programs. In conjunction with this program, Purdue is supporting Communities That Care® efforts in ten cities in seven states.

- Purdue implemented an extensive prescription medicine abuse awareness program targeted toward the middle school "tween" population. This program, called Painfully Obvious®, focuses on informing school-age children about the dangers of abusing prescription medicines. The program maintains a website, www.painfullyobvious.com, which provides educational information that can be downloaded without cost. Purdue distributes Painfully Obvious kits at conferences and programs to which the company has been invited to speak, and in collaboration with third-party organizations and state partnerships. The expenditures for this program to date are in excess of $4 million.

- Purdue has implemented the "Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System," a research-based initiative to study the prevalence and nature of abuse and diversion of seven opioid analgesics. The system actively collects

evidence concerning the abuse, diversion, and addiction potential of buprenorphine, fentanyl, hydrocodone, hydromorphone, oxycodone, methadone, and morphine. These are all prescription opioid pain medicines with recognized abuse potential. We believe that the RADARS System is the most comprehensive and advanced method of accumulating abuse and diversion data in the U.S. today. On approximately a quarterly basis, External Advisory Board meetings are held in the District of Columbia to facilitate attendance by representatives of various federal agencies. To date, observers from the Food and Drug Administration, Drug Enforcement Administration, Center for Substance Abuse Treatment (Substance Abuse and Mental Health Services Administration), and National Institute on Drug Abuse have attended these meetings. We have also invited the Center for Substance Abuse Prevention to join us, and we hope they will do so.

- Purdue has spearheaded an important educational program of the American Academy of Pain Medicine, overseen by Louis W. Sullivan, MD, former Secretary of the U.S. Department of Health and Human Services and President Emeritus of the Morehouse School of Medicine in Atlanta, Georgia. Dr. Sullivan chairs an advisory board that is guiding the development of a web-based "virtual textbook" for medical schools that will teach students throughout the continuum of learning about pain assessment and management; all modes of pain management (including pain-relieving procedures, physical modalities, psychological therapies, and the use of non-opioid analgesics); and the detection and management of abuse, addiction, and diversion. Purdue is providing more than $1 million to develop this groundbreaking educational tool.

- Working with former New York City Mayor Rudolph Giuliani, Purdue has spearheaded the formation of the "Rx Action Alliance," a coalition through which pharmaceutical companies, not-for-profit organizations, healthcare professionals, and government (both law enforcement and regulatory agencies) can work together to seek solutions to the public health problem of prescription drug abuse. So far, more than 30 entities have agreed to join in what we believe will be a major force to prevent prescription drug abuse while maintaining the right of patients with legitimate medical need to receive appropriate medications.

- Purdue hired an experienced pharmaceutical security expert and former FDA and DEA law enforcement official to head our Corporate Security Department. He has implemented several programs dealing with manufacturing security, supply chain and product integrity, and assistance to local law enforcement agencies with investigations of diversion of OxyContin.

- In an effort to combat the theft and illegal trafficking of prescription medications, Purdue conceived, developed, and funded RxPATROL™ (Pattern Analysis Tracking Robberies and Other Losses). This information clearinghouse is designed to collect, analyze, and share information on pharmacy robberies, burglaries, and theft of controlled substances. Launched by the National Community Pharmacists Association (NCPA), National Association of Drug Diversion Investigators (NADDI), and Pharmaceutical Security Institute (PSI), RxPATROL is intended to help protect pharmacists, guard against potential robberies and burglaries, and assist law enforcement efforts to apprehend and prosecute pharmacy robbers.

- Purdue distributes prescription medicine identification cards created by the National Association of Drug Diversion Investigators to law enforcement officers to assist them in quickly identifying tablets seized during arrests. As of December 31, 2003, Purdue had distributed more than 47,000 identification cards to officers in 210 agencies in 40 states.

To date, Purdue estimates that we have spent more than $225 million in our efforts to develop more abuse-resistant pain medications; educate healthcare professionals, patients, and the general public; and cooperate with law enforcement in curbing abuse and diversion. These costs are exclusive of lost sales as a result of suspension of formulations and discontinuation of distribution in Mexico. Purdue in no way benefits from the misuse of our products, and we remain committed to working cooperatively with all interested parties to prevent the social and criminal activities that lead to abuse and diversion of prescription medications.

Exhibit B-3

"Iatrogenic addiction" to opioids is addiction that develops in a person, without a prior history of substance abuse or addiction, who is using opioids as intended for a legitimate medical purpose, that is, the treatment of pain.

It has long been recognized by experts from around the world that such addiction rarely occurs, and that unfounded fears of addiction should not prevent patients with appropriate pain conditions from taking opioids for pain relief.

The United States government has spoken repeatedly to this issue. The U.S. Department of Health and Human Services (US Public Health Service, Agency for Health Care Policy and Research) concluded in 1994 that the definition of an addict "rarely applies to patients being treated with opioids for cancer pain." at p18 in Jacox A, Carr DB, Payne R, et al. *Management of Cancer Pain. Clinical Practice Guideline* No. 9, AHCPR Publication No. 94-0592. Similarly, a committee of the National Academy of Science's Institute of Medicine wrote in 1997 that "[r]esearch indicates that addiction in patients appropriately receiving opioids for pain is very small, ranging from roughly 1 in 1,000 to less than 1 in 10,000." Institute of Medicine Committee on Care at the End of Life, *Approaching Death: Improving Health Care at the End of Life* at 192-193. In July 2001, and many months after the first media reports of widespread abuse and diversion of OxyContin® (oxycodone HCl controlled-release) Tablets, the federal government's National Institute on Drug Abuse (NIDA) wrote that "[m]any studies have shown. . . that properly managed medical use of opioid analgesic drugs is safe and rarely causes clinical addiction. . . ." *NIDA Research Report - Prescription Drugs: Abuse and Addiction: NIH Publication No. 01-4881.* That same year, the Food and Drug Administration (FDA) advised patients that "[c]oncerns of addiction should not prevent patients with appropriate pain conditions from using OxyContin or other narcotics for pain relief." FDA Center for Drug Evaluation and Research, *OxyContin: Questions and Answers* at www.fda.gov/cder/drug/infopage/oxycontin/oxycontin-qa.htm. In October 2001, the US Drug Enforcement Administration and 21 health groups released a statement calling for balanced policy on prescription pain medications like OxyContin. In the press release, the following quote appears, " 'The repeated accounts of misuse have skewed peoples' perceptions about drugs like OxyContin. The reality is that the vast majority of people who are given these medications by doctors will not become addicted,' said Russell Portenoy, M.D., chairman of pain medicine and palliative care at Beth Israel Medical Center in New York City." available at http://www.dea.gov/pubs/pressrel/pr102301.html.

The World Health Organization (WHO) has also repeatedly examined the same issue and reached the same conclusion, noting as early as 1986 that "[w]ide clinical experience has shown that psychological dependence rarely, if ever, occurs in cancer patients receiving these drugs for chronic pain." WHO, *Cancer Pain Relief*, at p 56. Fourteen years later, in 2000, the WHO again called iatrogenic addiction "extremely rare." WHO, *Narcotic & Psychotropic Drugs: Achieving Balance in National Opioids Control Policy, Guidelines for Assessment*, at p 8. In so doing, it noted that its conclusions were supported by its own worldwide surveillance.

Medical societies that have examined this issue have also reached the same conclusion. In 1995, for example, the American Medical Association stated that the "Concern about addiction should never result in undermedication for acute pain. The occurrence of addictive behaviors after chronic pain therapy is also rare. Fear of inducing addiction should never be the basis for withholding opioid agents from a patient without a history of substance abuse." *Report 4 of the Council on Scientific Affairs (A-95)* available at http://www.ama-assn.org/ama/pub/article/2036-2539.html.
Similarly, in 1997 the American Academy of Pain Medicine and the American Pain Society issued a joint consensus statement that said the "...development of addiction when opioids are used for the relief of pain is low." AAPM/APS Consensus Statement, *The Use of Opioids for the Treatment of Chronic Pain* (1997), available at www.painmed.org/productpub/statements/pdfs/opioids.pdf. And in 2001, the American Academy of Pain Medicine issued a statement saying "...when opioids are prescribed and used appropriately in the treatment of pain there is minimal danger of creating an addictive disorder." *AAPM Release Statement on the Diversion and Abuse of Controlled Substances* (February 16, 2001).

The leading textbooks in the field have long noted that iatrogenic addiction is rare. For example, the leading textbook on pain medicine, *Bonica's Management of Pain, 2nd Edition* stated in 1990 that "[n]arcotic addiction occurs rarely, or not at all, in patients receiving narcotics for medical use." at p. 429. The same textbook, in the 3rd edition, updated in 2001, reiterated the point: "Fear of addiction has been an important factor in the underdosing of opioids in patients with severe pain, but opioid addiction rarely occurs in patients receiving opioids for medical purposes." at p. 1695. Similarly, a leading textbook on pharmacology, *Goodman and Gilman's The Pharmacological Basis of Therapeutics, 8th Edition*, stated in 1990 when discussing opioid analgesics that "addiction as a complication of medical treatment is quite uncommon." In the 10th edition of the same text (2001), it repeats this concept, stating "Patients with pain rarely develop abuse or addiction problems." at page 631 in Chapter 24, Drug Addiction and Drug Abuse.

There are also a large number of published studies in this area, some of which are discussed in a 1999 survey article by Rebecca Drayer. Drayer RA, Henderson J, Reidenberg M., Barriers to Better Pain Control in Hospitalized Patients. *Journal of Pain and Symptom Management* 17(6):434-440 (1999). When averaged, the 17 studies discussed in that article indicate an iatrogenic addiction rate of 0.1%. These studies comport with the experience of professionals with extensive experience in treating patients on opioids. In late 2002, for example, Dr. Kathleen Foley of Memorial Sloan-Kettering, widely considered one of the leading authorities on pain medicine in the world today, wrote, "the likelihood of addiction as a result of medically prescribed pain medicine is extremely low." Foley KM, *Patients in Pain, Casualties of the war on drugs*, Open Society Institute at page 2, 2(4).

In summary, the risks of iatrogenic addiction must be put into perspective with the benefits that opioids provide to many patients suffering in pain. While data are not available to establish the true incidence of addiction in people suffering from chronic pain, as has long been recognized by medical experts, the United States government and the World Health Organization, iatrogenic addiction is a rare phenomenon. Indeed, if this were not the case, the FDA would certainly not be advising patients - as it currently does on its website - that "[c]oncerns of addiction should not prevent patients with appropriate pain conditions from using OxyContin or other narcotics for pain relief."

Exhibit B-4

OxyContin®

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.

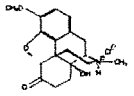
OxyContin Tablets are NOT intended for use as a prn analgesic.

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.

DESCRIPTION

OxyContin® (oxycodone hydrochloride controlled-release) Tablets are an opioid analgesic supplied in 10 mg, 20 mg, 40 mg, 80 mg, and 160 mg tablet strengths for oral administration. The tablet strengths describe the amount of oxycodone per tablet as the hydrochloride salt. The structural formula for oxycodone hydrochloride is as follows:



$C_{18}H_{21}NO_4 \cdot HCl$ MW 351.83

The chemical formula is 4, 5α-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride.

Oxycodone is a white, odorless crystalline powder derived from the opium alkaloid, thebaine. Oxycodone hydrochloride dissolves in water (1 g in 6 to 7 mL). It is slightly soluble in alcohol (octanol water partition coefficient 0.7). The tablets contain the following inactive ingredients: ammonio methacrylate copolymer, hypromellose, lactose, magnesium stearate, polyethylene glycol 400, povidone, sodium hydroxide, sorbic acid, stearyl alcohol, talc, titanium dioxide, and triacetin.

The 10 mg tablets also contain: hydroxypropyl cellulose.

The 20 mg tablets also contain: polysorbate 80 and red iron oxide.

The 40 mg tablets also contain: polysorbate 80 and yellow iron oxide.

The 80 mg tablets also contain: FD&C blue No. 2, hydroxypropyl cellulose, and yellow iron oxide.

The 160 mg tablets also contain: FD&C blue No. 2 and polysorbate 80.

CLINICAL PHARMACOLOGY

Oxycodone is a pure agonist opioid whose principal therapeutic action is analgesia. Other members of the class known as opioid agonists include substances such as morphine, hydromorphone, fentanyl, codeine, and hydrocodone. Pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis, and cough suppression, as well as analgesia. Like all pure opioid agonist analgesics, with increasing doses there is increasing analgesia, unlike with mixed agonist/antagonists or non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses. With pure opioid agonist analgesics, there is no defined maximum dose; the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression.

Central Nervous System

The precise mechanism of the analgesic action is unknown. However, specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and play a role in the analgesic effects of this drug.

Oxycodone produces respiratory depression by direct action on brain stem respiratory centers. The respiratory depression involves both a reduction in the responsiveness of the brain stem respiratory centers to increases in carbon dioxide tension and to electrical stimulation.

Oxycodone depresses the cough reflex by direct effect on the cough center in the medulla. Antitussive effects may occur with doses lower than those usually required for analgesia.

Oxycodone causes miosis, even in total darkness. Pinpoint pupils are a sign of opioid overdose but are not pathognomonic (e.g., pontine lesions of hemorrhagic or ischemic origin may produce similar findings). Marked mydriasis rather than miosis may be seen with hypoxia in the setting of OxyContin® overdose (See **OVERDOSAGE**).

Gastrointestinal Tract And Other Smooth Muscle

Oxycodone causes a reduction in motility associated with an increase in smooth muscle tone in the antrum of the stomach and duodenum. Digestion of food in the small intestine is delayed and propulsive contractions are decreased. Propulsive peristaltic waves in the colon are decreased, while tone may be increased to the point of spasm resulting in constipation. Other opioid-induced effects may include a reduction in gastric, biliary and pancreatic secretions, spasm of sphincter of Oddi, and transient elevations in serum amylase.

Cardiovascular System

Oxycodone may produce release of histamine with or without associated peripheral vasodilation. Manifestations of histamine release and/or peripheral vasodilation may include pruritus, flushing, red eyes, sweating, and/or orthostatic hypotension.

Concentration – Efficacy Relationships

Studies in normal volunteers and patients reveal predictable relationships between oxycodone dosage and plasma oxycodone concentrations, as well as between concentration and certain expected opioid effects, such as pupillary constriction, sedation, overall 'drug effect', analgesia and feelings of 'relaxation'.

As with all opioids, the minimum effective plasma concentration for analgesia will vary widely among patients, especially among patients who have been previously treated with potent agonist opioids. As a result, patients must be treated with individualized titration of dosage to the desired effect. The minimum effective analgesic concentration of oxycodone for any individual patient may increase over time due to an increase in pain, the development of a new pain syndrome and/or the development of analgesic tolerance.

Concentration – Adverse Experience Relationships

OxyContin® Tablets are associated with typical opioid-related adverse experiences. There is a general relationship between increasing oxycodone plasma concentration and increasing frequency of dose-related opioid adverse experiences such as nausea, vomiting, CNS effects, and respiratory depression. In opioid-tolerant patients, the situation is altered by the development of tolerance to opioid-related side effects, and the relationship is not clinically relevant.

As with all opioids, the dose must be individualized (see **DOSAGE AND ADMINISTRATION**), because the effective analgesic dose for some patients will be too high to be tolerated by other patients.

PHARMACOKINETICS AND METABOLISM

The activity of OxyContin Tablets is primarily due to the parent drug oxycodone. OxyContin Tablets are designed to provide controlled delivery of oxycodone over 12 hours.

Breaking, chewing or crushing OxyContin Tablets eliminates the controlled delivery mechanism and results in the rapid release and absorption of a potentially fatal dose of oxycodone.

Oxycodone release from OxyContin Tablets is pH independent. Oxycodone is well absorbed from OxyContin Tablets with an oral bioavailability of 60% to 87%. The relative oral bioavailability of OxyContin to immediate-release oral

dosage forms is 100%. Upon repeated dosing in normal volunteers in pharmacokinetic studies steady-state levels were achieved within 24-36 hours. Dose proportionality and/or bioavailability has been established for the 10 mg, 20 mg 40 mg, 80 mg, and 160 mg tablet strengths for both peak plasma levels (C_{max}) and extent of absorption (AUC). Oxycodone is extensively metabolized and eliminated primarily in the urine as both conjugated and unconjugated metabolites. The apparent elimination half-life of oxycodone following the administration of OxyContin® was 4.5 hours compared to 3.2 hours for immediate-release oxycodone.

Absorption

About 60% to 87% of an oral dose of oxycodone reaches the central compartment in comparison to a parenteral dose. This high oral bioavailability is due to low pre-systemic and/or first-pass metabolism. In normal volunteers, the $t^1/_2$ of absorption is 0.4 hours for immediate-release oral oxycodone. In contrast, OxyContin Tablets exhibit a biphasic absorption pattern with two apparent absorption half-lives of 0.6 and 6.9 hours, which describes the initial release of oxycodone from the tablet followed by a prolonged release.

Plasma Oxycodone by Time

Dose proportionality has been established for the 10 mg, 20 mg, 40 mg, and 80 mg tablet strengths for both peak plasma concentrations (C_{max}) and extent of absorption (AUC) (see Table 1 below). Another study established that the 160 mg tablet is bioequivalent to 2 x 80 mg tablets as well as to 4 x 40 mg for both peak plasma concentrations (C_{max}) and extent of absorption (AUC) (see Table 2 below). Given the short half-life of elimination of oxycodone from OxyContin®, steady-state plasma concentrations of oxycodone are achieved within 24-36 hours of initiation of dosing with OxyContin Tablets. In a study comparing 10 mg of OxyContin every 12 hours to 5 mg of immediate-release oxycodone every 6 hours, the two treatments were found to be equivalent for AUC and C_{max}, and similar for C_{min} (trough) concentrations. There was less fluctuation in plasma concentrations for the OxyContin Tablets than for the immediate-release formulation.

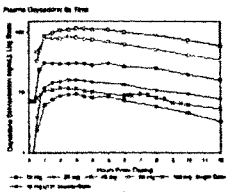


TABLE 1

Mean [% coefficient variation]

Regimen, Dosage Form	AUC (ng • hr/mL)†	C_{max} (ng/mL)	T_{max} (hrs)	Trough Conc. (ng/mL)
Single Dose				
10 mg OxyContin	190.7 [25.5]	10.6 [20.1]	2.7 [44.1]	n.a.
20 mg OxyContin	307.5 [26.9]	21.4 [26.6]	3.2 [57.6]	n.a.
40 mg OxyContin	472.1 [33.3]	39.3 [34.0]	3.1 [77.4]	n.a.
80 mg OxyContin*	1085.5 [32.3]	98.5 [32.1]	2.1 [52.3]	n.a.
Multiple Dose				
10 mg OxyContin tablets q12h	103.8 [28.6]	15.1 [31.0]	3.2 [69.5]	7.2 [49.1]
5 mg immediate-release q6h	99.6 [36.2]	15.5 [29.8]	1.6 [49.7]	7.4 [50.9]

TABLE 2

Mean [% coefficient variation]

Regimen, Dosage Form	AUC ∞ (ng • hr/mL)†	C_{max} (ng/mL)	T_{max} (hrs)	Trough Conc. (ng/mL)
Single Dose				
4x40 mg OxyContin*	1606.3 [34.7]	152.0 [26.9]	2.56 [42.3]	n.a.
2x80 mg OxyContin*	1858.3 [30.1]	153.4 [25.1]	2.78 [69.3]	n.a.
1x160 mg OxyContin*	1854.4 [30.5]	156.4 [24.8]	2.54 [26.4]	n.a.

†for single-dose AUC = $AUC_{0\text{-}inf}$; for multiple-dose AUC = $AUC_{0\text{-}\tau}$

*data obtained while volunteers received naltrexone which can enhance absorption.

OxyContin® is NOT INDICATED FOR RECTAL ADMINISTRATION. Data from a study involving 21 normal volunteers show that OxyContin Tablets administered per rectum resulted in an AUC 39% greater and a C_{max} 9% higher than tablets administered by mouth. Therefore, there is an increased risk of adverse events with rectal administration.

Food Effects

Food has no significant effect on the extent of absorption of oxycodone from OxyContin. However, the peak plasma concentration of oxycodone increased by 25% when a OxyContin 160 mg Tablet was administered with a high-fat meal.

Distribution

Following intravenous administration, the volume of distribution (Vss) for oxycodone was 2.6 L/kg. Oxycodone binding to plasma protein at 37°C and a pH of 7.4 was about 45%. Once absorbed, oxycodone is distributed to skeletal muscle, liver, intestinal tract, lungs, spleen, and brain. Oxycodone has been found in breast milk (see **PRECAUTIONS**).

Metabolism

Oxycodone hydrochloride is extensively metabolized to noroxycodone, oxymorphone, and their glucuronides. The major circulating metabolite is noroxycodone with an AUC ratio of 0.6 relative to that of oxycodone. Noroxycodone is reported to be a considerably weaker analgesic than oxycodone. Oxymorphone, although possessing analgesic activity, is present in the plasma only in low concentrations. The correlation between oxymorphone concentrations and opioid effects was much less than that seen with oxycodone plasma concentrations. The analgesic activity profile of other metabolites is not known.

The formation of oxymorphone, but not noroxycodone, is mediated by cytochrome P450 2D6 and as such its formation can, in theory, be affected by other drugs (see **Drug-Drug Interactions**)

Excretion

Oxycodone and its metabolites are excreted primarily via the kidney. The amounts measured in the urine have been reported as follows: free oxycodone up to 19%; conjugated oxycodone up to 50%; free oxymorphone 0%; conjugated oxymorphone ≤ 14%; both free and conjugated noroxycodone have been found in the urine but not quantified. The total plasma clearance was 0.8 L/min for adults

Special Populations

Elderly

The plasma concentrations of oxycodone are only nominally affected by age, being 15% greater in elderly as compared to young subjects.

Gender

Female subjects have, on average, plasma oxycodone concentrations up to 25% higher than males on a body weight adjusted basis. The reason for this difference is unknown.

Renal Impairment

Data from a pharmacokinetic study involving 13 patients with mild to severe renal dysfunction (creatinine clearance <60 mL/min) show peak plasma oxycodone and noroxycodone concentrations 50% and 20% higher, respectively, and AUC values for oxycodone, noroxycodone, and oxymorphone 60%, 50%, and 40% higher than normal subjects, respectively. This is accompanied by an increase in sedation but not by differences in respiratory rate, pupillary constriction, or several other measures of drug effect. There was an increase in $t^1/_2$ of elimination for oxycodone of only 1 hour (see **PRECAUTIONS**).

Hepatic Impairment

Data from a study involving 24 patients with mild to moderate hepatic dysfunction show peak plasma oxycodone and noroxycodone concentrations 50% and 20% higher, respectively, than normal subjects. AUC values are 95% and 65% higher, respectively. Oxymorphone peak plasma concentrations and AUC values are lower by 30% and 40%. These differences are accompanied by increases in some, but not other, drug effects. The $t^1/_2$ elimination for oxycodone increased by 2.3 hours (see **PRECAUTIONS**).

Drug-Drug Interactions (see PRECAUTIONS)

Oxycodone is metabolized in part by cytochrome P450 2D6 to oxymorphone which represents less than 15% of the total administered dose. This route of elimination may be blocked by a variety of drugs (e.g., certain cardiovascular drugs including amiodarone and quinidine as well as polycyclic anti-depressants). However, in a study involving 10 subjects using quinidine, a known inhibitor of cytochrome P450 2D6, the pharmacodynamic effects of oxycodone were unchanged.

Pharmacodynamics

A single-dose, double-blind, placebo- and dose-controlled study was conducted using OxyContin®

(10, 20, and 30 mg) in an analgesic pain model involving 182 patients with moderate to severe pain. Twenty and 30 mg of OxyContin were superior in reducing pain compared with placebo, and this difference was statistically significant. The onset of analgesic action with OxyContin occurred within 1 hour in most patients following oral administration.

CLINICAL TRIALS

A double-blind placebo-controlled, fixed-dose, parallel group, two-week study was conducted in 133 patients with chronic, moderate to severe pain, who were judged as having inadequate pain control with their current therapy. In this study, 20 mg OxyContin q12h but not 10 mg OxyContin q12h decreased pain compared with placebo, and this difference was statistically significant.

INDICATIONS AND USAGE

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 is **NOT** intended for use as a prn analgesic. Physicians should individualize treatment in every case, initiating therapy at the appropriate point along a progression from non-opioid analgesics, such as non-steroidal anti-inflammatory drugs and acetaminophen to opioids in a plan of pain management such as outlined by the World Health Organization, the Agency for Healthcare Research and Quality (formerly known as the Agency for Health Care Policy and Research), the Federation of State Medical Boards Model Guidelines, or the American Pain Society.

OxyContin is not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. OxyContin is only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate. (See American Pain Society guidelines.)

CONTRAINDICATIONS

OxyContin® is contraindicated in patients with known hypersensitivity to oxycodone, or in any situation where opioids are contraindicated. This includes patients with significant respiratory depression (in unmonitored settings or the absence of resuscitative equipment), and patients with acute or severe bronchial asthma or hypercarbia. OxyContin is contraindicated in any patient who has or is suspected of having paralytic ileus.

WARNINGS

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.

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 80 mg and 160 mg Tablets are for use only in opioid-tolerant patients requiring daily oxycodone equivalent dosages of 160 mg or more for the 80 mg tablet and 320 mg or more for the 160 mg tablet. Care should be taken in the prescribing of these tablet strengths. Patients should be instructed against use by individuals other than the patient for whom it was prescribed, as such inappropriate use may have severe medical consequences, including death.

Misuse, Abuse and Diversion of Opioids

Oxycodone is an opioid agonist of the morphine-type. Such drugs are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.

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 has been reported as being abused by crushing, chewing, snorting, or injecting the dissolved product. These practices will result in the uncontrolled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death (see **WARNINGS** and **DRUG ABUSE AND ADDICTION**).

Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients.

Healthcare professionals should contact their State Professional Licensing Board, or State Controlled Substances Authority for information on how to prevent and detect abuse or diversion of this product.

Interactions with Alcohol and Drugs of Abuse

Oxycodone may be expected to have additive effects when used in conjunction with alcohol, other opioids, or illicit drugs that cause central nervous system depression.

DRUG ABUSE AND ADDICTION

OxyContin® is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule II controlled substance. Oxycodone, like morphine and other opioids used in analgesia, can be abused and is subject to criminal diversion.

Drug addiction is characterized by compulsive use, use for non-medical purposes, and continued use despite harm or risk of harm. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common.

'Drug-seeking' behavior is very common in addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated 'loss' of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). 'Doctor shopping' to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction.

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction and is characterized by misuse for non-medical purposes, often in combination with other psychoactive substances. OxyContin®, like other opioids, has been diverted for non-medical use. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

OxyContin consists of a dual-polymer matrix, intended for oral use only. Abuse of the crushed tablet poses a hazard of overdose and death. This risk is increased with concurrent abuse of alcohol and other substances. With parenteral abuse, the tablet excipients, especially talc, can be expected to result in local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

Respiratory Depression

Respiratory depression is the chief hazard from oxycodone, the active ingredient in OxyContin®, as with all opioid agonists. Respiratory depression is a particular problem in elderly or debilitated patients, usually following large initial doses in non-tolerant patients, or when opioids are given in conjunction with other agents that depress respiration.

Oxycodone should be used with extreme caution in patients with significant chronic obstructive pulmonary disease or cor pulmonale, and in patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression. In such patients, even usual therapeutic doses of oxycodone may decrease respiratory drive to the point of apnea. In these patients alternative non-opioid analgesics should be considered, and opioids should be employed only under careful medical supervision at the lowest effective dose.

Head Injury

The respiratory depressant effects of opioids include carbon dioxide retention and secondary elevation of cerebrospinal fluid pressure, and may be markedly exaggerated in the presence of head injury, intracranial lesions, or other sources

of pre-existing increased intracranial pressure. Oxycodone produces effects on pupillary response and consciousness which may obscure neurologic signs of further increases in intracranial pressure in patients with head injuries.

Hypotensive Effect

OxyContin may cause severe hypotension. There is an added risk to individuals whose ability to maintain blood pressure has been compromised by a depleted blood volume, or after concurrent administration with drugs such as phenothiazines or other agents which compromise vasomotor tone. Oxycodone may produce orthostatic hypotension in ambulatory patients. Oxycodone, like all opioid analgesics of the morphine-type, should be administered with caution to patients in circulatory shock, since vasodilation produced by the drug may further reduce cardiac output and blood pressure.

PRECAUTIONS

General

Opioid analgesics have a narrow therapeutic index in certain patient populations, especially when combined with CNS depressant drugs, and should be reserved for cases where the benefits of opioid analgesia outweigh the known risks of respiratory depression, altered mental state, and postural hypotension.

Use of OxyContin® is associated with increased potential risks and should be used only with caution in the following conditions: acute alcoholism; adrenocortical insufficiency (e.g., Addison's disease); CNS depression or coma; delirium tremens; debilitated patients; kyphoscoliosis associated with respiratory depression; myxedema or hypothyroidism; prostatic hypertrophy or urethral stricture; severe impairment of hepatic, pulmonary or renal function; and toxic psychosis.

The administration of oxycodone may obscure the diagnosis or clinical course in patients with acute abdominal conditions. Oxycodone may aggravate convulsions in patients with convulsive disorders, and all opioids may induce or aggravate seizures in some clinical settings.

Interactions with other CNS Depressants

OxyContin should be used with caution and started in a reduced dosage (⅓ to ½ of the usual dosage) in patients who are concurrently receiving other central nervous system depressants including sedatives or hypnotics, general anesthetics, phenothiazines, other tranquilizers, and alcohol. Interactive effects resulting in respiratory depression, hypotension, profound sedation, or coma may result if these drugs are taken in combination with the usual doses of OxyContin.

Interactions with Mixed Agonist/Antagonist Opioid Analgesics

Agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, and butorphanol) should be administered with caution to a patient who has received or is receiving a course of therapy with a pure opioid agonist analgesic such as oxycodone. In this situation, mixed agonist/antagonist analgesics may reduce the analgesic effect of oxycodone and/or may precipitate withdrawal symptoms in these patients.

Ambulatory Surgery and Postoperative Use

OxyContin is not indicated for pre-emptive analgesia (administration pre-operatively for the management of postoperative pain).

OxyContin is not indicated for pain in the immediate postoperative period (the first 12 to 24 hours following surgery) for patients not previously taking the drug, because its safety in this setting has not been established.

OxyContin is not indicated for pain in the postoperative period if the pain is mild or not expected to persist for an extended period of time.

OxyContin® is only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate (See American Pain Society guidelines).

Patients who are already receiving OxyContin® Tablets as part of ongoing analgesic therapy may be safely continued on the drug if appropriate dosage adjustments are made considering the procedure, other drugs given, and the temporary changes in physiology caused by the surgical intervention (see **DOSAGE AND ADMINISTRATION**).

OxyContin and other morphine-like opioids have been shown to decrease bowel motility. Ileus is a common postoperative complication, especially after intra-abdominal surgery with opioid analgesia. Caution should be taken to monitor for decreased bowel motility in postoperative patients receiving opioids. Standard supportive therapy should be implemented.

Use in Pancreatic/Biliary Tract Disease

Oxycodone may cause spasm of the sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis. Opioids like oxycodone may cause increases in the serum amylase level.

Tolerance and Physical Dependence

Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Physical dependence is manifested by withdrawal symptoms after abrupt discontinuation of a drug or upon administration of an antagonist. Physical dependence and tolerance are not unusual during chronic opioid therapy.

The opioid abstinence or withdrawal syndrome is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate.

In general, opioids should not be abruptly discontinued (see **DOSAGE AND ADMINISTRATION: Cessation of Therapy**).

Information for Patients/Caregivers

If clinically advisable, patients receiving OxyContin Tablets or their caregivers should be given the following information by the physician, nurse, pharmacist, or caregiver:

1. Patients should be aware that OxyContin Tablets contain oxycodone, which is a morphine-like substance.
2. Patients should be advised that OxyContin Tablets were designed to work properly only if swallowed whole. OxyContin Tablets will release all their contents at once if broken, chewed, or crushed, resulting in a risk of fatal overdose.
3. Patients should be advised to report episodes of breakthrough pain and adverse experiences occurring during therapy. Individualization of dosage is essential to make optimal use of this medication.
4. Patients should be advised not to adjust the dose of OxyContin® without consulting the prescribing professional.
5. Patients should be advised that OxyContin may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g., driving, operating heavy machinery).
6. Patients should not combine OxyContin with alcohol or other central nervous system depressants (sleep aids, tranquilizers) except by the orders of the prescribing physician, because dangerous additive effects may occur, resulting in serious injury or death.
7. Women of childbearing potential who become, or are planning to become, pregnant should be advised to consult their physician regarding the effects of analgesics and other drug use during pregnancy on themselves and their unborn child.
8. Patients should be advised that OxyContin is a potential drug of abuse. They should protect it from theft, and it should never be given to anyone other than the individual for whom it was prescribed.
9. Patients should be advised that they may pass empty matrix 'ghosts' (tablets) via colostomy or in the stool, and that this is of no concern since the active medication has already been absorbed.
10. Patients should be advised that if they have been receiving treatment with OxyContin for more than a few weeks and cessation of therapy is indicated, it may be appropriate to taper the OxyContin dose, rather than abruptly discontinue it, due to the risk of precipitating withdrawal symptoms. Their physician can provide a dose schedule to accomplish a gradual discontinuation of the medication.
11. Patients should be instructed to keep OxyContin in a secure place out of the reach

of children. When OxyContin is no longer needed, the unused tablets should be destroyed by flushing down the toilet.

Use in Drug and Alcohol Addiction
OxyContin is an opioid with no approved use in the management of addictive disorders. Its proper usage in individuals with drug or alcohol dependence, either active or in remission, is for the management of pain requiring opioid analgesia.

Drug-Drug Interactions
Opioid analgesics, including OxyContin®, may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.
Oxycodone is metabolized in part to oxymorphone via cytochrome P450 2D6. While this pathway may be blocked by a variety of drugs (e.g., certain cardiovascular drugs including amiodarone and quinidine as well as polycyclic antidepressants), such blockade has not yet been shown to be of clinical significance with this agent. Clinicians should be aware of this possible interaction, however.

Use with CNS Depressants
OxyContin®, like all opioid analgesics, should be started at 1/3 to 1/2 of the usual dosage in patients who are concurrently receiving other central nervous system depressants including sedatives or hypnotics, general anesthetics, phenothiazines, centrally acting anti-emetics, tranquilizers, and alcohol because respiratory depression, hypotension, and profound sedation or coma may result. No specific interaction between oxycodone and monoamine oxidase inhibitors has been observed, but caution in the use of any opioid in patients taking this class of drugs is appropriate.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies of oxycodone to evaluate its carcinogenic potential have not been conducted.
Oxycodone was not mutagenic in the following assays: Ames Salmonella and E. coli test with and without metabolic activation at doses of up to 5000 μg, chromosomal aberration test in human lymphocytes in the absence of metabolic activation at doses of up to 1500 μg/mL and with activation 48 hours after exposure at doses of up to 5000 μg/mL, and in the in vivo bone marrow micronucleus test in mice (at plasma levels of up to 48 μg/mL). Oxycodone was clastogenic in the human lymphocyte chromosomal assay in the presence of metabolic activation in the human chromosomal aberration test (at greater than or equal to 1250 μg/mL) at 24 but not 48 hours of exposure and in the mouse lymphoma assay at doses of 50 μg/mL or greater with metabolic activation and at 400 μg/mL or greater without metabolic activation.

Pregnancy
Teratogenic Effects — Category B: Reproduction studies have been performed in rats and rabbits by oral administration at doses up to 8 mg/kg and 125 mg/kg, respectively. These doses are 3 and 46 times a human dose of 160 mg/day, based on mg/kg basis. The results did not reveal evidence of harm to the fetus due to oxycodone. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery
OxyContin® is not recommended for use in women during and immediately prior to labor and delivery because oral opioids may cause respiratory depression in the newborn. Neonates whose mothers have been taking oxycodone chronically may exhibit respiratory depression and/or withdrawal symptoms, either at birth and/or in the nursery.

Nursing Mothers
Low concentrations of oxycodone have been detected in breast milk. Withdrawal symptoms can occur in breast-feeding infants when maternal administration of an opioid analgesic is stopped. Ordinarily, nursing should not be undertaken while a patient is receiving OxyContin because of the possibility of sedation and/or respiratory depression in the infant.

Pediatric Use
Safety and effectiveness of OxyContin have not been established in pediatric patients below the age of 18. **It must be remembered that OxyContin Tablets cannot be crushed or divided for administration.**

Geriatric Use
In controlled pharmacokinetic studies in elderly subjects (greater than 65 years) the clearance of oxycodone appeared to be slightly reduced. Compared to young adults, the plasma concentrations of oxycodone were increased approximately 15% (see **PHARMACOKINETICS AND METABOLISM**). Of the total number of subjects (445) in clinical studies of OxyContin, 148 (33.3%) were age 65 and older (including those age 75 and older) while 40 (9.0%) were age 75 and older. In clinical trials with appropriate initiation of therapy and dose titration, no untoward or unexpected side effects were seen in the elderly patients who received OxyContin. Thus, the usual doses and dosing intervals are appropriate for these patients. As with all opioids, the starting dose should be reduced to 1/3 to 1/2 of the usual dosage in debilitated, non-tolerant patients. Respiratory depression is the chief hazard in elderly or debilitated patients, usually following large initial doses in non-tolerant patients, or when opioids are given in conjunction with other agents that depress respiration.

Laboratory Monitoring
Due to the broad range of plasma concentrations seen in clinical populations, the varying degrees of pain, and the development of tolerance, plasma oxycodone measurements are usually not helpful in clinical management. Plasma concentrations of the active drug substance may be of value in selected, unusual or complex cases.

Hepatic Impairment
A study of OxyContin in patients with hepatic impairment indicates greater plasma concentrations than those with normal function. The initiation of therapy at 1/3 to 1/2 the usual doses and careful dose titration is warranted.

Renal Impairment
In patients with renal impairment, as evidenced by decreased creatinine clearance (< 60 mL/min), the concentrations of oxycodone in the plasma are approximately 50% higher than in subjects with normal renal function. Dose initiation should follow a conservative approach. Dosages should be adjusted according to the clinical situation.

Gender Differences
In pharmacokinetic studies, opioid-naive females demonstrate up to 25% higher average plasma concentrations and greater frequency of typical opioid adverse events than males, even after adjustment for body weight. The clinical relevance of a difference of this magnitude is low for a drug intended for chronic usage at individualized dosages, and there was no male/female difference detected for efficacy or adverse events in clinical trials.

ADVERSE REACTIONS
The safety of OxyContin® was evaluated in double-blind clinical trials involving 713 patients with moderate to severe pain of various etiologies. In open-label studies of cancer pain, 187 patients received OxyContin in total daily doses ranging from 20 mg to 640 mg per day. The average total daily dose was approximately 105 mg per day.
Serious adverse reactions which may be associated with OxyContin Tablet therapy in clinical use are those observed with other opioid analgesics, including respiratory depression, apnea, respiratory arrest, and (to an even lesser degree) circulatory depression, hypotension, or shock (see **OVERDOSAGE**).
The non-serious adverse events seen on initiation of therapy with OxyContin are typical opioid side effects. These events are dose-dependent, and their frequency depends upon the dose, the clinical setting, the patient's level of opioid tolerance, and host factors specific to the individual. They should be expected and managed as a part of opioid analgesia. The most frequent (> 5%) include: constipation, nausea, somnolence, dizziness, vomiting, pruritus, headache, dry mouth, sweating, and asthenia.
In many cases the frequency of these events during initiation of therapy may be minimized by careful individualization of starting dosage, slow titration, and the avoidance of large swings in the plasma concentrations of the opioid. Many of these adverse events will cease or decrease in intensity as OxyContin therapy is continued and some degree of tolerance is developed.
Clinical trials comparing OxyContin with immediate-release oxycodone and placebo revealed a similar adverse event profile between OxyContin

and immediate-release oxycodone. The most common adverse events (>5%) reported by patients at least once during therapy were

TABLE 3

	OxyContin (n=277) (%)	Immediate-Release (n=225) (%)	Placebo (n=45) (%)
Constipation	(23)	(26)	(7)
Nausea	(23)	(27)	(11)
Somnolence	(23)	(24)	(4)
Dizziness	(13)	(16)	(9)
Pruritus	(13)	(12)	(2)
Vomiting	(12)	(14)	(7)
Headache	(7)	(8)	(7)
Dry Mouth	(6)	(7)	(2)
Asthenia	(6)	(7)	—
Sweating	(5)	(8)	(2)

The following adverse experiences were reported in OxyContin®-treated patients with an incidence between 1% and 5%. In descending order of frequency they were anorexia, nervousness, insomnia, fever, confusion, diarrhea, abdominal pain, dyspepsia, rash, anxiety, euphoria, dyspnea, postural hypotension, chills, twitching, gastritis, abnormal dreams, thought abnormalities, and hiccups.

The following adverse reactions occurred in less than 1% of patients involved in clinical trials or were reported in postmarketing experience.

General: accidental injury, chest pain, facial edema, malaise, neck pain, pain, and symptoms associated with either an anaphylactic or anaphylactoid reaction

Cardiovascular: migraine, syncope, vasodilation, ST depression

Digestive: dysphagia, eructation, flatulence, gastrointestinal disorder, increased appetite, nausea and vomiting, stomatitis, ileus

Hemic and Lymphatic: lymphadenopathy

Metabolic and Nutritional: dehydration, edema, hyponatremia, peripheral edema, syndrome of inappropriate antidiuretic hormone secretion, thirst

Nervous: abnormal gait, agitation, amnesia, depersonalization, depression, emotional lability, hallucination, hyperkinesia, hypesthesia, hypotonia, malaise, paresthesia, seizures, speech disorder, stupor, tinnitus, tremor, vertigo, withdrawal syndrome with or without seizures

Respiratory: cough increased, pharyngitis, voice alteration

Skin: dry skin, exfoliative dermatitis, urticaria

Special Senses: abnormal vision, taste perversion

Urogenital: amenorrhea, decreased libido, dysuria, hematuria, impotence, polyuria, urinary retention, urination impaired

OVERDOSAGE

Acute overdosage with oxycodone can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, bradycardia, hypotension, and death.

Deaths due to overdose have been reported with abuse and misuse of OxyContin®, by ingesting, inhaling, or injecting the crushed tablets. Review of case reports has indicated that the risk of fatal overdose is further increased when OxyContin is abused concurrently with alcohol or other CNS depressants, including other opioids.

In the treatment of oxycodone overdosage, primary attention should be given to the re-establishment of a patent airway and institution of assisted or controlled ventilation. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

The pure opioid antagonists such as naloxone or nalmefene are specific antidotes against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose. In patients who are physically dependent on any opioid agonist including OxyContin®, an abrupt or complete reversal of opioid effects may precipitate an acute abstinence syndrome. The severity of the withdrawal syndrome produced will depend on the degree of physical dependence and the dose of the antagonist administered. Please see the prescribing information for the specific opioid antagonist for details of their proper use.

DOSAGE AND ADMINISTRATION

General Principles

OXYCONTIN IS AN OPIOID AGONIST AND A SCHEDULE II CONTROLLED SUBSTANCE WITH AN ABUSE LIABILITY SIMILAR TO MORPHINE. OXYCODONE, LIKE MORPHINE AND OTHER OPIOIDS USED IN ANALGESIA, CAN BE ABUSED AND IS SUBJECT TO CRIMINAL DIVERSION.

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.

One OxyContin 160 mg tablet is comparable to two 80 mg tablets when taken on an empty stomach. With a high-fat meal, however, there is a 25% greater peak plasma concentration following one 160 mg tablet. Dietary caution should be taken when patients are initially titrated to 160 mg tablets (see DOSAGE AND ADMINISTRATION).

In treating pain it is vital to assess the patient regularly and systematically. Therapy should also be regularly reviewed and adjusted based upon the patient's own reports of pain and side effects and the health professional's clinical judgment.

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. The controlled-release nature of the formulation allows OxyContin to be effectively administered every 12 hours (see **CLINICAL PHARMACOLOGY; PHARMACOKINETICS AND METABOLISM**). While symmetric (same dose AM and PM), around-the-clock, q12h dosing is appropriate for the majority of patients, some patients may benefit from asymmetric (different dose given in AM than in PM) dosing, tailored to their pain pattern. It is usually appropriate to treat a patient with only one opioid for around-the-clock therapy.

Physicians should individualize treatment using a progressive plan of pain management such as outlined by the World Health Organization, the American Pain Society and the Federation of State Medical Boards Model Guidelines. Healthcare professionals should follow appropriate pain management principles of careful assessment and ongoing monitoring [See **BOXED WARNING**].

Initiation of Therapy

It is critical to initiate the dosing regimen for each patient individually, taking into account the patient's prior opioid and non-opioid analgesic treatment. Attention should be given to:

(1) the general condition and medical status of the patient;

(2) the daily dose, potency, and kind of the analgesic(s) the patient has been taking;

(3) the reliability of the conversion estimate used to calculate the dose of oxycodone;

(4) the patient's opioid exposure and opioid tolerance (if any);

(5) special safety issues associated with conversion to OxyContin® doses at or exceeding 160 mg q12h (see **Special Instructions for OxyContin 80 mg and 160 mg Tablets**); and

(6) the balance between pain control and adverse experiences.

Care should be taken to use low initial doses of OxyContin in patients who are not already opioid-tolerant, especially those who are receiving concurrent treatment with muscle relaxants, sedatives, or other CNS active medications (see **PRECAUTIONS: Drug-Drug Interactions**).

For initiation of OxyContin therapy for patients previously taking opioids, the conversion ratios from Foley, KM. [NEJM, 1985; 313:84-95], found below, are a reasonable starting point, although not verified in well-controlled, multiple-dose trials.

Experience indicates a reasonable starting dose of OxyContin for patients who are taking non-opioid analgesics and require continuous around-the-clock therapy for an extended period of time is 10 mg q12h. If a non-opioid analgesic is being provided, it may be continued. OxyContin should be individually titrated to a dose that provides adequate analgesia and minimizes side effects.

1. Using standard conversion ratio estimates (see Table 4 below), multiply the mg/day of the previous opioids by the appropriate multiplication factors to obtain the equivalent total daily dose of oral oxycodone.

2. When converting from oxycodone, divide the 24-hour oxycodone dose in half to obtain the twice a day (q12h) dose of OxyContin.
3. Round down to a dose which is appropriate for the tablet strengths available (10 mg, 20 mg, 40 mg, 80 mg, and 160 mg tablets).
4. Discontinue all other around-the-clock opioid drugs when OxyContin therapy is initiated.
5. No fixed conversion ratio is likely to be satisfactory in all patients, especially patients receiving large opioid doses. The recommended doses shown in Table 4 are only a starting point, and close observation and frequent titration are indicated until patients are stable on the new therapy.

TABLE 4

Multiplication Factors for Converting the Daily Dose of Prior Opioids to the Daily Dose of Oral Oxycodone*

(Mg/Day Prior Opioid x Factor = Mg/Day Oral Oxycodone)

	Oral Prior Opioid	Parenteral Prior Opioid
Oxycodone	1	—
Codeine	0.15	—
Hydrocodone	0.9	—
Hydromorphone	4	20
Levorphanol	7.5	15
Meperidine	0.1	0.4
Methadone	1.5	3
Morphine	0.5	3

***To be used only for conversion to oral oxycodone.** For patients receiving high-dose parenteral opioids, a more conservative conversion is warranted. For example, for high-dose parenteral morphine, use 1.5 instead of 3 as a multiplication factor.

In all cases, supplemental analgesia should be made available in the form of a suitable short-acting analgesic.

OxyContin® can be safely used concomitantly with usual doses of non-opioid analgesics and analgesic adjuvants, provided care is taken to select a proper initial dose (see **PRECAUTIONS**).

Conversion from Transdermal Fentanyl to OxyContin

Eighteen hours following the removal of the transdermal fentanyl patch, OxyContin treatment can be initiated. Although there has been no systematic assessment of such conversion, a conservative oxycodone dose, approximately 10 mg q12h of OxyContin, should be initially substituted for each 25 µg/hr fentanyl transdermal patch. The patient should be followed closely for early titration, as there is very limited clinical experience with this conversion.

Managing Expected Opioid Adverse Experiences

Most patients receiving opioids, especially those who are opioid-naive, will experience side effects. Frequently the side effects from OxyContin are transient, but may require evaluation and management. Adverse events such as constipation should be anticipated and treated aggressively and prophylactically with a stimulant laxative and or stool softener. Patients do not usually become tolerant to the constipating effects of opioids.

Other opioid-related side effects such as sedation and nausea are usually self-limited and often do not persist beyond the first few days. If nausea persists and is unacceptable to the patient, treatment with antiemetics or other modalities may relieve these symptoms and should be considered.

Patients receiving OxyContin® may pass an intact matrix "ghost" in the stool or via colostomy. These ghosts contain little or no residual oxycodone and are of no clinical consequence.

Individualization of Dosage

Once therapy is initiated, pain relief and other opioid effects should be frequently assessed. Patients should be titrated to adequate effect (generally mild or no pain with the regular use of no more than two doses of supplemental analgesia per 24 hours). Patients who experience breakthrough pain may require dosage adjustment or rescue medication. Because steady-state plasma concentrations are approximated within 24 to 36 hours, dosage adjustment may be carried out every 1 to 2 days. It is most appropriate to increase the q12h dose, not the dosing frequency. There is no clinical information on dosing intervals shorter than q12h. As a guideline, except for the increase from 10 mg to 20 mg q12h, the total daily oxycodone dose usually can be increased by 25% to 50% of the current dose at each increase.

If signs of excessive opioid-related adverse experiences are observed, the next dose may be reduced. If this adjustment leads to inadequate analgesia, a supplemental dose of immediate-release oxycodone may be given. Alternatively, non-opioid analgesic adjuvants may be employed. Dose adjustments should be made to obtain an appropriate balance between pain relief and opioid-related adverse experiences.

If significant adverse events occur before the therapeutic goal of mild or no pain is achieved, the events should be treated aggressively. Once adverse events are under control, upward titration should continue to an acceptable level of pain control.

During periods of changing analgesic requirements, including initial titration, frequent contact is recommended between physician, other members of the healthcare team, the patient and the caregiver/family.

Special Instructions for OxyContin® 80 mg and 160 mg Tablets (For use in opioid-tolerant patients only.)

OxyContin 80 mg and 160 mg Tablets are for use only in opioid-tolerant patients requiring daily oxycodone equivalent dosages of 160 mg or more for the 80 mg tablet and 320 mg or more for the 160 mg tablet. Care should be taken in the prescribing of these tablet strengths. Patients should be instructed against use by individuals other than the patient for whom it was prescribed, as such inappropriate use may have severe medical consequences, including death.

One OxyContin® 160 mg tablet is comparable to two 80 mg tablets when taken on an empty stomach. With a high-fat meal, however, there is a 25% greater peak plasma concentration following one 160 mg tablet. Dietary caution should be taken when patients are initially titrated to 160 mg tablets.

Supplemental Analgesia

Most patients given around-the-clock therapy with controlled-release opioids may need to have immediate-release medication available for exacerbations of pain or to prevent pain that occurs predictably during certain patient activities (incident pain).

Maintenance of Therapy

The intent of the titration period is to establish a patient-specific q12h dose that will maintain adequate analgesia with acceptable side effects for as long as pain relief is necessary. Should pain recur then the dose can be incrementally increased to re-establish pain control. The method of therapy adjustment outlined above should be employed to re-establish pain control.

During chronic therapy, especially for non-cancer pain syndromes, the continued need for around-the-clock opioid therapy should be reassessed periodically (e.g., every 6 to 12 months) as appropriate.

Cessation of Therapy

When the patient no longer requires therapy with OxyContin® Tablets, doses should be tapered gradually to prevent signs and symptoms of withdrawal in the physically dependent patient.

Conversion from OxyContin to Parenteral Opioids

To avoid overdose, conservative dose conversion ratios should be followed.

SAFETY AND HANDLING

OxyContin Tablets are solid dosage forms that contain oxycodone which is a controlled substance. Like morphine, oxycodone is controlled under Schedule II of the Controlled Substances Act.

OxyContin has been targeted for theft and diversion by criminals. Healthcare professionals should contact their State Professional Licensing Board or State Controlled Substances Authority for information on how to prevent and detect abuse or diversion of this product.

HOW SUPPLIED

OxyContin® (oxycodone hydrochloride controlled-release) Tablets 10 mg are round, unscored, white-colored, convex tablets imprinted with OC on one side and 10 on the other. They are supplied as follows:

NDC 59011-100-10: child-resistant closure, opaque plastic bottles of 100

NDC 59011-100-25: unit dose packaging with 25 individually numbered tablets per card; one card per glue end carton

OxyContin® (oxycodone hydrochloride controlled-

release) Tablets 20 mg are round, unscored, pink-colored, convex tablets imprinted with OC on one side and 20 on the other. They are supplied as follows

NDC 59011-103-10: child-resistant closure, opaque plastic bottles of 100

NDC 59011-103-25: unit dose packaging with 25 individually numbered tablets per card; one card per glue end carton

OxyContin® (oxycodone hydrochloride controlled-release) Tablets 40 mg are round, unscored, yellow-colored, convex tablets imprinted with OC on one side and 40 on the other. They are supplied as follows:

NDC 59011-105-10: child-resistant closure, opaque plastic bottles of 100

NDC 59011-105-25: unit dose packaging with 25 individually numbered tablets per card; one card per glue end carton

OxyContin® (oxycodone hydrochloride controlled-release) Tablets 80 mg are round, unscored, green-colored, convex tablets imprinted with OC on one side and 80 on the other. They are supplied as follows:

NDC 59011-107-10: child-resistant closure, opaque plastic bottles of 100

NDC 59011-107-25: unit dose packaging with 25 individually numbered tablets per card; one card per glue end carton

OxyContin® (oxycodone hydrochloride controlled-release) Tablets 160 mg are caplet-shaped, unscored, blue-colored, convex tablets imprinted with OC on one side and 160 on the other. They are supplied as follows:

NDC 59011-109-10: child-resistant closure, opaque plastic bottles of 100

NDC 59011-109-25: unit dose packaging with 25 individually numbered tablets per card; one card per glue end carton

Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

Dispense in tight, light-resistant container.

Healthcare professionals can telephone Purdue Pharma's Medical Services Department (1-888-726-7535) for information on this product.

CAUTION

DEA Order Form Required.

Purdue Pharma L.P., Stamford, CT 06901-3431

U.S. Patent Numbers 4,861,598; 4,970,075; 5,266,331; 5,508,042; 5,549,912; and 5,656,295

July 30, 2003 OT00367D-E 00PO17

Ms. TOLLE. Thank you, for the opportunity to be here today. I am Theresa Wells Tolle, I am a pharmacist and I am co-owner of Bay Street Pharmacy, which is an independent pharmacy in Sebastian, FL. I am the president of the Florida Pharmacy Association, and today I am here representing the American Pharmacists Association. APhA represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student and pharmacy technicians. And we are the largest national association of pharmacists in the United States.

APhA welcomes the opportunity to present the pharmacist's perspective on the abuse of prescription drugs, including controlled substances. As the medication experts on the health care terms, 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, legitimate, appropriate health care and preventing prescription drug abuse and diversion.

Prescription medications are safe and effective when they are used appropriately, and pharmacists are the health care providers who work most closely with patients to make certain patients use their medications appropriately. Prescription drug abuse is one type of medication misuse, misuse that we as pharmacists try to prevent. Pharmacists work collaboratively with prescribers to prevent the diversion of prescription medications and to identify incidents of abuse or addiction. As part of this process, pharmacists assess the appropriateness of every prescription order they review or dispense. I watch for individuals who attempt to fill fraudulent prescriptions, who are visiting multiple prescribers, or present prescriptions for unusually large quantities of medication. Every day, I assess the validity of prescriptions, by watching for errors in the content or the format of the communications. However, it is not always easy to determine if a prescription is legitimate, and I cannot view every patient as a potential drug abuser without compromising my responsibilities as a health care provider.

Identifying potential drug abusers is an area where collaborations with regulatory agencies makes sense. For example, the Florida Department of Health recently barred one of Florida's most prolific Medicaid prescribers from issuing any more prescriptions for controlled substances. Having either the Florida Board of Medicine or the Department of Health provide this information to the pharmacist community would help educate pharmacists about potentially illegitimate prescriptions.

Another area of collaboration between regulatory authorities and pharmacists is now occurring in my own practice. The narcotics detective of our local Sheriff's Department informs pharmacists about potential drug abusers as well as when a local prescriber's prescription blanks have been stolen. They do this with a fax alert. These efforts help pharmacists determine whether a prescription is legitimate. In both of these examples, the regulatory authorities are helping pharmacists by providing them information. However, in both examples the pharmacist has the final say in whether or not the prescription is for legitimate purposes, a determination they must make for every prescription presented to them.

APhA supports efforts to strike the balance of reducing prescription drug abuse and diversion, but without restricting patient access to drugs. 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.

Focusing on the subset of medications known as opiate analgesics, 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 needed, generating a sense of fear rather than respect for their legitimate purpose.

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. Reduction in the drug distribution process can delay access to medication therapy, and disrupt existing patient-pharmacist-prescriber relationships. Additionally any 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 the medication.

In a survey conducted by New York State's Public Health Council, 71 percent of physicians surveyed reported that they do not prescribe the most effective pain medication for cancer patients, if the prescriptions require a special State monitored prescription form for controlled substances, even when the medication is legal and medically indicated for a patient.

Efforts to limit abuse and diversion should be developed in collaboration with health professionals and consumers and designed for maximum benefit and minimum intrusion. State level tracking systems when well constructed can provide this benefit, and well constructed programs provide prescribers and pharmacists with relevant timely information about dispensed medication. We cautiously support efforts to heighten regulations in this area. Federal enforcement agencies such as 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. Drug therapy should be managed by health care professionals.

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.

It is important that patients do not lose access to medications because of a failure to prevent medication misuse. Solutions must not have a chilling impact on the effective drug therapy management. The solution requires the education of health care professionals, law enforcement personnel, and the public on the use and abuse of prescription medication.

APhA, and its members are committed to working with Congress, the FDA, the DEA, and 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.

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.

[The prepared statement of Ms. Tolle follows:]

Testimony
of the

American Pharmacists Association

To Do No Harm: Strategies for Preventing Prescription Drug Abuse

Submitted to the Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy and Human Resources

United State House of Representatives February 9, 2004

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Statement of the American Pharmacists Association
Before the Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy and Human Resources
United State House of Representatives

Investigative Hearing on
To Do No Harm: Strategies for Preventing Prescription Drug Abuse

February 9, 2004

Good afternoon, Mr. Chairman and Members of the Committee. I am Theresa Wells Tolle, a pharmacist and owner of Bay Street Pharmacy in Sebastian, Florida. I am here today representing the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA is the first-established and largest national association of pharmacists in the United States.

APhA welcomes the opportunity to present the pharmacist's perspective on the abuse of prescription drugs, including controlled substances. APhA and its members are committed to working with Congress, the Food and Drug Administration (FDA), the Drug Enforcement Administration (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. 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, legitimate, appropriate health care and preventing prescription drug abuse and diversion.

The Pharmacist's Role in Improving Medication Use: Limiting Diversion & Abuse

Prescription medications are safe and effective when used appropriately, but they can be deadly when used incorrectly. My colleague pharmacists and I are the health care providers who work most closely with patients to make certain patient use of medications is appropriate. Prescription drug abuse is one type of medication misuse — misuse that we try to prevent. 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. As part of this process,

pharmacists assess the appropriateness of every prescription order they review or dispense. I watch for individuals who attempt to fill fraudulent prescriptions, visit multiple prescribers, or present prescriptions for unusually large quantities of medication. Every day, pharmacists assess the validity of prescriptions, watching for errors in the content or format of the communications. However, it is not always easy to determine if a prescription is legitimate – no simple algorithm determines appropriate use. And importantly, I cannot view every patient as a potential drug abuser without compromising my responsibilities as a health care professional.

Identifying potential drug abusers is an area where collaborations with regulatory agencies makes sense. For example, the Florida Department of Health recently barred one of Florida's most prolific Medicaid prescribers from issuing any more prescriptions for controlled substances. Having either the Florida Board of Medicine or the Florida Department of Health provide this information to the pharmacist community would help educate pharmacists about potentially illegitimate prescriptions. Another area of collaboration between regulatory authorities and pharmacists is occurring now in my practice. The narcotics detective of our local Sheriff's Department now informs pharmacists about a potential drug abuser as well as when a local prescriber's prescription blanks have been stolen. These efforts help pharmacists determine whether a prescription is legitimate. In both of these examples, the regulatory authorities are helping pharmacists by providing them information. However, in both examples, the pharmacist has the final say in whether or not the prescription is for legitimate purposes — a determination they must make for every prescription presented to them.

Developing Appropriate Interventions

APhA fully supports efforts to examine possible strategies to reduce the abuse and diversion of prescription medications 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. Focusing on the sub-set of medications known as opiate analgesics , 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.[1]

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. 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. We caution, for example, 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.

Measures to curb abuse and addiction should be attempted, but measures that simply increase providers' paperwork or restrict access to one troublesome product will not solve the problem. Those suffering from chemical dependency will find another way to obtain the product or find another product to achieve the same effect. These individuals need help to treat their substance abuse and addiction. Efforts to limit abuse and diversion should be developed in collaboration with health professionals and consumers, and designed for maximum benefit and minimum intrusion. State-level tracking systems, when well-constructed, can provide this benefit. Well-constructed programs provide prescribers and pharmacists with relevant, timely information

[1] 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.

about dispensed medications. But such databases targeting abuse and diversion should not be confused with clinical programs to more broadly improve medication use.

These examples demonstrate the need for collaboration when developing interventions to limit prescription drug abuse and diversion. While it may sound trite, every action has a reaction — in this situation, some reaction that is positive, some reaction that is not. In 1982, for example, the state of Texas implemented a triplicate prescription law for controlled substances. A subsequent study of a 1200-bed teaching hospital found a 60% decrease in prescriptions for Schedule II controlled substances from 1981 to 1982.[2] This shows that simply increasing recordkeeping requirements discouraged use of these medications. It is highly unlikely that 60% of these prescriptions were unnecessary. And in a survey conducted by New York State's Public Health Council, 71% of physicians surveyed reported that they do not prescribe the most effective pain medication for cancer patients if the prescriptions require a special state-monitored prescription form for controlled substances—even when the medication is legal and medically indicated for a patient.[3]

We respect the desire to heighten regulation in this area, and cautiously support such efforts. 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.

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[2] Sigler K, Guernsey B, et al. Effect of a Triplicate Prescription Law on Prescribing of Schedule II Drugs. *American Journal of Hospital Pharmacy* 41 (1984), 108-111.

[3] New York State Public Health Council, Report to the Commissioner of Health, *Breaking Down the Barriers to Effective Pain Management: Recommendations to Improve the Assessment and Treatment of Pain in New York State,* January 1988.

Furthermore, non-medical enforcers will face substantial problems in distinguishing between legitimate medical use of prescription medications. Drawing the line is not easy for healthcare professionals with years of experience. It certainly will not be easy for law enforcement officers with no medical training. For example, many patients can tolerate and indeed require extremely high doses of controlled substances to relieve their pain and other symptoms. Health professionals have concerns with regulators making this distinction, and many do not feel secure that they will be protected if they aggressively manage pain with opioids.

Manufacturer-Level Efforts

APhA understands that one strategy to reduce the abuse and diversion of prescription medications has already been initiated by drug manufacturers. These efforts include reformulating products to reduce the potential for abuse. Certain additions to the medication can limit abusers who crush and inject the drug from obtaining the desired "high." APhA supports these product development efforts to reduce the potential for abuse of drug products and we encourage Congress and the FDA to work with manufacturers to accelerate the development and approval of reformulated versions. Reformulated versions continue to provide patients with effective pain management, while removing the stimulus for illegal abuse, and importantly for pharmacists, lessen the potential for pharmacy robberies related to prescription drug abuse.

Conclusion

It is important that patients do not lose access to valuable and effective medications because of a failure to prevent medication misuse. Any solutions must not have a chilling impact on effective drug therapy management. The solution requires the education of health care professionals, law enforcement personnel, and the public on the use and abuse of prescription medications.

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.

Mr. SOUDER. Well, I thank you each for your testimony. And I want to say up front, which you heard me say in my first panel, I really did not come into this hearing with much of a preconceived notion. I have seen some of the headlines in my own district. We focused on a lot of other issues and so I was not as knowledgeable as Mr. Mica or Mr. Norwood in the particulars. And among other things Eli Lilly, is a major player in Indiana and I have been a strong supporter of Eli Lilly. In the interest of full disclosure I have anesthesiologists and all sorts of different doctors on my finance committee, because when we ran for office in 1995 there was a lot of outrage about the nationalization of health insurance and so I am disporportionately hooked up with them.

Medical Protective, one of the largest malpractice insurers for doctors is based in my district, along with General Electric. But I am frustrated by your testimony. I have been getting the crap kicked out of me, with all do respect, for working too much with the medical industry. If the medical industry cannot understand the difference of a drug epidemic and wants to stand behind the shield of do not intervene, we are going to do some nice compromises in a drug epidemic, you bring a lot of the pressures on yourself.

I do not like a lot of what we in Congress passed in HIPAA regulations. I am tired of all the paperwork on every little thing, why can we not prioritize. OxyContin, right now is a priority type of thing, or the underlying thing underneath it. It is not aimed at Purdue Pharma, it is not aimed because it can spread. But let us lay a couple of things out in the record here. The difference between a heroin dealer and a cocaine dealer, is you are not them. You are dealing with prescription drugs that are paid for mostly by other people. One difference is that is the Federal taxpayer as an individual taxpayer do not pay for cocaine and heroin. There is a ethical difference when you ask the Federal Government, the State government, and other taxpayers to subsidize somebody's habit. That is going to bring additional pressures on that.

Second, that when the network is a legal distribution network that is approved by society, that it is going to bring different pressures on it. Now, it is absolutely true that the anesthesiologists, and people who understand pain reduction have to be primary players at the table, and that pharmacists cannot assume that everybody coming in there is a criminal. I appreciate that statement. On the other hand, when you have an epidemic in the community and when small town pharmacists are being held up at gunpoint in my district, and that in fact a fair number, which has not been established what percent, are in fact criminals who are doing it. It suggests that you are going to have to use a little more discretion. There is going to be some regulations with it, or what is going to happen is the entire pharmaceutical industry, the entire flexibility of the medical community is going to be taken away because the general public is not going to tolerate their money being spent. Which is different than cocaine and heroin. I am not arguing here that it would not move to something else, but we have the obligation as stewards of the taxpayers' dollars, to at least make sure our dollars are not being used this way. To make sure that those who are in legal trade are not. I am particularly outraged at the state-

ment that 71 percent of the doctors in New York State would say that they would not prescribe what is best for their patient based upon on a paperwork decision. And quite frankly, that leads us into a question of should their malpractice insurance go up.

In other words, maybe one of the ways to do this is to have a different criteria on the people who do not prescribe because they do not want legitimate paperwork. And to me, part of our responsibility in oversight is we have dumped so much illegitimate paperwork, chasing at the margins on the doctors, and quite frankly, by not controlling the lawsuits all the time. Because you can be harassed for everything, and that is part of the concern here. That sometime this could lead to a bunch of lawsuits on the drug company, on the pharmacist, or the doctors which is outrageous. The problem is we need to take responsibility how to address this, get control of the lawsuit question, but that should not prohibit us from trying to address legitimate concerns in that.

We can make some progress as we talked about here which you all have supported, but the underneath is what has caused me to erupt here as a friend, and say, look, this is different. What we are looking at is an epidemic, and if we do not try to treat epidemics like this, that our whole support system for not cracking down and having national socialized medicine system is going to collapse.

Because if we do not go after the bad guys aggressively and target those higher risk groups first and foremost. And we do not have a mechanism to identify those high risks. In other words, if you will not help us go after the highest risk areas, then everybody will become a suspect. And then there will be non health regulation by DEA in the pain relieving medicine. This cannot be kind of like a slap on the wrist and we are going to put a little warning up here and so on, because it is not going to work. The outrage of the community already over the general cost of prescription drugs, the general cost of health care is so large that we are walking on a very tight wire now. And having this kind of thing on the top of the other pressures on health care is going to bring consequences far beyond whether we tinkering around with OxyContin.

When we have an epidemic erupt we need everybody working together and saying we are going to focus on this right now. I would like to hear some of your reactions to that. Who wants to start.

Dr. BERCKES. I cannot speak to the 71 percent that was mentioned earlier and I hear and I understand from your perspective as well. The majority of the physicians that I have spoken to with respect to this issue when it became clear that I was going to be the one to talk about this today is that doctors do not want to have tools taken away that can help. And indeed I can tell you that the percentage of physicians that are responsible is very small.

I think we heard testimony about that, things have been published already. But I can also tell you the frustration from the point of view of a physician that cooperates with the Florida Board of Medicine in looking at these outrageous cases and what has to be done and the hoops that have to be jumped through to pull their license. OK, looking at records and I have cooperated with the board and I am glad to do that. There is not a lot of pain management physicians that have the qualifications and that are volunteering with that, and it takes a lot of time.

I have seen things and it is just beyond me how a doctor can get away with it for so long. The only thing is and I think Representative Norwood, brought this up earlier, it must be that the pain that they are going to incur is very small to the possible benefit. They are not going to hurt enough and it is not just taking away their license to practice medicine, but it is throwing them in jail, and I do not think it has been done enough, and I have seen enough and it makes me sick. But we apparently have a process that protects those that are causing the problems. And much more, it is much more of a problem than probably we suspected before.

When somebody walks into a pharmacy and presents a prescription for 540 OxyContin 80 milligrams month after month after month, there is something wrong with the whole process: where that originated, who is filling it, the whole thing. I mean it is just mind boggling. We do not want these tools taken away, and we know that they will be, and we are sensitive to the health care dollar. The health care dollar be it Medicaid, the future Medicare prescription benefit, we do not want this taken away, and we support any efforts that may enable the situation to get better.

Organized medicine supports this, please do not misinterpret anything I have said. We just do not want to go back to having our hands tied behind our backs, OK. The evolution of the speciality of pain medicine has been a relatively new one. And I believe patients are being served better, whether it is cancer patients or other non malignant type of pain, non-cancer pain. And at least what I see in my community is that there is less use of certain of these drugs by primary practitioners, and they are allowing the people with specialized knowledge to make the calls on this. And whether that is something that is a statewide trend or a nationwide trend, we have been led to believe because of the proliferation of pain management specialists that is happening. But when you see things like these incredible numbers of OxyContin being prescribed by small numbers of doctors one has to believe.

So, the one area that I am frustrated with as I have tried to think has to do with this Internet thing. I mean every time I turn on my computer and answer my e-mail I am offered all kind of things. I mean I do not know how that is regulated but that is a problem that I do not understand. Having a data base, a computer data base, is something I think certainly can help. But who pays for this. The money in the pie for health care is already smaller or at least relatively smaller because there are more people that we have to take care of with the same amount of money. So, who is going to pay for that system.

And I have seen things—you know, if we include oxycodone, just Schedule IIs but we do not include Schedule IIIs, we have shot ourselves in the foot. I mean, I can tell you, using hydrocodone is just as risky as using oxycodone.

I mean there is—and for the people who abuse it is the same thing. Why one is a II and one is a III, I am sure there is some interesting history about that, but if it is comprehensive I think we all can probably get a handle on it. But we have these issues of HIPAA that we are all dealing with HIPAA right now, and I do not know which way I am going with HIPAA. I know I am afraid of violating laws with HIPAA, and I do not know how that would

equate. But we should be able to with the resources of the Federal Government, the United States, be able to coordinate with those areas that are mandated by each State, to get a handle on this thing really quickly.

I firmly believe that and I pledge my support.

Mr. SOUDER. Probably, having to list our peyd when we go to the doctor is a over-regulation of HIPAA. That is the way it seems sometimes.

Ms. TOLLE. Dr. Berckes, did a great job in covering on a wide topic in a short period of time. I think definitely—one of you mentioned earlier an umbrella organization with the Federal Government, and then State control of that umbrella organization. To me that makes the most sense. Colonel McDonough said that there is controlled substance monitoring legislation that is proposed in Florida and I know there is in other States, I believe 18, there may be more, that currently have that kind of system in place.

I think if you can get something like that in place where at least you have an ability to look and see who is doing this, who is prescribing, the patients who are abusing the system. Yes, I have concerns with HIPAA and privacy violations, but I also, think at least there is an ability for us to know. There is a way for us to, a place for us to go to. We have groups like the Florida Department of Law Enforcement, who could be the coordinating group for that in the State of Florida.

As I mentioned, were are very fortunate in my county, because I have a Sheriff's Department that is very proactive, and they work with us and that works very effectively. I had a doctor who was closed down Monday a week ago, their controlled substance ability—or his ability to write controlled substance prescriptions was taken away from him. I knew that within 2 hours of that happening, because my local law enforcement agency let us know that. At the same time a pharmacy was robbed in our area, and we knew that as well, we also knew that the pharmacist recognized the suspect and that person was being questioned. Which kind of helped us breathe a sigh of relief that perhaps he was not coming to us next. But I think those types of coordinating efforts are very helpful. And I see that as an opportunity for us to move forward and solve this problem. I can tell you that there are people out there who are writing those 540 tablets of OxyContin, and unfortunately there are pharmacists who are filling them month after month, and there should be penalties. We need to make sure that those people are afraid, that they are going to be penalized.

Mr. SOUDER. This is also happening in meth, where we had one case where one of the biker gangs that have been developing a network of meth labs went to pharmacy training and got control of a pharmacy. And we have to be able to weed out the at risk groups so that we can keep the harassments down on legitimate pharmacies. To do that there has to be cooperation and information. Dr. Henningfield.

Dr. HENNINGFIELD. Congressman, I agree with everything you said. I think that we do have a serious problem with prescription drug abuse, and we do need to address it.

I have a couple of suggestions, I would like to keep an image in mind, and the image is a balloon. And what we have to be careful

is that we do not squeeze the balloon in one place so it pops up in another place, because that is what happened over decades with drug addiction.

We have some serious problems in our infrastructure, our monitoring system. We would not tolerate a CDC that told us a year or two after the fact when there was a new virus or epidemic, or hepatis outbreak. We expect comprehensive rapid, reliable monitoring for drug abuse. We have that for other diseases. We have made a lot of progress, I think the institutes have made a lot of progress, but if Congress further prioritizes this I believe that SAMHSA and other Federal agencies could do a better job and do a better job of integrating local information with Federal information as the CDC does.

Monitoring deaths and correctly attributing them is critical. The Florida Medical Examiners report, if you look at it in detail, you see that ascertaining actual cause of death is a complex business. Yet, as CDC knows with other diseases, you have to do that if you are going to fix the problem and prevent it in the future. We need a better, more systematic way of doing that.

The Internet is a hemorrhage, I do not know how to fix it. Prescription drug monitoring is a national system and a local system, that allows doctors to find out, how does this integrate them with our Federal monitoring systems. On treatment, our former surgeon general Dr. C. Everett Koop, he said, "it is easy to get addictive drugs, it is hard to get treatment; as a Nation, our challenge is to reverse this." That is a fact right now, and that means when people do get into trouble and they will get into trouble; no matter what we do, there will be some people in trouble. They have to have a place to go when they need it, and it has to be the right kind of treatment, and the one thing that has not been discussed directly today is also a conclusion of the GAO report and FDA, and DEA, and that is the concept of risk management programming.

The whole idea is the Controlled Substance Abuse Act came about when a lot of these problems were not on the radar screen. It took a simplistic approach, it is basically the chemistry. My laboratory at NIDA studied mainly the chemistry, and addiction potential. Now, we know it is much more than the chemistry. The concept of risk management programing and plans is that you a, identify all the potential risk associated with the drug; b, you develop solutions to the best of your ability to minimize those risks and still maximize the beneficial effects of the drugs.

Then you should have a monitoring system in place to fix it if it does not work. And if you do not have all that, you will have problems and they will recur and recur and recur. You could take the top 10 drugs of abuse, licit or illicit, off the market, ban them, and they would be replaced. You would just be squeezing the balloon in one place. So, I urge you to consider a comprehensive solution. There are things that you can do.

Mr. SOUDER. Mr. McDonough, do you want to comment on this?

Mr. MCDONOUGH. Mr. Chairman, very briefly, I could not agree with you more, the death rate is obscene. We do have to take steps and have to take strong steps immediately. We cannot hide behind the excuse that we have to be very careful as we go forward—it is

an epidemic, as you said. When you are dealing with an epidemic you have to take immediate action.

I would point out the validation system in the 18 States and the one we expect to put into place in Florida, is most used not by law enforcement, but by doctors. Doctors want to know what their patients are being prescribed, only then can they give good medicine. And since we have worked very closely with the Florida Medical Association as well as with the pharmacy folk, we know for sure that neither group tolerates murderers in their group. I will point out that Florida has been very aggressive in going after this from a law enforcement perspective and in identifying the extent of the problem.

That means, therefore, we get a lot of press on this. I suspect that these problems exist throughout the country, but I know that is why you are looking at it. Here for the purpose of addressing the issue for the entire Nation, and I laud you for that.

I also wanted to point out that it is very easy to play with data, although, it was reported that most deaths are poly drug deaths, I will tell you for sure in Florida, no kidding, that for half of the prescription drug deaths, the medical examiner identified a lethal presence of the prescription drug, the chemical compound in that. So, although there may be an attempt to lose that in the wash, forget it. It is the prescription drug in one half of those 3,200 plus deaths, that killed them. There may have been other drugs present, but it was the prescription drug that killed them.

Mr. SOUDER. Could I get a verification on that?

Mr. MCDONOUGH. Yes.

Mr. SOUDER. Would the prescription drug that killed them, if they had used that alone, or was the prescription drug on top of what they had in their system.

Mr. MCDONOUGH. Well, the doctor that does the autopsy says it, present in a lethal amount. Meaning that if oxycodone was present in the bloodstream, it was there in sufficient quantity to kill them.

Mr. SOUDER. Alone?

Mr. MCDONOUGH. Alone. The other drugs I guess they added that for the high. I might add it is very difficult to ascertain which was the prescribed drug that killed them. Because the autopsy does not go into the degree of investigation that a law enforcement person might. But it does appear to me that a predominant killer in the oxycodone deaths, is OxyContin. So, you are right to stress that. There was a series of articles published in the paper here in Orlando, that was able to trace a number of deaths, several hundred. And it gave a figure based on that review, an in-depth review, some 83 percent of the deaths they reviewed with oxycodone in the blood system, was traced to OxyContin. Therefore the author of that concluded it was OxyContin that killed them.

I stress this because it is so easy to talk about the caution we must exercise, of course we must exercise caution. But the fact of the matter is we are seeing 10 dead a day. So, if you are too cautious in preserving—that is one State, preserving that 10 dead a day, what you do allow to do—and not you, sir, of course—but the collective we, we allow those 10 to keep dying. Unacceptable, we have to be more aggressive than that, I do think that we can preserve what I call the three P's. No. 1, pain treatment adequately

done. No. 2, the privacy of the patient, and No. 3, the sanctity of the patient and the doctor and the relationship that ensues between those two.

After 3 years of working this in Florida, I have very little patience for that raised as a new concern. That is why we had every player come to the table and every player lay out their association's, their group's concerns, I think we have addressed them all. What we have not yet adequately addressed is 10 dead a day. That is where we have to get and we have to get there in a hurry.

Thank you.

Mr. SOUDER. Mr. Mica.

Mr. MICA. I will just continue, Director McDonough. I was quite stunned by the first panel, it seems there is great disconnect, at the Federal level, at least from enforcement. We had one of the chief DEA officials here who did not know about the extent of the problem. And then I guess the newspaper or media has revealed some of what is going on and it does not appear it is a priority to pursue that. You are our chief officer dealing with the problem of substance abuse in the State of Florida, what specifically would you recommend to fill the gaps, now the State has their agenda and I think we will have some testimony from a State Senator that we are going to submit to the record, as far as what the State intends to do. What specifically can we do to deal with again, the medical profession, whether it is a doctor, a pharmacist, or someone who is prescribing these legal narcotics in quantities that are killing people—what can we do from the Federal level, where do you see the gap? How do you see us filling that gap?

Mr. MCDONOUGH. I would say about three major things you could do in short order, sir. When I worked in ONDCP I was glad to take counsel and guidance from you. ONDCP has made this a priority, I think it could be stronger. It ranks up there, but from my vantage point it is the most deadly drug problem we are seeing in the country right now.

Mr. MICA. I do not know, Jim, if you were here when I talked about the disconnect, you know, you were around when we had the National Drug Education Program. It seems to me there is a disconnect there. As Dr. Meyer testified that part of this is education, and it is, but it does not appear that the Federal level we are able to shift gears to get information out. Do you see that problem and how do we address that?

Mr. MCDONOUGH. I do see the problem. I think you have the power to do that in very effective ways. First of all, is to have hearings such as this and second, to give direct guidance. I do not necessarily think it takes another law to do that, but, of course, when you stress it, when the Congress of the United States makes it a priority concern for whatever agencies respond to you at that level it becomes a concern as well.

Mr. MICA. But there is no—again, I see something missing, I loved your reports and all when you were with ONDCP, but by the time we get them the information is old and by the time we hold hearings on it, we are looking at—and the deaths figures I have are just dramatic off the charts, in the last couple of years, on this problem. So, we have not gotten the message in Washington, our Federal agencies are not responding whether it is law enforcement

or others, and we do not have a program in place. So, there is something wrong there and I think we need to get with John Walters and others to see how we could do that.

The second motive in question was dealing with the bad apples who are—and these things are not coming on the market just accidently or through the Internet. We have cases of physicians or pharmacists prescribing or issuing incredible amounts. What do we do with the bad apple, from the Federal level?

Mr. MCDONOUGH. Well, I think you need to go after any crook, and not just at the Federal level. Certainly that needs to be done, but along with State and local jurisdictions as well.

I would suggest, sir, if you work with the American Medical Association on this, they would be in the forefront of wanting to crack down on those among their ranks that would violate the laws.

Mr. MICA. Well again, I think we heard sort of the evolution of narcotics substances and the treatment of pain, and the lack of the law to keep up with the enforcement problem. That is part of it and that is going to require some adjustments to Federal statues and laws, which I think—I do not know if we will get the cooperation of some of the medical professionals, what do you think?

Dr. NORWOOD. John, I think——

Mr. MICA. They are not under obligation.

Dr. NORWOOD. I think the people who should be and I believe are most concerned are those that prescribe medications. We are talking about 12 doctors from Florida, well that helps ruin the reputations of thousands of doctors in Florida, and they want and the pharmacists too—we want these people caught, dealt with.

Mr. MICA. Take their license.

Dr. NORWOOD. Well, no that is not enough. Taking a license——

Mr. MICA. Someone said in jail.

Dr. NORWOOD. Well, what I said is they could practice in jail. Just simply taking their license makes the problem worst, it drives them underground.

Mr. MICA. Let me just conclude with a question, and I talked to a couple of pharmacists about the problem, and some pharmacists do respond, others are concerned about liability or they have other concerns. They see prescription shopping, they see over-prescribing of medication, what can we do from the Federal level, or is this a State issue, to protect the physician—or the pharmacist, but also, allow the pharmacist who sees this activity to be protected?

Ms. TOLLE. One of the things that was mentioned by one of you earlier was this—and I think it was Chairman Souder—the systems that are in place for payment of pharmacists through third party companies like where we submit an online claim and we get some information back, that the claim has been adjudicated and we are going to be paid for that. And I know that is part of your outrage, is that insurance companies and Medicaid are paying for this illicit use. One of the nice things about those programs too is that they send us alert messages back, and that really helps pharmacists. Now I do not know what the Federal Government can do, per se, but what you need to be aware of is that there are systems in place already where we are transmitting a prescription claim and getting it adjudicated, and it seems to me that a system like we are talking about with this controlled substances monitoring

would—you could do something very similar you could transmit and get some sort of message back about what this patient had received or something like that.

I think that the bill that Representative Norwood has proposed to provide funding——

Dr. NORWOOD. It is a draft.

Ms. TOLLE. OK, I am sorry.

Dr. NORWOOD. Work in progress.

Ms. TOLLE. I have seen the language, or I have seen the draft. I think what is being considered right now is a great idea. I think you are moving in the right direction with that. By helping to fund the States that are willing to do that, and I do not know if it could be a Federal program or if it needs to be State by State. But I think encouraging States to do some sort of monitoring program to allow, to help their professionals to get that message, to know what is out there.

And of course I agree with all the efforts to do educations, I like what was said about the genome project and what we are going to have in the future to identify perhaps before it ever happens, the people who are going to be subject to that, I think education is definitely a big part of it. In the whole mental health and the issue of depression and identifying patients who might be prone to it so we can stop it before it happens.

Mr. MICA. Do pharmacists need some protection against reporting folks, because I have heard that is also a problem, that they are reluctant sometimes.

Ms. TOLLE. I guess there is always a possibility of a pharmacist being concerned about liability, but if you are reporting somebody who is obviously violating the law, I do not know why there would be a liability concern.

Mr. MICA. OK.

Ms. TOLLE. I mean there may be pharmacists out there who have that concern, but it becomes pretty apparent after awhile, when a physician is prescribing outside the normal limit.

Dr. NORWOOD. Mr. Chairman, would you yield on that subject?

Mr. MICA. Yes, go ahead.

Dr. NORWOOD. Let me just point out and I have been working on this bill for awhile and our biggest single concern is liability in HIPAA. If we cannot get the job done, it is going to be for that reason.

Mr. MICA. OK, and then just—I am through Mr. Chairman, but while I have Ed McDonough, here, one of the most startling things I have learned today is that we have a Federal program, Medicaid in this case, we learned is being abused—actually a major conduit to putting lethal prescription drugs on the market and some years ago in fact our subcommittee or the predecessor of this subcommittee did a lot of work with the Florida Legislature in getting—Florida officials in getting a Medicaid task force, fraud task force. I do not know if that is still operating we had $1 billion between Medicaid and Medicare, in over-billing and fraudulent charges. Certainly if we have people dying as a result of distribution systems being set up through a Federal program for obtaining these prescription drugs, it should be the focus of attention.

Is it still in place? And if you do not have that information now I would certainly appreciate you reviewing it.

Mr. MCDONOUGH. No, sir, we have it, and we can do a better job with it, and we resolve to do a better job with it. We have a Medicaid fraud unit. The way the system works the Agency for Health Care Administration in Florida takes a look at the data. If you recognize something should be passed off for investigation, it needs to be done in a timely fashion.

Mr. MICA. I am aware of the procedure, but are they now—this is outside of some of their original purview and purpose but certainly, you know, it is against any policy that we would promote at the Federal level to have this going on. Are they pursuing——

Mr. MCDONOUGH. They are. If Senator Saunders had been able to come today, he would have laid out a number of hearings he has held. They were very well done hearings, in which he has given great incentive for the system to coordinate better, and he will now back that with a series of laws that will further strengthen it. Part of his appeal to you was to ask for the Federal laws in the Medicaid systems that would make the penalties appreciable should someone try to do the very thing that we are talking about.

Mr. MICA. Well, thank you. And we will take his testimony and recommendations back and your suggestions. Appreciate the panelists and I yield back.

Mr. SOUDER. Thank you. Dr. Norwood.

Dr. NORWOOD. Thank you, Mr. Chairman. Mr. McDonough back to the 12 physicians again and I do not want to belabor this but I am curious. Let us say they were indicted and found guilty or even one of them was. In Florida law what would be the penalty?

Mr. MCDONOUGH. If there were deaths involved most likely we are looking at manslaughter. In fact, we had a historic case of manslaughter, one doctor in Pensacola, four counts. I actually think there were 11 dead associated with his practice. But if there is a deceased, it is manslaughter, and then the requisite penalty that comes with that, a long time in prison. Now, it is difficult to get a manslaughter case, as you know, and even harder to get a murder case. But we are looking at that as well.

Dr. NORWOOD. Well, simply the overuse or allowing the overuse of Schedule IIs and IIIs where there is not a death incurred but, however, we see clearly from the record this particular person is way over-prescribing this drug, what can you do to stop it before a death occurs?

Mr. MCDONOUGH. You get into the gradations of when a crime is committed. Was it lack of education, was it an administrative problem? If it is at the lower end of the spectrum, then the Board of Pharmacy, if it is a pharmacist can move, or the Board of Medicine, if it is a doctor can move. They can suspend that license or revoke that license. Since it takes a while to revoke a license, in extreme case of administrative error, most likely the Secretary of Department Health would revoke a license. If you cross the line into criminal activity, then you can prosecute for the violation of the law. You cannot be a drug dealer under any law, a drug pusher.

Dr. NORWOOD. So, it is criminal activity to start with.

Mr. MCDONOUGH. At that point that I just described yes, when you were wantonly pushing the drugs knowing you do not have a legitimate patient, you have done only a cursory or no physical examination, when it is done on such a scale that the rational man would say this guy is pushing pills, you have a case.

Dr. NORWOOD. How many deaths in Florida, from OxyContin occurred from people taking OxyContin in a prescribed manner?

Mr. MCDONOUGH. That is a very tough question, I do not have an exact figure.

Dr. NORWOOD. You need to be real sure, do not guess on that. Now that is important. There are many drugs—penicillin will kill you. And it can kill you taken in a prescribed manner with antiphylactic shock. There are many, many drugs out there that were used, thank God every day, but they can kill you in normal usage and there are that many more that can kill you if you are over-taking the particular drugs. I do not know how many—Doc, do you have any idea how many medications are available out there to health givers that actually cause the deaths of patients if taken in an overdose?

Dr. BERCKES. Virtually everything that is a prescribed drug and many things that are not prescribed drugs have the potential to cause death.

Dr. NORWOOD. I guess water can too, you know, taken in an overdose.

Dr. BERCKES. Right.

Dr. NORWOOD. Let me ask you—this is just a simple question I am curious about, I know you are a particular expert in pain management, I also know though physicians do not get through medical school and all the subsequent training without having a fairly good idea about some pharmacology. Maybe some in New York, but most of them I know about have a pretty good education in that. Do you really think there is any physician in Florida that would not understand that there are dangers in some of these drugs in terms of being addictive. Do you think they are actually out there practicing medicine that do not know that?

Dr. BERCKES. I think that there are a lot of—there are many physicians that do not understand the potential, I am not making excuses for them.

Dr. NORWOOD. I do not see how you get through med-school and not understand the potential at least for addiction they may not understand it at the level you know, but they know when they write that script for, you know, Ms. Jones, we have to be careful here.

Dr. BERCKES. There is a couple of things. First of all, there are a lot of studies that have shown that when narcotics are used to control pain, you do not get the addiction. There is a small percentage of people predisposed. But I think speaking of the larger issue and I try to avoid using brand names, but OxyContin is one we can not avoid. I believe because I was in this boat when this drug was rolled out, despite the education that was provided by Purdue, those of us that are using narcotics are very familiar with a sister drug, called MS Contin. MS Contin is made by the same company, and it is morphine sulfate. Classically one of the advantages of MS Contin versus immediate released morphine is that the abuse po-

tential was virtually eliminated, because of the sustained release preparation that this company I assume patented. There was not the ability for it to be abused, or it markedly decreased.

A lot of us believed incorrectly that using oxycodone in the form of OxyContin would afford us some of that same protection. The sustained release chemical in the way that oxycodone is released in the OxyContin it turns out is nothing like the MS Contin, so I believe there was a lot of confusion where there was intent to prevent the abuse, potential abusing oxycodone preparations by using OxyContin. We inadvertently did just the opposite.

I do not believe, I am sure there is a lot of scientific data that they had to go through with the FDA to get there. I do not believe there was any deliberate misinformation put out there, but this was an unintended thing, just to clarify.

But indeed there are doctors that think they are doing the right thing, and one of the other things especially that I have noted with this drug, when for whatever reasons you calculate the drug and you maybe are giving a little bit too much, and patients forget when they take medications. I forget, when I am prescribed by my doctor, if I do not write it down. All it takes is taking an extra OxyContin if you are already getting the higher level and you take another one you are dead in a few hours.

Dr. NORWOOD. I have a few more questions I have to get answers to, and a quick answer on this. Severe pain, moderate pain, the FDA refers to that a lot. I have never understood how you actually define severe pain and moderate pain. One patient has a problem that can be solved by an aspirin and the other patient has the same thing and they need a barbiturate, how do explain that, can you use severe and moderate in a sensible way? Because what is severe for one patient may be absolutely moderate for another. Do we understand that yet?

Dr. BERCKES. These are subjective monitors, OK. There is no easy way.

Dr. NORWOOD. But that is not how FDA writes it.

Dr. BERCKES. No, and I think there is too much wiggle room there and I do not know how to—we use classically and it is being incorporated as the fifth vital sign, the visual analog scale of pain. Where 10 is the worst pain imaginable and 0 is no pain. But we know that people report differently. The same pain is reported differently because of their different thresholds, because of the way they are made up. There is no way to use just one pain measurement OK, to say for sure what this is. So we use historical precedent. We know that a crush injury of an extremity is certainly different than the surgical wound caused to fix a hernia, and these are all different things. This is, sir, the art of medicine, trying to hook it together with science, and there is no way—especially in this whole area of pain medicine, there is no meter that I can have a patient put their hand on and I can tell where their pain is. If there was I think we would have a better way to handle it.

So, it is the subjective complaint and following patients on a very close basis that you are going to do the best job.

Dr. NORWOOD. Well you answered it how I wanted you to answer it, and I particularly wanted——

Mr. SOUDER. Would the gentleman yield?

Dr. NORWOOD. Of course.

Mr. SOUDER. I am fascinated with this subjective question because to me, the greater the addiction potential and the greater that we see abuse of that I would think that you would move toward a tighter application at the medical profession. For example, I just had hernia surgery, I was being asked all the way through, at least as well as I remember and afterwards as far as my pain medication, what level of pain can you tolerate. The answer is you want to tolerate no pain.

Dr. NORWOOD. Correct.

Mr. SOUDER. And so, if you are given choices you will keep taking it. The question is that if something is highly addictive and been abused, should the standard ratchet up, other than the individual identifying, which is kind of underneath. If this is an art, should the art be more constrained the more high risk you are——

Dr. NORWOOD. Part of the problem, Mr. Chairman, is, at least in the 1970's I think health care givers were overly constrained and a lot of people suffered during those years, because physicians and dentists alike were very hesitant to write some of these prescriptions for the very reasons that we are here about. On the other hand, there is a moral obligation as a health care giver to try to deal with the pain the best you can, and it is subjective. I just want to be careful that when we start legislation in Washington we remember that. The FDA in my view tries to make it black and white and it really is not that.

Ms. Tolle.

Ms. TOLLE. Yes, sir.

Dr. NORWOOD. Ms. Tolle, do you have a computer in your pharmacy?

Ms. TOLLE. Yes, sir.

Dr. NORWOOD. Do most pharamcists today in Florida, have computers?

Ms. TOLLE. Yes, sir. My understanding is there is may be a few in south Florida, that are primarily Latino pharmacies, that may not be computer based, but I would say probably 95-plus percent at least maybe greater.

Dr. NORWOOD. How would you operate today without a computer——

Ms. TOLLE. I have no idea.

Dr. NORWOOD [continuing]. Due to the large different variety number of payers.

Ms. TOLLE. Right.

Dr. NORWOOD. We know that too. We think most of you have it and part of our thinking in this legislation we have here is that as you swipe a card through your computer and send it to Blue Cross and Blue Shield there is not any reason on a Class II or III that same information cannot go to Mr. McDonough.

Ms. TOLLE. That is correct.

Dr. NORWOOD. There has to be—in our view, there has to be some single source in the State of Florida that is monitoring this if we are ever going to get a handle on it. And the question becomes, Mr. Chairman, who is entitled to know about that information? That scares us to death. I know it would be helpful to you, Doctor, to be able to monitor that particular data base and know

and find out if your next patient got a Class II 2 days earlier. It would be helpful for you to know. On the other hand, if you did not then where is your liability. And who else gets to know in terms of HIPAA?

That is the problem that we are running into in trying to build this bill. If we can put privacy in it, and if we can limit the liability so that if for some reason the data you swipe through did not go through unintentionally then the next thing you know you are in court. I think we can solve this problem except that I do not know how to solve the Internet, and I am open to any suggestions. I think we can solve this problem if we can solve privacy and liability.

Ms. TOLLE. Can I comment on Internet?

Dr. NORWOOD. If you have the answer, baby, I am ready.

Ms. TOLLE. I do not necessarily have the answers but I have some friends from Florida Department of Law Enforcement here in the audience, and one of which I was speaking with last week when we had a drug symposium in Tallahassee, and again today. And he suggests to do reverse tracking on these sites. Where you can track the source where this medication is coming from. So you would need somebody who was well versed in tracking, much like a child pornography type of investigator, where you understand the computer science and you could follow those headers, and work backward. And maybe that would help solve some of the problem with these sites, I know that many of—I know it is multi-level, I understand that it is a really big process.

But that is one point that I have not heard brought up today, and I felt like it was definitely worthy of being mentioned.

Dr. NORWOOD. The problem is my 13 year old daughter goes on the Internet and types in a particular drug and sure enough, if she will just lie about her age, it is going to be filled and the way they do that is they have a rogue physician there that works at the site who signs every prescription.

We are trying to figure out how we can make them make sure that you sign the prescription without intruding too much, and causing you too much liability.

Ms. TOLLE. We do have proposed language in Florida this year for Internet prescribing—for the Internet in particular and that language requires a prescript—an actual physical assessment of the patient. A pharmacy is not allowed to fill a prescription based on an Internet questionnaire if they are aware that it is an Internet only questionnaire only.

Dr. NORWOOD. I know that you do have that, but that is going to bring down the rath of God on us. You know, what we are trying to do is work with all parties here, and there is going to be a lot of parties that are not real happy that they have to answer to you about a physical before they prescribe. That may end up being the way it is dealt with, but it is certainly something that is going to cause a lot of grief trying to get 218 votes, I can tell you that.

Mr. Chairman, I thank you, and I yield back.

Mr. SOUDER. That is valid point, it is amazing what you can—if you would wait just a second, I have a question for you as well. I wanted to note that this is not that dissimilar in some ways from how we work with other narcotics. In other words, one way you

look at where the production is, who is making the stuff that goes into the stuff, whether it is a controlled area or uncontrolled area. That can be problematic if it is not uncontrolled, but watching for leakage and slippage from the controlled area where it is being made, I understand Tanzania and other places like that, you look and see where the quantity, if it is not going to you, is there slippage there and are there other places that are being supplied.

And second would be the manufacturing of it, who is getting it and track those locations, and then, if indeed it winds up that because of restrictions here it goes outside like to India or other places, then the obvious delivery system becomes critical, because we are not going to be able to get it on the Internet, for the most part. We are going to have to get it in the delivery system, or the manufacturing or the growing.

The question I have for you is under current HIPAA and where does this go since we heard that many of these people are probably drug users, is that a criteria and is there a mandatory check to see if somebody has been picked up for a drug conviction before? And make that group if there are more prone to being addictive or seeking it for the wrong reason, why would that not be an automatic background check required in the prescription?

Dr. NORWOOD. Well, Mr. Chairman, I do not recall and I do not believe that is in HIPAA, but however——

Mr. SOUDER. Would it be prohibited?

Dr. NORWOOD. It is prohibited, among the other law already. Part of this is we have a lot of laws on the books, we do not enforce some of them. And the DEA—I am not as rough on them as John is, they will never have enough people to enforce this. There is no way on Earth that they could have enough people in the State of Florida to actually do what we need to do.

Mr. SOUDER. Dr. Berckes, when you as an anesthesiologist, do a background check, the person is asked whether or not they are using substances, the question is is there a background check to see if they have ever been arrested?

Dr. BERCKES. No. In my practice and that is not the general practice, however, in cooperation with our Sheriff's Department and the detectives, we have had a real close working relationship. What I have is that every patient that walks into the office every time, not just the first time, they sign an affidavit in addition to me gathering the information that may have changed since the last time they were in the office, whether that was the day before or a month before. They sign an affidavit that they have not received any other controlled substances from any other physicians or if they have, who that doctor is and what it is. That has worked really well because then when they sign that and we do all the legal stuff correct, then that is data that I guess the district attorney has been able to use for the prosecutor.

Dr. NORWOOD. Yeah they can, but you know—remember, this person who is in there to beat you out of this Percocet is going to burn your building down if you do not give it to him one way or the other. They are going to sign anything you say.

Dr. BERCKES. They do. What I am saying is that has helped on the law enforcement end. But, there is no way that I can physically do a background check with any tool that is available now to know

the veracity of the information that patient is given me. I mean there is a lot of things as far as the sniff test we can tell——

Mr. SOUDER. There are two types of things, that is why I thought we were maybe getting into HIPAA questions, because this is another type of way to address this, because some of these people may not be trying to beat the system, they may just have in the past used narcotics that shows in the risk assessment, that in fact they have a tendency to become more addicted, and not be able to get off. And they may not realize that even though—and they may not want to release that to you.

The question is and this is one of our pop up questions. Because we are having to get this for border control now, we are looking at when you get on an airplane, are there certain things that are basically in the system. It is a huge civil rights debate, but the question here is that you are also, protecting—we are not just looking for legal protection for the doctors, which we need to look for too. Because what people do not understand when you get sued it is not you who necessarily pays, it is everybody who comes to your practice who has to pay higher rates because of the malpractice insurance.

So, we have to do a lot of these things to protect you which is paperwork, and maybe—although most prosecutors probably do not waste their time on somebody who falsified a document, at least it is another level. The question is, that just seems like basic information, if risk assessment is that critical for the addiction and the danger, that you would have a pop up that would say that we can check and see who is an abuser. Now that is not necessarily an abuser of OxyContin. I was thinking more of the statistics that 2.8 times likely heroin, 1.7 cocaine, three times before have used, if we are picking it up in the autopsies, and if we are picking it up in the research, it seems like it ought to be something that ought to be much more restrictive at the beginning.

Because OxyContin, the difference—what I would put here is, yes all these other drugs may be at risk and it may shift. But this is not a maybe, what we heard from the DEA is they have never had anything that caused this much death.

Even though it also may be relieving more people of pain, if we can figure out how to manage those two questions and if there is a level of use; once it reaches an epidemic proportion and there is X number of deaths in society, all of a sudden civil liberties waiver on if you have been a narcotic. I was just wondering what we are running into, because I am not a doctor, and I——

Dr. NORWOOD. Well, I do not think HIPAA envisioned that there would be a source of information on people's medical records that stores up the usage of narcotics. Having said that, I have no doubt in my mind that if we did do that, that somebody is going to read into HIPAA why it is against that.

Dr. BERCKES. I just wanted to say I do this everyday, and I have been fooled. There is no way that anybody that does this can say you cannot be fooled that you cannot be scammed. But I want to dispel what I believe is the myth that writing one prescription of OxyContin or any other controlled substance, even if somebody who is genetically predisposed to drug abuse or addiction, that you are going to turn them into an addict. That is where the close monitor-

ing of the drug and using the smallest hammer that you need and then ratcheting up as required. That is the only way that you are going to do it.

So, you can be fooled, but it is those tools and there is no substitute for that face-to-face looking at the patients seeing what they are doing and having them account for every pill. Can they scam you? Sure, but it cuts down on it drastically if they know they are being accounted for. And I can tell—it is hard to measure, but I can tell the people that come in that is all that they want. OK, and then they usually leave, yeah and the people working in my office, they are scared with some of these folks. And I am looking for their protection, but that does not keep us from the mission of what we are trying to do. And luckily, at least in my situation there is a close tie in with law enforcement.

What I have seen too much of I believe in the press is that you can have good intentions, write one prescription and you have turned somebody into a street drug addict. Sir, that does not occur. It is a continual misuse of medications. OK, the unbridled prescription without keeping track of what is going on, that is what leads to the problem.

Mr. SOUDER. Because many pain killers are prescribed for multiple use over a period of time, if you have a predisposition, you are more at risk than if you do not have a predisposition.

Dr. BERCKES. Yes.

Mr. SOUDER. What I was kind of addressing is that it seems to me that you would get stopped for driving 62 miles an hour in a 55 zone. They can figure out what happens to you, why can we not when we are prescribing a potentially high risk addictive drug that can cost you your life, why can we not get this information that State cop has on the highway, about your past drug and alcohol addiction. It just seems like a disconnect.

Dr. BERCKES. Right. And there is never too much information, and asking those questions is something that the prudent practioner does. I mean we are required to, to practice good medicine.

Mr. SOUDER. You are asking the questions, but you do not have a way to verify it.

Dr. BERCKES. But there is no way to check on the veracity of the answer, I mean, the whole doctor-patient relationship is predicated on trust and valid information. And how we can—there is no 100 percent way, there are subtle things you look at with a patient—the way they come in, what they are saying, who they are with, how they got to your office, these are all the subtle things that you have to look at, but we still are going to be fooled.

But I am just concerned we already have a DEA, every doctor that prescribes narcotics in this country has a DEA number. So, it seems like we already have that data base, at least on the prescriber end.

So, I am interested in how are we going to—there is one way, there are two ways of monitoring it. It seems like we have the data base with the DEA, with the DEA number, Dr. Norwood. The DEA number you have on all the doctors in this country, we are all required to have DEA number.

So, that data base is there. But what is the information that we should be requiring and linking up in a national system for the patient. And that is where the HIPAA thing comes in. Because I tell you what, when I go online, OK, with my Bank of America account, here in Florida they know exactly what is going on in California, immediately. OK, and because it is that cross, I think the technology is there but I am concerned about folks that come into Florida. I mean it does not take long to get from the State of Washington to Florida. OK, and you think you are doing the right thing with the drugs and I would like to know, because if they are trying to scam me, they are not going to tell me well, what at 4 p.m., the pain doctor in Seattle gave them. OK, and then they are showing up in my office. I would love to have that information.

It just seems to be the privacy thing, but what are we going to use driver license number, Social Security numbers, you know we already have the prescribers with DEA. And what is the other thing, because whatever that other number is then we have fraud that is potential on that end. And that is where my biggest question is, and I think if we could address that, it is not a very sophisticated computer system that would need to figure it out. But it is who is going to look at it. I am asking the questions, I do not know, but it seems like we have it right here. And with respect to when we have a crisis, what do you do with a practitioner.

Well, I am chief of staff in a hospital, and when I have evidence that a physician is really out of line I am obligated and I have the legal ability to summarily suspend practice of that physician in that institution, until I get together all of the entities I need to see what is really going on. And we have a hearing process, and all the rest of it. And it seems to me that the Board of Medicine has a similar thing, but there seems to be a disconnect between the what is happening out in the street and the Board of Medicine. And then issuing, and how they can issue that appeal, that is not a Federal thing, but it seems like there could be Federal guidelines.

Mr. SOUDER. I thank you.

Dr. HENNINGFIELD. May I just add one part of the balloon that has not been directly touched on? And that is that one of the highest risk groups is young adults. And if we take a really long range view of this problem, we have to be looking at community efforts, we have to be looking at educational efforts. We know from our surveys that kids who have an increased perception of harm, that is a technical term, are less likely to abuse drugs. No kid should go to a party and have something offered and then be reassured that this is not a street drug, it is a prescription drug. Or what if they are reassured that it is not OxyContin, do not worry, it is something else? Kids should be getting a clear message from every source that using any prescription drug without a prescription is potentially lethal, and that prescription pain killers can be as lethal and as addictive as any other drugs.

I have looked at the textbooks, this message it is not there, our system has not caught up. I do not think it takes a law to stimulate this. But working with Federal agencies like NIDA, and substance abuse prevention office of SAMHSA, you can encourage them to work more aggressively to get out the messages. And package them if you will, because the message here is a little tricker

than it is for cocaine. The message for cocaine is easy, "do not use any, any time from any source." With a prescription drug it is a more complicated message. And there is work there that our Federal agencies that have good people could do with encouragement and probably some funding from you.

Mr. SOUDER. I thank you for your testimony, we will probably have some additional written questions, if you want to submit any additional testimony. This stuff is very difficult, I know when this committee was actually divided into human service separate from the drug policy. Chris Shays was head of Subcommittee on Human Services and I was his vice chair, and we went through a number of things on the second use of drugs, which is the un-talked about huge thing in America, which is where the real kind of profit of the pharmaceutical companies often come from word of mouth, and hey, this works for this over here. And boosts the sales, and it is something that in our society it is very difficult to tackle the messages of what is safe and when.

Furthermore, our research on the interactive properties of these different types of both over-the-counter, yet alone prescription drugs. And trying to do this is very difficult, but when we have an epidemic level like we have had on one, it is an opportunity both to educate and help the public understand how best to manage it.

Well, thank you for you time, thank you for coming today.

Third panel come forward. Now if each of the witnesses will stand and raise their right hands.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

We thank you for your patience and as we do with all of the panels by tradition of the committee, the administration witnesses rise on the first panel, and then as the panel evolves we get more and more into the individuals and the individual practitioners and it has been a very helpful structure how we generally do this. I thank you for coming, Mr. Pauzar you are first.

STATEMENTS OF FREDERICK W. PAUZAR, FATHER; DOUGLAS DAVIES, M.D., MEDICAL DIRECTOR, STEWART-MARCHMAN CENTER; PAUL L. DOERING, M.S., DISTINGUISHED SERVICE PROFESSOR OF PHARMACY, UNIVERSITY OF FLORIDA; KAREN O. KAPLAN, M.P.H., SC.D., PRESIDENT AND CEO, LAST ACTS PARTNERSHIP; AND CHAD D. KOLLAS, M.D., MEDICAL DIRECTOR, PALLIATIVE MEDICINE, M.S. ANDERSON CANCER CENTER ORLANDO

Mr. PAUZAR. Thank you, Chairman Souder, Representative Mica, Congressman Norwood, for the opportunity to testify here today.

My name is Fred Pauzar and I am the father of Chris Pauzar, a brilliant 22 year old who died from OxyContin 76 days ago, just 2 days before Thanksgiving. The tragedy of losing a child is not something one should ever be forced to imagine, I will simply submit to you that the pain from this loss is so great, it overshadows nearly everything else in my life.

But each life that can be saved through the enactment of proper legislation and regulatory standards and procedures will be a life whose potential for greatness, whose contributions to mankind,

may still be achieved. Each premature and needless death, such as that of my own son, is a heart-shattering occurrence that also deprives society of all the brilliance, all of the achievements, all of the greatness that will now never come to pass.

OxyContin was originally prescribed to my son for a minor injury to his shoulder. His frequency of dosage increased over time until he was taking 200 milligrams or more per day. All along, he was reassured that the long-term use of this drug was not harming him, both by his physician and by Purdue Pharma literature that suggested the appropriateness of prescribing OxyContin for pain that would be "expected to persist for an extended period of time."

When my son ultimately realized that he was addicted to this drug, experiencing flu-like symptoms and physical and emotional distress when he stopped using it, he needed and he sought regular therapy and medical support to detoxify, and to learn to live without Oxy in his life. Unfortunately, after breaking the pattern of daily use he wrongly decided to take it one more time, actually saying one more time would not kill me, the very evening that he died.

Since my son's death, I have been stunned by facts related to the marketing, prescribing, use and abuse of the drug that killed him. And I have been astounded that a clear and insidious correlation exists between the market penetration this drug has achieved and the toll of death it has left behind.

OxyContin came into existence in 1995, when according to U.S. District Judge Sidney Stein, Purdue Pharma deceived the U.S. Government by engaging in "inequitable conduct before the Patent and Trademark Office" in order to patent OxyContin. Its sales literally skyrocketed since, thanks in part to very aggressive marketing and the promulgation of performance claims that have not held up to scrutiny.

In 1995 and 1996 Oxy was sold as a chronic pain medication for use with cancer patients—very appropriate. Then in 1997, Purdue Pharma began to push this drug into a new market, such as back pain and injury. At the same time the company was reaching down into the broader market of moderate pain treatment, it added a more potent dosage, beginning the manufacture of 80 milligram tablets to complement the smaller 10, 20, and 40 milligram pills they were already producing, and so, by 1998, fully two-thirds of all Oxy prescriptions issued were for non-cancer pain.

Cleverly, Purdue Pharma paid for hundreds of physicians to travel on junkets where they were educated about the benefits of OxyContin, a Schedule II drug without a ceiling on allowable dosage. Meaning it is very difficult to decide when you are over-prescribing. Those physicians were, in the manner of a pyramid, told they would be paid speaker's fees for talking to other doctors about the benefits of OxyContin.

By 1999, Purdue Pharma's objectives included a reach toward one-half billion dollars in sales of their star drug, with their marking efforts targeting more consumer groups including seniors with direct to consumer advertising. It has been said that there was no DTC advertising and that is incorrect, because you could have walked into a number of different doctors' offices and seen placards in full color showing a grandfather with a grandson fishing in a stream, talking about how long term relief is at hand.

Again, while the marketing efforts sought to aggressively broaden market penetration, the manufacturing side of the company delivered an even more potent tablet once again, a 160 milligram pill.

By 2001, Purdue Pharma had comfortably rocketed past the $1 billion mark in sales from this single drug, with the company noting in passing that the challenges presented by mounting evidence of OxyContin abuse in Florida, Maine, Ohio and other States, "will continue to be a threat to the continued success of OxyContin tablets."

In 2002, OxyContin sales hit the $1.2 billion level, representing more than 80 percent of Purdue Pharma's total revenue, due in part to the advantage handed Purdue Pharma by our own FDA. As Purdue Pharma's marketing group noted in the face of mounting evidence that deaths in Florida and other States from OXyContin were exceeding deaths from heroin, despite what we were told earlier by the DEA representative. I am quoting now, "It is unlikely that an opioid approved by the FDA in the future will have as broad of an indication as OxyCOntin now enjoys." The company knew that only too well.

And in this regard Purdue Pharma is certainly correct. With the unwitting actions of many fine physicians who relied on the marketing promises made by an aggressive Purdue Pharma sales force, with the calculated and illicit actions of a small percentage of doctors who abused the system, and with a system that statewide and federally has been slow to communicate and to recognize the danger of this drug and to respond in an appropriate fashion, the daily death toll continues to mount.

In Florida alone, we can argue whether it is one person a day or 10 a day that die from this drug, but we know that the loss is truly incalculable but nonetheless devastating and real.

May you have the wisdom and the courage to deal effectively with this threat to our children and our society overall by taking effective steps now to monitor and curb the improper marketing and use of Oxy. And may you never know the pain that I along with thousands of parents before me and hundreds if not thousands more since, now feel.

Thank you, and I will be happy for your questions.

Mr. SOUDER. Well, thank you for sharing with us the pain that you feel in your family, and your trying to address the problems.

Dr. Douglas Davies is medical director of the Stewart-Marchman Center, thank you for being with us.

[The prepared statement of Mr. Pauzar follows:]

Written Testimony of Frederick W. Pauzar
Before the Government Reform Committee's
Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Winter Park, Florida, February 9, 2004

Chairman Souder, Representative Mica and other distinguished members of the Criminal Justice, Drug Policy and Human Resources Subcommittee, thank you for the opportunity to testify before you today.

My name is Fred Pauzar and I am the father of Chris Pauzar, a brilliant 22-year old man who died from a toxic dose of OxyContin 76 days ago, on November the 25th, 2003. Although the tragedy of losing a child is not something one should ever be forced to imagine, I will simply submit to you that the pain from this loss is so great it overshadows nearly everything else. Each life that can be saved through the enactment of proper legislation and regulatory standards and procedures will be a life whose potential for greatness, whose contributions to mankind, may still be achieved. Each premature and needless death - such as that of my own son - is a heart shattering occurrence that also deprives society of all the brilliance, all of the achievements, all of the greatness that will now never come to pass.

OxyContin was originally prescribed to my son for a minor shoulder injury, an injury for which he might have taken acetaminophen or ibuprofen. When he found it difficult to stop taking OxyContin, he was assured by his physician that its continued use was safe and he carried on. His frequency of dosage increased and, eventually, he was taking 200 milligrams or more per day. All along he was reassured that the long-term use of this drug wasn't harming him, both by his physician and by Purdue Pharma literature that suggested the appropriateness of prescribing OxyContin for pain that would be "...expected to persist for an extended period of time." He concluded logically that, the drug is suitable for use on an extended basis and that taking it on an extended basis would not be harmful.

When my son ultimately realized that he was uncontrollably addicted to this drug, experiencing flu-like symptoms and great physical and emotional distress when he stopped using it, he needed and sought regular group and private therapy and other medical support to detoxify and to learn to live without OxyContin in his life. Unfortunately, after breaking the pattern of daily use, he wrongly decided to take it into his body one more time, saying that "one more time won't kill me" on the evening that he died.

Since my son's death, since learning of the greatest pain any parent might experience, I have been stunned by the facts related to the marketing, prescribing, use and abuse of the drug that killed him. And I have been astounded that a clear and insidious correlation exists between the market penetration this drug has achieved and the toll of death it has left behind.

OxyContin came into existence in 1995, when Purdue Pharma deceived the U.S. Government by engaging in "...inequitable conduct before the Patent and Trademark Office..." (January 5, 2003, U.S. Dis. Judge Sidney H. Stein) in order to patent OxyContin. Its sales have literally skyrocketed, thanks in part to uniquely aggressive advertising and the promulgation of performance claims that have not held up to scrutiny.

In 1995 and 1996 it was sold as a chronic pain medication for use with cancer patients. Then in 1997 Purdue Pharma began to push this drug into new markets such as back pain and injury. At the same time the company reached down into moderate pain treatment, it adding a more potent dosage, beginning the manufacture of 80-milligram tablets to complement the smaller 10, 20 and 40-milligram pills already on the market. By 1998, fully two-thirds of all Oxy prescriptions issued are for non-cancer pain.

Cleverly, Purdue Pharma paid for hundreds of physicians to ravel on junkets where they were educated about the benefits of OxyContin, a Schedule II drug without a "ceiling" on dosage. Those physicians were, in the manner of a pyramid building fashion, told they would be paid speakers' fees for talking to other doctors about the benefits of OxyContin

By 1999, Purdue Pharma's objectives included a reach toward one-half billion dollars in sales of their star drug, with their marketing efforts targeting more groups including seniors with direct to consumer (DTC) advertising. Again, while the marketing effort seeks to aggressively broaden market penetration, the manufacturing side of the company delivers an even more potent tablet, a 160-milligram pill.

By 2001, Purdue Pharma had comfortably rocketed past the one billion dollar mark in sales from this single drug, with the Company noting in passing that the challenges presented by mounting evidence of OxyContin abuse in Florida, Maine, Ohio and other states "...will continue to be a threat to the continued success of OxyContin tablets."

In 2002, OxyContin sales hit the $1.2 billion level, representing more than 80% of Purdue Pharma's total revenue and the vast majority of its profitability, due in part to the advantage handed Purdue Pharma by the FDA. As Purdue Pharma's marketing group noted in the face of mounting evidence that deaths in Florida and other states from Oxy exceed deaths from heroin, "It is unlikely that an opioid approved by the FDA in the future will have as broad of an indication [or indicated usage] as OxyContin now enjoys."

And in this regard Purdue Pharma is surely correct. With the unwitting actions of many fine physicians who relied on the marketing promises made by an aggressive Purdue Pharma sales force, with the calculated and illicit actions of a small percentage of doctors who abuse the system, and with a system that statewide and federally has been slow to recognize the danger of this drug and respond in appropriate fashion, the daily death toll continues to mount.

In Florida alone, more than one person dies on average each day from the intake of Oxy. The loss is truly incalculable but nonetheless devastating and real.

May you have the wisdom and the courage to deal effectively with this threat to our children and our society overall by taking effective steps to monitor and curb the improper marketing and use of this devastating drug. And may you never know the pain that I, along with thousands of parents before me and hundreds more since, now feel.

Thank you.

Dr. DAVIES. Good morning. Thank you for opportunity to address the panel.

The perspective I bring is one of a physician and I do have some pain management that I do as part of my practice. I worked as an anesthesiologist for many years. Currently, I am an addictionologist in the University of Florida Department of Psychiatry, Division of Addiction Medicine. I also bring to you the perspective of being a person in recovery from the disease of opiate addiction.

As we have heard already, substantial quantities of prescription drugs are being illegally diverted in Florida, which results in a tremendous amount of death, it fuels the disease of addiction. Statewide the numbers I have seen included a 120 percent increase in treatment center admissions over the past 2 years for prescription opiates at our center. There is a summary of data available from Dr. Ernest Cantley the head of Stewart-Marchman showing more like a 400 percent increase in our admissions for treatments for opiates.

Diversion consumes State resources through associated medical expenses trying to take care of these people, through Medicaid fraud that we heard abundantly, and through treatment expenses if people are fortunate enough to make it to treatment. Prescription diversion certainly involves many scenarios—prescription fraud, illegal resale of prescriptions, doctor shopping, pharmacy shopping, and loose prescribing by practitioners characterized by the five Ds. Those are doctors that are duped, well-meaning physicians that who are simply getting slickered by patients looking for the drugs.

There are, on the other hand, dishonest practitioners. I know in my own community, my patients everyday tell me that so and so is a prescription mill, and so and so is a pill doctor. Physicians who are dated, who simply do not have adequate knowledge of how to—what are appropriate uses for these drugs. Physicians who for various reasons are dysfunctional, and simply cannot say no to patients, and physicians who are disabled by their own substance abuse issues.

Prescription drugs have overshadowed street drugs in several categories. In 2002, benzodiazepines accounted for more overdose deaths than cocaine. And in 2002, oxycodone, hydrocodone and methadone and benzodiazepines individually were involved in more overdose deaths than heroin. The problem is getting worse and there are abundant laws to deal with the perpetrators of prescription diversion. However, I believe it remains needlessly complicated to identify who these people are in the State of Florida.

When I have a patient sitting in front of me and I am being asked to perform an assessment to see whether or not they have a problem with prescription drugs, I have to spend hours on the telephone trying to call numerous pharmacies, assuming the patient is using his real name at the pharmacy and that he is even going to local pharmacies. Even when a patient reveals names of practitioners to me that are known to be pill doctors, it remains a daunting task as we heard earlier this morning to gather data on these people, and to investigate them.

Many other States do currently, and we have heard several numbers this morning 15 to 18 States at least currently have prescrip-

tion monitoring systems. And in 2002, a GAO report described their effectiveness in reducing the diversion, by reducing inappropriate prescribing by practitioners and by serving a deterrent for doctor shopping, and by reducing the resources that have to be expended on investigation.

The current prescription validation program up for consideration in this State, would establish an electronic data base containing prescriptions of patients over the age of 16. For it to make any sense it certainly need to cover all controlled drugs not just drugs in the higher schedules, but all controlled substances. It would make this information available to physicians, to pharmacists, to medical quality assurance personnel, and to law enforcement. And then some very simple requirements for reducing prescription fraud. It would require simply the quantities be written out, it is much harder to alter a prescription where all of the number quantities are written out, rather than stated in their numeral form. Require picture ID to pick up prescriptions. There is a typo here saying I recommend you use of counterfeit prescription forms, actually I recommend the use of counterfeit-proof prescription forms, and that this whole system would be administered by the Department of Health.

There is already a great deal of funding in place for this program. Purdue Pharma is said to be providing the State with $2 million for the development of software to get this set up and the Department of Justice has also established a line of funding for this program. Certainly with the national scope of what we are talking about today this does need to be a national program. I know in the State of Florida this has been up for consideration for several years and shot down for several years. I certainly hope this is the year that is going to pass.

Thank you very much.

Mr. SOUDER. Thank you. For the record, for my information, but also, for those who reads the record is Stewart-Marchman Center a specialist center or general hospital treatment.

Dr. DAVIES. We provide all the addiction services for Volusia and Flagler County.

[The prepared statement of Dr. Davies follows:]

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

INVESTIGATIVE HEARING TITLED

"TO DO NO HARM: STRATEGIES FOR PREVENTING PRESCRIPTION DRUG ABUSE"

WINTER PARK, FLORIDA

PRESENTED BY:

DR. DOUGLAS S. DAVIES
MEDICAL DIRECTOR
STEWART-MARCHMAN CENTER, INC.
DAYTONA BEACH, FLORIDA 32124

Substantial quantities of prescription drugs are being illegally diverted in Florida. This results in death (36% of 9,116 "drug deaths" in 2002, or 2,324 people), it fuels the disease of addiction (a 120% increase in treatment center admissions over the past two years for prescription opiates) and consumes state resources through associated medical expenses, Medicaid fraud, and treatment expenses. Prescription diversion involves many scenarios – prescription fraud, illegal resale of prescriptions, theft, "doctor shopping", "pharmacy shopping", and loose prescribing by practitioners characterized by the "D's"

- Duped – by patients seeking drugs
- Dishonest – "prescription mills" or "pill doctors"
- Dated – in their knowledge of appropriate uses of controlled substances
- Dysfunctional – can't say no to patients
- Disabled – by their own substance "abuse"

Prescription drugs have overshadowed "street drugs" in several categories:

- In 2002, benzodiazapines accounted for more overdose deaths than cocaine (1625 v. 1307)
- In 2002, oxycodone, hydrocodone, methadone, and benzodiazapines individually were involved in more overdose deaths than heroin

The problem is getting worse and there are abundant laws to deal with perpetrators of prescription diversion. However, it remains needlessly complicated to identify who these people are in the State of Florida.

If I am trying to care for a patient that I suspect has a problem with prescription drugs, I have to spend hours on the telephone calling each of numerous pharmacies, assuming the patient is using their own name and that they are using local pharmacies. Even when patients reveal names of practitioners that are easy sources of prescriptions, it remains a daunting task to investigate these prescribers.

Fifteen other states currently have prescription monitoring systems. In 2002 a GAO report described their effectiveness in reducing diversion, by reducing inappropriate prescribing, by serving as a deterrent for doctor shopping and by reducing resources expending on investigations.

"The Florida Prescription Validation Program" would:

- Establish an electronic database containing recent prescriptions of patients over the age of 16
- Make this information available to physicians, pharmacists, medical QA personnel, and law enforcement

- Set requirements for reducing prescription fraud
    - Require quantities to be written out
    - Require picture ID to pick up prescriptions
    - Recommend use of counterfeit prescription forms
- Be administered by the Department of Health

Funding: Florida's agreement with Purdue Pharma provides the state with $2million for development of software to implement the program. Florida has received $300,000 from the Department of Justice to establish the program.

Mr. SOUDER. Thank you. Next witness is Professor Paul Doering, a distinguished service professor of pharmacy practice, College of Pharmacy, University of Florida, who informed me that if his son had been playing for the Colts, they would have been in the Super Bowl rather than the Patriots. Unfortunately he switched teams.

Mr. DOERING. To the Stealers.

Mr. DOERING. Good afternoon, gentlemen, my name is Paul Doering and I am distinguished service professor of pharmacy practice at the College of Pharmacy, University of Florida, in Gainesville, FL. And it is my honor to be here this afternoon.

You know I went to pharmacy school in the 1960's and 1970's and they say if you were a member in the 1960's and the 1970's you were not there. I remember them vividly, because that was a time in which I came to the stark realization that the very same drugs that help people ease pain and make the suffering of surgery a little bit easier are the same ones that just as easily can cause severe injury and death when used inappropriately. This reality really hit home when I volunteered my time to assist in a methadone maintenance program for heroin addicts, a program that was being run out of Shands Hospital in Gainesville.

You know, in a strange sort of way, we as pharmacists are in denial: we do not like to admit that the very same pharmaceutical drugs that might be the answer for one person's problem is the problem for the next person.

Working with heroin addicts and focusing on the drugs they used, is suddenly realized, kind of like a light bulb going on, that as a pharmacist I do know something about drug abuse after all. Since that time, I have been spending a substantial part of my career trying to help people to understand the downside risks that accompany the use of all drugs, but especially the recreational use of prescription drugs. Now, after all morphine is morphine is morphine, whether it is used to get high or used to relieve the pain of surgery. Its dangers are the same as are its bad effects when combined with alcohol or other drugs, and the risks associated with taking more medicine than prescribed.

Today, there has been a shift away from the abuse of so-called street drugs, more toward the pharmaceutical drugs. And although abuse of the OTC drugs is a growing problem, perhaps a point for discussion on another day, the problem of prescription drug diversion is what is wreaking havoc all across our nation. I will not repeat the statistics that you have heard over and over again, but we all agree that this is a huge problem.

It is especially a problem for pharmacists, because we find ourselves smack dab in the middle of this issue, and let me tell you why. The Code of Ethics of the American Pharmacists Association states, among other things the following: A pharmacist promotes the good of every patient in a confidential and compassionate, and confidential way. Pharmacists place concerns for the well-being at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. And with a caring attitude and compassionate spirit a pharmacist focuses on serving the patient in a private and confidential manner.

Now, unfortunately, we spend an inordinate amount of time trying to sort out the patient presenting a narcotic script for some legitimate purpose from the patient who has obtained the prescription under false pretenses or who alters the prescription or outright forges the prescription for the purposes of abuse or resale. Unfortunately, most of us as pharmacists are not experts at handwriting analysis nor have we gone to the police academy to hone our skills at conducting an investigation. We are taught to trust the patients we serve and to be "caring and compassionate" as our Code of Ethics requires. Imagine our shock and frustration when a vial of pills from our pharmacy is found at the scene of a death investigation where a young adult has died from pills up and injected. Ours is a careful balancing act: while we want to keep drugs out of the hands of those who have no business having them, we must provide them with the caring attitude and compassionate spirit patients so rightly deserve.

One of the most valuable tools that we, as pharmacists have to combat the problem of drug diversion is open and honest communication. This includes communication between the patient, the doctor, the law enforcement community, and the regulatory boards of other health professionals. But unfortunately, while we do have laws in place to guide the pharmacist, sometimes laws can be difficult to apply on a daily basis. For example, Federal law tells us that the tenets of a lawful prescribing dictate that, to be lawful, a prescription for a controlled substance must be: No. 1. Issued for a legitimate medical purpose. No 2. By an individual prescriber acting in the usual course of his professional practice. No. 3. And documented in the medical records.

Now, all this may sound straight forward but, we as pharmacists, have difficulty determining if the medication is ordered for a legitimate medical purpose. Furthermore, we may not know what constitutes the usual course of practice for one physician versus another type of specialist. And we almost never have access to the patient's medical record.

Looking at the problem from the patient's perspective, the therapeutic imperative should likely prevail. This theory compels the pharmacist to always dispense opioid analgesics when they are appropriate for a patient. On the other hand, the regulatory imperative commands us to never dispense opioid analgesics when they are inappropriate. And now matter how hard we try, no pharmacist can be faithful to both imperatives.

I think it would be wonderful if we had some technology that would allow us, for example, that somebody would give their fingerprint on some type of technology or pad that would validate and verify through some monitoring system. And I urge the adoption of such kind of system but only when the safeguards of confidentiality and privacy are indicated.

And I have longer comments that will appear in the record, and I appreciate your attention, today.

Mr. SOUDER. Thank you for coming and we will make sure the full statement is submitted and also, any additional materials.

Our next witness is Karen Kaplan, president and chief executive, Last Acts Partnership.

[The prepared statement of Mr. Doering follows:]

The Congress of the United States
House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy, and Human Resources

An Investigative Hearing entitled "To Do No Harm: Strategies for Preventing Prescription Drug Abuse."

Winter Park, Florida
February 9, 2004

A Pharmacist's Perspective on Prescription Drug Diversion and Abuse

presented by:

Paul L. Doering, M.S.
Distinguished Service Professor of Pharmacy Practice
College of Pharmacy
University of Florida

Good Morning, Ladies and Gentlemen. My name is Paul Doering and I am Distinguished Service Professor of Pharmacy Practice at the College of Pharmacy, University of Florida, in Gainesville, Florida. I am honored to be here this morning.

I went to pharmacy school in the late 1960's and early 1970's and came to the stark realization that the very same drugs we were learning in the classroom (the ones that can ease pain and suffering and cure disease) could just as easily cause severe injury and death if used inappropriately. This reality really hit home when I volunteered my time to assist in a methadone maintenance program for heroin addicts, a program being run out of Shands Hospital in Gainesville. In a strange sort of way, we as pharmacists are in denial: we don't like to admit that the very same pharmaceutical drugs that might be the answer for one person's problem *is* the problem for the next person.

Working with heroin addicts and focusing on the drugs they used, I suddenly realized, like a light bulb suddenly lighting up, that as a pharmacist I do know something about drug abuse after all. Since that time I have spent a substantial part of my career helping people understand that downside risks that accompany the use of all drugs, but especially the recreational use of prescription drugs. After all, morphine is morphine is morphine, whether it is used to get high or used to relieve the pain of surgery. Its dangers are the same, its bad effects when combined with alcohol or other drugs, and the risks associated with taking more medicine than prescribed.

Today, there has been a shift away from the abuse of so-called "street drugs," more towards the pharmaceutical drugs. Although abuse of over-the-counter (OTC) drugs is a growing problem, it is the problem of prescription drug diversion that is wreaking havoc all across our nation. Data from the Drug Abuse Warning Network (DAWN) suggest

that prescription drugs account for about 25-30% of all drug abuse. As the dispensers of most prescription drugs, pharmacists are unwittingly finding themselves smack dab in the middle of the problem. Let me tell you why.

The Code of Ethics of the American Pharmacists Association states, among other things, the following:

A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner. A pharmacist places concern for the well-being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.

Unfortunately, we spend an inordinate amount of our time trying to sort out the patient presenting a narcotic prescription for some *legitimate* purpose from the patient who has obtained the prescription under *false pretenses* or who alters or outright forges the prescription for the purpose of abuse or resale. Unfortunately, most of us as pharmacists are not experts at handwriting analysis nor have we gone to the police academy to hone our skills at conducting an investigation. We are taught to trust the patients we serve and to be "caring and compassionate" as our Code of Ethics requires. Image our shock and frustration when a vial of pills from our pharmacy is found at the scene of a death investigation where a young adult has died from injecting pills crushed up and injected. Ours is a careful balancing act: while we want to keep drugs out of the hands of those who have no business having them, we must provide them with the caring attitude and compassionate spirit that patients so rightly deserve.

One of the most valuable tools that we, as pharmacists, have to combat the problem of drug diversion is open and honest communication. This includes communication between the pharmacist and the patient, the pharmacist and the doctor, the pharmacist and the law enforcement community, and the pharmacist and the regulatory boards of the other health professions. While there are laws in place to guide the pharmacist, sometimes law can be difficult to apply on a daily basis. For example, under federal law [21 CFR 1306.04 (a)], the tenets of lawful prescribing dictate that, to be lawful, a prescription for a controlled substance must be:

1. issued for a legitimate medical purpose
2. by an individual practitioner acting in the usual course of his professional practice
3. documented in the medical records

Although this may sound straightforward, as pharmacists we sometimes have difficulty determining if the medication is ordered for a "legitimate medical purpose." Furthermore, we may not know what constitutes the "usual course of professional practice" of a particular physician and we almost never have access to the medical record. One of the daunting aspects of this federal law is the chilling reminder that "...corresponding responsibility rests with the pharmacist who fills the prescription."

This strikes the fear in some pharmacists that they may be arrested or disciplined if they fill a prescription that turns out to be issued not in accordance with the definition of a lawful prescription. So, what ends up happening? Sometimes patients who really need the medicine suffer needlessly or are inconvenienced because the pharmacist has doubt about the authenticity of the prescription.

On the other end of the spectrum, sometimes drugs wind up in the hand of those who have no legitimate medical need for the drugs and are simply obtaining the drugs for illegal purposes. The tools we currently have available to separate out one from the other are minimal. Good judgment, open communications, and a health dose of common sense are not enough to prevent errors being made in both directions.

Looking at the problem from the patient's perspective, *The Therapeutic Imperative* would likely prevail. This theory compels the pharmacist to "Always dispense opioid analgesics when they are appropriate for a patient." On the other hand, The Regulatory Imperative commands us to "Never dispense opioid analgesics when they are inappropriate for a patient." No matter how hard we try, no pharmacist can be faithful to both imperatives. What we need are better tools to help us determine who is an abuser and who is a patient in legitimate need of the drug.

Some have proposed stronger regulation of certain drugs or drug categories. While this may seem to be a giant step in the right direction, my 30-plus years of experience in teaching drug prevention tells me that this is simply a stop-gap measure. If these hearing were being held 25 years ago, we wouldn't be debating whether Oxycontin or Percocet should be removed from the marked or more tightly controlled. Instead, we would be talking about "714s" or Quaalude as this popular drug of abuse was called. If this were 15 years ago, we would be talking about Dilaudid, a potent drug of abuse that is experiencing somewhat of a resurgence in popularity. I suppose if we go back even farther, we would be focusing on the drugs Milltown and Equanil. None of these are, in and of themselves, particularly bad drugs. Instead they are reasonable drugs that are being used in an unreasonable way.

I am a member of an organization called the National Association of Drug Diversion Investigators (or NADDI for short). The position of this organization is clear-cut: Legitimate patients with pain should not suffer because practitioners are fearful of law enforcement. Unfortunately, this is sometimes easier said than done. I fear that there are patients out there that are suffering needlessly because their doctors are afraid to prescribe narcotic pain killers. With increasing evidence that drug diversion is growing and not diminishing, this trend will likely continue. So what should be do about it?

First, I believe that we need to increase the amount of education and training given to health professionals on the subject of drug abuse, in general, and drug diversion, in specific. We must re-double our efforts with young people as it pertains to drug education, beginning with the earliest grades in school. We must figure out a way to make technology work to our advantage. I am sure that pharmacists would embrace any tools that could be used to identify known drug abusers and keep from filling their

prescriptions. However, we must respect the right of confidentiality that is crucial to our health care system. It would be wonderful if we could simply ask a patient to touch their thumb to an electronic pad and instantly know if they are passing bad 'scripts all over town. I'm afraid it's not that simple. Whatever tracking systems are developed, we must insure that the patient's right to privacy is protected and that inputting data into the system is practical. Whereas one may expect to hear differing opinions among the 190,000 pharmacists in our country, all would agree that we need help in carrying out our job. Most pharmacists that I know are hard working, honest, caring, and sincere people who only want the best for the patients we serve. It is my hope that we can all work together to better control who has access to our prescription drugs and how that access is obtained.

Thank you very much for your kind attention to these comment.

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Ms. KAPLAN. Thank you, Mr. Chairman and members of the subcommittee, I am, as you said, Karen Kaplan, president and chief executive officer of Last Acts Partnership. Last Acts Partnership is a national not-for-profit organization that is dedicated to improving the care and caring near end of life.

You have heard compelling testimony today, and my message is one of balance. I appreciate the opportunity to testify concerning prescription medications, the opioid analgesics. You have heard they are controlled substances and they are controlled for good reason, but they are also indispensable medications for the relief of severe pain, especially pain near the end of life.

My remarks focus on the critically important need for balance, balance in the effort to address use, abuse, and diversion of the drugs. We must ensure that prescription pain medications are available to patients who need them even as we do all that we can to prevent these drugs from becoming a source of harm or abuse.

Under-treatment of pain is a major public health crisis. Medical experts agree that 90 to 95 percent of all serious pain can be safely and effectively treated. Yet, there is overwhelming evidence that under-treatment of pain is pervasive throughout our health care system. Inadequately managed pain was reported by approximately 50 percent of seriously ill and dying hospitalized patients. In nursing homes nearly 300,000 patients are in pain on any given day as we are talking here today. More than 40 percent reported being in continuous pain for many months. The people who rely on these medications are our mothers and our fathers and they will be us.

We have made some progress in recognizing pain as a serious medical problem. For example, the Joint Commission on Accreditation of Healthcare Organizations added pain as the fifth vital sign, and you have heard about that already.

In 2000, Congress and the President declared this as the decade of pain control and research. So we must ask, with all the advances in pain medications and treatment, why is under-treatment of pain still so prevalent in the United States?

The answer is complex, but two major obstacles are particularly relevant to today's hearing. The first is a lack of physician education, a lack of physician education in palliative care. American medical schools provide little or no required education in palliative care according to a 2001 Institute of Medicine study. Only 1 of 125 medical school are accredited by the AMA offered pain management as a separate course. This appalling situation must change if all physicians are to gain competency in pain management—and all must.

The second major obstacle to appropriate pain treatment is good physicians' fear of investigations by medical boards and law enforcement agencies, for prescribing opioids. This chilling effect was demonstrated by a recent survey of 1,400 New York State physicians, 30 to 40 percent of whom report that fear of regulators has influenced their prescribing practices.

Another face of this, a study of New York City pharmacies found that many, especially those in non-white neighborhoods, had inadequate supplies of commonly prescribed opioids. The reason cited by 20 percent of the understocked pharmacies in minority communities, was fear of investigations by the DEA. These practices based

in fear can be found in every city, they may reduce some drug diversion, and abuse but they also condemn thousands of patients with intolerable pain to needless suffering.

Opioids are absolutely essential to good pain management, physicians must be knowledgeable about their use and should not hesitate to prescribe them when appropriate, for fear of reprimand or reprisal.

So, I return Mr. Chairman to the need for a balanced approach, one that recognizes the need to reduce abuse and diversions of these drugs but one that also recognizes that people in severe pain, particularly men, women and children with terminal conditions, must have access to medications that can ease their pain and help give them and their families peace.

In furtherance of this goal, Last Acts Partnership and 20 other national pain and health organizations joined the DEA in October 2001 to develop a consensus statement regarding prescription pain medications. It reads in part: "Both health care professionals and law enforcement and regulatory personnel share a responsibility for ensuring 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 medication is made available. The roles of both health professional and the law enforcement personnel in maintaining this balance is critical."

This statement is attached to my testimony, it has been disseminated widely, used in many different settings. There are now 42 organizations participating in what is known as the Pain Forum. Many also belong to the RX Alliance chaired by former Mayur Guiliani, also looking for ways to invigorate balanced approaches.

We continue to seek ways to advance this dialog, and to provide a comprehensive answer to this. We have recently developed and will be publishing shortly a question and answer guide for non-pain specialists, physicians, pharmacists, and law enforcement personnel.

I applaud your work here today, I appreciate the opportunity to testify, and would be happy to answer any questions you have.

Mr. SOUDER. Thank you.

Our clean-up hitter for today, is Dr. Kollas, who is medical director, Palliative Medicine—in Indiana, anything over five words we have to wrestle with—Head of the M.D. Anderson Cancer Center in Orlando, in Orlando Regional Health Care.

[The prepared statement of Ms. Kaplan follows:]

Statement of Karen Orloff Kaplan
President and Chief Executive Officer
Last Acts Partnership

Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
U.S. House of Representatives

"To Do No Harm: Strategies for Preventing Prescription Drug Abuse"

Field Hearing
February 9, 2003
City Hall, Winter Park, FL

Mr. Chairman and Members of the Subcommittee, I am Karen Orloff Kaplan, president and chief executive officer of *Last Acts Partnership*, a national not-for-profit organization dedicated to improving care and caring near the end of life.

We represent more than 30,000 individual members, more than 1,000 national, state, and local organizations, and nearly 400 grass roots coalitions committed to our shared goals of educating the public, informing medical and health care professionals, and promoting policy reforms to improve the way we care for people nearing the end of life.

We appreciate the opportunity to come before the Subcommittee today to discuss strategies for preventing prescription drug abuse, particularly as they relate to the prescription pain medications known as opioid analgesics. While opioids are controlled drugs – and rightfully so for the many reasons that have already been outlined here today – they are also indispensable medications and are absolutely necessary for the relief of many types of pain, but especially pain near the end of life.

My testimony will focus on the central principle of ***balance***, which we strongly believe should underscore all of our efforts with respect to addressing use, abuse and diversion of controlled substances. Specifically, we must ensure that prescription pain medications are available to the patients who need them and that we do all that we can to prevent these drugs from becoming a source of harm or abuse.

Undertreatment of Pain

Undertreatment of pain is a major public health issue in the United States. Without providing a detailed review of the history of the undertreatment of pain – especially given that we have already heard from a distinguished palliative care physician, Dr. Kollas, on the panel today – let me just briefly share with you a couple of relevant facts and statistics.

Medical experts agree that about 90 to 95 percent of all serious pain can be safely and effectively treated. Yet an overwhelming amount of evidence has documented the undertreatment of pain throughout our healthcare system.

Probably the most glaring example is in our nation's nursing homes. According to a national study completed in 1999, nearly 300,000 nursing home patients are in daily pain and more than 40 percent of elderly residents who reported being in pain were still in severe pain two to six months later. This study is especially alarming when you consider that nearly one half of all people who live into their 80s will spend some time in a nursing home. This is only one of numerous studies documenting untreated and undertreated pain in nursing homes and throughout American healthcare settings.

I'd like to quickly share one pain patient's story with you. At age 85, William Bergman was dying of lung cancer. He was admitted to Eden Medical Center in Northern California in February 1998, complaining of intolerable pain. During a five-day hospital stay where an internal medicine specialist treated him, nurses charted Mr. Bergman's pain level at 10 – the worst rating on their pain intensity scale. Despite his family's repeated requests that his pain be addressed, Mr. Bergman's internist sent him home – still in agony – with inadequate medication. Ultimately, his family contacted another physician who took a more aggressive approach, and Mr. Bergman died at home soon afterward.

But progress has been made in our recognition of pain as a critical medical problem.

The Bergman case inspired the California legislature to pass a new law requiring that physicians who fail to prescribe, administer or dispense adequate pain medications be charged with unprofessional conduct and be investigated by the California Medical Board. Physicians found guilty of undertreating pain must then complete a pain management education program.

Also in 1999, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) developed new standards for pain assessment and management in hospitals, hospices and other healthcare facilities. The new standards require that pain be added to the four vital signs providers regularly check with their patients (the others are temperature, pulse, respiration, and blood pressure). JCAHO is the nation's predominant standards-setting body in healthcare, accrediting more than 16,000 healthcare organizations and programs in the U.S.

In 2000, the U.S. Congress got involved as well, acknowledging the undertreatment of pain and approving a provision – which the President signed – declaring the next ten years the "Decade of Pain Control and Research."

Even more recently, a U.S. General Accounting Office (GAO) report released in December of 2003 recognized that the World Health Organization and others continue to report that the "inadequate treatment of cancer and noncancer pain is a serious public health concern."

So we must ask ourselves this question: with all the advances in pain medications and treatment, and the general recognition by not only the U.S. but the international health care communities of the crisis in pain management, why is the undertreatment of pain still so prevalent in the United States?

There are a number of factors that help answer this question, including inadequate reimbursement policies and patients' own beliefs and misperceptions about opioids. For the purpose of this hearing however, I will briefly focus on two of the obstacles most relevant to our discussion today: the lack of provider education and fear of scrutiny by law enforcement and regulatory agencies.

The first obstacle, lack of education, was documented in a 2001 Institute of Medicine (IOM) study that showed medical schools across the country provide little or no required education in palliative care. It is one of a number of recent studies that suggest that many physicians have too little training and experience with pain assessment and treatment. Another found that only one in 125 medical schools accredited by the American Medical Association offered pain management as a separate course. This situation must change if medical students are to graduate knowing state-of-the-art pain management.

A second significant obstacle to appropriate pain treatment is medical practitioners' fear of scrutiny by law enforcement and regulatory agencies for prescribing opioids to treat pain. This is commonly known as the "chilling effect." For instance, a recent survey of 1,400 New York State physicians conducted by the state's Department of Health found that 30 to 40 percent of respondents reported that fear of regulators has influenced their prescribing practices.

A 2000 study of pharmacies in New York City, which appeared in the New England Journal of Medicine, found that many pharmacies, especially those in non-white neighborhoods, had inadequate supplies of commonly prescribed opioids. Of the under stocked pharmacies surveyed in minority communities, 20% cited "fear of fraud and illicit drug use that might result in investigations by the Drug Enforcement Administration" as the reason for not carrying ample supplies. This example illustrates both the reality of the "chilling effect" and the exacerbated difficulty for some minority patients in accessing these important medications.

A Call for Balance

Nothing in my testimony today is at all intended to diminish the legitimate concerns about abuse and diversion of prescription pain medications. As I stated previously, my primary goal in testifying before the Subcommittee today is to push strongly for balanced approaches to addressing the problems associated with abuse and diversion. To do this, we must weigh any proposed actions directed at abuse and diversion against the concerns of legitimate patients who rely on these medications just to maintain a quality of life that most of us take for granted.

In October of 2001, *Last Acts* and 20 leading national pain and health organizations joined with the Drug Enforcement Administration (DEA) to release a consensus statement calling for a balanced policy governing the availability of prescription pain medications. At a national press conference in Washington, DC, then DEA Administrator Asa Hutchinson stood with groups representing physicians, nurses, pharmacists, and patient advocates, to emphasize the need to work together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need. I have included a full copy of the consensus statement with my testimony.

This unprecedented collaboration was a result of a partnership with the DEA spearheaded by *Last Acts* and the Pain & Policy Studies Group at the University of Wisconsin, Madison, the leading expert organization in the country on federal and state pain laws, regulations and guidelines.

Original signatories to the joint statement included the American Medical Association, American Cancer Society, American Academy of Family Physicians, Oncology Nursing Society, American Pain Society, American Pain Foundation, American Pharmaceutical Association, American Society of Anesthesiologists, National Academy of Elder Law Attorneys, and the National Hospice and Palliative Care Organization, among a number of others.

The consensus statement has been disseminated widely and used in a number of different settings to forcefully urge that any discussion about the abuse of prescription pain medications be focused on the central principle of balance. It reads, in part:

"Both health care 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."

Subsequent to the development of the consensus statement, the Pain Forum was reconvened in Washington, D.C. to review the efforts of law enforcement, regulatory, and health organizations to promote the balance concept. The forum also provided an opportunity for information sharing and cooperation, as well as a discussion about next steps. *Last Acts*, the DEA, and the Pain & Policy Studies Group again sponsored the meeting. It included participants from more than 42 different organizations representing a broad array of health, law enforcement, and industry groups, including the DEA, NIDA, ONDCP, and FDA.

As a result of this meeting, we continue to pursue opportunities under the auspices of the Pain Forum, including a current initiative to develop a question-and-answer guide for physicians, pharmacists, and law enforcement personnel.

Conclusion

Drug abuse exacts a huge social cost and some have been tempted to address the problem of prescription pain medication abuse by greatly limiting access. But this is not a balanced solution. It only exacerbates the already severe problem of undertreatment of pain in this country.

Controlled prescription drugs, such as opioids, are essential for the care of patients, but they clearly carry a risk. They can become the object of abuse, or be the target for diversion to an illicit market. This potential justifies concern among the health care community and those in law enforcement and drug regulation, and we must make real efforts to minimize diversion and abuse of these drugs.

Focusing only on the abuse potential, however, could lead to the erroneous conclusion that these medications should be avoided, when in truth, opioids are absolutely essential to good pain management and should be prescribed *more often when medically indicated* to control certain types of pain. Physicians and other health care providers should be knowledgeable about their use and should not hesitate to prescribe them when appropriate for fear of reprisal.

We must work together to assure a balanced approach to preventing abuse and diversion while ensuring the legitimate rights of patients in pain to receive appropriate treatment.

As the joint statement concludes: "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."

Again, I appreciate the opportunity to testify before you today, and would be happy to answer any questions that you have.

Dr. KOLLAS. Thank you. On behalf of the Cancer Center and Orlando Regional Healthcare I want to thank Chairman Souder, and the subcommittee for inviting me to testify today. I would also like to thank Representative Mica and his office for their support and thank those who contributed to the research that I will be presenting in part.

My testimony will focus on the views of cancer patients regarding their experiences with pain medications. My goal is to give them a voice in this subcommittee's discussions. We surveyed 1,200 randomly identified patients who received care at the M.D. Anderson Cancer Center Orlando, between August and November 2003. The details of the methodology are available in the written testimony that I submitted earlier.

I want to point out that 52 percent of cancer patients reported that they experienced pain daily; 41 percent agreed that pain interfered with their ability to work and be productive; 20 percent felt that they could not preform routine activities, these include getting dressed, driving the car, shopping for groceries due to pain; 43 percent of them expressed concerns about using pain medication because its potential for addiction. I would also note that of those patients who had concerns about addiction, they reported pain twice as often as those without concerns.

The results confirmed that many cancer patients suffer from pain on a daily basis, and that it affects the ability to live their lives in a free and productive manner. With regard to OxyContin and their pain experience, about 41 percent of the respondents had used OxyContin to manage their pain, whereas 59 percent reported using other opiate analgesics for their pain. In the first group, 82 percent reported the OxyContin relieved their pain, but 72 percent in the latter group responded that they received pain relief with other opiate medications. Additionally, 53 percent of those taking any opiates agreed that opiate analgesics were the only medications that helped their pain.

These results suggest that opiate analgesics offer effective relief for cancer pain even when other analgesics failed. They also suggest that some cancer patients may have better control with OxyContin than with other opiates, although I would strongly caution the committee that this was not intended as a formal comparison of pain medications. And rather reflects the view of the patients that we surveyed.

Additionally we asked some questions about the cancer patients' experience with the media and OxyContin, 43 percent disagreed that the media had adequately addressed the issue of cancer pain, but we found no relationship between concerns about addiction and attention to media coverage. Given this, I would suspect that cancer patients value their own pain experience more than what they read, hear, or view in the media. Fear of OxyContin or other opiate analgesics is a complex multi-factorial phenomenon, not simply the result of intense media coverage.

This subcommittee has accepted the challenge of preventing diversion and abuse of prescription medication while preserving legitimate access to those medications. Our survey of cancer patients reaffirms that opiate analgesics, including OxyContin, offer relief for pain often more effectively than non-opiate analgesics. In spite

of media attention to prescription pain medicines, cancer patients seem to base their opinions of opiate analgesics on their own experiences.

In light of our patients' view, I would offer several guiding recommendations to the subcommittee regarding it mission. Because cancer patients need pain medication, we would discourage regulatory efforts that would reduce legitimate access to opiate analgesics, including sustained release oxyocodone. However, we recognize clearly that the government has an obligation to protect those who suffer from the diversion of use of analgesics.

I would applaud this subcommittee's efforts to develop regulatory mechanisms that would protect these people. I would also remind the subcommittee that those who misuse prescription medications often suffer from underlying untreated psychiatric illnesses that influence their drug abuse. Successful solutions to the problem of diversion and abuse should take this phenomenon into account.

Last, I would encourage the subcommittee to continue challenging medical professionals to help create new policy through frank discussions. We believe that education in pain management helps medical providers to recognize and avoid diversion or misuse of prescription drugs. I would add at this point that I feel medical providers should welcome the opportunity and the responsibility to serve in this battle to help prevent misuse and diversion of prescription drugs.

I would strongly encourage the development of other strategies that emphasize an educational approach, and I would specifically cite House Resolution 1863, the National Pain Care Policy Act of 2003.

I would also note that electronic monitoring which is being considered in Florida has shown to be effective in other States, including a specific example of Connecticut. The only concern I have with regard to electronic monitoring has to do with HIPAA violations, and we have talked about some of those issues, at least in a preliminary fashion, today.

Although the subcommittee faces formidable challenges, I conclude my testimony on a positive note. When we mailed our surveys, we hoped that our patients would entrust their voice to us, and they did so. They embraced the belief that their views and concerns would reach your ears, and now they have. Although we face a difficult task, we face it openly and with resolve to succeed. Because of this, I have renewed hope for a better future for all patients in pain, and I would be very happy to entertain you questions.

Thank you.

[The prepared statement of Dr. Kollas follows:]

"To Do No Harm:

Strategies For Preventing Prescription Drug Abuse Act"

Congress of the United States, House of Representatives

Committee on Government Reform

Subcommittee on Criminal Justice, Drug Policy and Human Resources

-- Testimony by --

Chad D. Kollas, MD, FACP, FCLM

Medical Director, Palliative Medicine

M. D. Anderson Cancer Center Orlando & Orlando Regional Healthcare

Orlando, Florida

Introduction

On behalf of M. D. Anderson Cancer Center Orlando and Orlando Regional Healthcare, I would like to thank Chairman Mark E. Souder and the Subcommittee on Criminal Justice, Drug Policy and Human Resources for inviting me to testify at this hearing. I would also extend special thanks to Representative John Mica of Winter Park, Florida, and his office for their gracious assistance and support.

I would also like to acknowledge the support and efforts of those who contributed to the research that led to this testimony, particularly the work of Susan Dempsey-Walls, RN, MN, Mary Ella Mahoney, PharmD, Pam Nicolenko, RN, Jeanne Adam, and the Orlando Regional Healthcare Market Research. I thank as well Beth Boyer Kollas, MS,

MDiv, PhD, for her assistance with scientific review and editing. I also would like to thank each of the patients who returned completed surveys, thereby giving me the opportunity and privilege to bring the voice of cancer patients to the important discussions that will characterize this hearing.

My testimony will focus on conveying the views of central Florida's cancer patients regarding their unique experiences with prescription pain medications, an issue that has received substantial attention in the news media in Orlando over the last four months. I hope that I am able to faithfully express their practical and valuable insights at this hearing to help in this subcommittee's worthwhile effort to reduce prescription drug diversion and misuse, while protecting the interests of patients with legitimate needs for pain management.

Background

In the fall of 2003, the misuse and diversion of the prescription opiate analgesic, OxyContin® (sustained-release oxycodone), received intense media coverage in central Florida following national reports of alleged OxyContin® abuse by a prominent talk-radio personality. In my palliative medicine outpatient practice at M. D. Anderson Cancer Center Orlando (MDACCO), several patients described difficulty obtaining prescription pain medications and shared that their friends and families had expressed increased concerns about addiction to pain medications. A few expressed specific concerns that OxyContin® would be "pulled from the market," causing them fear about the potential to suffer from increased cancer pain. Many patients expressed specific concerns that the

newsprint media did not address adequately or fairly issues related to cancer pain. They also expressed frustration about the lack of a widely visible forum in which they could voice their concerns about the media's lack of attention to their pain issues.

In November 2003, the news media announced the plan to convene this congressional subcommittee's congressional hearing, thereby providing a unique and powerful opportunity for cancer patients to voice their concerns and opinions about prescription pain medication issues. After meeting with other interested MDACCO and Orlando Regional Healthcare (ORH) providers, we began efforts to objectively characterize our patients' opinions about the issues related to management of their pain with prescription medications, including OxyContin®. Our goal was to better serve our patients by giving them a voice in the important discussions that will arise in this subcommittee hearing. To achieve this goal, we developed a survey designed to examine the experiences of cancer patients with prescription pain medications, including their perceptions of news media coverage of pain, their physicians' pain management, and the characteristics of their pain experience.

Survey Design

Before distributing surveys, we obtained approval from the MDACCO Institutional Research Board to conduct the study with a waiver of consent, as participant's consent would be implied by survey completion and return. Given the sensitive nature of the study issue, we did not collect information that would allow identification of any participants. All survey costs were funded by MDACCO and ORH.

The study group included 1,200 randomly identified patients who had received care at MDACCO between August and November 2003. Each of these patients received a survey and explanatory cover letter dated December 30, 2003. We asked them to complete the survey and return it using the U. S. Postal Service in an enclosed, self-addressed, stamped envelope by January 16, 2004. The cover letter emphasized that the intent of the study was to collect information for presentation at this committee hearing. We also explained that the survey did not represent an effort to identify patients who misused their medications, nor were we seeking information on behalf of a pharmaceutical company or other interest.

ORH Market Research collected surveys, entered and analyzed data preliminarily, then created a summary database spreadsheet with a report containing descriptive statistics. The study's principal investigator subsequently analyzed selected data to uncover comparative relationships, using SPSS 11.0 for Windows [SPSS, Inc., 2001]. For the purpose of this subcommittee hearing and related to the limited amount of time available to testify, I will report the study's main results with a brief interpretation of their meaning. We plan to formally publish more detailed results in a peer-reviewed medical journal at a later date.

Main Results and Discussion

Response Rate and Demographics.

The response rate for the survey was 16.7% (190 surveys returned), and 69.4% of respondents were female. The age distribution of respondents was as follows:

18-35 years:	2%
36-50 years:	30%
51-64 years:	12%
65-80 years:	45%
81 years or older:	12%

Pain Experience in Cancer Patients.

Just over half (52%) of the cancer patients who responded to the survey reported that they experienced pain *daily,* and 41% agreed that pain interfered with their ability to work and be productive. One-fifth of respondents agreed that they could not perform routine activities -- getting dressed, driving the car, shopping for groceries -- due to pain. About 27% of respondents felt that pain had adversely affected relationships with loved ones and friends. Furthermore, 43% of respondents expressed concern about asking for or using pain medication because of its potential for addiction. Of particular note, patients with concerns about addiction reported pain twice as often as those without concerns (statistically significant difference; $p = 0.01$). Additionally, although 80% of respondents agreed that their healthcare providers took their pain complaints seriously, fewer (68%) reported that they were satisfied with their current pain management overall.

These results confirm that cancer patients suffer from a significant amount of pain on a daily basis, and that their pain affects their ability to live their lives in a free, productive manner. Cancer patients expressed concerns about addiction, although they are part of a group suffering from a type of pain that has traditionally received more social acceptance than other types of pain, such as chronic, musculoskeletal pain, for

example. Furthermore, although two-thirds of cancer patients were satisfied with their pain management, medical research suggests that patients can achieve better results through the efforts of well-trained pain management providers (see Rich B; Wm Mitchell L. Rev., 2000].

OxyContin® and the Pain Experience.

About 41% of respondents currently used or had used OxyContin® to manage their pain, while 59% currently used or had used other opiate analgesics for their pain. In the first group, 82% reported that OxyContin® relieved their pain, but fewer respondents in the second group (72%) reported pain relief with other opiates. Furthermore, over 87% of the responding cancer patients who currently use or have used other opiates agreed that they would not take opiates if they had no pain compared to 91% in the subgroup taking OxyContin®. Both of these differences between groups were statistically significant. Both groups reported the similar levels of satisfaction (70%) with how they felt when taking pain medication, and both groups reported no difficulty with side effects at an equal rate (about 70%). Additionally, 53% of those taking *any* opiates either now or in the past agreed that opiates analgesics were the *only* medications that helped their pain.

These results suggest that opiate analgesics offer effective relief for cancer pain, often in cases in which other analgesics have failed. The results also suggest that OxyContin® *may* produce higher success rates in the control of cancer pain than other opiates, although we would strongly caution the subcommittee the study was not intended as a formal comparison of pain medications. Our main point of emphasis would be, rather, that OxyContin® clearly has a legitimate use in the treatment of pain in cancer

patients, and may – in certain cases – offer more favorable analgesia than other opiate medications.

The Media and OxyContin®.

About two-thirds of respondents agreed they followed most of the television and newspaper coverage of OxyContin®. About 30% agreed the coverage of OxyContin® was fair and balanced, but 27% disagreed and 43% were neutral or unsure. In contrast to this, however, 43% disagreed that the media adequately addressed the issue of cancer pain, while 16% agreed and 40% were neutral or unsure. Of greatest interest to the study investigators, however, we found no relationship between concerns about addiction and attention to media coverage.

These results show that although most of the cancer patients who responded to our study followed the media coverage of OxyContin®, it did not significantly increase their fears of addiction. Many cancer patients agree, however, that the recent newspaper and television media coverage of OxyContin® did not adequately address cancer pain. Based upon these observations, we suspect that cancer patients value the personal, experiential lessons of the cancer pain and their own experiences with opiate analgesia more than what they read, hear or view in the media. We also believe that this confirms that fear of addiction to OxyContin® or other opiate analgesics is a complex, multi-factorial phenomenon, rather than the result of intense media coverage [for a comprehensive discussion, see Weinmann BP; J. Legal Med., 2003].

Conclusion

The Subcommittee on Criminal Justice, Drug Policy and Human Resources has accepted the difficult task of preventing diversion and abuse of prescription medications, while preserving access to pain medications for patients with legitimate needs. Our survey of cancer patients in central Florida reaffirms that opiate analgesics, including OxyContin®, offer relief from cancer pain, in most cases more effectively than non-opiate analgesics. Although a great deal of media attention has focused on the addictive nature of opiates, particularly OxyContin®, cancer patients seem to base their opinions of opiate analgesia on their own experiences, a practical approach that reflects – at least in my opinion – a good bit of wisdom. Although the media effect upon our patients was relatively weak, and in spite of the clear benefits that they receive from opiate analgesia, some cancer patients continue to express concerns about addiction to OxyContin® and other pain medications. This suggests that concerns about addiction arise from many causes, including personal and societal attitudes about pain and analgesics, physicians' values, attitudes and practices, and governmental policy regarding prescription drugs [see Weinmann, 2003].

In light of our patients' views, we offer several guiding recommendations to the subcommittee regarding its approach to developing strategies to prevent prescription drug abuse and diversion. Because they legitimately need pain medications, we would discourage regulatory efforts that would reduce cancer patients' access to opiate analgesics, including sustained-release oxycodone. In the past, some regulations have limited patients' access to pain medications, including multi-copy prescription programs, laws that failed to define "inappropriate or excessive use" of opiates, and programs that

limited opiate dosages and/or dosing frequency without attention to tolerance and differences in pain perception [see Weinmann, 2003]. At the same time, we recognize our government's clear obligation to protect the lives of those who suffer due to the diversion and abuse of prescription analgesics, and we applaud this subcommittee's earnest efforts to develop regulatory mechanisms that would protect these people. We also remind those involved in this hearing that people who misuse prescription medications often suffer from underlying untreated psychiatric illnesses that influence their drug abuse. Successful solutions to the problem of diversion and abuse should take this phenomenon into account. Lastly, we would encourage the subcommittee to challenge medical professionals to help create new policy through frank discussions and the continued pursuit of clinical excellence in pain management for all patients with legitimate pain issues. In our experience, specialized education in pain management helps physicians to recognize and avoid diversion or misuse of prescription drugs. We encourage the development of strategies that emphasize this educational approach, such as House Resolution 1863, the National Pain Care Policy Act of 2003.

Although this subcommittee faces formidable challenges, I conclude my testimony on a positive note. When we mailed our surveys, we hoped that our patients would entrust their voice to us. They did so, embracing the belief that their views and concerns would reach your ears -- as they now have. Although you face a difficult task, we have chosen to face it together – patients, physicians, pharmacists, politicians – openly and with resolve to succeed. Because of this, I have renewed hope for a better future for all patients in pain.

Mr. SOUDER. Well let me start off with just a couple of things to clarify for me, since I am medically challenged. My wife is an occupational therapist and she does the thinking in this area, and I kind of wander in and she is always kind of envious that I am at the hearings and she thinks that I am a ignoramus on the subject and she knows the details. But you gradually pick up bits and pieces, just enough to be dangerous. But I want to clarify a couple of things.

My mother-in-law recently died of cancer. Her pain definitely was greater in the last stages than it was earlier, is that usually true?

Dr. KOLLAS. It can be, we see that commonly. It depends on the cancer.

Mr. SOUDER. But it is not always true?

Dr. KOLLAS. It is not always true, but it is true very often.

Mr. SOUDER. And so, would the pain killer use likely escalate as you go through cancer treatment, or increasingly is the same thing being prescribed all the way through?

Dr. KOLLAS. No, the use of the medication may escalate. Actually you bring up a point that I wanted to make earlier. Physicians are sort of used to dealing in population medicine, it is what they teach us in medical school. They want us to view people in categories of diseases if you will. So we think of people as having hypertension, or we think of them having diabetes, or we think of them having cancer.

To do good pain management you have to abandon that view somewhat and look at people as individuals. Every one is different. So the right dose of a pain medication for one person may not be the right dose for another patient.

Certainly, you are going to see general trends, and it is not uncommon for patients with cancer at the end to have more difficulty with pain. And in fact in my experience, the few people that we have seen on dosages of pain medication of opiate medication that would stagger the subcommittee's members all occurred related to end of life care. Given that, that is why it is hard to answer that question, it depends upon the individual patient. And it also raises the importance how physicians need to be trained to take that into account. It is a very different approach than what we learned in medical school, where it is very disease based. We try to look at—palliative medicine particularly is focused on relieving suffering in multiple dimensions, and that is a very different approach.

Legislation that would encourage that type of education is extremely important and I would argue that physicians should be asking to be empowered to take a more active role in this, to help prevent misuse and diversion medications, because clearly the more you know, the better you are able to do those things. We might get fooled by patients once in a while, but it is a lot tougher to be fooled by a patient when you know more about what the techniques are used to divert medications.

Mr. SOUDER. If a cancer patient is younger and mobile even if it may be likely failed, is the mere factor of their mobility, their ability to hold a job—well, let me first ask a fundamental question about OxyContin.

Dr. KOLLAS. Sure.

Mr. SOUDER. Does this impact your ability to do certain types of work if you are taking a dose?

Dr. KOLLAS. It can, it is individualized. Let me give you an example, I have a patient who is 48 years old. She has metastatic breast cancer. I asked today—I did not ask today but I asked if I could discuss her case with you today. I saw her in the hospital about 2 weeks ago, she was having a stabilization surgery to help her spine, because she has metastatic disease to her spine. At any rate, she works for one of the technical companies that is based in the Orlando area. She has been able to continue working at her job, awake and alert despite the fact that she takes 640 milligrams of oxycodone every 6 hours. When she gets a refill prescription and she goes to the pharmacist, she tells me I am very scared because look at all the tablets that I take. Yet, she is awake and alert.

Now, when she comes to see me, I document that in my note, I do a physical examination. The physical burden of her cancer is just tremendous, I mean the surgery that she underwent is a laminectomy, she had a spinal fusion involving four segments of her spine. Afterwards we actually had to convert her from oral medication to medication that she could use intravenously, using a portable pump. Because she is to the point where literally it becomes a physical problem to have to take that many pills. They could get stuck together and cause her to have a intestinal obstruction.

So, when you ask me the question are people able to function cognitively when they take OxyContin, my answer is yes, but everybody is different. Some patients do better than others.

Mr. SOUDER. Let me ask, are there restrictions in driving in Florida?

Dr. KOLLAS. Yes, there are restrictions in driving in Florida.

Mr. SOUDER. Is it not also true that alcohol has a different impact on different people?

Dr. KOLLAS. Absolutely.

Mr. SOUDER. And yet, our laws that regulate do not respect that difference. In other words, we do not say some people can handle three beers, and some people can handle two beers because they have to protect on the whole.

Dr. KOLLAS. Sure.

Mr. SOUDER. Would you not agree, and one of the things—to me, this debate is not predominately about people at the end of life or who are probably—in other words, when we dealt with certain waivers, for side effects on AIDS, for AIDS patients——

Dr. KOLLAS. Right.

Mr. SOUDER [continuing]. We basically said they are dying, if they are willing to take the side effects, because they are dying.

Dr. KOLLAS. Sure.

Mr. SOUDER. The question here is that predominately on the moderate pain, or other types of things other than cancer. While it is a concern that we do not pass laws—but quite frankly, one thing, Ms. Kaplan, that you can probably be relieved of after today is that doctors and pharmacists do not have to worry about being prosecuted by DEA, that if anything for them to use that as excuse, simply is not valid around the country.

One of the things I wondered, if I can take it along—I wanted to put that point into the record that I do not view this hearing as predominately related to the cancer, or the highest risk, or where the pain is greatest. I view this as we are trying to identify in the middle and I would like to have one more comment. I also, wonder, Ms. Kaplan, whether there is a concern of the people who say that they are worried about prescribing, whether you have discovered they are worried about being sued. I would assume there is more concerns about the losses and the malpractice then there is about the DEA, because, the fact is that we are not doing that much in the country on law enforcement.

Ms. KAPLAN. I think that I would agree that the issue of the chilling effect may be largely a perception issue, and requires some fairly active public education on the part of the DEA, and they are indeed addressing that issue.

In terms of the second part if you would restate the second part of——

Mr. SOUDER. Do you not believe that one of the things that causes doctors not to prescribe is that they are concerned about lawsuits?

Ms. KAPLAN. I think that is not the case in this situation, doctors in fact are being sued successfully for under-treatment of pain. So that should be a push in the other direction. There clearly is a malpractice crisis in the country. I do not think this plays—fear of over-treating plays a large role anymore in that.

Mr. SOUDER. That is kind of a different angle on it. Mr. Mica.

Mr. MICA. Well, first I want to thank Fred Pauzar. I have known Fred for a number of years through business, I cannot imagine the pain and the absolute incredible loss he has experienced and there are other parents and loved ones out here that have lost people they care about.

This hearing is not going to bring anyone back. What it will do and I compliment you Fred and others who pursue this, is to try to get government to respond to a situation of prescription drug abuse, and bad people who have also gamed the system and caused untold pain, and created an incredible challenge for us. Unfortunately, I have known too many parents, I know Fred, and I have known others who have lost their children in the community. I could name names of parents of kids, I hope I do not have to do another one of these hearings ever, or request a hearing like this.

But it is sort of a challenge of our times, this is what—we are talking about this particular narcotic that is available since 1995. We were talking about that earlier, how long has it been available, and then if you look at the statistics, they are off the chart. I read—I knew the problem, and I read the same day of Chris's death that we announced the hearing. Again, nothing is going to bring back your son or some of the others, but from this hearing and from your very admirable efforts, hopefully we can bring some of this situation under control.

And this is the process that works, sorting it out, work with my colleague, Dr. Norwood, to have legislation pending, and I have learned that there are other proposals before Congress, and maybe we can craft something. It is also obvious that people do need remedies for pain. I have been through the same thing, Mr. Souder,

with family members that have passed away in the last couple of years, and had to endure incredible pain and seeking relief. We want to achieve a balance, but we also want to achieve a protection so that we do not have anyone suffer the way some of the folks who came out today have.

So, again, not so much as a question, but a statement to say thank you for your testimony.

From the pharmaceutical standpoint, again, I think we are trying to achieve a balance and protection and some system. I do not know if you were here, when I relayed that we had several demonstrations projects in the Medicaid area to try to come up with software that will resolve this. Are you familiar with any of those.

Dr. DOERING. Yeah, as a matter of fact one of the things I did not tell you another hat that I wear, I do a lot of consulting work in cases that are being prosecuted. The one that Mr. McDonough talked about earlier in Pensacola, I testified twice in that case. I was involved in several cases close by and I remarked to one of my colleagues at the break that it was interesting that a current case that I am working on in the panhandle was brought forth by Medicaid fraud.

Now, you do not typically think of them as, or I do not, as the enforcement arm in criminal activities involving narcotic drugs. But it is the Medicaid fraud, and apparently they have a system that others do not, where they can look on paper and say whether it is, wow, look how much we are spending or wow, look how much they are prescribing. But that current case has evolved into a well-coordinated multi-jurisdictional type of task force.

Now, as you well know, prosecuting these kinds of cases is lengthy, it is costly, and sometimes people are falsely accused. I have a new respect for the legal system. I was a consultant in a case with DEA that just pled actually a doctor there in Arizona; Phoenix, AZ; Tuscon, AZ. And I do not want to tell these taxpayers how much of their money was spent that I know that on April 15 that is going to be a large part of expenditure. Is it worthwhile? Absolutely. If one bad doctor, one bad pharmacist it taken off the street, it is worth the effort.

But, you know, I believe in the 80/20 rule. I believe that these 12 prescribers that we heard about earlier today, I mean if they are really accounting for that much of the diversion and the bad prescribing and the deadly use of these drugs, that is where the focus ought to be. I learned a long time ago, you look where the light is, and if that is where the light is, I mean with all due respect to my colleagues on the left here who made a very convincing presentation, I do not think that is where the light is. I think the light is with people who are either fully educated who are cradled with the D's that you mentioned, that are criminally involved. We have to take them off the streets and put them in jail.

Dr. KOLLAS. May I just add something?

Mr. MICA. You want to respond?

Dr. KOLLAS. One of the points that I wanted to emphasize is just that. Realize that I am involved in treating a group of patients, when I say I relieve their pain it has the same sort of analogy that I would use for a politician kissing a baby. You make cancer patients' pain better, people are going to say that is a good thing.

That is pretty close to a no-brainier. I think there is a problem with physician involvement in diversion and misuse of these medications. You guys keep talking about these 12 physicians in Medicaid. I live in Florida, so I get to read the paper and one the physicians that they were talking about was writing prescriptions for patients who were dead.

Please hold the physicians accountable when they do this. That is clearly criminal, and it gives everyone else who is trying to do an honorable job of this, a bad name. And it is difficult enough, I mean, you know, looking at people in an individualized fashion is very labor intensive, it is important. I am very passionate about what I do and I view it as an honor and privilege to be able to do it. But, please when you see physicians that are clearly doing it related to obtaining money or obtaining some other favor for writing a prescription, put them in jail. We will be safer and we would not have to have these meetings anymore.

Mr. SOUDER. Dr. Norwood.

Dr. NORWOOD. Mr. Chairman, you are to be commended on this hearing, and especially for the witnesses that we have had testify this morning. I think it has become very clear to all of us in the room and all of us on the dias up here that this is a very complex, it is a very difficult problem.

All of us are in great sympathy with you, Mr. Fred Pauzar, and want to do anything we can to see that kind of thing cannot happen again.

On the same token, Ms. Kaplan, I associate with your remarks a lot, what you are saying about under-prescribing for pain is equally important, and it is particular important if it is your mother dying of cancer. It gets to be a lot bigger subject matter at that point. I am in great sympathy with the majority of physicians who get their profession black-balled because of some 10, 12, whatever the number is really, really, bad people in my view. I agree with you, Doctor, they would serve out the rest of their days practicing medicine in prison. Those that would violate the Hippocratic Oath I do not think very much of, is probably the best way I can say it without the chairman having a fit.

But the poor physician is caught in the process of if I do I get sued; if I do not, I get sued, and that is not a good situation.

I associate with your remarks when you are talking about the code that pharmacists have to live by in dealing with confidentiality. That is going to be one of the real difficult problems with us in dealing with this problem. Obviously, if we are going to solve it, somebody has to have a data bank. I do not think the Federal Government needs a data bank, but I think Florida does, and I think they need to be able to talk to the data bank in Georgia, because you can run back and forth between Tallahassee and Valdosta and load up.

But who actually gets to go into that data bank. The liability questions of that are gigantic, and very difficult to solve.

Last, Doc, what do you do, I know you know—you know who the pill shops are. I know in my town, or I used to when I was really into all this. What do you do with that information, when you know that?

Dr. DAVIES. I do not do a whole lot with it, right now.

Dr. NORWOOD. Why not?

Dr. DAVIES. It would just be—I do not know if there is a forum to go to with it. The State rules, the laws are not real clear to me. And the source of my data—there is so much stigma around addiction and around addicts, although plenty of my patients are us, they are not street level addicts.

Dr. NORWOOD. You do not have to do the investigation. Are you not morally responsible to at least let DEA know something is going on here that is wrong. It is their job to do the investigation. And it is the court's job to make the determination of innocence or guilt. But should you not call up your DEA folks, and say something is not right over here on Third Street.

Dr. DAVIES. I would feel a lot better about that if I had access to real data and real numbers. And not just what they are going to tell me is hearsay from patients. I mean, I have a great concern about it and that is precisely why I brought it up.

Dr. NORWOOD. I knew you did, and I am not trying to criticize you about this, I am just saying that you guys know, I know you know. You may not have proof but that is not your job. But you know what is going on out there in your community, you know who the bad guys are, and all I am saying is spread the word. Let those agencies that are responsible for dealing with that, deal with that. But there are so few employees at the DEA, if they do not get a little help from us out in the field, if we do not direct them a little bit, when we know bad guys are out there, it just takes them that much longer if they ever catch them and stop them. And if the people are not guilty, fine. That is what the whole system—that is what our justice system is all about.

Mr. Chairman, I just congratulate you. There are a couple of bills going around, being worked on in Washington and they do not all necessarily take the same course, but all of them involve data collection, so somewhere out there we can find out who is prescribing what. Some people want to do it on a Federal level, I do not fit into that category. I really think it is more of a State thing.

But I pledge to work with you and Mr. Mica to do whatever we can do there to solve this problem.

Mr. SOUDER. I want to thank Congressman Mica for being persistent in raising the subject and making sure we had this hearing, to Mr. Norwood, for his leadership in the area, and both of them for their chairmanship in multiple areas in Congress.

I want to make sure that in the record we note a couple of other things.

First, Dr. Davies, I really like the five D's because it illustrates how this is not one solution. In other words, for the data, that is clearly an education effort in the form of HHS and other institutions doing more to get the information out. We have heard a lot about that today. But the duped, the dishonest, the dysfunctional, disabled all require different approaches. There may be some clustering and all those are part of this problem.

I think a hearing like this helped us clarify where some of the targets should be in larger targeting. We do not know that all 12 of those individuals are guilty of any violation, they may in fact have more Medicaid patients, which may be that is why they were among that. They may be among the inner city urban area, for ex-

ample. There were certain suggestions implied that they certainly should be the places you start. That there are certain things you might look at at the Federal level, but in that as our committee having both authorizing and direct oversight over the national ad campaign, over ONDCP and HIDTAs, we understand that DEA and our dollars are stretched very narrowly and that the south border right now is so porous that much of that has to be focused on and the Carribean. And we cannot go off into each new hot thing that is the focus, and divert large amounts or we will get none of them licked. We have to kind of focus in but we also have to have secondary efforts in emerging threat efforts inside that. And we are helping identify that with this hearing.

But let me say something and end this on a less than comfortable note. That fact is what Mr. Pauzar raised was more complicated, and that was not just about massive diversions, not just about people who were former addicts, who use this which make them higher risk, not just about big abusers. But are there risks to individuals, because we are going down to moderate use, which is much more explosive than what we can agree on here, and we have obligations in our society to look at some of the traditional ways of prescribing. The secondary use of those drugs, the interaction of those drugs, and the dependencies and risks that are occurring beyond the kind of OK, these 12 people are terrible, because your son probably was not getting it from 1 of those 12 people. He probably was not a previous addict, and then all of a sudden he is dead, and we have another class here that is much more complicated, he was not dying of cancer, and these, this zone is really where the political difficulty comes. We will probably be able to address the more egregious things. Do you want to add something?

Mr. PAUZAR. Mr. Chairman, thank you for that. You are correct, my son was not a drug addict, and he was not taking prescriptions that he obtained from 1 of these so-called 12. Twelve is an arbitrary line that was drawn, simply because the gross magnitude of the quantity of prescriptions that were being written presumably illicitly by those 12 doctors was so egregiously horrific that it stands out. But that does not mean the number is 12, the number may be 100, it may be 20. There are a number—a small number fortunately, a minority of physicians who are over-prescribing and prescribing inappropriately.

But your remarks that this is a very complex situation is very apt. The solution is not one thing. It is not going to be a tracking bill, that requires tracking. It is not going to be more dollars for DEA, or better education for people at DEA about what really is going on in some of the burgeoning new markets of drugs, illicit drugs and prescription drugs that are being abused. It is a very complex three dimensional puzzle and it requires communication between the agencies, and it requires action to be taken legislatively, and it requires action to be taken on a State level too, where the boards of medicine and others are regulating the physicians.

Because it will not stop; simply to track the information and to know that it is there, is not an answer. We had an awful lot of data before we lost our last space shuttle, but that data just was not analyzed and it was not acted on correctly. So, the organizations

that are vested right now with power and with a mandate to act, have to be informed and they have to communicate with one another, and there has to be stronger teeth in the legislative attempts that you take. And certainly drugs like OxyContin have to be taken away from moderate pain relief, because if anything has been shown here today, that has been talked about today by everyone is that we do not want to deprive terminal cancer patients of OxyContin. You do not want to deprive people who are severely afflicted with pain from those arsenals that are available to them to deal with that pain to make their lives manageable, but you want to take people who can take Tylenol instead and make sure they never receive a script, that they are never given a prescription for something that might well kill them as it did my son.

So, it is an extraordinary complex problem, and I appreciate your attention on this but I also appreciate the fact that it is going to take a lot more than this hearing and a lot more than one piece of legislation to cure it. But every day that goes by just in this State alone, I am not sure—is it one person who dies Congressman Mica or is it 10, in Florida? I know that what we have, based upon the statistics that we see, even in the time we have been talking here, there had probably been one to two deaths in the State, in this State alone, from OxyContin or oxycodone. So, I am enormously distressed by the problem because of my own loss, but I am more distressed, and believe it or not I am more distressed by what I see tomorrow. Because every day that goes by without decisive action means that there are more parents like myself.

Thank you.

Dr. KOLLAS. I just wanted to add something to that, and I hate to add another layer of complexity on your task. Using OxyContin, for example, for moderate pain, on the surface it seems to be something that is a bad idea, we should not do that there are other medications available. What I would do is caution you when you approach it that way. There are over-the-counter medicines that are every bit as lethal as OxyContin, people have not chosen to abuse them because they may not have the same sort of effects that opiate medications do. But if you take more than 8 grams of Tylenol you can die from liver disease. If you take too much Advil you can die from renal failure. Sometimes you are forced to use medication for moderate pain when you would rather use something else. If somebody has difficulty with renal insufficiency than a morphine-based medicine might not be the best choice for them when they have moderate pain, they may have an allergy. If they are hemophiliac they may not be able to take medicines that aspirin or that are nonsteroidal anti-inflammatory drugs.

The point that I want drive home to the panelists is that there is a certain level of expertise that is involved in pain management. You know I went to medical school, I know what a cardiac cathererization is, I know what they do when they do the procedure. I am not a cardiologist, I do not do them. You would be nuts to let me do a cardiac cath on you, OK. What I do know is that I have special training that allows me to handle something that is medically sophisticated, that many of my colleagues do not have. So, I really think that part of what you need to consider is, who is able to prescribe these medicines, and what is their amount of

training and if it is that all doctors should be prescribing pain medicine because pain is such a broad problem, then all doctors need more education in pain medication and in pain management. And if you want to say there is specialized cases in pain management that requires special expertise then it would be wise to recognize that. It would be wonderful if there was American Board of Medical Specialities acknowledgment of palliative medicine as a specialty. There is not yet. I would love to see that happen and I think that would go a long way to help with some of these issues.

But understand that this is an important area of medicine that is more complex than—I think you have an appreciation of it, but it is more complex than you even realize. And please use the resources—clearly from today's hearing, there are many resources available to you and we are all committed to making this problem better.

Mr. SOUDER. Well, I appreciate those comments and as somebody who is, as I have said several times, a very strong supporter of doctors and the medical industry as a whole, let me again make this statement. Everybody would like best to be left alone, small businesses would like to be left alone, everybody would like to be left alone. And I know that in health care this is something we hear on abortion law, it should be between patient and doctor, but you know what when society makes the decision, there are restrictions on it. Same with illegal narcotics, and there is a point, for example, as we try to work through incredibly difficult issues in Medicare, Medicaid payments and now the private sector mimics it. What kind of health insurance—Dr. Norwood, has been involved in this, trying to redo health care since he has gotten elected. And we run into lawsuit questions, where do we make compromises. But when the Federal Government crosses the point where we are carrying most of the health care cost than the private sector, which was not doing cross transfer and now all of a sudden you have HMOs and others who are necessarily already restricting the medical profession to make necessarily the kind of in depth consultive type traditional, this is my doctor, this is the patient, where you are trying to run lots of different people through where there is not heavy backaground checks. And then all of a sudden, we have an explosion of 10 deaths of a day in the State of Florida, related to one thing, I am sorry, it is not just doctor-patient anymore. It is a lot more complicated than that, and we need to make sure we do not overreact and overstate it.

But there are going to be controls, because of who is paying for it, because of the reactions in society and then we have to make sure that we do not do irreparable harm to others who are benefiting, but we have heard testimony today that this has had greater than any other prescribed drug in the number of deaths. So to not act, suggests some irresponsibility. And one of those things is to look at yes, moderate pain is something that requires maybe certain waivers. We should not make it so blanket, but it is not something that—we are not living in a just leave us alone world at this point. And no group likes that, and I think we have as great a danger of over-regulation as under-regulation, but at a ceratin point you say this as reached the point, a threshold where action is going to be required. And I would say that clearly this coming.

Now one other thing, we are dealing with ephedrine and things that go into aspirin and so on are some of the main components of meth labs and clearly even as Mr. Doering said, look there are over-the-counter problems right now too, it is not just prescription. We are going to deal with it more, and quite frankly, the more successful we are at controlling our borders, the more problem we are going to have with domestic produced drug questions, and that is why we have to get into prevention programs, treatment programs, of all type. But at the same time that means that there is going to be more pressure with our addiction problems in the United States, unless we more effectively communicate the dangers of getting, as we have heard multiple times, warning people about the interaction, unless the drug companies get more aggressive and unless the pharmacies rather than just say trust, trust, but verify and unless the doctors do trust but verify. This is not Marcus Welby M.D., and I know the younger people do not even know what I was talking about.

Things have changed and we all need to change with it and helping make sure, hey look, we like over-simplifying government, we have to deal with laws that reach broadly, not an individual law for each case, so we have to balance that, but we are going to have to do that. I am tending to go on here.

Any additional statements you want to get in, you can submit them for the record, we will probably have some additional questions.

Once again, I thank Mr. Mica, and Mr. Norwood, thank everybody here for their patience as we went through this hearing.

With that, the subcommittee stands adjourned.

[Whereupon, at 1:30 p.m., the subcommittee was adjourned.]

[The prepared statement of Hon. Dave Weldon and additional information submitted for the hearing record follows:]

Statement of Rep. Dave Weldon
To the Committee on Government Reform

February 9, 2004

Mr. Chairman:

Thank you for allowing me to address the Subcommittee today.

I am Dr. Dave Weldon and I represent the 15th Congressional District of Florida in the House of Representatives. I am also a physician. Prior to coming to the Congress in 1994, I practiced internal medicine for 15 years both in the Army and eight years in private practice. During that time period, I had an extensive opportunity to treat many patients with a variety of conditions, which required high doses of narcotic pain relievers to manage their condition. I also experienced those who were seeking to abuse the system to secure these drugs for illicit purposes.

The patients in serious need of these drugs included terminal patients with metastatic bone cancer, which can be excruciatingly painful. It also included many patients with chronic conditions that were unmanageable by any other method other than through the use of narcotic pain relievers.

Several years ago, it was recognized by the medical community working in coordination with government officials that many patients with chronic pain and many terminal patients were being grossly undertreated with narcotic pain relievers due to fears on the part of the attending physicians over using these drugs.

These fears included: (1) the possibility of Drug Enforcement Agency (DEA) investigations of their medical license for prescribing excessive amounts of narcotics, (2) the possibility of turning patients into "narcotic addicts," and (3) the development of complications from high doses of narcotic pain relievers and the associated complications that can occur from them such as severe constipation.

Without adequate pain management, most patients are unable to engage in work, family, and community life. The severe and chronic pain they experience leaves them desperate, depressed, and unable to heal from their primary injury or condition. For terminal patients, such as those suffering from cancer, the inadequate treatment of pain reduces their already diminished quality of life.

It was in this environment that government and medical officials came together and recognized that there was a serious problem in that many of these patients were being undertreated because of unwarranted fears and concerns of practitioners. Specifically, the medical community and the government came together to recognize that narcotic pain relievers can be used in very high doses for (1) the management of terminally ill patients and (2) for extended periods of time in patients with chronic pain conditions. The

medical community also learned how to properly manage the complications of narcotic pain relievers. This is still being learned and implemented.

Following this, an extensive education program was pursued on the part of the government and health care professionals to educate prescribing physicians, particularly, in the specialty of anesthesiology and oncology.

I was involved in this entire process in my clinical practice. I saw many patients who had been undertreated moved into the new environment where they could receive the proper doses they needed so that their pain could be properly managed and they could return to a functional level in society.

Understandably, as there has been more widespread prescribing of these drugs in this new environment and those who suffer from pain have been the largest beneficiaries. There has also been a much greater tendency for some of these products to be siphoned off and used illicitly.

In the last six years of my private practice, prior to coming to Capitol Hill, I accumulated a fairly extensive group of patients that I was managing with a variety of chronic pain syndromes. Many of these patients came to my practice because other physicians in the community were not treating their pain properly and, specifically, in many instances, were under prescribing the necessary medications to provide them adequate relief. It would be most unfortunate if we were to turn the clock back on these patients causing them to suffer unnecessarily.

Give this practice experience I believe it is important that we address the problems of whereby these drugs are siphoned off for illicit purposes, but that we do so in a manner that does not harm patient care. Millions of Americans continue to suffer significant pain on a regular basis, including millions who suffer acute pain as seen with surgery or an injury and chronic pain. In our efforts to curb abuse, we should not hinder proper pain management.

One of the difficulties that I came across in my practice was determining the degree of pain a patient was suffering, or whether in deed the individual was suffering pain. If I was suspicious of the patient, I would have my medical stall call around to several area pharmacies to see if the individual was currently receiving other pain medications from other physicians. If he was, I would not prescribe medication. This was a burdensome and less precise method of checking for individuals who might be doctor shopping for illicit drugs.

While some progress has been made in addressing the barriers to effective pain management, there is still work to be done. Some patients still do not receive the proper medication. Also, some patients have fears of addiction that may make them and their families reluctant to take prescribed opioid medications. Fears of addiction and fear of regulatory scrutiny can dissuade doctors from prescribing them or pharmacists from

dispensing prescriptions for these medicines. These fears translate into untreated or undertreated pain.

Because of the reluctance to use or to prescribe appropriate pain medication, some people with chronic pain have to see several doctors or have travel to another community to find a doctor willing to fully treat their pain. We must ensure that we able to segregate out these individuals from those who are doctor and pharmacy shopping to secure these drugs for illicit purposes.

The barriers to appropriate pain management are beginning to be addressed. Health care professionals, policy makers, the public, and the media are becoming more aware of the undertreatment of pain. In 2001, the Joint Commission on Accreditation of Healthcare Organizations, the largest accrediting body in the United States, issued new standards which require all of its 19,000 hospitals, nursing homes, and other health care facilities to assess and treat pain, and inform patients about their right to effective pain care. If a facility does not meet these standards, they may lose their accreditation.

Many states have adopted guidelines for the use of opioids to treat pain. Professional societies have created guidelines for pain treatment and many have endorsed the Federation of State Medical Boards guidelines.

Despite these encouraging moves, many patients do not have their pain completely managed. One of the reasons for this is our society's very real concern about drug abuse.

Drug Abuse

Unfortunately, in addition to their benefits to patients suffering with pain, opioid drugs can and are abused. For that reason, their use is controlled by the Drug Enforcement Administration. Federal government surveys, such as the National Survey on Drug Use and Health, continue to demonstrate that the abuse of prescription medications of all types, but especially opioid pain medicines, is on the rise.

Abuse of and addiction to drugs is a serious concern to all Americans. Despite laws and regulations, drug abusers, and the criminals who supply them, attempt to fraudulently obtain these medicines. The source of these legitimate medicines for illicit purposes comes mostly from illegal diversion by people who abuse them or traffic in them, not from patients appropriately using drugs prescribed for them by their physician to control their pain. Criminal traffickers and abusers will pose as patients, sometimes with bogus medical records, to obtain these medicines from well-intentioned physicians. They will also alter or forge prescriptions; they may steal them in transit from legitimate suppliers; they may rob pharmacies or patients; they may get jobs as pharmacy assistants, in hospitals or in nursing homes to gain access to these drugs.

Thus, we are left with a perplexing dilemma. How do we, as a nation, ensure that patients with legitimate medical need have access to these medicines, while minimizing

the diversion and abuse of these medications with their attendant societal and economic costs?

There are no easy solutions to this dilemma. Yet, we must address this two-edged sword of benefit from legitimately prescribed opioids and harm that results from their abuse. Only by working together can we hope to arrive at that critical balance between appropriate medical use and abuse of these medicines. What we need is for healthcare professionals, law enforcement officials, regulators, legislators, the media, the pharmaceutical industry, patients, their families, community groups and educators to become aware of the need to fully treat pain and the problem of drug abuse; to stress the appropriate use of pain medications, while also stressing that prescription drug abuse is a serious problem; to learn how to keep drugs available to people who would suffer needlessly for lack of access while keeping them out of the hands of people who may abuse them.

As we seek to address this issue in the Congress we must weigh all of these factors. I commend you for having this hearing and look forward to working with you ensure that we fully address these issues.

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U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

May 24, 2004

The Honorable Mark Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions posed to Mr. Thomas W. Raffanello, Special Agent in Charge of the Miami Division of the Drug Enforcement Administration, following Mr. Raffenello's appearance before the Subcommittee on February 9, 2004. The subject of the hearing was: "To Do No Harm: Strategies For Preventing Prescription Drug Abuse."

We hope that you will find this information helpful. If we may be of additional assistance, we trust that you will not hesitate to call upon us.

Sincerely,

William E. Moschella
Assistant Attorney General

Enclosure

cc: The Honorable Elijah Cummings
Ranking Minority Member

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY & HUMAN RESOURCES

"TO DO NO HARM: STRATEGIES FOR PREVENTING PRESCRIPTION DRUG ABUSE"

FEBRUARY 9, 2004

FOLLOW-UP QUESTIONS FOR THE RECORD FOR
MR. THOMAS W. RAFFANELLO
SPECIAL AGENT IN CHARGE, MIAMI DIVISION
DRUG ENFORCEMENT ADMINISTRATION

1. During the hearing you testified that the laws against illegal distribution of controlled substances over the Internet are very vague. What changes in the current federal laws would DEA like to see made? What new steps can Congress take to assist your law enforcement efforts to combat the illegal distribution and use of prescription drugs?

DEA is moving aggressively to enforce existing prohibitions against the illegal dispensation of controlled substances. At the same time, DEA and the Justice Department have been reviewing Federal law to determine whether changes need to be made. We look forward to working with the Congress on this issue.

2. From newspaper reports discussed at the hearing, it is clear that a relatively small number of doctors are prescribing very large amounts of oxycodone and other controlled substances in Florida. This information was based on data maintained by the Medicare/Medicaid system. Does the DEA monitor Medicare/Medicaid information and if so, how? How is this information used for law enforcement purposes?

Although the DEA does not monitor Medicare or Medicaid databases, information is routinely exchanged among the agencies. In Florida for example, DEA Special Agents and Investigators exchanged case related information directly with the Medicaid Fraud Control Unit.

3. What other kinds of information does DEA keep track of in its efforts to stop illegal diversion of prescription drugs? What factors go into a decision by DEA to open investigations into illegal use or distribution of prescription drugs?

The DEA monitors emerging drug trends through the Automation of Reports & Consolidated Orders System (ARCOS), an electronic reporting system for all manufacturers and distributors of Schedule II and Schedule III narcotic controlled substances. DEA is able to analyze the reported transactions and determine unusual purchasing patterns. DEA investigations focus on large scale trafficking organizations of pharmaceutical controlled substances that have a significant international, national, or regional impact.

4. Does the number of conditions for which a drug is approved by the US Food and Drug Administration impact the illegal use of the drug? In other words, if the number of approved uses increases, does that increase the potential for the drug to be diverted or misused? Should drugs like OxyContin be approved for use in treating moderate or even lesser levels of pain? Does the number of conditions for which a drug is approved by the FDA impact the illegal use of drugs?

The more approved uses there are for a particular drug results in more prescriptions written, which often equates to a higher frequency of diversion. For example, stocks in pharmacies are larger so robberies will cull a greater amount of a particular drug to be used illicitly. High-dose, single entity products like OxyContin® are ideal for patients who are or become opiate tolerant and need 24-hour coverage for an extended period of time for severe pain management. For moderate pain, other immediate release products will alleviate the pain. High-dose products are highly desirable for use as a heroin substitute by narcotic addicts. As has been publicly stated in the past, the DEA believes OxyContin® should only be used for severe pain management.

5. On February 15, 2004, the Washington Post reported that "top officials" at DEA were working to reclassify hydrocodone combination products (i.e., drugs that are made up of hydrocodone and another medicine, as opposed to pure hydrocodone) as Schedule II drugs). What is the status of this reclassification effort? What potential impact would it have on DEA's ability to combat the diversion and abuse of these drugs?

The DEA has received a petition to reschedule hydrocodone combination products, such as Vicodin® and Lortab® from Schedule III to Schedule II of the CSA. We are currently in the initial phase of gathering available data to be forwarded to the Department of Health and Human Services for review. We do not anticipate imminent action to reschedule hydrocodone products. Schedule II controls would prohibit prescription refills, eliminate call-in prescriptions, and provide greater security and oversight of these drugs. It also would put doctors on notice that these products have been extensively abused and more careful prescribing is needed.

6. During the hearing, the Subcommittee discussed several proposals for the creation of a database or databases to monitor the distribution and prescription of controlled substances. What form should such a database take, and who should create and maintain it? Should a single federal database be created? Or should each state create its own database? If the latter, how would we ensure that they would be linked and capable of sharing information with each other?

The Prescription Monitoring Programs (PMPs) offer the best approach to monitoring prescription use and abuse. Federal funding has been available for the states to initiate and improve PMPs through a grant program known as the Harold Rogers Prescription Drug Monitoring Program. Since fiscal year 2002, Congress has appropriated $16.5 million to the Department of Justice for PMPs. Twenty-two states, representing approximately 50 percent of the practitioners and

pharmacists registered with the DEA, currently operate PMPs.

A state by state approach to developing these programs provides the states with a high degree of flexibility in the design and implementation of the programs. The DEA and the National Association of State Controlled Substance Agencies are coordinating their approaches in order to capture basic data from each PMP in an effort to develop procedures for State officials to identify and track questionable substances between states.

7. Approximately what percentage of DEA's time and resources is expended in connection with illegal distribution of prescription drugs? How does that compare to the agency's efforts with respect to illegal drugs such as marijuana, cocaine and heroin?

Last year, the DEA expended 5.4% of its total work hours in connection with the illegal distribution and use of prescription drugs and 83.6% of total work hours combating illegal opiates, cocaine, cannabis, and other dangerous drugs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

APR 26 2004

Dear Mr. Chairman:

Thank you for the letter of March 4, 2004, following up on the testimony of Dr. Robert J. Meyer, Director of the Office of Drug Evaluation II at the Food and Drug Administration's (FDA or the Agency) Center for Drug Evaluation and Research (CDER), delivered on February 9, 2004, before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. Below are your questions followed by our response.

1. **What legal changes would need to be made to give FDA greater authority to regulate how prescription drugs are prescribed and used after they are given initial approval? What additional changes in the current Federal laws would FDA like to see made? What new steps can Congress take to assist your regulatory efforts to combat the illegal distribution and misuse of prescription drugs?**

   The Administration has not determined at this time whether to propose legislation to give FDA greater authority to regulate how prescription drugs are prescribed and used after they are given initial approval. However, FDA would work with Congress if it decided to consider such legislation.

   FDA's primary responsibility is to ensure that marketed drugs are safe and effective for their labeled indications. When used correctly, prescription drugs, including opioids, play a very important role in the management of pain and illness. FDA does not regulate the practice of medicine. Medical practitioners can prescribe medications to their patients for on and off-label indications. Primary responsibility in preventing the illegal distribution of prescription drugs resides with State Medical Boards, which license medical practitioners, and State Boards of Pharmacy, which license pharmacists. FDA does, however, take seriously its role in approving drug labels for prescription drugs to ensure that proper instructions and warnings are available to educate the consumer on the correct use of a particular medication. In addition, the Drug Enforcement Agency (DEA) is the primary Federal agency charged with criminal enforcement for drug abuse. FDA recently partnered with DEA and the White House Office of National Drug Control Policy to carry out a coordinated drug strategy to confront the illegal diversion and abuse of prescription drugs. The

National Drug Control Strategy brings the efforts of FDA, Federal substance abuse prevention and treatment agencies, and law enforcement to bear on the factors contributing to rising prescription drug abuse.

2. **Does the number of conditions for which a drug is approved by FDA impact the illegal use of the drug? In other words, if the number of approved uses increases, does that increase the potential for the drug to be diverted or misused? Should drugs like OxyContin be approved for use in treating "moderate" or even lesser levels of pain?**

At the September 9 and 10, 2003, Advisory Committee meeting on issues of risk management for the controlled-release opiate drug products, witnesses presented testimony that suggests there is a correlation between how widely a drug is used and the potential for abuse and misuse of that drug.[1] The witnesses suggested that if a drug is very commonly prescribed and commonly used in many settings, it has a higher likelihood of abuse as a result of its wide use. There is not, however, a clear, close relationship between the number of approved uses for a drug and its level of distribution and usage in the community. Drugs with only a single indication may have very widespread use if that single indication is quite common (for example, a new statin drug for hypercholesterolemia may be widely used, due to the prevalence of the condition in the population). On the other hand, a drug that is indicated for treatment of a number of uncommon conditions (for example, rifampin, an antibiotic approved for treatment of tuberculosis and a number of other uncommon infections) may have quite limited usage. Pain is a very common condition in our society, affecting millions of patients, and the extent of use of a drug is driven by many factors beyond indications. The indication for OxyContin is for "the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time." This indication not only bounds the appropriate severity of pain that a patient should have, but also sets other important parameters for the indicated use. For example, OxyContin is not appropriate, by this indication, for "as needed" use nor for short-term use, like after minor trauma or a dental extraction.

FDA approved OxyContin for "moderate to severe" pain rather than just "severe" pain for several reasons. First, pain is not monotonic, and even in patients with chronic painful conditions, their pain tends to wax and wane. Patients with chronic pain may rate their pain as severe one day and only have more moderate levels on another. Further, it is clear from a number of scientific studies that if one looks at significant functional impairment as a threshold for defining significant pain (which is a subjective assessment), many patients with such dysfunction will only rate their pain as moderate or moderately severe, rather than severe. Therefore, patients with pain that importantly limits their daily activities may only rate their pain subjectively as moderate or moderately severe. The question of whether OxyContin and other potent opiates should be limited to severe pain only was posed to the Advisory Committee in the September 2003 meeting. The committee strongly recommended that FDA maintain the indication to include moderate pain. Misuse and abuse of a drug is not driven by FDA's approved indication. However, legitimate use in practice may be

[1] September 2003 Advisory Committee Transcript -- DEA's Role in Risk Management of Opiate Analgesics: Terrance Woodworth, M.S.
http://www.fda.gov/ohrms/dockets/ac/03/transcripts/3978T1.htm

restricted (when formularies or practice guidelines require following labeled indications), thus negatively affecting the legitimate use of OxyContin.

3. **How does FDA determine what the approved dosage or dosages of a prescription drug will be? How does FDA determine what uses will be approved for a drug?**

   In general, the approved doses for a drug and the approved uses (or indications) are determined by substantial evidence from clinical trials, as called for under the Federal Food, Drug, and Cosmetics Act. For opiates, one needs to determine the lowest effective doses (to help define an appropriate starting dose for the particular drug in question) as well as examine higher doses, since pain intensity and patient's pharmacodynamic responses (that is, responses to a therapy at any given dose) will vary. A further consideration for opiates is that some degree of tolerance is common with chronic use, so that patients may need higher doses over time to maintain satisfactory pain control. Therefore, a range of doses is commonly approved for opiate drug products, such as OxyContin.

   As above, the uses or indications for a drug are generally derived from the substantial data provided in clinical trials. For well-established drug classes, including the opiates, prior data from other clinical trials of like or similar drugs and data from the scientific literature may also inform the indications given, so that for a particular drug, the uses approved may not be strictly dictated by the clinical studies done to approve the drug. In the case of products like OxyContin the approved uses were informed both by the clinical studies provided by the sponsor as well as what was otherwise known about the use of opiates in the treatment of chronic pain.

4. **On February 15, 2004, the Washington Post reported that "top officials" at the Drug Enforcement Administration were working to reclassify hydrocodone combination products (i.e. drugs that are made up of hydrocodone and another medicine, as opposed to pure hydrocodone) as Schedule II drugs. Would FDA support such a change? Why or why not? Has the abuse of hydrocodone been a significant problem?**

   As of April 13, 2004, FDA's CDER has not received a petition or an official request from DEA to conduct a medical and scientific recommendation to place hydrocodone combination products under Schedule II of the Controlled Substance Act (CSA). Since we have not seen the petition referred to, the basis for DEA's position is unknown to FDA. The determination to impose additional or more stringent controls upon a particular class of drug products, as publicly proposed by DEA, requires thorough evaluation of the full impact upon patients, the public, the medical community, and manufacturers.

   Drug scheduling recommendations are made by the Assistant Secretary of the Department of Health and Human Services (DHHS) after full scientific and medical evaluation of proposed scheduling actions by FDA and DHHS, and often following extensive interagency deliberations and meetings. Hydrocodone is already controlled

under Schedule II, the most stringent level of control for an approved drug. Only combinations of hydrocodone with acetaminophen or aspirin, containing less than 15 mg of hydrocodone are in Schedule III.

Prescription drug abuse and misuse are significant public health problems. FDA is serious about confronting these health problems through the coordinated Federal effort outlined in the National Drug Control Strategy. In particular, FDA's CDER shares the concerns of the Substance Abuse and Mental Health Services Administration (SAMHSA) and other Federal agencies about the increased abuse of opioid analgesic medications by adolescents as well as by adults. In HHS databases such as SAMHSA's DAWN, the frequency of emergency room mentions for hydrocodone analgesic combination product misuse/ abuse appears high. However, these very effective, safe Schedule III analgesics are the most commonly prescribed (opioid prescription) analgesics for acute dental, surgical, and perioperative pain as well as for other chronic medical conditions. The combination hydrocodone products are recommended by the WHO Analgesic Ladder and in other pain management guidelines when non-steroidal and over-the-counter medications have proved inadequate to manage pain, and prior to treatment with the higher potency, higher risk, single entity Schedule II opioid analgesics such as morphine, oxycodone, or hydromorphone. When rates of abuse and misuse for hydrocodone-emergency room related mentions are adjusted for the number of retail prescriptions (that is their frequency of use), the rates of abuse and misuse for this class are significantly lower than for oxycodone (Schedule II) analgesics and have remained relatively constant for the last five years. Nevertheless, as previously stated, a recommendation for initial scheduling or rescheduling of a drug requires the evaluation of all the information available at the time of the request.

The determination to impose or not impose stringent controls on a substance or drug is based upon a comprehensive, consistent and uniform evaluation of medical and scientific factors.

Pursuant to Title 21, United States Code (U.S.C.) 811(b) of the CSA, the Secretary of the DHHS is required to consider in a scientific and medical evaluation eight factors determinative of control under the CSA. The eight factors are listed below:

A. The drug's actual or relative potential for abuse;
B. Scientific evidence of the drug's pharmacological effects;
C. Scientific knowledge about the drug or substance in general;
D. History and current patterns of abuse;
E. The scope, duration and significance of abuse;
F. The risk (if any) to the public health;
G. The drug's psychic or physiologic dependence liability; and
H. Whether the substance is an immediate precursor of a substance that is already controlled.

Following consideration of the eight factors, the Secretary must make three findings to recommend scheduling of a substance under any of the Schedules of the CSA. To place a substance into Schedule II of the CSA, the substance needs to meet the criteria set forth in 21 U.S.C. 812(b)(2), as follows:

A. The drug or other substance has a high potential for abuse;
B. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and
C. Abuse of the drug or other substances may lead to severe psychological or physical dependence.

5. **During the hearing, the Subcommittee discussed several proposals for the creation of a database or databases to monitor the distribution and prescription of controlled substances. What form should such a database take, and who should create and maintain it? Should a single federal database be created? Or should each state create its own database? If the latter, how would we ensure that they would be linked and capable of sharing information with each other?**

   Any database to monitor the distribution and prescription of controlled substances would fall under the jurisdiction of DEA. Because DEA is the lead Federal agency in enforcing the CSA, FDA would defer to DEA in determining the most appropriate architecture of such a database.

Thank you for having provided FDA the opportunity of testifying before the Subcommittee. If there are further questions, please let us know.

Sincerely,

for Amit K. Sachdev
Associate Commissioner
for Legislation

BROWN UNIVERSITY Division of Biology and Medicine
DEPARTMENT OF COMMUNITY HEALTH

Testimony of David Egilman, M.D. MPH

House Committee on Government Reform

Subcommittee on Criminal Justice, Drug Policy and Human Resources

February 9th, 2004

Orlando, FL

Chairman Souder and Members of the Committee, my name is David Egilman.

I am a medical doctor and Clinical Associate Professor of Community Medicine at Brown University. I am board certified in Internal Medicine and Preventive-Occupational Medicine. My curriculum vita sets forth more fully my qualifications.

I received a Bachelor of Science from Brown University in Molecular Biology in 1974. I received a medical degree from Brown University in 1978. I completed a three-year medical residency in Internal Medicine at Strong Memorial Hospital in Rochester, New York, in 1981. I completed a three-year training program in epidemiology, called the National Institutes of Health Epidemiology Training Program, in 1984. As part of this program, I completed a Master's in Public Health at the Harvard School of Public Health. At Harvard, I studied epidemiology, statistics and occupational medicine, industrial hygiene, warnings and occupational and environmental law. I completed a third residency in preventive medicine in 1994. I served two years at the National Institute for Occupational Safety & Health (NIOSH), designing and

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conducting small and large epidemiologic studies.

Since 1978, I have published a variety of letters and medical articles on the issues that relate to the manner in which cause-effect determinations are made in medicine (the epistemology of medicine). I have discussed the normal, accepted process of causal determination in medicine in several peer-reviewed articles. In addition, I presented these ideas at the American Public Health Association (APHA) meetings in 1984. I have also studied, taught, and published articles on the history of medical ethics and the duty to warn. I have taught and conducted research on the history of the development of medical and corporate ethics during the 20th century. I have on two occasions testified before congressional committees on the issue of medical ethics, warnings and corporate responsibility. In addition, I have published two papers on the topic of the history of the development of medical ethics.

For the past nine years, I have taught a course at Brown University called "The Development of Medical and Scientific Knowledge in the 20th Century." This course deals specifically with issues pertinent to OxyContin addiction and abuse: the history of the development of knowledge of the health effects of various substances including corporate knowledge, the history of the development of government regulations including the Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA), and the history of the development of product warnings. My views on medical epistemology have been cited by the Massachusetts Supreme Court and been adopted by the Wyoming Supreme Court. I have also published on these topics. I served as guest faculty at the Appellate Judges Seminar Series on issues related to medical epistemology and the *Daubert* decision. I have testified on the issues discussed in this report in over 100 cases over the past 19 years. I have also testified twice before Congressional

subcommittees.

I have reviewed the history of warnings from the published literature, and from internal corporate documents and organizational documents. I presented a paper at the 2000 Annual Conference of APHA on warnings. I teach about warnings at Brown University, including FDA drug-related warnings. I testified before Congress on the history and development of informed consent as well as current informed consent practices. I have been accepted as an expert by the court in *Keenan v. Parke-Davis et al.*, PC 84-1667 (Rhode Island), on the issue of drug warnings. I have reviewed corporate documents specifically having to do with warning practices throughout this century. I have studied the efficacy of warnings. I served as a consultant to Federal-Mogul Corporation on issues related to warnings.

OxyContin is a Schedule II narcotic which was approved by the Food and Drug Administration in 1995. The active ingredient in OxyContin is oxycodone, which is a synthetic, morphine-like substance. The drug was originally marketed for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days, like cancer pain. In this testimony, I will address the following four main points:

1. Purdue implemented a **marketing strategy** to undermine patient and physicians appropriate reservations of abuse, diversion, addiction and death by overdose of OxyContin.
2. Purdue implemented a **labeling strategy** to downplay addiction risk in the patient package inserts and in materials prepared for distribution for patients given to healthcare providers and patients.
3. Purdue misrepresented Oxycontin's effective dosing schedule. They claimed that OxyContin worked for 12 hours: it didn't and doesn't.

4. Patients can and do become addicted from taking drugs that were prescribed by physicians.

1.Purdue implemented a marketing strategy to undermine patient and physicians appropriate reservations of abuse, diversion, addiction and death by overdose of OxyContin.

Purdue Pharma has aggressively marketed OxyContin through an advertising campaign that misled health providers and the public about the dangers of OxyContin. . Physicians often have a reluctance to use opioids because of the well-founded fear that patients could become addicted. In order to overcome doctors' correct understanding of the risk of addition to opioids, Purdue Pharma developed the marketing piece "Myths about Opioids." Ironically and tragically, rather than dispelling a myth, Purdue created one.

Purdue labels a myth the statement that "Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids."[1] As a practicing physician who had an active primary care practice, Purdue's information on OxyContin, as provided in the *Physicians Desk Reference,* gave me the impression that in general, patients would not become addicted to OxyContin if it were prescribed to them for pain. Unfortunately, I first became aware of the serious problems associated with OxyContin use through experiences with my patients. These real-life experiences contradicted the promising scenario Purdue provided in its marketing materials and "warnings." My patient experience revealed that addiction was a serious consequence of the prescription of OxyContin for pain. After this experience, I was shocked when I found Purdue's "Pain Management Prescribing Guide" at the family practice hospital where I teach. Instead of having the print emphasize the

dangers of addiction, the book placed the most emphasis on the side effects of constipation.

2. Purdue implemented a labeling strategy to downplay addiction risk in the patient package inserts and in materials prepared for distribution for patients given to healthcare providers and patients.

A review of the product labeling for OxyContin from 1997 to 2001 underscores Purdue's failure to warn adequately regarding abuse or addiction. The major inadequacies of the labels include omissions of pertinent information and misrepresentations about the characteristics of OxyContin. I provide some examples below.

Omissions:

a. Purdue failed to warn about the risk of addiction in the label's "Warning" or "Precautions" and "Information for Patients/Caregivers" sections;[2,3,4,5,6]

b. Purdue failed to include "prior drug addiction" under the "Contraindications section" for the use of OxyContin. In a section titled "Use in Drug Abuse and Addiction," the label read "[OxyContin] has no approved use for the management of addictive disorders,"[7]

c. Purdue failed to list any of the symptoms of opioid withdrawal;[8]

Misrepresentations:

d. Purdue told physicians that "delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."[9] This assumption is unsupported by any study. In fact, while it is true that OxyContin has a slower release component, OxyContin also has a fast release component. Therefore, if

the speed of absorption affects the addiction potential, then OxyContin's fast release component would presumably increase the risk of addiction.[10]

e. Purdue stated that "tolerance and physical dependence in pain patients are not signs of psychological dependence."[11] This is not true. Tolerance and physical dependence to a drug are typical, hallmark, diagnostic symptoms of substance dependence. *The Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) describes the criteria for substance dependence which include both tolerance and withdrawal. "Criteria for Substance dependence: (1) Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of the substance. (2) withdrawal, as manifested by either of the following: (a) the characteristic withdrawal syndrome for the substance (b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms."[12]

The inadequacy of the OxyContin warning label is further underscored when it is compared to other addictive oral controlled-release opioid analgesics containing morphine sulfate. MS Contin (Purdue Frederick) and OraMorph SR (Roxanne) are marketed as controlled-release 12-hour pain control products like OxyContin, and are Schedule II drugs with the same abuse liability as OxyContin. Unlike the OxyContin label, the labels for MS Contin and OraMorph SR state that the product may cause addiction upon repeated use. The MS Contin label states that "psychological and physical dependence may develop upon repeated administration."[13] The OxyContin label does not address issues related to psychological and physical dependence. The MS Contin and OxyContin labels are strikingly different, even though

Purdue authored both labels and should have known that both medications carried similar risks of addiction.

The OraMorph SR (Roxanne) label acknowledges the addiction risk even more clearly: "Morphine is the most commonly cited prototype for a narcotic substance that possesses an addiction-forming or addiction-sustaining liability. A patient may be at risk for developing dependence to morphine if used improperly or for overly long periods of time."[14] Unlike the OraMorph label, OxyContin fails to alert physicians that, "Individuals with a history of opioid or other substance abuse or dependence, being more apt to respond to euphorogenic and reinforcing properties of morphine, would be considered to be at greater risk." Also, unlike the OxyContin label, the OraMorph SR label does not weaken its statements regarding addictive potential by citing the product's "delayed absorption" characteristics or by proclaiming that "reports" of addiction are "rare."

Purdue claimed that reports of addiction were rare before the drug was sold without performing any tests for addiction in its pre-market trials. The studies Purdue claimed proved low addiction incidence did not actually prove this point. Obviously, reports of addiction to OxyContin could not exist before the drug even hit the market. In fact soon after Purdue marketed the drug, reports of addiction became all too common. They were so common that local newspapers began to report this problem in 1999. A search of LexisNexis revealed hundreds of press reports by 2001. There was not a comparable number of press reports for either MS Contin or OraMorph SR. In comparison to OxyContin, reports of addiction from other comparable drugs were "rare." See attached table for further comparisons between the OxyContin, MS Contin, OraMorph and Percocet package inserts. (See attached as Exhibit 1.)

Purdue Pharma's own internal reports highlight problems with prescription drug abuse

back to 2000. In 2001, a Purdue newsletter called *@Purdue* included an article entitled, "A Busy Schedule for Dr. Haddox Produces Some Balanced Media." (See attached as Exhibit 2.) The article describes how Purdue sent one of their most prominent physicians, Dr. Haddox, to the Appalachian States, "visiting the communities most affected by the abuse and diversion of OxyContin Tablets." Over a seven month period in 2000, Dr. Haddox was on the road for 122 days dealing with "reports" of abuse of OxyContin. As a practicing physician, I would have wanted to know that one of Purdue's head doctors was traveling for 122 days dealing with issues of drug addiction related to OxyContin use. This would have allowed me to gauge the extent of the problem and to place the "rare" reports of addiction statement in perspective.

Beginning with the launch of the drug in 1996, Purdue's physician-directed promotional pieces, including advertisements, brochures, and videos, asserted that, "less than 1% of patients taking opioids actually become addicted."[15] They also asserted that the development of addiction to opioid medication is "rare," and classify as "myth" that "opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids." [16, 17] These statements are untrue, unsupported and unacceptable.

Purdue Pharma also provides information to doctors and consumers through "Partners Against Pain," which it bills as as "alliance of patients, caregivers and health care providers" but in reality represents the interests of Purdue. The Partners Against Pain's website and publications are published and copyrighted by Purdue Pharma. Purdue uses this site to misinform healthcare providers and patients about the risks of use of OxyContin. For example, a booklet available from the site, "A Guide to Your New Pain Medication and How to Become a Partner Against Pain" reassures readers that OxyContin does not present an addiction risk.[18] This booklet follows the "Frequently Asked Questions" format and askes, "Aren't opioid pain

medications like OxyContin Tablets "addicting"? Even my family is concerned about this." Purdue proffers the following answer:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

The "guide to patients" misleads patients into believing that their motivation for taking OxyContin is the sole determinant of whether they are, or will become, addicted to their pain medication. However, iatrogenic addiction is a real risk with any prescribed narcotic.

In 2001, in another question and answer section of the website Purdue declared: "When you feel pain, your pain is real… Remember: You have every right to ask [doctors and nurses] to help you relieve the pain as much as possible." This answer is self-serving and scientifically flawed. Implying that patients have a right to as much opioid as they wish minimizes the risk of addiction and perpetuates misinformation about addiction and pain perception. Medical literature shows that addiction pain and physiological pain overlap, and separating them presents unique challenges to the physician.[19] Addiction has been shown to make patients even more sensitive to pain - and thus more likely to request pain medications.[20] For example hyperalgesia, or diminished pain tolerance, is a sign of opioid withdrawal.[21] Patients who are dependent on opioid medication will sometimes undergo withdrawal symptoms that manifest as pain.[22]

Purdue has also misled patients with their pamphlet and informational video, both called, "From One Pain Patient to Another," which encouraged patients to doctor-shop to find providers who were most willing to prescribe narcotics. Purdue told patients, "Don't be afraid about the things you've heard about these drugs [opioids]," and, "..find the right doctor." One patient is quotes as saying, "I think it is very unfortunate that so many physicians are reluctant to treat

people like me, who have moderate chronic pain, with opioids."[23] Purdue undermined the conservative and cautious prescribing practices of many responsible health practitioners. This is yet another example of how Purdue actively misinformed and inadequately warned patients and physicians of the addiction risks and withdrawal symptoms associated with OxyContin.

3. Purdue misrepresented Oxycontin's effective dosing schedule. They claimed that OxyContin worked for 12 hours: it didn't and doesn't.

Purdue has centered its promotional and marketing focus for OxyContin on the every-12-hour dosing schedule. For example, when OxyContin was first introduced, Purdue stated that OxyContin offered a "significant advantage" because "unlike short-acting pain medications, which must be taken every 3 to 6 hours—often on an 'as needed basis,' OxyContin tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night." Purdue's 1998 OxyContin Budget Plan describes the importance of q12h dosing to sales: "Our marketing research indicates that the most important feature of OxyContin tablets, beyond the familiarity of oxycodone, is the q12h dosing schedule. In all seven pre-launch market research projects conducted among 626 healthcare professionals, this was the most compelling reason to prescribe the OxyContin Tablets."[24]

However, Purdue's marketing materials misrepresented the effective dose interval of OxyContin. Many OxyContin patients needed additional pain medication within the 12 hour period. This inadequacy was known to Purdue even before they started to sell the drug. One of the first clinical trials showed that "half of the patients used IR (immediate release) oxycodone rescue almost daily," revealing that the drug was not able to relieve pain for the full 12-hour dosing schedule.[25] Scientists at Purdue and other independent labs conducted a number of

clinical tests that found that OxyContin did not relieve pain for 12 hours. (Hagen and Babul, 1997, Kaplan et al, 1998.) Thus, it seems clear that Purdue has misrepresented the efficacy of its drug in an effort to distinguish it from generic drugs and thereby increase sales and profits at the expense of the healthcare and patient communities.

Purdue was well aware that for many patients OxyContin only relieved pain for 8 to 10 hours. Instead of telling the doctors to give patients three pills a day, Purdue told doctors to increase the amount of drug a patient took every 12 hours without changing the frequency of dosing, ultimately leading to a higher dose per day without solving the problem of a lapse in efficacy. In a marketing piece for doctors called, "Counseling Your Patients and Their Families Regarding the Use of Opioids to Relieve Pain," Purdue instructed doctors how to answer questions from patients who are hesitant to use opioid therapy.[26] One questions posed states, "If I develop tolerance to this drug, what's left for me to take when I <u>really</u> need pain relief?" Purdue suggests that a doctor might reply by saying, "Tolerance to opioids may occasionally occur. Usually all it takes to correct this situation is to increase the dose. Remember, opioids are not limited to a "maximum" dose as nonopioids are- an effective dose can be found for virtually any type or severity of pain."

Increasing the dose but keeping the dose frequency the same does not solve but instead compounds the problem. It makes it more likely that the patients will become addicted. When a doctor increases the dose of OxyContin that a patient is receiving, the physical dependence symptoms increase. Eventually, instead of feeling pain relieve, the patients only experience physical dependence and tolerance without getting the benefits of the drug.

4. Patients can and do become addicted from taking drugs that were prescribed by physicians

Purdue has maintained that people who take narcotics are not likely to get addicted if they obtain the narcotics by filling a legal prescription. As the Rush Limbaugh case clearly shows, there is nothing about the prescription process that reduces the addiction danger of opioid narcotics. A prescription is a piece of paper and does not affect the way the body responds to the drug. I wish it were different. I wish my prescriptions could protect my patients from becoming addicted. But unfortunately, and what Purdue denies, is that it can not. But the risk of addiction is related to a complex set of psychological and physiological characteristics that are determined by the patients. The way the patient gets the drug does not determine whether or not a patient will become addicted to the drug.

Much of the information that I base my statements on are not in the public domain but have only come to light as a result of the discovery process in lawsuits against Purdue Pharma. This is essential medical information. Purdue should stop hiding this critical scientific information from physicians and patients. This committee has the authority and the responsibility to make this information public. It should do so, so that doctors and patients can make informed decisions about the drugs that they are dispensing and taking. As Justice Brandeis so eloquently said, "sunlight is the best disinfectant."

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[1] "Dispelling Myths about Opioids," Purdue Pharma.
[2] *Physicians' Desk Reference*, OxyContin Package Insert, 51st ed. Montvale, NJ: Thompson PDR. 1997.
[3] *Physicians' Desk Reference*, OxyContin Package Insert, 52nd ed. Montvale, NJ: Thompson PDR. 1998.
[4] *Physicians' Desk Reference*, OxyContin Package Insert, 53rd ed. Montvale, NJ: Thompson PDR. 1999: 2572.
[5] *Physicians' Desk Reference*, OxyContin Package Insert, 54th ed. Montvale, NJ: Thompson PDR, 2000:2539.
[6] *Physicians' Desk Reference*, OxyContin Package Insert, 55th ed. Montvale, NJ: Thompson PDR, 2001.
[7] *Physicians' Desk Reference*, OxyContin Package Insert, 1997, 1998, 1999, 2000 and 2001.
[8] Ibid.
[9] Ibid.
[10] *Physicians' Desk Reference*, OxyContin Package Insert, 57th ed. Montvale, NJ: Thompson PDR, 2003, 2852.
[11] *Physicians' Desk Reference*, OxyContin Package Insert, 1999, 2000 and 2001.
[12] *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.* Washington, D.C.: The American Psychiatric Association, 1994: 181.
[13] *Physicians' Desk Reference*, MS Contin Package Insert, 51st ed. Montvale, NJ: Thompson PDR, 1997, pg. 2150.
[14] *Physicians' Desk Reference*, OraMorph Package Insert, 51st ed. Montvale, NJ: Thompson PDR, 1997, 2360.
[15] "Dispelling Myths about Opioids," Purdue Pharma.
[16] Ibid.
[17] "I Got My Life Back," Partners Against Pain Brochure, Purdue Pharma, 1997, 8700300165.
[18] Purdue Pharma (n.d.) "A Guide to Your New Pain Medication and How to Become a Partner Against Pain."
[19] Compton, P., and Gebhart, G.F., "The Neurophysiology of Pain in Addiction," as seen in The Principles of Addiction Medicine, American Society of Addiction Medicine, (2nd ed. 1998), at 901, 912-914.
[20] Ibid. at 912.
[21] Ibid.
[22] Dickinson, "Use of Opioids to Treat Chronic, Noncancer Pain," *West J Med* 2000; 172:107, 111.
[23] "From One Patient To Another," Purdue Pharma pamphlet and video.
[24] Purdue Pharma Budget Plan, 1998, 4-41.
[25] Citron ML, Kaplan R, Parris WC et al, Long-Term Administration of Controlled-Release Oxycodone Tablets for the Treatment of Cancer Pain, *Cancer Investigation*, 1998;16(8): 563.
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Curriculum Vitae

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EDUCATION

Brown University -1970-1974, BS, Molecular Biology, 1974, Sigma Xi
Brown University -1974-1978, MD
Harvard School of Public Health - 1981-1982, MPH.

POSTGRADUATE TRAINING

University of Rochester, Rochester, NY, Internship and residency in Internal Medicine, 1978-1981
National Institutes of Health, Epidemiology Training Program, 1981 - 1984
Carney Hospital, Boston Massachusetts, Residency in Preventive Medicine, 1992 - 1993
National Institute of Occupational Safety and Health, Residency in Occupational Medicine, 1983 - 1984

UNIFORM SERVICE

US Public Health Service, 1981-1984

PROFESSIONAL LICENSES AND BOARD CERTIFICATION

1981	Diplomat of American Board on Internal Medicine	
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	Rhode Island State Medical License	6742
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ACADEMIC APPOINTMENTS

1996 - Pres. Clinical Associate Professor, Department of Community Health, Brown University, Providence, RI.

1990 - 1996 Clinical Assistant Professor, Department of Community Health, Brown University, Providence, RI.

1985 - 1990 Clinical Instructor, Department of Community Health, Brown University, Providence, RI.

1995 - 2002 Clinical Instructor in Health Sciences, Bouve College of Pharmacy and Health Sciences, Northeastern University, Boston, Massachusetts.

HOSPITAL APPOINTMENTS

Courtesy Staff, Memorial Hospital, 1987 - Pres.

MEMBERSHIPS IN SOCIETIES

2003 - Pres. Member, American Society for Environmental History
2002 - Pres. Member, Environmental Health & Safety Council, International Facility Management Association.
1990 - Pres. Member, International Commission on Occupational Health.
1989 - Pres. Member, American Medical Association.
1988 - Pres. Member, American Public Health Association Committee on Health Based Exposure Limits to Toxic Substances.
1986 - 1989 Chairperson, Rhode Island Committee for Health Rights in Central America.
1984 - Pres. Member, American Society of Internal Medicine.
1979 - Pres. Member, American Public Health Association.
1978 - 1992 Brown Medical Association, member Board of Directors.
1992 - Pres. Member American College of Occupational and Environmental Medicine
1997 - Pres. Member Board of Directors, Citizens for Responsible Care in Research

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Egilman, D.S., Evidence of Continued Corruption of the Epidemiological Literature, APHA, November 2002.

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Egilman, D.S., Bagley, S., *The Corporate Corruption of Epidemiology:* The Asbsestos, Beryllium, Tobacco Industries and the Role of Attorneys and Public Relations Firms, IEA World Conference of Epidemiology, August 2002.

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Egilman, D.S. AIDS Behind Bars: HIV and Correctional Institutions. World AIDS Day Conference, Brown University December 2001

Egilman, D.S. Chronic Beryllium Disease and the Politics of Occupational Health, APHA, October 2001.

Egilman, D.S. Role of Insurance Companies in Industrial Health: Example of the Asbestos Tragedy, APHA, October 2001.

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Presenting the State-of-the-Art Expert in a Defense Premises Liability Case, A Trial Demonstration, Andrews Publications Asbestos Litigation Conference, May 2000.

Guest faculty, Appellate Judges Seminar Series, "Use of Expert Testimony", Portsmouth, NH, September 15,1998

Participant, Institute of Medicine, Division of Health Sciences Policy, Town Meeting on Clinical Research in the Public Interest, National Academy of Sciences, Washington, D.C. July 10-11, 1997

Egilman, D., Health Effects of Silicone Breast Implants: Corporate Misconduct, February 26, 1997

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Egilman, David: Science, Epistemology, And The Law, Guest Lecture for Toxic Torts: Professor Daynard, Northeastern University Law School, Boston, MA, July 1991.

Egilman, David: Lead and Other Environmental Hazards, Grand Rounds, Charlton Memorial Hospital, Fall River, MA, Mar. 1991.

Egilman, David: International Health Work: First Do No Harm, Family Medicine Grand Rounds, Memorial Hospital of Rhode Island, Feb. 1991.

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Egilman, David: Theories of Causation - A Comparison of the Tobacco Institute, Chemical Manufacturers and Bayesian Approaches, APHA, Nov. 1984.

Kubetz, Sheila, Egilman David: Right To Know - Use of Media to Promote Use of the Law, APHA, Nov. 1983.

Egilman, David: Right To Know - How to Use the Information, APHA, Nov. 1983.

Egilman, David: Isocyanate Exposures in Spray Painting, APHA, Nov. 1982.

UNIVERSITY TEACHING ROLES

1992 - 1994 Preceptor, Affinity Group Program, Brown University Medical School, Providence, RI.

1995 - Pres. Clinical Instructor in Health Sciences, Bouve College of Pharmacy and Health Sciences, Northeastern University, Boston, Massachusetts. Preceptor for Physicians Assistant training program.

1988 - Pres. Clinical Associate Professor, Department of Community Health, Brown University, BIO 168 Health and Politics In Latin America or The Development of Scientific Knowledge in the Twentieth Century, 1987 - Pres.; GISP Police and the Community 1998-1999;
Fall 2002 BC168 Science and Power: A Bioethical Inquiry: History of and contemporary issues in the ethics of biology and medicine, with an emphasis on corporate ethics and the history and development of informed consent and warnings.

PROGRAMS AND WORKSHOPS

2002-2003 The Philanthropy Workshop, The Rockefeller Foundation
2002 Ethical Fitness Seminar, Institute for Global Ethics

Exhibit 1
Comparison of OxyContin, MS Contin, OraMorph and Percocet Package Inserts

	OXYCONTIN 1997-2000[1]	MS CONTIN 1997-2000[2]	ORAMORPH 1997-2003[3]	PERCOCET 1997-2003[4]	OXYCONTIN 2003[5]	MS CONTIN 2003[6]
Description	1997- "Warning- May be habit forming. 10mg 20 mg 40 mg" 2000- "May be habit forming" no longer present	1997- "MS Contin 200 mg, For use in opioid tolerant patients only. Warning- May be habit forming." 2000- "May be habit forming" no longer present	"Each tablet for oral administration contains Morphine sulfate....15 mg, 30 mg, 60 mg, 100 mg (Warning: May be habit forming)	1999-2000 "Each Tablet Contains Oxycodone Hydrochloride – 5 mg, May be Habit Forming."	"80 mg and 160 mg for use in opioid tolerant patients only."	"200 mg for use in opioid tolerant patients only."
Indications and Use	"...indicated for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days."	"MS Contin is a controlled- release oral morphine formulation indicated for the relief of moderate to severe pain. It is intended for use in patients who require repeated dosing with potent opioid analgesics over more than a few days."	"OraMorph SR is indicated for the relief of pain in patients who require opioid analgesics for more than a few days."	"Percocet is indicated for the relief of moderate to moderately severe pain."	"indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time."	"MS Contin is a controlled-release oral morphine formulation indicated for the relief of moderate to severe pain. It is intended for the use in patients who require repeated dosing with potent opioid analgesics over periods of more than a few days. The MS Con 200 mg tablet strength is a high dose, controlled-release, oral morphine formulation indicated for the relief of pain in opioid-tolerant patients only."

Drug Abuse and Dependence (Addiction)	"Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug. 'Iatrogenic Addiction' to opioids legitimately used in the management of pain is very rare."	"Opioid Analgesics may cause psychological and physical dependence."	"Opioid Analgesics may cause psychological and physical dependence."	"Percocet tablets are a Schedule II controlled substance. Oxycodone can produce drug dependence and has the potential for being abused."	"OxyContin is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule II controlled substance. Oycodone, like morphine and other opioids use in analgesia, can be abused and is subject to criminal diversion."	"Opioid analgesics may cause psychological and physical dependence. "
Warnings (Drug Dependence/ Misuse Abuse and Diversion)	No warnings section	"Morphine can produce drug dependence and has a potential for being abused. Tolerance as well as psychological and physical dependence may develop upon repeated administration."	"Morphine is the most commonly cited prototype for a narcotic substance that possesses an addiction-forming or addiction-sustaining liability. A patient may be at risk for developing dependence to morphine if used improperly or for overly long periods of time."	"Oxycodone can produce drug dependence of the morphine type and therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may devlop upon repeated administration of Percocet, and should be prescribed and administered with the same degree of caution appropriate to the use of other oral opioid containing medications."	"...Concerns about abuse, addiction and diversion should not prevent the proper management of pain. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients."	"Morphine can produce drug dependence and has a potential for being abused. Tolerance as well as psychological dependence may develop upon repeated administration.... Abrupt cessation or a sudden reduction in dose after prolonged use may result in withdrawal symptoms."

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[5] *Physicians' Desk Reference*, OxyContin Package Insert, 57th ed. Montvale, NJ: Thompson PDR, 2003.
[6] *Physicians' Desk Reference*, MS Contin Package Insert, 57th ed. Montvale, NJ: Thompson PDR, 2003.

SPECIAL ISSUE ON OXYCONTIN® AND PRESCRIPTION DRUG ABUSE

@purdue

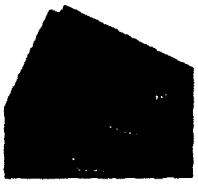
Exhibit 2

A QUARTERLY MAGAZINE FOR AND ABOUT THE PEOPLE OF PURDUE • 2ND QUARTER 2001

the road ahead

also in this issue

PURDUE



@purdue

This quarterly magazine is for and about the people of Purdue. It is a source of information and inspiration, helping to build a sense of community and connection throughout our organization. This constructs also appears on Purdue's intranet website.

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Michael Friedman on Protecting Patient Access to OxyContin

I was as surprised as any of you when OxyContin® Tablets began to garner negative media attention last fall. Our prescription analgesics, while extremely successful with physicians and those patients who need them most, have not been household names. I believe that those who did know our products knew of them for the benefit they bring to patients.

All that changed when the print and broadcast media reported that drug abusers had discovered that OxyContin could be misused to produce a very potent "high." Apparently, by crushing the tablets, abusers of the drug could compromise the controlled-release delivery system, allowing 12 hours of medication to be snorted or injected for maximum rapid effect. The media reports that the medication has now become a street drug for some addicts, especially in certain areas along the spine of the Appalachian Mountains. This came a a shock, because we had experienced almost no abuse and diversion in our 16 years of marketing MS Contin® Tablets. As law enforcement officials throughout the affected regions of the country began making arrests in connection with the criminal abuse and diversion of OxyContin, the media got hold of the story — and OxyContin was catapulted into the spotlight.

We are deeply concerned about the abuse of our drug. We are also deeply concerned that sensationalized reports of criminal acts of some may endanger access to proper and effective pain management for those patients who rely on OxyContin to treat their pain. We have undertaken a number of initiatives to deal with these issues. Howard Udell, *Executive VP and General Counsel; Dr. David Haddox, Senior Medical Director, Health Policy; Robin Hogen,* Executive Director, Public Affairs, and I have spent much of the last eight *months* meeting with law enforcement authorities, regulatory agencies, other governmental officials, and the media. Many others throughout our organization have also been working with and educating law enforcement and healthcare providers about the need for our products and about the responsible use of opioid analgesics, so that authorities and health professionals can cooperate in the effort to prevent criminal misuse of this important medication.

"We will not allow our patients to become the innocent victims in this struggle."

We have prepared this special issue of *@Purdue* to share with you some of what your company is doing to deal with diversion and the problems this is creating for patients, physicians, and the company. Our initiatives are guided by our fundamental commitment to relieving the chronic pain of our patients, whose interests are being endangered by drug abusers and diverters. We will not allow our patients to become the innocent victims in this struggle. It is distressing for all of us to see Purdue's good name in sensational news headlines. At the end of the day, I am convinced that the combined efforts of authorities, health professionals and all of us at Purdue will ensure that the legitimate therapeutic benefits of OxyContin realized by our many patients are not jeopardized by the criminal conduct of others.

Michael Friedman
Executive Vice President and
Chief Operating Officer

Frequently Asked Questions

Many recent articles have contained troubling misinformation about OxyContin®. We have been working hard to correct this misinformation, and hope you will find the answers to these frequently asked questions helpful in understanding this complicated public health issue.

Q: Why didn't Purdue anticipate the current outbreak of abuse and diversion of OxyContin® Tablets, and respond to it more rapidly?

A: Purdue has been working aggressively to address the abuse and diversion problem ever since it was first brought to the company's attention last year. Our 16 years of experience with the marketing of MS Contin® Tablets, another Schedule II controlled-release analgesic, gave Purdue no reason to anticipate that the patterns of diversion would appear to be so different with OxyContin Tablets.

We have been praised by the U.S. Attorneys in Maine and Kentucky, the Attorneys General of Virginia and Maryland, and other knowledgeable law enforcement officials for taking a highly responsible approach to prescription drug abuse. At a press conference in Richmond on March 1, 2001, the Attorney General of Virginia said that Purdue is to be complimented for "jumping into this situation with both feet" to work on a solution "as soon as it learned of the problem."

Q: Has Purdue been questioned by the Drug Enforcement Administration (DEA) regarding its marketing practices?

A: We have met with the Food and Drug Administration (FDA) and the DEA, at our own request, to discuss our education and prevention programs that address the abuse and diversion problem, and to seek their counsel and cooperation in those efforts. At a recent meeting with the DEA, we welcomed the opportunity to explain how we market OxyContin Tablets and our efforts to ensure that promotion is proper and within approved labeling guidelines.

We have reached an understanding with the DEA on three important points: (1) that OxyContin should only be prescribed to patients where use of an opioid is appropriate for moderate to severe pain lasting more than a few days; (2) that OxyContin should only be prescribed by physicians who are knowledgeable about the use of opioids in the treatment of pain; and that (3) none of the efforts to reduce abuse and diversion should interfere with the ability of patients in pain to receive OxyContin Tablets for appropriate medical uses.

Despite press reports to the contrary, DEA has assured us that it is not their intention to change the approved indication for OxyContin or limit prescribing of the medication to a small group of pain specialists. Purdue's efforts to reduce the illegal diversion of OxyContin complement DEA's own program, and we continue to work together to support our common objective: to stem the illegal abuse of OxyContin while ensuring that the medication remains available to the many legitimate patients who rely on it.

Q: Have Purdue's marketing practices contributed to the abuse and diversion of OxyContin?

A: No. Our marketing practices are conservative, responsible, and in rigorous conformance with the FDA-approved labeling of this drug. Ever since 1984, when the company introduced our first opioid analgesic, MS Contin, Purdue has been a leading advocate for responsible pain management. Few U.S. medical schools currently offer courses in pain management, and we have worked to supplement the education of more than 1 million healthcare professionals in this complex science, which involves multiple disciplines such as pharmacology, neurophysiology, and neurology. The company conducts numerous medical education seminars, symposia, and outreach efforts each year on appropriate pain management. We neither use direct-to-consumer advertising nor provide analgesic product samples.

continued on page 11

"It is important for healthcare professionals to learn how to minimize the misuse, abuse, and diversion of opioids so that these effective medications will remain a useful and significant part of the management of pain. Purdue has a strong, long-standing commitment to this education. Our Medical Education Department remains dedicated to improving patient care and quality of life through programs conducted at the national, regional, state, as well as international levels."

— Christopher Neumann, PharmD, Senior Director, Medical Education

Purdue Pharma's 10-Point Plan to Reduce Prescription Drug Abuse and Diversion

Without Compromising Patient Access to Proper Pain Control

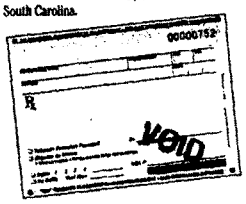
"Dealing with the abuse and diversion of OxyContin has been one of the most complex challenges of my career. The sales force is on the front line of this struggle. Fortunately, thanks to the cooperation and effort within Purdue, we have been focused on helping patients and healthcare providers during this time. I am certain that the dedication and cooperation displayed by Purdue during the past year will enable us to overcome the challenge of OxyContin abuse."

- Jim Lang, VP, Sales

Prescription drug abuse is an important public health problem in the United States. It affects some 4 million Americans – more than those who abuse cocaine and heroin combined. Purdue has created a multifaceted prevention and education program to help reduce prescription drug abuse. Our 10-point plan includes the following initiatives:

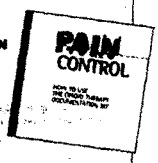
1 CONTINUING MEDICAL EDUCATION PROGRAMS are being provided by Purdue in those regions of the U.S. that have been most affected by prescription pain medication abuse. These high-quality, non-promotional educational programs — which were implemented as soon as Purdue became aware of the problem — teach healthcare professionals how to manage real pain and to reduce the diversion of prescription drugs by abusers.

2 TAMPER-RESISTANT PRESCRIPTION PADS are being offered by Purdue to physicians at no cost in regions with the highest reported incidence of prescription drug abuse. To date, these pads have been distributed to physicians in Maine, Virginia, West Virginia, Tennessee, Alabama, Ohio, Pennsylvania, and Florida. They will soon be rolled out in Delaware, Washington, Missouri, Alaska, Mississippi, North Carolina, and South Carolina.

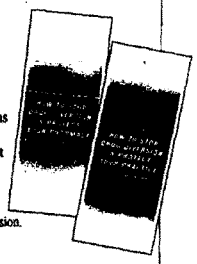


3 DRUG ABUSE PREVENTION AND EDUCATION PROGRAMS FOR MIDDLE SCHOOL STUDENTS are being created by Purdue to combat prescription drug abuse at the age when many kids start experimenting with drugs and alcohol. The company is working with the Community Anti-Drug Coalitions of America and other organizations to educate parents, teachers, and students about the social and emotional consequences of prescription drug abuse as well as its physical risks.

4 OPIOID DOCUMENTATION KITS are being offered to help physicians assess pain properly and to distinguish between legitimate patients with pain and abusers who pretend to be in pain.



5 ABUSE AND DIVERSION BROCHURES have been mailed to nearly 500,000 physicians and more than 60,000 pharmacists throughout the country, providing valuable information about preventing prescription drug diversion.



6 A MAJOR STUDY OF PRESCRIPTION MONITORING PROGRAMS is being underwritten by Purdue. Working with the health care and law enforcement communities, the study will seek to develop a model prescription monitoring program that would prevent "doctor shopping" by drug abusers and allow legitimate patients to receive appropriate prescription medicines.

7 **EDUCATIONAL PROGRAMS WITH THE LAW ENFORCEMENT COMMUNITY,** including the National Association of Drug Diversion Investigators (NADDI), several State Attorneys General, and the National Association of State Controlled Substance Authorities (NASCSA), have been developed to better understand the undertreatment of pain and to combat prescription drug abuse.

8 **RESEARCH** on the prevalence and root cause of the abuse of specific prescription drugs is being collected by Purdue-sponsored researchers so that more effective prevention programs can be developed and evaluated.

9 **CROSS-BORDER SMUGGLING** is being addressed, in cooperation with the DEA, to prevent our products from being smuggled into the U.S. from Mexico and Canada. Tablets sold in Canada and Mexico will have unique markings to enable law enforcement to identify where the product was dispensed.

10 **ABUSE-RESISTANT MEDICINES** are the number one priority in our research labs. Purdue is spending tens of millions of dollars to test and to develop new forms of pain relievers that would be resistant to abuse while providing legitimate patients with safe and effective pain relief.

Solving the public health problem of prescription drug abuse will require the cooperation of many elements of our society – law enforcement, schools, parents, religious organizations, healthcare providers, social service agencies, regulatory bodies, and the pharmaceutical industry. Purdue is taking the lead within our industry in addressing this critical social problem because we believe it is the right thing to do.

Looking ahead, we are working to identify geographic areas where drug abuse might spread. Based on this analysis, we will intensify our education and prevention activities in those regions of the country.

We are deeply troubled by the human tragedy of prescription drug abuse and are doing our part to help. We are also firmly committed to keeping pain-relieving medicines available for the millions of legitimate patients who need them most.

We will not let patients suffer in silence. We are committed to being true Partners Against Pain®.

"Purdue has ongoing training programs to ensure that all our sales representatives and managers fully understand the OxyContin package insert and promote the product within strictly defined guidelines. We have just completed a special training initiative for 150 representatives and their managers from regions identified as areas of possible future abuse and diversion. In all these programs, our goal is to help physicians and pharmacists avoid abuse and diversion. In Mexico and Canada, we have taken proactive steps to reduce the possibility of OxyContin dispensed in those countries entering into illicit U.S. channels, and to ensure that our representatives promote OxyContin based on its approved U.S. labeling. We have changed the product's marking for tablets sold in both Mexico and Canada, and limited larger quantity sales to authorized wholesalers, hospitals, and clinics."

— Ron Levine, VP, Sales Administration

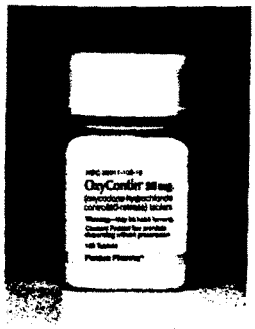
Howard Udell on Purdue's Partnership with Law Enforcement in Fighting Prescription Drug Abuse

The first we heard of significant abuse and diversion of OxyContin® Tablets were reports from Maine last fall. We requested a meeting with U.S. Attorney Jay McCloskey because we wanted to understand what was happening. I went to Maine with Michael Friedman and Dr. J. David Haddox in October to meet with Jay and other state law enforcement officials. The meeting was illuminating. We learned a great deal about the situation in Maine and how OxyContin was being diverted into illegal drug trafficking. But perhaps the most important lesson from that first meeting was that we were all on the same side and could work together to reduce prescription drug abuse.

"Most people have been delighted with our cooperation – and eager to work with us to ensure that pain patients aren't victimized by those who illegally abuse prescription drugs."

Since then, we've been collaborating with senior law enforcement officials in those regions of the country that have been most affected by the abuse and diversion issue. We have visited each region personally in an effort to understand the area's unique problems and develop appropriate solutions. Like Purdue, local law enforcement is committed to doing the right thing, and only by meeting face to face can we develop an effective dialogue that enables us to work together.

Maine became the model for our intensive initiative to tackle the serious public health problem of prescription drug abuse. Most of the people we've dealt with over the past six months — including U.S. Attorneys, state Attorneys General, the Drug Enforcement Administration, and the U.S. Food and Drug Administration — have been delighted with our cooperation and eager to work with us to ensure that pain patients aren't victimized by those who illegally abuse prescription drugs. In fact, many law enforcement officials have asked us to introduce our educational, nonpromotional programs in their regions. These programs are designed to teach physicians and pharmacists how to spot and avoid prescription drug abuse – how to be part of the solution, not part of the problem. Some law enforcement officials have even participated in our programs. The Ohio Attorney General, Betty Montgomery, recently asked us to make a presentation at her annual meeting of more than 1,000 law enforcement officials.



In the last eight months, we have visited a dozen or more states and talked with hundreds of representatives of law enforcement and regulatory agencies. It has been very gratifying to see them recognize our desire to be part of the solution to prescription drug abuse once they meet us, listen to us, and begin to understand that "we want to do the right thing." Over and over we hear the same refrain: "It's so refreshing to meet a company that wants to work with us to help solve this problem."

"The highest priority for International Research & Development is to develop products that are as effective as opioids for pain relief but have reduced potential for abuse. Our efforts include several approaches. One approach is to develop opioid analgesics that have inherently low abuse potential. Another approach is to develop products that are effective for pain when taken as directed but are unappealing when tampered with or abused. Six different product development teams have been formed to pursue these approaches. Further in the future are our research efforts to discover new analgesics that have little or no abuse potential.

"The first product emerging from our development efforts has been submitted to the FDA for approval. In addition, discussions are taking place with the FDA on a second product – a controlled-release oxycodone product – that also contains an opioid antagonist that is undesirable to addicts. Since the opioid antagonist will only be released if the product is abused, patients using the product as directed will not be exposed to the antagonist."

"We need to keep in mind, however, that there are difficult technological and regulatory challenges ahead of us, and market-ready products are still some time away."

— **Paul Goldenheim, MD, Executive VP, Worldwide Research and Development**

The Decade of Pain Control & Research

Last October, the U.S. Congress declared the 10-year period beginning January 1, 2001 to be the "Decade of Pain Control and Research." This is only the second Congressionally declared medical decade in history — the first being the "Decade of the Brain" in the 1990s. This important development is helping to bring the need for pain medicine to the attention of people in both the public and the private sectors.

The American Academy of Pain Medicine, an organization representing physicians who specialize in the practice of pain medicine, released the following statement on the diversion and abuse of controlled substances at its annual meeting in February:

> We are very concerned and strongly opposed to the diversion and abuse of controlled substances and support law enforcement efforts to stop these criminal activities. However, there is an issue of greater importance to public health resulting from the inadequate treatment of patients with serious pain disorders.
>
> To help prevent these problems, the American Academy of Pain Medicine worked with the U.S. Congress to declare this the Decade of Pain Control and Research, worked with the Federation of State Medical Boards to create a clinical guideline for the appropriate use of opioid medications in treating pain, and is developing an educational program for primary care professionals on pain assessment, opioid usage, and detection of addiction and prevention of diversion.
>
> Millions of people have suffered unnecessarily because of barriers to effective pain treatment. Exaggerated and unrealistic fears of addiction are paramount among these barriers, which should not be re-erected in response to publicity regarding drug abuse. Physicians should not be afraid to provide adequate analgesia when able to do so, and patients with acute pain or pain from cancer, AIDS, and other serious diseases should not fear the use of opioids, which are safe when used appropriately.
>
> Experience and investigation have shown that when opioids are prescribed and used appropriately in the treatment of pain there is minimal danger of creating an addictive disorder. Evidence to date indicates that substance abuse problems have not increased as a result of the increased availability of therapeutic opioids. The public health problem represented by misuse of prescription opioids is miniscule in comparison with that of untreated and unrelenting pain.

Glossary of Terms

A-buse (a byōōz') Abuse is the intentional self-administration of a drug in a manner that deviates from prevailing societal norms. Examples of abuse include:

- Alcohol (legal drug): driving while intoxicated
- Heroin (illicit drug): any use
- Prescription opioid (legal medication): parenteral use of oral formulation

All people suffering from untreated addiction abuse drugs. However, all people who abuse drugs do not suffer from addiction.

Di-ver-sion (di vûr'zhən) Diversion is any act that results in a prescription medication or a precursor chemical being conveyed out of a legal distribution system. This applies to both controlled substances and uncontrolled prescription drugs.

Some examples of diversion include:

- Theft from a manufacturer, wholesaler, dispenser, or patient
- Obtaining medication by prescription fraud
- Consuming medication prescribed for someone else

Mis-use (mis yōōs) Misuse is any legal use of a medication that varies from accepted medical practice. For example:

- A physician prescribing a twice-a-day medication to be taken four times a day
- A patient taking eight 600 mg ibuprofen per day for pain relief, without being aware of the risk entailed

Tol-er-ance (tol'ər əns) Tolerance is a state of adaptation, induced by repeated exposure to a chemical, that results in the diminution of at least one of the drug's effects. Tolerance to the effects of opioids develops variably. Tolerance to respiratory depression typically develops early in therapy, whereas tolerance to constipation rarely develops at all.

When drugs are abused, tolerance to euphoria develops rapidly, driving the abuser to employ progressively larger doses.

Tolerance, though commonly present in addiction, is not addiction.

Phy'si-cal De-pen-dence (fiz'i kəl di pen'dəns) Physical dependence is a state of adaptation, induced by repeated exposure to a chemical, that is manifested by the emergence of a drug- or class-specific abstinence (withdrawal) syndrome by:

- abrupt cessation of exposure,
- rapid reduction of the dose, or
- administration of an antagonist.

Physical dependence, though commonly present in addiction, is not addiction. Rather, it is an expected consequence of repeated exposure to certain medications, including opioids, benzodiazepines, some anti-hypertensives, and caffeine.


The Gadsden Time
A Busy Schedule Produces Some
TIME
The Potent Perils Of a Miracle Drug
"I'm very, very committed to what this company stands for. We have a product that has been a boon to the quality of life for endless numbers of people. That product is being disparaged, and I don't want to let that happen."
Newsweek
PainKillers
Vicodin and OxyContin: Hot Drugs That Offer Relief—And Danger
DR. J. DAVID HADDOX
The Herald-Dispatch
OxyContin
ets bad rap,
octors say
METRO
$25K

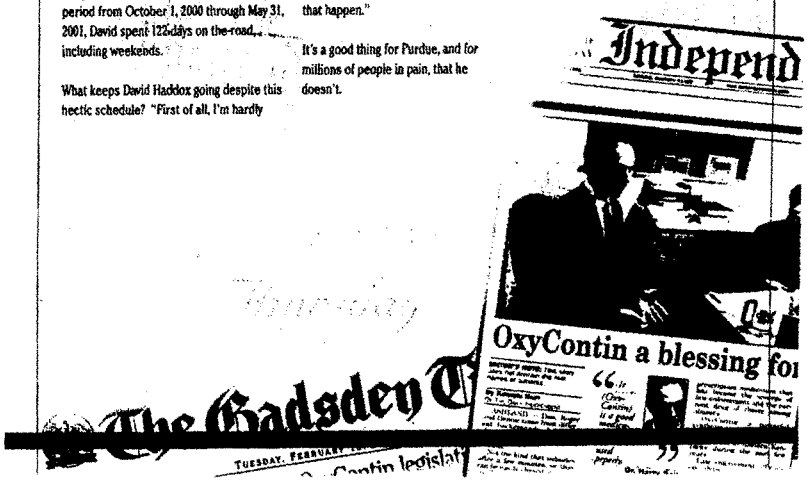
for Dr. Haddox Balanced Media

Many people find traveling the Appalachian Trail to be a great way to unwind — but for J. David Haddox, DDS, MD, Purdue's Senior Medical Director of Health Policy, recent trips up and down the spine of the Appalachians have been anything but relaxing. A native of West Virginia, David is a specialist in both addiction and pain management. He has been spending a good portion of his time visiting the communities most affected by the abuse and diversion of OxyContin® Tablets — meeting with community leaders and law enforcement officials to discuss ways in which Purdue can help manage the critical issue of prescription drug abuse. In the eight-month period from October 1, 2000 through May 31, 2001, David spent 122 days on the road, including weekends.

What keeps David Haddox going despite this hectic schedule? "First of all, I'm hardly alone in this intensive effort," he says. "In fact, I've never seen such a remarkable example of teamwork before. People throughout the company are working together in the effort to reduce the abuse and diversion of OxyContin, and I'm extremely grateful for the support I'm getting from my co-workers, my supervisors — and my wife.

"And perhaps most important," David adds, "I'm very, very committed to what this company stands for. We have a product that has been a boon to the quality of life for endless numbers of people. That product is being disparaged, and I don't want to let that happen."

It's a good thing for Purdue, and for millions of people in pain, that he doesn't.



Pamela Bennett Advocates for Patients in Pain — and Their Families

▲ *Pamela Bennett meets with Steven Steiner (right) and Robert Layman of DAMMADD (Dads and Mad Moms Against Drug Dealers).*

"We need to educate and inform ourselves so we can empower the millions of pain patients who are without a voice," says Pamela Bennett, RN, BSN.

"The media frenzy over the abuse and diversion of OxyContin® Tablets is evoking a variety of emotions from patients," Pamela adds. "Some are angry at the thought that drug abusers would be allowed to 'rob' them of a medication that has given many of them their lives back. Others fear being left without good pain relief."

Ever since Pamela joined Purdue in January as Director of Advocacy, she has been working tirelessly to align the company with grassroots efforts to combat prescription drug abuse. In addition to harnessing the energies of patients and their families, she reaches out to people who have lost their loved ones through drug abuse –making sure that their efforts are focused on the social problem of drug abuse rather than *vilifying any one drug.* When Pamela became aware of the website "OxyKills.com," for example, she contacted the Bisch family, whose 18-year-old son Eddie had died from an overdose of several drugs. A couple of months later, recognizing that Purdue was working hard to combat drug abuse and educate people about the appropriate use of prescription medications, the Bisch family changed the name of the website to "OxyABUSEkills.com" and wrote: "OxyContin is a great drug for people who need it and use it properly under a doctor's supervision BUT this site is about its DEADLY dangers when it is MISUSED."

Pamela is also working with DAMMADD, an organization co-founded by Steven Steiner, who lost his son to a drug overdose. DAMMADD – "Dads and Mad Moms Against Drug Dealers" – raises bounty money for people who turn in drug dealers, and Purdue has pledged $50,000 to help in this innovative effort.

• What the Pain Patients Say •

For years we have heard from patients about how effectively OxyContin® is managing their pain. These encouraging letters, phone calls, and e-mails confirm why we're doing what we do. But some doctors have told us that they are switching patients to drugs they regard as less effective because the media has made OxyContin a controversial drug. There are reports of pharmacies that will no longer carry the drug for their patients. Each day we receive heart-rending letters from patients who fear that it will become more difficult for them to obtain relief from their pain. Here are a few examples of what the patients have to say about OxyContin:

"My life [since my accident] is a miserable daily struggle to survive the pain. OxyContin has been the only medication that helps significantly. I am really concerned about all this one-sided reporting by the major papers. I don't know what I would do if this medication were taken off the market."

"I sustained a back injury two years ago and suffer with terrible chronic pain. I am 32 years old and, essentially, after my accident, my life was over until I started using OxyContin. OxyContin is a wonderful drug as it 'eradicates' my pain. This is a good drug with helpful properties when properly taken. In essence, it can give a person their life back."

"With OxyContin, I feel I'm in control because I don't have to take the prescription as often. I'm now able to work and enjoy activities with my family. Two years ago I could not. This medication has saved my life."

"I was injured six years ago, and tried every pain prescription the doctors prescribed to no avail. Nothing worked till OxyContin, and while nothing takes all the pain away, it makes me more comfortable and allows me to get a little sleep."

"I am very scared that my doctor will discontinue treating pain with OxyContin. I am in fear that my life will be changed forever, suffering constant and intense pain will be my future, and my biggest fear is what will happen to my children if I can no longer care for them."

"I hope that all the bad press about the abuse of this medication on the streets doesn't affect the supply to those of us that need it in order to breathe and not scream in pain with every little move."

"My life would be so drastically worse without the use of OxyContin. Just because there are others who abuse the drug, it shouldn't hurt those who need it to live a more comfortable life. If the abusers do not have access to this anymore, they will just grab something else."

"I am petrified that I might not be able to find a doctor to continue my treatment, especially with all the negative press surrounding OxyContin. I work 50 to 60 hours a week and without proper pain control I don't know if I would be able to continue holding a job."

Frequently Asked Questions *continued from Page 3*

Q: Is it true that OxyContin is a dangerous drug that gives a "heroin-like" high?

A: Heroin is an illegal drug with no legitimate medical purpose; it is taken only to get "high." OxyContin is an FDA-approved medication which, when taken orally, is slowly absorbed into the bloodstream and provides pain relief — not a "high." Cases cited to support this erroneous charge are invariably instances of willful abuse, not patients taking the medication under the direction of a physician.

The U.S. Attorney for the Eastern District of Kentucky, who recently directed the arrest of 207 drug traffickers, said that "OxyContin is a good product that plays an important role in medicine — the problem is that there are bad people doing bad things to a good product."

Q: Is Purdue planning to reformulate OxyContin to make it less appealing to abusers?

A: We are spending millions of dollars on the research and development of pain relievers that will be more resistant to abuse and diversion and at the same time safe and effective for legitimate patients. Purdue began this research effort before it first became aware that OxyContin was becoming popular with drug abusers in a few parts of the country. This is not an easy project, and it will take years of research plus full FDA evaluation before these drugs can be brought to market.

"The media business today is extremely competitive, with reporters under pressure to develop eye-grabbing stories that sell newspapers and draw TV viewers. Unfortunately, stories about patients getting their lives back thanks to an important medication like OxyContin are not as sexy as stories of drug abusers discovering the newest 'high.' We find ourselves in the frustrating position of remaining champions for the silent majority of patients whose stories are not being told and providing balance to the sensational stories of addiction and abuse that have portrayed OxyContin in a negative light.

"Recently the media is beginning to be more balanced and to focus more on the patients' side of the story."

— Robin Hogen,
Executive Director, Public Affairs

OxyContin: A Sense of Balance

By John Burke
Director, Warren County, Ohio Drug Task Force
Retired Commander, Cincinnati Police Pharmaceutical Diversion Squad

The recent news media barrage on the abuse of OxyContin has caused an acute awareness of the drug's potential for abuse. The news of over 200 people arrested in eastern Kentucky and southwestern Virginia slammed into the headlines earlier this year.

Prior to that, Maine and Ohio had indicated significant patterns of abuse of OxyContin. The fact that this news hit during February — "sweeps" month — only fueled the media fire.

Scores of diversion "experts" (including myself) were bombarded with interview requests by the local and national press on the OxyContin issue. Most of my peers that I spoke with were frustrated with the media when being interviewed. The media were anxious to hear stories of OxyContin abuse, but were largely disinterested in comments that the drug had a very legitimate function with the vast majority of its users.

Don't Believe Everything You Hear

I recently invited a local television station to spotlight a pharmaceutical diversion investigator who I hired to address the overall problem of prescription drug abuse in our county. The TV crew photographed the investigator meeting pharmacists in our county and allowed him a brief statement about drug diversion. The reporter then asked me specifically about OxyContin. I told him that I did not know how much of a problem the drug was in our area; my new investigator needed some time to work on cases before making such a determination.

The story aired two nights later, and I knew as soon as I saw the promotional piece that there was a problem. The story strongly insinuated that I hired an investigator specifically because of the OxyContin abuse issue! This, of course, was totally untrue, but rebuttal opportunities are few and far between.

OxyContin Abuse Versus Legitimate Use

When abused, OxyContin is crushed and either snorted or prepared for injection into the body. It allows the abuser to get a rush of oxycodone – exactly what drug diverters crave in their daily pursuit of another "fix." This method is nothing new – Percocet, Percodan, and Tylox have all been abused this way for years. We have encountered addicts injecting 60 to 70 pills a day to satisfy their habits.

Of course, this mechanism of action is exactly the opposite of what the legitimate pain patient receives when taking OxyContin orally. The oxycodone is released gradually during the day, providing the patient with a steady supply of pain relief, allowing the patient the ability to be a functional part of society.

While recently visiting a large private pharmacy out West, I had the pleasure of meeting a nurse, who as an employee of the pharmacy, counseled pain patients. I had the chance to talk to her and watch her work for a few hours. It was obvious that she had a passion for her job, and did it very well. It was only later that she told me that each day she took two time-released oxycodone and wore a fentanyl patch because of chronic pain problems. So much for the stereotype view of the drugged chronic pain patient!

Solving the OxyContin Abuse Problem

So what is the answer to this dilemma of drug abuse and legitimate pain patients? I think it's important to remember that OxyContin is only the current prescription drug of abuse getting media attention. Hydrocodone has long been the number one prescription drug of abuse, and usually overshadows the oxycodone products. Benzodiazepines (i.e., alprazolam and diazepam) are another huge source of abuse in the prescription drug world.

Therefore, the answers to reducing OxyContin abuse are the same answers for reducing prescription drug abuse in general. Education should be one of the top priorities for the general public, law enforcement, and maybe, most importantly, health care professionals who prescribe controlled substances.

Health care professionals need to become more familiar with how to detect and prevent drug diversion in their practices. Little, if any, education is provided in medical and pharmacy school to prepare a health care professional for the tactics employed by the professional drug seeker. Therefore, it is up to the individual health care professionals to educate themselves and to always remain alert.

Health care professionals should also always cooperate with law enforcement and regulatory agencies in identifying and prosecuting drug diverters – even if the drug diverters are other health care professionals. Physicians and pharmacists trafficking in prescription drugs commonly affect hundreds of their "patients" by perpetuating their addiction or providing thousands of dosage units to be sold on the streets.

In turn, law enforcement agencies need to devote more resources to the problem of prescription drug abuse. This is a significant drug problem in every area of the United States. The 200 arrests made recently in Kentucky and southwest Virginia highlight the positive impact law enforcement can have on prescription drug abuse, but such action needs to be taken in every state.

Finally, although we need to be aggressive when pursuing those who would divert or sell pharmaceuticals, we also need to make certain we do not adversely impact legitimate pain patients. We must remember that probably the majority of all pain medications are taken properly by legitimate patients. A fringe group has recently called for the removal of OxyContin from the market because of its recent abuse statistics. Instead, let us not give criminal prescription drug offenders the power to dictate any of the prescription drugs practitioners prescribe and pharmacists dispense. Eliminating proven pharmaceuticals is not only dangerous, but is the equivalent of "throwing out the baby with the bath water." Instead, let's go after the abusers while safeguarding those patients who are in legitimate pain.

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January 27, 2004

Congressman John Mica
U.S. House of Representatives
2445 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Mica:

It has come to my attention that there are hearings scheduled concerning "regulatory and other matters related to pain management advocacy. " I would like to testify on behalf of my patients who are functional and working because pain medication is available.

I am a physician who practices the medical management of pain. My average patient has chronic non-cancer pain and is working full time with their pain managed with opioid (narcotic) medications. My patients would be on disability without access to these pain medications. My patients live in fear of the possibility of regulations, which would prevent them access to their medications.

My patients are NOT drugged up addicts but rather people who work full time as teachers, physicians, nurses, and executives. My patients are NOT lying on the couch collecting welfare but rather helping you when you buy a car, go into a 7-11 or build a house. Pain medications allow them to have full complete lives caring for their families and building our communities. Without treatment, many would be not only non-productive but also suicidal.

We all desire to prevent abuse of narcotic medications. More regulations will limit access to patients who are functional only because of the medications. A state-wide reporting system (such as Kentucky's) would enable us to track all prescriptions obtained for controlled substances would aid in diminishing abuse of these controlled medications. I speak throughout the country to physicians on regulatory issues surrounding controlled substances. I understand the "Kentucky system" works well.

I emphasize with anyone who has lost a loved one because of a drug overdose. I lost my 23 year old son because of "drugs" and nothing is more painful that losing a son. As a physician, we check every patient for a criminal record. We work closely with local law enforcement. We maintain strict guidelines for our patients. We mandate that they use one pharmacy. We request that all controlled medications be kept in a safe and labels destroyed before discarding empty bottles. The most important message is that we must differentiate between appropriate drug use and drug abuse.

My background is internal medicine, oncology and before being a physician, I was a nurse in a burn unit. I have spent over 20 years caring for patients in pain. I prescribe OxyContin (as well as other pain medications.) I am probably one of the "biggest writers" of opioids (narcotics) in the country, a fact for which I am neither proud nor ashamed. My patients would give everything to be cured of their pain, but until that is a medical reality, we need to guarantee that

they have the medications necessary for an acceptable quality of life and a productive life.

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Statement of
Abbey Strauss MD
1050 NW 15th Street, #207
Boca Raton, Florida

I am a physician in South Florida. In the course of my practice I treat many people with chronic pain.

At the risk of some redundancy, a short historical overview from my point of view will provide a basis for my opinions.

I have treated chronic pain patients for over a decade, and I recall how difficult it was many years ago to get the care these people needed. I recall thinking how we had the tools to make so many of their lives better, but because of fear and misinformation, they were left to suffer. The agony for many of these people was that treatments for their pain were not esoteric or complicated – in fact, proper medications were already available. Patients would tell me that their continued suffering was in response to people who misused opiates. That was one of the big educational problems -- the challenge for medicine and the regulatory agencies was to acknowledge that the mere use of an opiate did not carry the assumption that the patient was addicted (in the classic definition) to the drug, that the doctor was not simply maintaining an dysfunctional addiction, or that the doctor or patient were associated with the seedy side of life. The fact was that the same drug – a narcotic -- was being used for two very different purposes. This ought not to have been such a difficult concept to grasp. After years of educational efforts, things did fortunately get better by the mid 1990's.

The problems blocking adequate care disappeared for a while. Fears from lack of education or the attitude that opiates were not safe tapered to the point where people got the care. But once the door opened, the pendulum swung too far. Unscrupulous doctors and pharmacies (and recently the internet ones) took advantage of the more accepting clinical milieu. Many worked using the pretense of clinically questionable pain clinics or practices to funnel narcotics to inappropriate patients. With the rise of the abuse, the media found material for scandalous sounding stories. Some government agencies then exploited overgeneralizations from the "war on drugs" to foster a sense of fear, deceit and old fashion opiodphobia back into the pain treatment world. I personally spent many hours on television, the radio and in the press, trying to keep the balance so people would see that the majority of opiate users were completely legitimate. The larger world of careful doctors trying hard to work with real patients was being lost within the yellow-journalism. Media over-played the problems but underplayed the equally profound benefits that this same medication was also saving more lives than it was ruining.

The real problem before this committee resides in how or why the drug is used. Improper narcotic use is not a new problem, but the source of the narcotics shifted. The media's headlines were not about the absolute differences between the motivations for using an opiate. As noted above, this is the circumstance of two groups who use the exact same medications but for two very different reasons. The use end points are not the same, and

this reality had been lost. Years ago this reality was lost, and I hope it will not be lost again in new legislation that is the response to the improper prescription, selling or use of opiates. We cannot set back the comfort zone in which good doctors treat honest people in chronic pain.

The other major historic hurdles for the pain treatment community was to convince the larger community that needing opiates was not a sign of psychological weakness (in that they were not strong enough to carry though in spite of the pain), that needing these medications was not a indicator of some other psychopathology, or that any particular dose was an maximum or acceptable dose.

The high costs of these medications also led to additional tensions between patients, doctors and insurance companies. These are usually long term use items whose cumulative costs are quite high.

Medicine has shown many times that the necessary therapeutic dose ranges between individuals may be quite wide. No one can automatically assume an inappropriate use of any medication simply by looking at the quantity used. Ask any psychiatrist about the needs some patients have for unusually high doses – the answer will be that some people need them. When this is looked at scientifically, we now know about the role of variables such as hepatic metabolisms, absorption differences, concurrent medications and protein binding issues, possible genetic differences yet beyond our understanding, and so on. Sadly. the often "public counting of pills" has become a flag that insults the legitimate patient and frightens others. Newspapers often report that someone got "thousands of tablets," assigning to the number a meaning that in fact might have no clinical foundation. It is a common scare tactic. Fortunately the enlightened medical community and sophisticated pain patients are aware of this. That some people need such large quantities is suggestive of at least two reasons – (1) the medications are not manufactured in large enough dose formulations[1], or (2) there are many people who need these doses for therapeutic effect.. The concept of what a proper or average dose is too limited and is based on a unrealistic or biased framework. Indeed, some people respond to unusually low doses of medications

The key issue here, and one which is a central theme to my comments to the committee, is not just the fact that many people use these opiate medications, regardless if they are using large or small doses. Rather I hope the committee will absolutely capture the pivotal concept of knowing the motivation for anyone using the medication. The measurable end point to treatment is the change in the person's quality of life. The number of people who's lives are better with proper narcotic use far outweighs the numbers who misuse the medications. That needs to be painted to the regulatory community in the most graphic ways. I also emphasize that any recommendation from this committee to control the misuse of the medications must not unrealistically hinder or

[1] Some the cost of the branded formulations is so great that people have to use less expensive, and smaller dose forms (i.e., a 5 mg tablet rather than a 30 mg one). If the generic is not as good (which many people report), then the absolute quantity needed for equal benefits may be considerable, compensating for the loss of potency in the generics.

burden the process needed for the legitimate doctor and patient to do what is necessary for that better quality of life.

My personal algorithms is based on a simple statement: that the legitimate patient uses the medications to return to life, while the addict uses the medications to escape from life.

One problem is knowing how to trust a patient. Pain is so subjective. For a long time the general assumptions was that patient had to prove that their pain was real. So patients struggled in convincing doctors they were "for real." Initially doctors were skeptical because of their own under-training or ill-founded biases, and in combination, patients often did not get adequate care from a single provider. So they would go from doctor to doctor. This has been called pseudoaddiction, and it has virtually disappeared as doctors felt more skilled and comfortable in managing pain cases. One clue to the difference between a proper and illegitimate patient is if the doctor hopping continued in spite of the doctor giving realistic doses. The patient no longer had to go from doctor to doctor to get a quantity of medications genuinely needed for pain control. If the patient continues to do this in this day and age, it is more suggestive of improper medciation use than pseudoaddiction. This is usually not reflected in the media exposes about narcotic use.

A fair number of my psychiatric colleagues treat pain. The reasons for this are that as psychiatrists, we can better handle complex cases of emotional turmoil from the impact of pain on someone's life, as well as knowing better how to fine tune medciation use. Also, our exposure to the causes and management of addictions is much greater than many of our non-psychiatric colleagues, should this be an issue in a particular case. We also tend to spend more time with patients, getting to know them, teaching coping skills, etc. Most of the cases I've read about when a doctor is over prescribing (or mis-prescribing) narcotics is when the doctor is not a psychiatrist or when there is no effort to establish a therapeutic relationship. The time spent by them with a patient is much less, and there is much less energy spent to addressing the larger issues of a person's life. One variable here is that most insurance companies strictly limit any psychiatric benefits, so many people have to go elsewhere for treatment.

Over the years only a very few of my patients have not been honest with me. Eventually the dishonesty becomes evident and I have been forced to ask them to leave my practice. This usually follows if they refuse to accept the reality of what they are doing, or if they refuse to modify or seek the needed treatment for the associated problems unpinning the dishonesty or the improper use of medications. This is a very small percentage. I would like to offer the committee a pie graph reflecting this statistic, but in absence of a graph, I would estimate that I have had only 1-2% of all my chronic patients not be honest with me or who attempted to misuse my willingness to treat their pain with opiates. The reason for this is that I try to spend time with them and to get to know them.

Concern has been voiced that the opiate producing pharmaceutical companies have over-promoted the use of their products, which in turn allegedly fostered some of the improper use of the medications. While in fact the company does have a sales force, the vast majority of physicians simply listen to the drug representatives as a source of information

and then apply that information to their patient's clinical needs. A prescription follows only if it is appropriate to those needs.

In the recent Ft Lauderdale Sun-Sentinel series called "Drugging the Poor" the reporter addressed the improper use of medications. He listed doctors and pharmacies that were very high prescibers of narcotics. He spoke about the tremendous costs of providing this care to the Medicaid system. There was very little in the piece about the real benefits of these medications. There was not enough emphasis that the medication costs to the state are the product of the pharmaceutical industry's prices. Indeed much of the cost factors would be diminished if the medications simply cost less money. The implication was clearly made that anyone properly involved in the use of these medications was also, somehow, motivationally similar to the prescribing doctors, pharmacies and patients who were abusing Oxycontin's availability. The reporter emphasized the problems with those doctors and pharmacies (and indeed some real problems existed) without adequate attention to the fact that perhaps some, if any, of the patients under the care of those doctors, did in fact properly benefit from pain relief under their care.

I would offer the following recommendations:

1. Recognize that chronic pain is a real and is often under treated in our country. The reason for this is mostly fear and lack of knowledge on the doctor's part. The benefits won over the last several decades must not be lost in an effort to stop the relatively few who are improperly capitalizing on the more accepting environment for pain treatment. This accepting environment is actually the acceptance of the use of opiates.
2. Allow schedule 2 medications to be sent electronically to a pharmacy. Patients would be required to use only one pharmacy. This would eliminate all fraudulent scripts. Sufficient internet security exists to encrypt the prescriptions. No written prescription would be given except for small amounts (such as after a tooth is pulled) or in a one time emergency.
3. A computerized monitoring system should be established to follow narcotic prescriptions. When a prescription is presented to a pharmacy, the pharmacy's computers will compare it to a data base. If some question about dosing changes, refills or other irregularities appear, then the data base will notify the pharmacist who can then call the doctors for clarification. The data base would tell the pharmacist from which doctor the patient was also getting prescriptions for narcotics. I do not think this data base needs to be open to law enforcement since I believe it will self-police the use of narcotics. It would simply be impossible for someone to get multiple prescriptions or to forge a prescription. I believe Purde Pharma has offered to fund such a program in Florida.
4. The above recommendations will do little to prevent inappropriate prescription use if the same doctor is giving a continuous supply to an inappropriate patient. This is a much more difficult problem to address. The telling factor cannot be merely the quantity of medication used. Proof that legitimate pain is being treated must be available. An unbiased but experienced committee may be needed to review the case. Care must be made not to assume too early on in the doctor-

patient relationship that improper medication use exists – it may take time for the patient to find a balance between pain control and getting their life in order. This may allow for some inappropriate use to continue for a while. Issues of patient-doctor confidentially will arise. The central issue for any judgment on a potential misuse situation will be on how the medciation is affecting a person's life over time. That must be reflected in the clinical notes. Treatment must be followed over sufficient time for the patient's life and dose to stabilize, as well giving enough time for the patient to learn to live with the pain, the establishment of coping skills, and other interventions to better control the pain and it's impact on their lives. Pain treatment is a time consuming process. High dose chronic pain patients may have to accept the knowledge that their medical charts may be reviewed. Additional levels of confidentially protection may be needed if a psychiatric process is also occurring. This is the problem with dual diagnosis treatment – a patient with pain and perhaps history of substance abuse deserves treatment for the pain, but this combined treatment approach must be done by those able to do so. Any potential for a formalized outside review of the treatment plan must be carefully tooled so as to not chill a patient's comfort in being honest and addressing the more intimate aspects of his life and problems with his doctor.

5. I believe that the availability of Oxycontin did not in and of itself create new onset narcotic abusers. The propensity to misuse the medication existed before hand. Some of the abusers were narcotic addicts who benefited from a pharmaceutical grade drug supply, and it was certainly medically and legally safer to get the medciation from a doctor and pharmacy than on the street. This applied to using not choosing to use other narcotics as well, such as heroin. I'm certain that a certain percentage of Oxycontin users were recreational or experimental drug users. I'm also certain that some people use it because of the socially lax, dangerously permissive and attractive attitude that exists in our culture about drug use. The psychology, biochemistry and sociology of substance abuse is complex, massive and still not able to prevent substance abuse. But I would recommend that programs be given to teenagers and young adults for jobs and schools, and to make them integrated parts of a community. We need to study and learn from those cultures which have less of a substance abuse problem, and we have to be willing to adopt some of the lessons from those cultures.
6. Many substance abusers may also need long term mental health care, but many have no or limited access to it – this needs to be changed. Likewise, little can be done to prevent a physician or other person from willfully choosing to practice improper medicine. The Medical Boards must address this problem. Physicians should be required to take pain management courses for license renewal.
7. For the most part this is not a problem whose solution lies in law enforcement outside of removing those who intentionally capitalize in the trade of improper prescriptions. Law enforcement can work with health care and educational resources. Ultimately scaring people with legal consequences to substance abuse has failed – the number of people incarcerated for drug problems shows this approach has failed. We feel good too easily by sending law enforcement officers but historically this approach has never worked. If we had as many social workers as police officers, then perhaps we might have a chance to correct the problem.

8. I also recommend that additional funds be allocated into research for new pain treatment modalities, into more research on substance abuse, and into providing additional money for proper substance abuse treatment. I also recommend that monies be given to schools to provide after school clubs and activities to give young people a sense of emotional connection and importance to their community and in their families.

The beauty of a cliché is that contains truth. The cliché in this situation is this: Oxycontin is not the problem. Oxycontin reflects the problem.

My name is Teresa Ashcraft and two years ago, September 23, 2001, my first born son, Robert Lee Ashcraft, Jr., died from an accidental overdose of OxyContin. My son died from recreational use of OxyContin, the pills he took were still from a prescription. He was a 19 year old boy, who for whatever reason thought it would be cool to take OxyContin, he suffered the consequences and paid for it with his life.

I truly understand the need for a powerful drug such as OxyContin for those who suffer from chronic pain and cancer. Now I, along with many others, suffer from unbearable pain. There are nights I can't sleep, there are days it is hard to get out of bed; I miss enjoying the little things that use to give me and my family pleasure. MY PAIN IS GRIEF, there is no wonder drug out there that can relieve my pain.

As I stand before you right now, somewhere, another family member is losing the battle to OxyContin, by getting a phone call that their loved one has died, or they walk into a bedroom and finding their loved cold and blue, dead from OxyContin. Another PREVENTABLE DEATH!

The problems with OxyContin starts way back when Purdue Pharma mislead the FDA. This had a domino effect. Once it made it past the FDA, Purdue Pharma aggressively marketed this drug, and mislead many of our doctors. The epidemic began when it was unleashed for the moderate pain-suffer. This is how it got out onto our streets and into our communities. Purdue Pharma only saw one thing...PROFITS. They KNEW this drug was WAY TOO POWERFUL. I guess you could say Purdue also got addicted, addicted to the almighty dollar.

Purdue Pharma tends to blame those who overdose on OxyContin as addicts. Well, my son was no addict. OxyContin, along with alcohol, was the only drugs found in my sons system, there was not even marijuana found in him... I have his autopsy report to prove it. Now...I can almost read some of your thoughts, it was because he mixed it with alcohol. Think about it...if it were only the alcohol I would not be standing before you today. I can also give you proof of those who have died from just taking OxyContin. Please just go to the web site www.oxyabusekills.com.

The monitoring system...I fully support a monitoring system for prescription drug abuse. I know there are those who oppose it. There are doctors and patients who oppose the monitoring system....but why....doctors are out there to save lives, and patients. If they are not abusing a drug, then what is there to worry about? Just Help Us! My only problem with the monitoring system is it should have been in place way before a drug like OxyContin was approved. Now the makers of OxyContin want to help fund this system...why is that...is Purdue Pharma starting to feel a little guilty? They want to pledge $2 million dollars.... In my opinion, their money is blood money from those who have already died from this drug.

There is one more issue I have concerning OxyContin. It is our Justice System. Where are all the arrest of dealers....from the prescription abusers...they are the ones who have allowed it out of the pharmacies, out of their homes and into the hands of our children

and loved ones. In almost every case of illegal use of this drug, someone can tell you exactly where the person got this drug from, but yet there are no arrests. It is my understanding, that the illegal distribution of OxyContin, which results in death, is murder. I have spoken with the Volusia County State Attorneys office and I told them, the teenager my son got it from, got it from his mother's prescription. Along with statements from others who were there when the teenager approached my son with the OxyContin, statements from those who were there when the OxyContin went from one hand to the other. This teenager even admitted he gave my son the drug...still no arrest. I also told the State Attorneys Office that this teenager was still selling this drug...guess what...5 months ago, another teenager, from my same block, died from OxyContin. You know who his best friend was...the same teenager my son got the OxyContin from. It doesn't take a detective to figure this one out...we have a problem in our Justice System.

Please...Purdue Pharma must be held accountable for their actions, along with those who have abused their prescriptions, and yes, some doctors who have broken their oath to save lives. We as parents and loved ones must have some Justice. From the unborn child who will be born addicted to this wonder drug called OxyContin, to the addicts that have been created from OxyContin ... to those of us who are already suffering from the pain of losing a child or loved one.

Stop the killings; this panel holds THE POWER TO STOP IT NOW.

Justice For Bobby
Born: November 16,1981
Died: September 23,2001
Cause of Death
OXYCONTIN

After reviewing the newspaper articles on the background for this Hearing, I saw that the history of these accidental deaths was omitted.

Parents are often in denial about their children's problems and have no knowledge if their child used and abused drugs previously.

I find it very difficult to believe that a person with no history of self medicating would suddenly decide they can handle 3 and 4 times the dose prescribed. Most often they have a pattern of using more medicine than prescribed, and this gives them a false sense of security. No one would take a handful of pills without already having done so successfully in the past.

By crushing one time-released tablet a single dose becomes 3 doses, two tablets become 6, and three become 9. Other factors combined with the use that lead to death are not mentioned. It is easier to make the pill assume full responsibility, and let the victim be innocent.

Drug addiction and the need to continue the, "good feeling" is not cured by restricting access. These restrictions only serve to restrict the people who do need to use this medicine to live a decent life.

Please enter this letter as testimony against more regulation.

Sincerely,
Mickayla Wheeler

February 3, 2004
Criminal Justice, Drug Policy, and Human Resources Subcommittee

About a year ago, I started to have terrible back pain from an area that had troubled me on and off for 50 years. Fifty years ago it was diagnosed by X-ray (pre-MRI) as spinal stenosis; a gradual deterioration of the vertebrae in my back. The onset of the unbearable pain was so swift that I didn't know what to do. One of my feet ballooned up, rendering me unable to walk. For three months I shuffled from doctor to doctor, including three visits to hospital emergency room doctors and all they would look at was my foot; even though I kept saying, "I think it's my back." Finally, I found a doctor who was willing to listen, and he sent me to a pain doctor after an MRI showed that I suffered from spinal stenosis. Even then, three specialists later, they were still looking at my foot which had turned black from the dead nerve endings. I think I could document having seen 12 physicians, and despite that fact only ONE person gave me medicine that temporarily alleviated the pain; and that was a "pain" nurse who administered Darvocet until I was barely out of pain in one of my hospital visits.

It should have been obvious to anyone that I was not "drug shopping." I was a fat, 70-year-old lady with a severe pain problem. On reflection, I find it hard to believe that I was never lucky enough to find a doctor who would prescribe medicine to ease my pain, when so many others were able to get enough on which to overdose. I was under the impression (from my experiences) that only a pain doctor could prescribe narcotic medications.

I was given instructions with my prescription for oxycontin. (1), my doctor only accepts patients who are referred to him by another physician, and they must bring their medical records with them. (2), he accepts no walk-ins. (3), he issues one prescription per month. (4), if the prescription is lost, the patient will not receive another one until the next month. (5), if the pills are lost, the patient will not receive a new prescription until the next month. (6), prescription refills are not permitted; each month the patient has to visit the doctor for a new prescription (no extra charge).

My doctor is an anesthesiologist by profession, which makes a lot of sense when you think about it. He is trained to administer anesthesia to patients during a surgical procedure; therefore, he more than likely knows how much and which narcotic medicine will do the job. Oxycontin, apparently, relieves pain that is caused by trauma to nerve endings. Dr. Smith also administered two epidural injections to my spine--again, the sort of procedure that he would be skilled enough to administer as an anesthesiologist. An operation is not in my foreseeable future.

My doctor told me that the advantage of oxycontin is that it is timed-release, making it very desirable for allaying the chronic pain of illnesses like mine--spinal stenosis. Oxycontin is not polluted with additives like Tylenol. When my problem first erupted a little over a year ago, my regular physician was prescribing medication that was (as I eventually found out) loaded with Tylenol. I happened to read up on these medications in my drug book, and found that I was inadvertently almost overdosing on Tylenol. On

Tylenol, yet! Did you know that overdosing on Tylenol can damage your kidneys? I didn't! Piggy-backing one medication on top of another should not be permitted, in my opinion. I would think it is much safer to take two separate pills. I have been told that many medications have Tylenol piggy-backing in them. This makes one wonder which pharmaceutical company needs to be investigated.

Rep. Mica, as you know, every medicine dispensed these days comes with a fact sheet, which makes one wonder which part of the words, this medication is a narcotic analgesic, the patients who overdosed did not understand. I talked to Dr. Smith about the possibility of my becoming addicted to oxycontin. He told me that in any given population, 10 to 15% of the population can possible become addicted to substances like oxycontin. He also said that these same people would be more likely to become addicted to other substances.

People died when overdosing on oxycontin, and the figures do seem to be off the wall; however, nowhere did I see statistics on the number of people whose chronic pain was alleviated by all of the narcotic analgesics put together. I worked in Winter Park Hospital many years ago and I'll never forget the screams of one woman who was dying in unbearable pain, because physicians were not allowed to administer narcotic analgesic pain relievers.

One last point. I read somewhere that Purdue Pharmaceuticals bought the rights to Oxycontin from some other pharmaceutical company several years ago, and they didn't pay an excessive amount for it. Now I don't know what Purdue paid for those rights, but I calculated that they must have recouped their costs many times over several years ago. The problem with Oxycontin is that there doesn't seem to be a generic that would serve the same purpose because, if there was, I'd be first in line to buy it. My Oxycontin costs me approximately $240 a month for 90 pills of 20mg size. Again, I don't understand why they are so expensive. Codeine has been around for more years than most of us have been alive, and timed-release technology has been around for many years also, so what makes these particular pills so expensive? I remember the time (early seventies) when a person could buy cough medicine with codeine over the counter, so it must not have been thought to be addictive; however, I do understand that there are dangers associated with codeine.

Very Sincerely Yours,
Mary Cornell
715 Woodvalley Way
Orlando, Florida 32825
BlueGenes@att.net

Written Testimony for inclusion in Congressional Hearing in Orlando, Florida – February 9, 2004

Marianne Skolek

137 Buttercup Court

Whitehouse Station, NJ 08889

908-285-1232

Website: www.oxydeaths.com

Her name was Jill Carol Skolek. She was born on February 26, 1973 and she died on April 29, 2002. She was my daughter. She was the mother of Brian Patrick who was 6 years old when she died and she was the sister of Michael now 21 years old.

Jill died at 29 years old because she had the misfortune of being prescribed a "blockbuster" drug called OxyContin in January 2002. She didn't have terminal cancer – she had a herniated disk and obviously a physician who did not know the dangers of the drug he was prescribing.

In October of 2002, a woman named Chelly Griffith called me from Davenport, Iowa and told me she had been prescribed OxyContin for 3-1/2 years and lived a nightmare and, in fact, had just begun to regain her life and family after going through detox to get the effects of this "non-addictive" drug out of her system. "Could we work together at finding out how this happened?" Thus began a 16 month journey of research and media activity to prevent other families from being devastated and to expose the company for what we felt was the mass marketing of a Schedule II "addictive" narcotic that should not be prescribed for moderate pain.

Here is some of the information that the panel should consider in their findings of why OxyContin has not only devastated the State of Florida, but virtually every State in our country. The Timeline provided below should bring to light how OxyContin "addiction"

not to mention abuse and diversion was marketed so skillfully throughout our country. It is as follows:

1995

National Clearinghouse Guidelines – Clinical Practice Guidelines for chronic non-malignant pain syndrome states "there is no blanket recommendation for the use of opioids for more than 1-10 days."

OxyContin tablets launched in the U.S. by Purdue Pharma LP

1995-1996

J. David Haddox, DDS, MD (Chair) serves as President of the American Board of Pain Medicine

(Haddox at this point is a paid speaker for Purdue Pharma -- and ultimately a full-time employee of Purdue Pharma)

1997

J. David Haddox, DDS, MD ((Chair) writes and oversees Consensus documents for the use of opioids from the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine.

1998

J. David Haddox, DDS, MD co-author and President of the American Academy of Pain Medicine writes a commentary in the Journal of Law, Medicine & Ethics (winter 1998). In his commentary Dr. Haddox provides information and suggests uses for opioids.

2000

Purdue Pharma LP relocates to Stamford, CT constructing a building of 13 stories and 529,000 square feet, which houses over 1,000 employees.

Purdue Pharma LP builds new manufacturing facility in Wilson, NC

Purdue Pharma LP U.S. sales top $1 billion.

Purdue Pharma LP is issued a Warning Letter by the FDA from the Division of Drug Marketing, Advertising and Communications. May 4, 2000 issue of the "New England Journal of Medicine" promotes OxyContin in a manner that is false or misleading. A) Misleading Efficacy Presentation and B) Misleading Safety Presentation.

2001

April 3, 2001

DEA Press Release "Emergency Narcotic Addiction Treatment" is made available to physicians to clarify that they must obtain a subspecialty certification to prescribe Schedule II narcotics for detoxification, which also falls directly under "tapering" the dose. Purdue Pharma LP states in the package insert that "Physicians can provide a dosing schedule to taper the dose of OxyContin." This is in conjunction with Cessation of Therapy.

July 18, 2001

FDA announces there will be extensive changes to OxyContin labeling as well as a new black box Warning and letters to physicians nationwide.

2002

Purdue Pharma prints Patient Information Sheet that states patients should read it carefully "There may be something new." This same sheet also states "There is a risk of abuse or addiction with narcotic painkillers." This is very interesting since Dr. Haddox was interviewed by the television news show "48 Hours" and he stated that "less than 1% of patients taking OxyContin will become addicted." Purdue Pharma LP has repeatedly maintained that OxyContin causes *physical dependence, but not addiction.*

2003

Purdue Pharma LP is issued a Warning Letter from the Director of the Division of Drug Marketing, Advertising and Communications of the FDA. Purdue Pharma LP was charged with several violations pertaining to Lack of Important Risk Information, Omission of Material Facts related to abuse liability and FATAL Risks. Minimization of risk in information presented and over broadening of the indication where they suggest that OxyContin can be used in a much broader range of pain patients than has been proved to be safe and effective.

Purdue Pharma LP released the following statement following the Warning Letter by the FDA – that all violations were an "honest misunderstanding." If this is true, it was an "honest misunderstanding" on the following dates as well when they were served with Warning Letters for the same conduct with a Schedule II controlled substance:

October 15, 1993

March 24, 1994

March 25, 1994

June 7, 1994

July 7, 1994

October 3, 1994

May 4, 2000

July 18, 2001

Purdue Pharma LP has been issued Warning Letters 9 times since 1993 for the same marketing violations, however, there is no record of regulatory action, seizure or injunction.

Purdue Pharma LP has deceived this country by deliberately changing terminology to fit the marketing practices and guidelines needed to present a Schedule II narcotic as a SAFE drug for moderate to severe paint. J. David Haddox, DDS, MD wrote, co-wrote and edited the very medical journals the country's physicians turn to for guidance when prescribing opioids. It is not only inappropriate but also unethical for a physician to write the guidelines so that his employer will benefit financially.

In a document released by Paul Goldenheim, M.D., Purdue Pharma in a publication entitled "My Word" posted on January 22, 2004, Dr. Goldenbeim refers to a "scientific study published in the Journal of Analytical Toxicology" entitled "Oxycodone Involvement in Drug Abuse Deaths: A DAWN Based Classification Scheme Applied to an Oxycodone Postmortem Database Containing Over 1,000 cases – not only is J. David Haddox of Purdue Pharma a contributor of the report, but on Page 57 of the report it states "Purdue Pharma funded this research. The authors not employed by Purdue Pharma LP serve as consultants and received compensation for their participation in this research."

(Is this an impartial report since an employee of Purdue Pharma was a contributor of the report and Purdue Pharma funded this research? You be the judge).

Here is Goldenheim's release dated January 22, 2004:

MY WORD

OxyContin manufacturer: Don't forget the patients

By Paul Goldenheim, M.D. My Word

Posted January 22, 2004

In the past few weeks, the Orlando Sentinel has reported on several new state and federal initiatives to address the problem of prescription-drug abuse in Florida. State Sen. Burt Saunders announced hearings to examine Medicaid fraud as it relates to the illegal diversion of prescription drugs; a separate task force, headed by Attorney General Charlie Crist and Florida drug czar James McDonough, will investigate the same issue; and U.S. Congressman John Mica announced that a House subcommittee will hold a hearing in February on this subject.

As the manufacturer of OxyContin (oxycodone HCl controlled-release) Tablets, we share these concerns about prescription-drug abuse in Florida. This problem is not a new phenomenon, however, and we must be careful that any proposed "cure" does not do more harm than the "disease" itself. In other words, measures designed to curb illegal trafficking and abuse of prescription drugs must not restrict access for patients who need these medications.

It is our hope that lawmakers will consider three very important points when addressing this problem. First, and most important, these medications when used appropriately help alleviate the pain of thousands of Floridians who otherwise would suffer needlessly. Second, it is the abuse of these medications, not the medications themselves, that is the cause of the problem. Third, according to the Florida Medical Examiners reports, the majority of drug-related fatalities occur from a lethal cocktail of several drugs.

A scientific study published in the Journal of Analytical Toxicology reported the analysis of more than 1,000 autopsies of drug overdoses involving oxycodone from 23 states, including more than 300 from Florida, which occurred between August 1999 and January 2002. The study found that greater than 90 percent of deaths where oxycodone was present were due to drug abuse. In that same study, 268, or 94 percent, of those deaths in Florida involved drug abuse. All of them had multiple drugs present at autopsy.

Purdue Pharma has been on the front lines in the fight against the illegal trafficking and abuse of prescription drugs. In the state of Florida alone, we have spent more than $150,000 to educate 680 law-enforcement officers about how to combat prescription-drug trafficking. We have distributed some 35,000 tamper-resistant prescription pads to 2,200 physicians throughout the state, and sponsored over 500 educational programs for more than 135,000 health-care professionals on the appropriate use of pain medications.

We are also underwriting "Communities That Care" programs in Tampa, Tallahassee and Palm Beach County to identify and address the root causes of substance abuse in these communities, at a cost of $25,000 per site.

In addition, Purdue has pledged $2 million toward the development of an innovative prescription-monitoring program in Florida that, once completed, could be shared with other states across the country. And we are working with the state's legislative leadership to gain support for the legislation needed to establish a prescription-monitoring program.

Purdue is taking these steps to ensure that criminal activity does not determine health-care policy in Florida. As lawmakers seek solutions to the problem of prescription-drug abuse, they must be sure that responsible health-care professionals can continue to provide effective and appropriate care to patients suffering from serious, unrelenting pain.

Paul Goldenheim, M.D. is executive vice president and chief scientific officer for

Purdue Pharma L.P.

The word "addiction" is not in Purdue Pharma's vocabulary even though any Schedule II "narcotic" such as OxyContin is known as addictive by even lay people. As a result of their resistance to the word "addiction", the word "**Pseudo-Addiction**" was coined by J. David Haddox, DDS, MD of Purdue Pharma. In other words, if a victim of OxyContin fears becoming "addicted" to Purdue Pharma's blockbuster drug, they are actually experiencing "**Pseudo-Addiction**" which is far less threatening to the innocent victim taking OxyContin. For your edification, here is the information on **Pseudo-Addiction**:

Pseudo-Addiction

> Pseudo-addiction is defined as an abnormal drug-related behavior making chronic pain patients look like addicts. Interestingly, this behavior ceases when opioid doses are increased and pain improves (Weissman and Haddox, 1989). It further is stated that this drug-related behavior is actually a search for relief – "pseudo-addiction." It is noted that there is little specific evidence for the concept of pseudo-addiction, which originated from **one case report** (Weissman and Haddox, 1989). With the exception of one large-scale report as an abstract (McCarberg and Laskin, 2001) – **no studies on pseudo addiction exist.**

Although the pseudo-addiction concept lacks significant scientific support – it has become widely accepted within the pain-physician community.

J. David Haddox was involved in rewriting the consensus statement in the treatment of pain which resulted in the promotion of products made by his company – Purdue Pharma --and coining a word "pseudo-addiction" with only one case report. Conspiracy? Conflict of Interest? Too hard to contemplate that it could happen? It did happen and the greatest marketing ploy of an addictive Schedule II narcotic was perpetrated throughout the country claiming thousands of lives through death and addiction and resulting in almost $2 billion in the sale of OxyContin in 2002 alone to Purdue Pharma

It is time for the government agencies in place to protect us to stop this travesty. This has nothing to do with pain management – it has to do with profit management and Purdue Pharma profited at the cost of thousands of innocent victims of a sniper-marketed drug called OxyContin.

Thank you for the opportunity to present my written testimony to the State of Florida. I will continue all my efforts to have congressional hearings held in Washington, D.C. this year.

Her name was Jill Carol Skolek. She was my daughter. She was Brian's mommy – and she didn't deserve to be prescribed OxyContin. Please don't forget her name – Purdue Pharma will never forget her name.

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

s 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 health care 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 health care 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

As a Florida citizen, I am writing to express my objections, and outrage at the "war on Florida doctors and patients". Please, this must stop now. This is making it harder and harder for us to obtain the medicine we need to function. I know, as I have no insurance now, and cannot get treated without documentation. (mri, etc.) My doctors say it is just to risky for them! What is happening to medicine in the US? I suffer from chronic pain, and cannot get help because the doctors are afraid of legal penalties? Anything can be harmful if misused, a firearm, auto, or medicine. This is a matter of personal responsibility, not more laws. Please do not make life harder for us.

James Parker
Pensacola, Florida

I am a Hospice and Palliative Medicine Physician with over 20 years of experience in care of People with Pain, both terminal and chronic. I am Board Certified in both Hospice and Palliative Medicine, and Pain Management. As a Pain Physician, I have frequent encounters with the drug abusing population. As a Physician I have even more exposure to People with Pain who are in need of compassionate care and, when appropriate, the necessary pharmacologic and or procedural interventions to assist in their living. Substance abuse is a very unfortunate disorder. It causes the people that suffer from it and those that love them, a great deal of pain. It seems clear to me, from my sizable experience, that substance abuse has little to do with the legality of the medication or the means by which it is obtained. While these may be issues early in the course, they quickly fall by the side. People who abuse prescription medications have a disorder that needs to be identified by physicians and they need appropriate, timely intervention to prevent the problem progressing in its destruction of their lives. The prevalence of illegal substances in the halls of substance abuse makes it clear that making a substance illegal will not prevent its abuse; it will however prevent its appropriate medical use. The last 2 decades have seen a maturing of the medical field with respect to the management of people's pain. We have learned a great deal and there is much to be learned. I strongly encourage the actions to investigate and prosecute the individuals involved in illegal acquisition and diversion of any controlled substance. However, I can not state strongly enough that our legal and regulatory bodies can do nothing but harm by going further than this. People with Pain are counting on a reasoned and responsible action on the part of the government and want to remind you that it is people who are breaking existing laws that are largely the problem here. Much of the ignorance in the medical community has been created by the heretofore prohibitive view of opiates in chronic pain. Please allow medicine to be medicine. Enforce the law, prosecute the law breakers, but don't make the lives of People with Pain or the care provided by their caregivers any more difficult than it already is.

David M. McGrew, MD
President - Hospice & Palliative Physician Services, LLC
Medical Director - Hernando Pasco Hospice, Inc.
2003 President - American Academy of Hospice and Palliative Medicine

January 25, 2004

Chairman Mark Souder:

I was advised by Congressman Porter Goss's office to submit my experience with oxycontin to you, to be included in the official record of your congressional hearings to be held in Winter Park, FL on February 9, 2004. I plan on attending the hearings, but apparently there will not be time for citizens to speak.

My name if Jeff Taylor. I am a Captain with the Lee County Sheriff's Office in Ft. Myers, Florida. I have been a law enforcement officer for approximately 30 years, the past 26 years here in Lee County. On June 19th, of 2003, while at my office, another Lieutenant advised me that I needed to respond to Gulf Coast hospital. He advised that my 18-year-old son, Matthew, had overdosed and was being transported to the hospital. This was a complete surprise to me, since I had no knowledge that my son had ever experienced any type of drug. Upon arriving at the hospital, numerous other Sheriff's officers were present, and crying. I had believed that Matt was simply sick, and that perhaps if he had taken any type of drug, this would be a good learning experience. I waited for the ambulance to arrive, and I saw them carry my son from the ambulance. I approached Matt, who appeared to be sleeping. I touched his shoulders, hugged him and realized how cold he was. Working in homicide for 12 years, there was no doubt that the Lord had taken Matt away. Hospital officials attempted to bring him back, but to no avail. Of course I was completely devastated, along with my wife, and two other children.

I learned that on the previous evening, Matt had attended a party at a residence with approximately 30 other young people. At some point in the evening, Matt had taken oxycontin. We did not know what drug it was until sometime later after receiving reports of the examination and toxology. He then spent the night at a friend house. He was having difficulty breathing, and his friends just felt that he had too much to drink. At approximately 10:00 a.m., they finally decided to call 9-1-1, however at that time, it was too late.

I always warned my children about the consequences of using any type of drugs, including over indulging in alcohol. Never in my wildest dreams would I suspect my son of ever taking a drug that would end his life.

Matthew had planned on going into the Army. He wanted to be a Ranger. We had gone to the army recruiter; however, Matt needed a few more credits in order to graduate from high school. He accomplished this, and we had a graduation party for him approximately one month prior to his death. Matt was not addicted to oxycontin, or any other drug. He was an outgoing, super kid with his whole life in front of him. I taught him to dive, and he due to the fact that I am also the commander of the Underwater Operations Unit, he dove with many of my men who are on the unit. They asked if they could be his pallbearers.

Matthew did not have a job at this time, so I know he was not purchasing any type of drugs. Also, none of the checks that he had received for graduation were even cashed. I believe that someone gave him the oxycontin, and due to the fact that he had not used it, had no tolerance for the drug.

After this occurred, I attempted to find out everything that I could about the drug. I found it hard to believe that as a 30-year law enforcement professional, spending six years in a narcotic task force, I knew so little about this lethal drug. I stumbled into a website "oxyabusekills.com", and found hundreds of stories, similar to Matt's. I was completely astounded when I began reading the stories. Also, I found story after story of deaths that were occurring when the people were using oxycontin exactly as prescribed, and they died anyway. I felt that if I did not have knowledge of this drug, and how dangerous it was, how could an 18 or 19 year old know this information. I have also contacted Purdue Pharma, and it seems that they don't have a clue of the death and destruction that their oxycontin has caused.

I certainly have no problems with prescribing oxycontin or any other type of medication for those in severe pain, or those who are terminally ill. I do believe that oxycontin has been prescribed for anyone with any type of pain, and there are absolutely no safeguards to prevent the abuse with

children. I am also aware that Purdue Pharma is a 1.8 billion-dollar company with 80% of their profits gained from marketing oxycontin. No one twisted my son's arm to take oxycontin. I know for a fact that if he had known it could cause death, he would never have taken it. He was a great kid, with a super future in front of him. I have enclosed a photo, so you can see whom we are talking about. I am only one father who has experience a loss, but there are hundreds and hundreds of other families, just like mine. If Purdue had not marketed this drug so irresponsibly for the sake of shear profits, the oxycontin would not have been readily available to our youths.

I am presently working on a power point program that I will be able to present within the schools to warn young people about this deadly narcotic.

I pray that you and your committee will do whatever is possible to stop this epidemic. Please ensure that these deaths do not continue. Do this for Matt, and all those other young people who have been cheated out of their futures. God Bless you and your committee.

Respectfully Submitted,

Captain Jeff Taylor

Captain Jeff Taylor
16020 S. Pebble Ln.
Ft. Myers, Fl. 33912

Home # (239) 590-9250
Cell# (239) 851-2459

To Do No Harm: Strategies For Preventing Prescription Drug Abuse

My name is Edward J Bisch. On February 19, 2001 I lost my only son Eddie to a tragic and needless overdose death that involved oxycontin.

Prescription drug abuse is a terrible problem but some drugs are more addictive and lethal than others.

On August 28, 2001 I attended a hearing in Pennsylvania Titled:

OXYCONTIN: ITS USE AND ABUSE
HEARING
BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SEVENTH CONGRESS
FIRST SESSION
AUGUST 28, 2001
Serial No. 107–54

Now almost 2.5 years later I am attending yet another Congressional hearing on this rising scourge. OXY related deaths have skyrocketed to epidemic proportions. Accurate National death numbers simply do not exist and Purdue Pharma seems to challenge any death statistics (including the DEA's), that do not come from their limited company sponsored survey.

Now Oxycontin deaths outpace heroin deaths in the state of Florida. Oxy has taken root and no one will ever know just how many heroin deaths all started with this tiny pill.

Little did I know in August of 2001, while officials of Purdue Pharma testified how distraught they were about the problem they were actually spending 200 million dollars that year promoting OxyContin to general practitioners for MODERATE pain.

I since have learned that this lip service and the public relations campaigning by Purdue is far from their actual intentions which is SELL as much as possible irregardless of the public's safety.

Many good suggestions came from the 2001 hearing including my testimony but few if any were actually implemented. Instead Purdue sponsored a few ineffective Public Relations friendly programs, as long as it did not affect their sales.

I learned that the one impact thing that could be done is for the FDA to reclassify oxycontin for SEVERE PAIN ONLY. This WAS and IS the one thing that could make a major difference in stopping this still growing epidemic.

Purdue will tell you that they are concerned for the patients but while they trot out patients with multiple ailments and surgeries to speak they marketed the drug for moderate pain patients who could of found relief with a less dangerous drug.

Please, I do not want to attend yet another Congressional hearing 2.5 yrs from now with yet more grim statistics. Nor do I ever want to attend a Palladone hearing, their next time released drug that they want to unleash on the population for moderate pain.

Purdue denies responsibility and likes to put the blame for this epidemic on the doctors, patients, pharmacists, law enforcement, so called abusers and the media. They claim the media exaggerated the problem. The stories on my website show that these reports are not exaggerated but if anything still under reported.

I have included attachments from my website www.oxyabusekills.com which has almost 1 million hits in less than 3 years and includes thousands of death and addiction stories along with my memorial page that has over 300 names on it.

When people ask me through my website (**Why do you blame Purdue Pharma for the OXYCONTIN epidemic?)** I answer:

The trail of addiction and death due to the Oxycontin epidemic was fueled by the over prescribing and easy street access to this powerful narcotic. Instead of acknowledging the problem, Purdue denied it, as they aggressively marketed this powerful narcotic to general practitioners for moderate pain. They downplayed the risks and exaggerated the benefits; however, they were not selling widgets, but a powerful drug that can cause addiction that often leads to death.

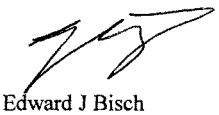
Here are just a few of the many examples of their corporate greed, which have been documented in newspapers, magazines, television, the GAO report and the book, *Painkiller.*

Sales representatives for Purdue Pharma have come forward to reveal the aggressive marketing practices that Purdue trained them to use. They reported the tactic of "targeting general practitioners," advising them that less than 1% of patients get addicted and that OxyContin is less likely to be abused. One representative for Purdue Pharma claims to have been fired for refusing to deal with "PILL MILL" doctors.

- Purdue Pharma was aware of the doctors who were writing HUGE numbers of prescriptions for OxyContin, but never once offered this data to law enforcement, even after they received a large number of death reports resulting from over prescribed OxyContin. Not until Congressman Greenwood scolded Purdue at the 2001 hearing did they share this data.
- In the year, 2001, Purdue Pharma spent two hundred million dollars in advertising to promote OxyContin, even after they had knowledge of the hundreds of addiction and death reports.
- Many of the death reports are from relatives and the addiction reports from patients, many of whom should never have been prescribed OxyContin.
- Purdue Pharma reported they were shocked that people were crushing OxyContin in spite of the proof that Purdue Pharma was warned that this had also happened to another one of their time-released drugs, MS Contin.

- A Clinical Researcher employed by Purdue Pharma alleges in a lawsuit filed against the pharmaceutical company that he had informed Purdue management of a flaw in the design of the drug's time-released coating. In addition, this employee claims that he was advised to not alert Purdue Pharma's in-house drug regulators of this flaw, including the government. Shortly thereafter, this employee's job was terminated.
- Purdue Pharma approached the FDA for OxyContin's approval, claiming that "research" showed that less than 1% of those who used the drug would become addicted; however, recent media reports refute that claim, contending that Purdue Pharma had evidence that the addiction rate would be much higher.
- Many elected officials, along with law enforcement who once fought the OxyContin epidemic, have been hired by Purdue Pharma and, now, as paid employees of the company, tout OxyContin's "safety and effectiveness." Including the FDA official who approved the "less likely abused label"
- "Cutting a deal" with Florida's former State Attorney General, Bob Butterworth, on his last day in office, included Mr. Butterworth accepting a two million dollar donation for a prescription monitoring program to be engineered by one of his closest friends who Purdue Pharma had hired as a lobbyist, under the terms that the state would drop its investigation into Purdue Pharma's marketing practices.
- The FDA produced warning letters to Purdue Pharma, addressing their "false and misleading" advertising in magazines and promotional materials.
- A New York Federal Judge recently ruled that Purdue Pharma misled government officials to prevent other companies from marketing a generic form of OxyContin.
- Purdue Pharma has from the outset pursued a policy of denial and spinning the truth. Such as sponsoring their own studies if the independent results do not suit their liking.
- Purdue uses outdated DAWN data that preceded the oxy epidemic which misleads people with outdated data.
- Purdue Pharma is now attempting to get approved a time-released Dilauded pain killer to treat moderate pain called **Palladone**, and it is reportedly ten times stronger than OxyContin.

Respectfully,



Edward J Bisch
PO BOX 29364
Philadelphia PA 19125

Attachment A: 08/28/01 testimony
Attachment B: Memorial page
Attachment C: Death Stories
Attachment D: Addiction Stories

Joan Sayers
6 Liberty Street
East Haven, CT 06512

January 28,2004

Dear Chairman Souder,

I have heard both sides concerning the "miracle drug" oxycontin (synthetic heroin). It's obvious that it has caused more harm than good- but they, Purdue Pharma and the FDA have refused to restrict it to SEVERE PAIN ONLY. My son was prescribed oxycontin for scoliosis for over two years. Matthew didn't have pain from scoliosis and he died in 2001 at the age of twenty two, soon after a visit from this drug-dealing doctor. The doctor had his license restricted by the medical board, and recently the courts banned him from practicing for a year. The judge even remarked that this doctor had extreme indifference to human life and that his motives were money-driven.

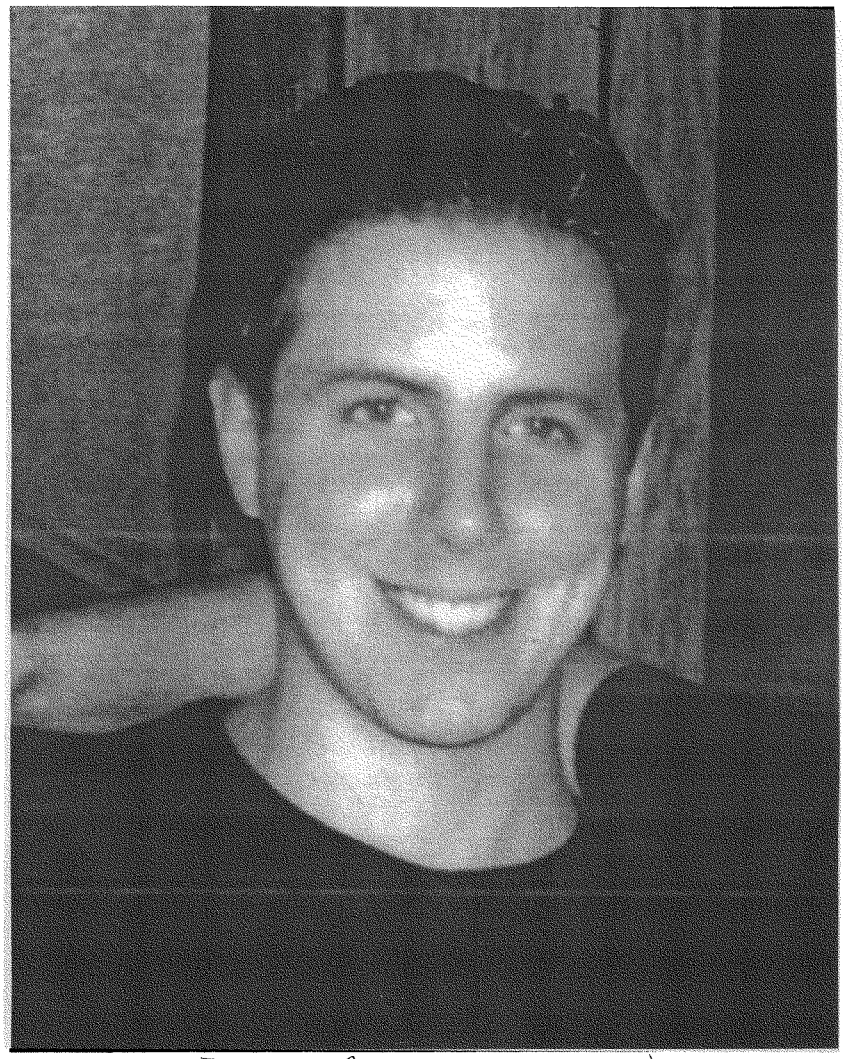
Matthew should never have had easy access to this deadly painkiller, especially for something minor like scoliosis. But this kind of abuse is happening everywhere, hence the epidemic on the streets.

Just recently ephedra was banned when it hasn't caused nearly the scourge on society that oxycontin has. Why is that? I'm sure there were people who could have given favorable testimony to its use- but it was banned nonetheless.

The easy availability of oxycontin has caused an epidemic of addiction and death. The obvious solution is to restrict it, but of course we know that it has come down to profits over people.
I urge you to do what Purdue Pharma and the FDA has failed to do – which is the only decent and humane thing- restrict it to SEVERE PAIN ONLY or BAN it altogether.

Sincerely,

Joan Sayers



Matthew David Gersz 11/12/78 - 1/16/2001

Leona Hancock
P.O.Box 2312
Wichita Falls, Texas 76307

February 24, 2004

Rep. Mark E.Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Government Reform Committee
U.S.House of Representatives
B-373 Rayburn Building
Washington, DC 20515

Dear Rep Mark E.Souder:
Thank you for the work your subcommittee is doing on oxycontin.

I am writing for our family to express our great concern regarding the safety of oxycontin. My son Billy Edwin Hancock died at Hill Air Force Base Utah. July 29,2002 at his home. We feel that a doctor who starting treating Billy at Hill Air Force Base caused his death. He left our family a 12 year old son and a wife.

He was given a huge amounts of oxycontin. Billy informed the Doctor he was taking to much The Doctor new he was addicted to oxycontin and continued to give him more and more insisting this drug was safe and he could not take enough to hurt him. The doctor even post dated Prescriptions for Class 2 Narcotic Oxycontin
He did not evaluated and my sons condition continued to deteriorated.
My son son did not drink alcohol or do street drugs.
He never injected Oxycontin,snorted , inserted rectal or IV used it. He was addicted.

The Doctor failed to follow the pain guidelines. The doctor, if he new my son was addicted why he didn't offer drug treatment. No alternative for his back problems was offered. This assurance by Doctors that this drug is safe is misleading and wrong.

You can die from it with out snorting,injecting,inserting, rectal or IV drug using it. This drug also mask other Physical problems which can cause these serious Disease process to go on untreated.
The FDA failed at least 2 times to protect the citizens when lied to by Purdue.
The doctors makes million of dollars and the drug companies makes Billions and the people who trust Dr's dies. I really feel there is no safe way to give this drug. Not enough studies support this drug. The drug is very addicting and patients are not warned of the dangers.
This drug is being given to active duty military who are world wide qualified. How do they justified this.

Why is the FDA allowed to look the other way when drugs like this get on the market.
I feel that many more deaths could be attributed to oxycontin because it looks like Resp/Cardic arrest if no autopsy is done. Many of this drug death may be allowed to be classified as Natural.I feel this drug Causes Cardiac arrest. Respiratory arrest. This is a Public Health issues. Please for the sake of others please get this drug off the Market. I am only one mother who's loss of a son due to greed on the part of drug company and unethical Doctor and Drug Representatives. I assure you there are many more and who's voice will echo thoughout the country until something is done to save our children and your's.

Thank You,

Leona Hancock
Mother of Billy Edwin Hancock

ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEES
Energy and Air Quality
Health (Vice Chairman)

EDUCATION AND THE WORKFORCE
SUBCOMMITTEES
Select Education
Workforce Protections (Chairman)

House Army Caucus
House Rural Health Care Coalition
Congressional Sportsman's Caucus

Charlie Norwood
9th District, Georgia

Congress of the United States
House of Representatives

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http://www.house.gov/norwood

Congressional Immigration Reform Caucus
Military Veterans Caucus (Co-Chair)
Nuclear Cleanup Caucus

February 10, 2004

Burt Rosen
Vice President, Federal Government Affairs
Purdue Pharma L.P.
700 13th Street, NW
Suite 525
Washington, DC 20005

Dear Mr. Rosen,

On February 9, 2004, I was privileged to participate in a hearing of the Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources in Winter Park, Florida. I have taken a very specific interest in combating prescription drug abuse and will soon introduce a bill that attempts a comprehensive effort at limiting prescription drug abuse.

During the hearing, one of the witnesses, Frederick W. Pauzar, gave oral testimony and submitted accompanying written testimony making charges against Purdue Pharma with respect to OxyContin that I found disturbing. I am concerned about those charges and request that you please promptly comment on them to the extent that you are capable.

Sincerely,

Charlie Norwood
Member of Congress

PURDUE Purdu Pharma L.P.

February 13, 2004

Congressman Charles Norwood
2452 Rayburn Building
Washington, DC 20515

Dear Congressman Norwood:

I am writing in response to your letter requesting that Purdue Pharma comment on the charges raised by the written testimony of Frederick W. Pauzzar submitted to the Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources. I enclose our comments.

Please let me know if we can provide any further clarification or information.

Regards,

Burt Rosen
Vice President, Federal Government Affairs

Enclosure

RESPONSE OF PURDUE PHARMA L.P. TO THE REQUEST FOR CLARIFICATION FROM THE HONORABLE CHARLES NORWOOD

Congressman Norwood has requested that Purdue Pharma L.P. ("Purdue") clarify certain issues raised by the written testimony by Frederick W. Pauzar presented to the Subcommittee on Criminal Justice, Drug Policy and Human Resources of the Committee on Government Reform.

An untimely death such as the Pauzar family has experienced is tragic. While words cannot soothe the pain of so deep and personal a loss, we are sorry for their heartache and extend our sympathies to them. Given his loss, Mr. Pauzar's concerns and questions are clearly understandable. Purdue shares Mr. Pauzar's overriding desire for appropriate controls on Schedule II medications. Purdue has been combating the abuse, misuse and diversion of OxyContin® (oxycodone HCl controlled release) Tablets and we know that real solutions to these issues can be found in an understanding of the facts. We do not know all of the facts surrounding this tragic incident, but we would like to address some of the more important misunderstandings and misconceptions raised in Mr. Pauzar's testimony.

1. The testimony states that "a clear and insidious correlation exists between market penetration [OxyContin] has achieved and the toll of death it has left behind." The General Accounting Office as well the courts have not found a causal link between Purdue's marketing of OxyContin and abuse, addiction or deaths.

As set forth in the previously submitted Statement of J. David Haddox, Purdue's Vice President, Health Policy, in December 2001, the GAO was asked to answer this question: "Is there a direct correlation between the marketing strategies of the drug [OxyContin] and its excessive abuse?" The GAO's lengthy and comprehensive investigation was unable to establish that correlation and its report clearly says so. While the GAO noted that the increased availability of OxyContin in the marketplace may have increased the opportunities for abuse and diversion, the GAO specifically noted that the historic predisposition of certain areas to prescription drug abuse also may have contributed to OxyContin abuse and diversion, particularly when coupled with the profit potential resulting from the illicit sale of OxyContin (see page 32 of the GAO Report).

One federal court that considered this issue and found no evidence that Purdue's marketing practices caused the inappropriate prescribing or diversion of OxyContin 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."
(Foister, et al. vs. Purdue Pharma L. P., et al., E.D.Ky. Dec. 27, 2001).

2. The testimony states "OxyContin came into existence in 1995, when Purdue Pharma deceived the U.S. Government by engaging in '...inequitable conduct before the Patent and Trademark Office...' (January 5, 2003, U.S. Dis. Judge Sidney H. Stein) in order to patent OxyContin." The statement suggests that Purdue's statements to the Patent and Trademark Office somehow resulted in Food and Drug Administration (FDA) approval to market OxyContin. This is incorrect. It confuses the roles of the FDA and the Patent and Trademark Office, and is a misunderstanding of Judge Stein's ruling.

OxyContin came on the market in late December 1995 after FDA approved the medication following an evaluation of Purdue's New Drug Application, including its clinical trial results, concluding that OxyContin is safe and effective when used according to the approved labeling for the medication. Any statements Purdue made to the Patent and Trademark Office have nothing to do with the approval of the medication for safety and efficacy by the FDA. No part of the FDA approval process depends on the enforceability of its patents or statements made to the Patent and Trademark Office (PTO). The two application processes are separate and distinct.

In his opinion, Judge Sidney Stein of the U.S. District Court for the Southern District of New York did find that Purdue's patents covering OxyContin were unenforceable due to "inequitable conduct."[1] The judge found inequitable conduct in connection with Purdue's representations to the PTO concerning a benefit of Purdue's invention. Judge Stein, however, also expressly found that the specific benefit of OxyContin that Purdue had stated in its patent applications was subsequently established to be correct and supported by evidence that Purdue produced at the trial. "Accordingly, Purdue has proven that the [drug formulations (i.e., OxyContin) covered by the] patents in suit adequately control pain for approximately 90% of patients within a four-fold dosage range." (Op. at 30.) Judge Stein's decision does not question the validity of OxyContin as an effective medication and it has nothing to do with representations made to the FDA about the safety, efficacy, or claims of OxyContin.

Further, former Patent Commissioner Bruce A. Lehman recently wrote a commentary[2] on Judge Stein's decision, concluding that his finding of "inequitable conduct" was based on a "misreading of the law and Patent Office Regulations" and is, therefore, "likely to be corrected on appeal."

3. The testimony states that sales of OxyContin "have literally skyrocketed, thanks in part to uniquely aggressive advertising and the promulgation of performance claims that have not held up to scrutiny." This statement is similar to the assertions made in

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[1] Purdue has filed a motion requesting expedited review of Judge Stein's decision by the Appellate Court.

[2] "Patents - The OxyContin Case-A Decision Unlikely to Stand", Pharmaceutical Law & Industry, BNA Inc., Volume 2 Number 5, Friday, January 30, 2004.

numerous personal injury lawsuits filed against Purdue and elsewhere. Where such assertions have been tested, they have been found wanting.

To date, 77 lawsuits concerning OxyContin have been dismissed or otherwise concluded in the company's favor without the payment of any money in settlement, and no case has been lost. The Florida Attorney General conducted a year-long inquiry into Purdue's marketing practices in Florida that ended with no finding of wrongdoing. Most recently, the General Accounting Office concluded, after a two-year study, that it "could not assess the relationship between the growth in OxyContin prescriptions or increased availability with the drug's abuse and diversion because the data on abuse and diversion are not reliable, comprehensive, or timely."[3]

Purdue's marketing has not been uniquely or inappropriately aggressive. Unlike some other manufacturers of opioids, including some manufacturers of other Schedule II medications, Purdue promotes its Schedule II opioid analgesics only to health care professionals and not to consumers. Purdue places ads for these products in medical journals, not in popular magazines or on television.[4]

---

[3] Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem, December 2003, p. 29.

[4] Dr. John Jenkins, Director of the FDA's Office of New Drugs (part of the FDA's Center for Drug Evaluation), addressed this point in remarks before the U.S. Senate Health, Education, Labor And Pensions Committee on February 12, 2002, and commended Purdue for choosing not to engage in direct-to-consumer advertising for OxyContin:

> U.S. SENATOR CHRISTOPHER J. DODD . . . Dr. Jenkins, Purdue Pharma chose not to engage in direct to consumer advertising of OxyContin, is that not correct?
>
> DR. JENKINS: To our knowledge, they have not done any direct to consumer . . .
>
> SEN. DODD: Oh, OK, but there are currently no prohibitions against, with the Schedule 2 drugs, Purdue Pharma would have been completely within its rights on a Schedule 2 product to market that product directly to consumers, is that not correct?
>
> DR. JENKINS: That's correct.
>
> SEN. DODD: So they made that decision not to do that. Now the question arises, do you believe that there should be some restrictions on Schedule 2 drugs in terms of should they all be following the Purdue Pharma formulation of just to physicians and health related agencies and the like. I don't know who else they could do it to.
>
> DR. JENKINS: Senator, I think we can commend Purdue Pharma for the decisions they have made not to engage in that activity. Whether there's need for changes in the act would require legislation, I don't think it's appropriate for me to comment without the administration having a chance to take a position on any proposed legislation.

Hearing of the Committee on Health, Education, Labor, and Pensions (February 12, 2002) (emphasis added).

In fact, Purdue has been a leader in providing health care professionals important tools to help them prescribe opioids appropriately to their patients. Purdue has distributed to physicians many educational items designed to provide important information about the appropriate use of OxyContin and other opioid analgesics. Purdue's educational efforts were directed at teaching physicians how to prescribe these drugs responsibly for appropriate patients in accordance with the FDA-approved product label for OxyContin.

As one of many examples to encourage physicians to properly assess pain and monitor the use of opioid analgesics in patients with pain, and avoid inappropriate prescribing or being misled by diverters, Purdue has distributed "opioid documentation kits" since 1997. Additionally, Purdue has distributed to healthcare professionals over 300,000 copies of the "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" (the "Model Guidelines"), prepared by the Federation of State Medical Boards of the United States, Inc (FSMB). In May of 1998, the FSMB approved the Model Guidelines after development by a panel of experts and with the support of the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine and Ethics, the University of Wisconsin Pain and Policy Studies Group and the Drug Enforcement Administration. Purdue began distributing the Model Guidelines to physicians in early 1999 shortly after they became available and well before the current experience of OxyContin abuse. Both the opioid documentation kit and the Model Guidelines emphasize the need to properly evaluate patients and help teach physicians about proper documentation and alert them to the possibilities of abuse and diversion at the same time that proper pain management is emphasized.

Furthermore, Purdue has provided adequate warnings about the risk of abuse and addiction posed by OxyContin. The OxyContin Package Insert always has warned about the risk of abuse and addiction, dating from OxyContin's introduction to the market in December 1995.

Each form of the Package Insert (PI) for OxyContin, as well as the Physician's Desk Reference ("PDR") entry for OxyContin, has featured as a prominent part of its caption a large "CII" symbol advising physicians that OxyContin is a Schedule II controlled substance. This is the caption from the current Package Insert:

OXYCONTIN® CII

(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

10 mg 20 mg 40 mg 80 mg* 160 mg*

*80 mg and 160 mg For use in opioid tolerant patients only.

Thus, the very first thing a physician sees when he or she reviews the OxyContin PI is a large "CII" symbol warning him or her that OxyContin "has a high potential for abuse," the abuse of which "may lead to severe psychological or physical dependence."[5]

Prescribing Schedule II drugs such as OxyContin calls for the exercise of the highest degree of diligence in appropriate prescribing practices. The PDR's "Key to Controlled Substances Categories" reiterates that substances bearing the CII designation have "HIGH POTENTIAL FOR ABUSE." Moreover, a physician can only prescribe controlled substances after specifically registering with the U.S. Drug Enforcement Administration to do so. Thereafter, the physician must comply with a variety of heightened restrictions on each prescription of a CII substance that are inapplicable to other controlled substances, including prohibitions on refills (requiring a new written prescription from a prescriber each time the medicine is continued), requirements that the prescription be in writing, and mandates that prescriptions be signed by the physician (subject to very limited exceptions). See 21 C.F.R. §§ 1306.11, 1306.12. These heightened restrictions are a constant reminder to physicians of the risks associated with CII medications such as OxyContin.

Further, the CII indication is only the first of a number of warnings about the risk of abuse in the original FDA-approved OxyContin Package Insert. For example, from its inception, the PI has contained a "DRUG ABUSE AND DEPENDENCE (Addiction)" section whose opening sentences state:

> "OxyContin is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule II controlled substance. Oxycodone products are common targets for both drug abusers and drug addicts."

Other sections of the original PI that warn of the risk of abuse include the "Information for Patients/Caregivers" section, which states "OxyContin is a potential drug of abuse," and the "Safety and Handling" section, which states "care should be taken to prevent diversion and abuse."

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[5] The Controlled Substances Act provides that a Schedule II substance means:

> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
>
> (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(21 USC Sec. 812(b)(2).)

Moreover, since July 2001, the first page of the OxyContin PI has contained a "boxed warning" whose opening sentences are:

> **"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."

(Emphasis in original.)

Courts have found that Purdue's warnings on abuse and addiction in even the pre-July 2001 package insert on abuse and addiction have been adequate. In a September 30, 2003 opinion addressing the adequacy of Purdue's warnings, United States District Judge Arthur Spiegel of the Southern District of Ohio found that, from the outset, Purdue has given appropriate warnings about these risks. In that decision, Judge Spiegel concluded that plaintiffs' claims that Purdue failed to warn of the risks of abuse and addiction associated with OxyContin, and that Purdue negligently promoted OxyContin, "crumble" in the face of the clear warnings provided in the Package Insert. Harris v. Purdue Pharma, L.P., No. 1:01-CV-00428 (S.D. Ohio Sept. 30, 2003) (emphasis added). And in a December 30, 2003 Order granting Purdue summary judgment dismissing the claims of 8 plaintiffs, United States District Judge Danny C. Reeves of the Eastern District of Kentucky held that "OxyContin's insert clearly set forth the potential dangers of the drug and the best manner in which to minimize those dangers." Foister v. Purdue Pharma, L.P., No. 6:01-268-DCR (E.D.Ky.Dec.30, 2003).

4. Another misconception repeated in the testimony is that that Purdue originally sold OxyContin "as a chronic pain medication for use with cancer patients", then "began to push [it] into new markets such as back pain and injury" and "reached down into moderate pain treatment." The implication that Purdue somehow improperly expanded the market into non-malignant, moderate pain is simply inconsistent with the FDA's approval of the medication.

Neither FDA nor Purdue has ever intended to limit OxyContin to cancer or severe pain. When initially approved, OxyContin was indicated for the "management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days". Since July 2001, the indication has been for the "management of moderate to severe pain

when a continuous, around-the-clock analgesic is needed for an extended period of time."[6]

From the outset, OxyContin was developed to treat not only moderate to severe pain in cancer patients, but to treat millions of other pain sufferers who also experience around-the-clock moderate to severe pain for an extended period of time. Indeed, the clinical studies that formed the basis upon which OxyContin was approved included patients with moderate, non-malignant pain. Patients experiencing around-the-clock moderate to severe non-cancer pain deserve no less level pain relief than cancer patients.[7]

During an FDA Anesthetic & Life Support Drugs Advisory Committee meeting on September 9, 2003, medical experts presented an overview of medical and scientific facts surrounding the under treatment of pain and the historical and appropriate use of opioid pain medications. These experts urged the FDA and the Advisory Committee to rely on these facts in their deliberations and warned against unnecessarily restricting the legitimate medical use of opioid medications[8]. The majority of the advisory panel members expressed an opinion that restricting modified-release opioid medications such as OxyContin for use in severe pain only would be a disservice to millions of pain sufferers. The next day the panel voted overwhelmingly in favor of maintaining the indication for OxyContin for moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. We believe these distinguished scientists and physicians were correct in their judgment that OxyContin's use should not be further restricted and that the current FDA-approved indications are appropriate.

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[6] As FDA's Dr. Robert J. Meyer testified before the Subcommittee:

> "For the extended release products that contain high concentrations of an opioid drug, appropriate patients would have moderate to severe pain (i.e., pain that impacts on a person's ability to function) that requires continuous, around-the-clock therapy for adequate control over an extended period of time. While this description clearly would apply to many patients with cancer pain, it also properly includes many patients with chronic, non-cancer pain, such as those with severe osteoarthritis or many patients with neuropathic pain." Statement by Robert J. Meyer, M.D., Director, Office of Drug Evaluation II, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, page 2.

[7] As Dr. Meyer further stated: "Millions of Americans suffer from chronic pain. The medical and lay literature has documented inadequacies of the treatment of pain, both from cancer and from non-malignant causes." Statement of Dr. Meyer, page 2.

[8] For more details on the health care professionals invited to testify on this subject, please see text of presentations made by Steven Passik, PhD and Arthur Lipman, PharmD at the FDA meeting in September available at http://www.fda.gov/ohrms/dockets/ac/cder03.html#AnestheticLifeSupport.

5. The testimony also shows a misunderstanding of the nature and purpose of the physician education and training programs sponsored by Purdue.

Up until September 2000, Purdue held speakers' training programs, which were rigorous educational sessions intended to enhance the participants' skills as public speakers and to educate them on pain management issues involving opioids and other pain treatments. These programs were not designed to promote OxyContin. In fact, Purdue specifically asked the guest lecturers and educators at these programs -- most of who were nationally prominent pain management specialists -- not to promote OxyContin, but to focus instead on proper pain management. Purdue did pay the cost of travel, meals, and lodging of the physician or pharmacist attendees, but expenses for any spouses that may have accompanied participants were not covered, and the attendees did not receive honoraria.

When Purdue did conduct these programs, they were very limited. From 1996 until September 2000, Purdue sponsored a total of only 42 speakers training programs (averaging less than ten per year over this period). Only a small percentage (less than 1% annually) of the physicians whom Purdue's sales representatives called on attended these types of meetings.

6. The testimony states that Purdue targeted "seniors with direct to consumer (DTC) advertising". As mentioned above, Purdue has voluntarily chosen not to engage in any direct to consumer advertising or promotion for its prescription medications.

Perhaps the testimony is referring to a swing music CD featuring an elderly couple on the cover that Purdue mailed only to physicians who filled out a Business Reply Card specifically requesting it. When mailed, the CD contained the OxyContin Tablets name, including the generic name and Schedule II symbol "CII", and was accompanied by a package insert with full prescribing information, warnings, cautions and other FDA approved information. Purdue did not intend for physicians to distribute the CD to patients as is made clear by the fact that we shipped only one CD at a time in response to the specific request of a health care professional. Purdue no longer provides this item or other nominal promotional items carrying the OxyContin brand to physicians.

7. The testimony claims that OxyContin has caused widespread deaths. It states that there is "mounting evidence that deaths in Florida and other states from OxyContin exceed deaths from heroin" and that "[i]n Florida alone, more than one person dies on average each day from the intake of OxyContin." Certainly, every death due to prescription drug use or abuse is a tragedy, but to understand and solve this problem, an understanding of the facts, rather than misinformation or anecdotal information is necessary.

The best source of facts on this important issue is a peer-reviewed study published in the Journal of Analytical Toxicology[9] (JAT), funded by Purdue but conducted by external forensic experts. That study found that the vast majority of drug abuse deaths involving oxycodone (96.7%) are related to the ingestion of multiple drugs, not solely oxycodone (3.3%). Further, this study found that in deaths involving *only* oxycodone, the specific pain medicine OxyContin® (oxycodone hydrochloride controlled-release) Tablets was present in 12 (1.3%) of the cases.

While we disagree with many of the assertions in the testimony, we share Mr. Pauzar's and the Subcommittee's concern about the deadly, serious problem of prescription drug abuse. As testimony provided at the hearing showed, the abuse and illegal trafficking of OxyContin is only one part of the much larger problem of prescription and illegal drug abuse. Purdue is committed to working with law enforcement, the medical community, legislators and other members of society to help alleviate this problem. As Dr. Haddox outlined in his testimony, we have launched many initiatives to combat the abuse and diversion of OxyContin. An extensive description of Purdue's efforts to fight the abuse and diversion of prescriptions drugs was attached to Dr. Haddox's testimony as Exhibit B-2, another copy of which is attached to this submission as Exhibit A.

We respect the Subcommittee for holding the February 9th field hearing and look forward to continue to work collaboratively with members of Congress and others to combat the serious problem of prescription drug abuse.

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[9] Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme Applied to an Oxycodone Postmortem Database Containing Over 1000 Cases, Journal of Analytical Toxicology, ISSN 0146-4760, Volume 27, Number 2, March 2003, pp. 57-67. In the interests of full disclosure, we point out that Purdue provided financial support for this study. That support does not invalidate its conclusions, which withstood rigorous peer-review prior to publication and have not been invalidated in the professional literature since publication.

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 available at http://www.purduepharma.com/PRESSROOM/PI/OXYCONTIN_PI.PDF.

EFFORTS BY PURDUE PHARMA TO ADDRESS ABUSE AND DIVERSION OF PRESCRIPTION DRUGS

While there are limits to what an individual company can do to prevent the social and criminal activities associated with prescription drug abuse, some highlights of the efforts made by Purdue Pharma L.P. to address abuse and diversion of OxyContin® (oxycodone HCl controlled-release) Tablets and other prescription drugs are as follows:

- After learning about the initial reports of problems relating to OxyContin abuse and diversion in Maine in March of 2000, Purdue immediately formed a response team made up of our top executives and physicians who immersed themselves in this problem and made it a key corporate priority. The initial efforts resulting from the team's plan included: (1) initiating meetings with public officials, including U.S. Attorneys, State Attorneys General, state legislators, regulators, administrative personnel, Secretaries of Public Safety, law enforcement personnel, and community leaders in more than 12 states where abuse was reported; (2) collecting as much information as possible on the methods by which OxyContin was diverted and abused; (3) working with federal, state, and local officials on measures to reduce abuse and diversion; and (4) immediately developing and distributing brochures educating pharmacists and physicians on the various actions they could take to prevent diversion of prescription medicines and reduce abuse. More than 770,000 of these brochures have been distributed to physicians and 546,000 have been distributed to pharmacists nationwide.

- As Terry Woodworth, then Deputy Director of DEA's Office of Diversion Control, testified at a Congressional hearing, "The best means of preventing the diversion of OxyContin is to increase awareness of the proper use of this product, as well as its high potential for abuse." Beginning in late April of 2000 and continuing to the present, Purdue has sponsored or provided educational programs on prevention and investigation of pharmaceutical drug diversion, proper pain management, and recognizing addiction for more than 5,800 law enforcement officers in 30 states.

- In addition to providing training to healthcare professionals on abuse and diversion issues, Purdue has contributed more than $1 million to numerous drug abuse prevention organizations to help combat prescription medicine abuse. Recipients include Community Anti-Drug Coalitions of America (CADCA) and the National Center on Addiction and Substance Abuse (CASA) at Columbia University.

- With funding and active involvement from Purdue, CADCA developed a "Strategizer" and "Tool Kit" to help its constituent community organizations address prescription drug abuse. These resources have been distributed to 5,000 CACDA member organizations around the country. Purdue also provided funding for five CADCA community forums on prescription drug abuse in a number of states. These forums are intended to raise public awareness of prescription drug abuse and engage the community in finding ways to address this societal problem.

- Purdue has prepared numerous informational bulletins and training programs for our Professional Sales Representatives and their management in an effort to communicate the importance of the appropriate use of OxyContin to our employees, and to emphasize the need to ensure that healthcare professionals understand the abuse potential of our medication. Our representatives were told that in the 100 counties where abuse potential was highest, their goal was to provide physicians with additional information regarding abuse and diversion as well as tools (including opioid therapy documentation kits) for proper pain assessment. If physicians were not willing to use these tools, our representatives were instructed to ask them to **stop** prescribing OxyContin.

- Purdue established a toll-free number and notified physicians and pharmacists that they should call us if they had questions or concerns regarding Purdue's sales representatives or its advertising and promotional activities. This toll-free number now appears on all promotional materials used in the distribution for OxyContin, and it will appear on all materials as they are reprinted. All advertising for Purdue prescription products is restricted to medical journals and directed at professionals; Purdue has never advertised its prescription products directly to patients.

- Purdue initiated meetings with the FDA at which we proposed revisions to the OxyContin labeling that ultimately resulted in a Boxed Warning highlighting the appropriate indications for the use of OxyContin tablets as well as the abuse potential and dangers of the medication. Purdue also initiated and developed a Patient Information Sheet, intended to accompany each prescription, which alerts patients to the risk of misuse and abuse of the medication.

- Purdue mailed a "Dear Healthcare Professional" letter to more than 500,000 healthcare professionals, informing them of the new Boxed Warning and prescribing information. Purdue also ran an advertisement featuring the Boxed Warning in medical journal for six months. In addition, our representatives were instructed to review the Boxed Warning with all doctors and pharmacists upon whom they called.

- While Purdue does not think the distribution of OxyContin "conversion chart scroll pens" was inappropriate, we nonetheless discontinued distribution of this item in July 2001.

- In response to a suggestion by an Assistant U.S. Attorney who expressed concern that Purdue's sales representatives should not benefit inordinately from prescriptions written by an individual doctor, Purdue revised its Sales Representative compensation plan to cap sales commissions from prescriptions by any single physician.

- Purdue has provided more than 230,000 free tamper-resistant prescription pads to over 15,000 physicians in 32 states and the District of Columbia to aid in combating prescription fraud

- Purdue voluntarily – and without request by any governmental agency – suspended shipment of the 160 mg. OxyContin tablets.

- When alerted by the staff of a Congressional committee to the problem of diversion of OxyContin from Mexico into the United States, Purdue voluntarily took escalating steps to prevent such diversion. First we changed the markings on the tablets to allow law enforcement to identify product crossing the border from Mexico. This was in response to a suggestion made by the staff of that committee, who told us that major pharmaceutical companies had refused to comply with their request to do the same. Subsequently, we imposed limitations and restrictions on sales to Mexico. Finally, upon learning of a significant theft of OxyContin in Mexico in December 2001, Purdue discontinued all sales to Mexico. While such action resulted in a costly lawsuit by the Mexican licensee, Purdue refused to resume shipments to Mexico.

- Purdue has spent more than $175 million to date in an effort to develop new formulations of pain medicines that would be more resistant to abuse while providing safe and effective pain relief to patients who use the medicines as intended. Patents on new formulations have been filed, and Purdue is actively working with the FDA in an attempt to expedite appropriate clinical trials and regulatory review.

- Purdue has actively participated at the state level to support enactment and funding of well-designed Prescription Monitoring Programs (PMPs). We feel that if structured properly, PMPs will provide an early warning system for physicians and pharmacists to prevent "doctor shopping", identify individuals who are abusing prescription medicines so they can be treated, and assist law enforcement in minimizing abuse and diversion. Purdue also supports efforts in Congress to provide grants to the states for funding their PMPs.

- To support state efforts to implement PMPs, Purdue has agreed to contribute up to $2 million toward the efforts of the State of Florida to design and acquire the software necessary to support the most sophisticated PMPs. When developed, this software will be available to any state at no cost.

- Purdue hired the State of Pennsylvania's former Executive Director of Community Partnerships to head our Community Partnerships program, which is developing community-based anti-drug abuse programs. In conjunction with this program, Purdue is supporting Communities That Care® efforts in ten cities in seven states.

- Purdue implemented an extensive prescription medicine abuse awareness program targeted toward the middle school "tween" population. This program, called Painfully Obvious®, focuses on informing school-age children about the dangers of abusing prescription medicines. The program maintains a website, www.painfullyobvious.com, which provides educational information that can be downloaded without cost. Purdue distributes Painfully Obvious kits at conferences and programs to which the company has been invited to speak, and in collaboration with third-party organizations and state partnerships. The expenditures for this program to date are in excess of $4 million.

- Purdue has implemented the "Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System," a research-based initiative to study the prevalence and nature of abuse and diversion of seven opioid analgesics. The system actively collects

evidence concerning the abuse, diversion, and addiction potential of buprenorphine, fentanyl, hydrocodone, hydromorphone, oxycodone, methadone, and morphine. These are all prescription opioid pain medicines with recognized abuse potential. We believe that the RADARS System is the most comprehensive and advanced method of accumulating abuse and diversion data in the U.S. today. On approximately a quarterly basis, External Advisory Board meetings are held in the District of Columbia to facilitate attendance by representatives of various federal agencies. To date, observers from the Food and Drug Administration, Drug Enforcement Administration, Center for Substance Abuse Treatment (Substance Abuse and Mental Health Services Administration), and National Institute on Drug Abuse have attended these meetings. We have also invited the Center for Substance Abuse Prevention to join us, and we hope they will do so.

- Purdue has spearheaded an important educational program of the American Academy of Pain Medicine, overseen by Louis W. Sullivan, MD, former Secretary of the U.S. Department of Health and Human Services and President Emeritus of the Morehouse School of Medicine in Atlanta, Georgia. Dr. Sullivan chairs an advisory board that is guiding the development of a web-based "virtual textbook" for medical schools that will teach students throughout the continuum of learning about pain assessment and management; all modes of pain management (including pain-relieving procedures, physical modalities, psychological therapies, and the use of non-opioid analgesics); and the detection and management of abuse, addiction, and diversion. Purdue is providing more than $1 million to develop this groundbreaking educational tool.

- Working with former New York City Mayor Rudolph Giuliani, Purdue has spearheaded the formation of the "Rx Action Alliance," a coalition through which pharmaceutical companies, not-for-profit organizations, healthcare professionals, and government (both law enforcement and regulatory agencies) can work together to seek solutions to the public health problem of prescription drug abuse. So far, more than 30 entities have agreed to join in what we believe will be a major force to prevent prescription drug abuse while maintaining the right of patients with legitimate medical need to receive appropriate medications.

- Purdue hired an experienced pharmaceutical security expert and former FDA and DEA law enforcement official to head our Corporate Security Department. He has implemented several programs dealing with manufacturing security, supply chain and product integrity, and assistance to local law enforcement agencies with investigations of diversion of OxyContin.

- In an effort to combat the theft and illegal trafficking of prescription medications, Purdue conceived, developed, and funded RxPATROL™ (Pattern Analysis Tracking Robberies and Other Losses). This information clearinghouse is designed to collect, analyze, and share information on pharmacy robberies, burglaries, and theft of controlled substances. Launched by the National Community Pharmacists Association (NCPA), National Association of Drug Diversion Investigators (NADDI), and Pharmaceutical Security Institute (PSI), RxPATROL is intended to help protect pharmacists, guard against potential robberies and burglaries, and assist law enforcement efforts to apprehend and prosecute pharmacy robbers.

- Purdue distributes prescription medicine identification cards created by the National Association of Drug Diversion Investigators to law enforcement officers to assist them in quickly identifying tablets seized during arrests. As of December 31, 2003, Purdue had distributed more than 47,000 identification cards to officers in 210 agencies in 40 states.

To date, Purdue estimates that we have spent more than $225 million in our efforts to develop more abuse-resistant pain medications; educate healthcare professionals, patients, and the general public; and cooperate with law enforcement in curbing abuse and diversion. These costs are exclusive of lost sales as a result of suspension of formulations and discontinuation of distribution in Mexico. Purdue in no way benefits from the misuse of our products, and we remain committed to working cooperatively with all interested parties to prevent the social and criminal activities that lead to abuse and diversion of prescription medications.

Statement of
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I am a physician in South Florida. In the course of my practice I treat many people with chronic pain.

At the risk of some redundancy, a short historical overview from my point of view will provide a basis for my opinions.

I have treated chronic pain patients for over a decade, and I recall how difficult it was many years ago to get the care these people needed. I recall thinking how we had the tools to make so many of their lives better, but because of fear and misinformation, they were left to suffer. The agony for many of these people was that treatments for their pain were not esoteric or complicated – in fact, proper medications were already available. Patients would tell me that their continued suffering was in response to people who misused opiates. That was one of the big educational problems -- the challenge for medicine and the regulatory agencies was to acknowledge that the mere use of an opiate did not carry the assumption that the patient was addicted (in the classic definition) to the drug, that the doctor was not simply maintaining an dysfunctional addiction, or that the doctor or patient were associated with the seedy side of life. The fact was that the same drug – a narcotic -- was being used for two very different purposes. This ought not to have been such a difficult concept to grasp. After years of educational efforts, things did fortunately get better by the mid 1990's.

The problems blocking adequate care disappeared for a while. Fears from lack of education or the attitude that opiates were not safe tapered to the point where people got the care. But once the door opened, the pendulum swung too far. Unscrupulous doctors and pharmacies (and recently the internet ones) took advantage of the more accepting clinical milieu. Many worked using the pretense of clinically questionable pain clinics or practices to funnel narcotics to inappropriate patients. With the rise of the abuse, the media found material for scandalous sounding stories. Some government agencies then exploited overgeneralizations from the "war on drugs" to foster a sense of fear, deceit and old fashion opiodphobia back into the pain treatment world. I personally spent many hours on television, the radio and in the press, trying to keep the balance so people would see that the majority of opiate users were completely legitimate. The larger world of careful doctors trying hard to work with real patients was being lost within the yellow-journalism. Media over-played the problems but underplayed the equally profound benefits that this same medication was also saving more lives than it was ruining.

The real problem before this committee resides in how or why the drug is used. Improper narcotic use is not a new problem, but the source of the narcotics shifted. The media's headlines were not about the absolute differences between the motivations for using an opiate. As noted above, this is the circumstance of two groups who use the exact same medications but for two very different reasons. The use end points are not the same, and this reality had been lost. Years ago this reality was lost, and I hope it will not be lost

again in new legislation that is the response to the improper prescription, selling or use of opiates. We cannot set back the comfort zone in which good doctors treat honest people in chronic pain.

The other major historic hurdles for the pain treatment community was to convince the larger community that needing opiates was not a sign of psychological weakness (in that they were not strong enough to carry though in spite of the pain), that needing these medications was not a indicator of some other psychopathology, or that any particular dose was an maximum or acceptable dose.

The high costs of these medications also led to additional tensions between patients, doctors and insurance companies. These are usually long term use items whose cumulative costs are quite high.

Medicine has shown many times that the necessary therapeutic dose ranges between individuals may be quite wide. No one can automatically assume an inappropriate use of any medication simply by looking at the quantity used. Ask any psychiatrist about the needs some patients have for unusually high doses – the answer will be that some people need them. When this is looked at scientifically, we now know about the role of variables such as hepatic metabolisms, absorption differences, concurrent medications and protein binding issues, possible genetic differences yet beyond our understanding, and so on. Sadly, the often "public counting of pills" has become a flag that insults the legitimate patient and frightens others. Newspapers often report that someone got "thousands of tablets," assigning to the number a meaning that in fact might have no clinical foundation. It is a common scare tactic. Fortunately the enlightened medical community and sophisticated pain patients are aware of this. That some people need such large quantities is suggestive of at least two reasons – (1) the medications are not manufactured in large enough dose formulations[1], or (2) there are many people who need these doses for therapeutic effect.. The concept of what a proper or average dose is too limited and is based on a unrealistic or biased framework. Indeed, some people respond to unusually low doses of medications

The key issue here, and one which is a central theme to my comments to the committee, is not just the fact that many people use these opiate medications, regardless if they are using large or small doses. Rather I hope the committee will absolutely capture the pivotal concept of knowing the motivation for anyone using the medication. The measurable end point to treatment is the change in the person's quality of life. The number of people who's lives are better with proper narcotic use far outweighs the numbers who misuse the medications. That needs to be painted to the regulatory community in the most graphic ways. I also emphasize that any recommendation from this committee to control the misuse of the medications must not unrealistically hinder or

[1] Some the cost of the branded formulations is so great that people have to use less expensive, and smaller dose forms (i.e., a 5 mg tablet rather than a 30 mg one). If the generic is not as good (which many people report), then the absolute quantity needed for equal benefits may be considerable, compensating for the loss of potency in the generics.

burden the process needed for the legitimate doctor and patient to do what is necessary for that better quality of life.

My personal algorithms is based on a simple statement: that the legitimate patient uses the medications to return to life, while the addict uses the medications to escape from life.

One problem is knowing how to trust a patient. Pain is so subjective. For a long time the general assumptions was that patient had to prove that their pain was real. So patients struggled in convincing doctors they were "for real." Initially doctors were skeptical because of their own under-training or ill-founded biases, and in combination, patients often did not get adequate care from a single provider. So they would go from doctor to doctor. This has been called pseudoaddiction, and it has virtually disappeared as doctors felt more skilled and comfortable in managing pain cases. One clue to the difference between a proper and illegitimate patient is if the doctor hopping continued in spite of the doctor giving realistic doses. The patient no longer had to go from doctor to doctor to get a quantity of medications genuinely needed for pain control. If the patient continues to do this in this day and age, it is more suggestive of improper medciation use than pseudoaddiction. This is usually not reflected in the media exposes about narcotic use.

A fair number of my psychiatric colleagues treat pain. The reasons for this are that as psychiatrists, we can better handle complex cases of emotional turmoil from the impact of pain on someone's life, as well as knowing better how to fine tune medciation use. Also, our exposure to the causes and management of addictions is much greater than many of our non-psychiatric colleagues, should this be an issue in a particular case. We also tend to spend more time with patients, getting to know them, teaching coping skills, etc. Most of the cases I've read about when a doctor is over prescribing (or mis-prescribing) narcotics is when the doctor is not a psychiatrist or when there is no effort to establish a therapeutic relationship. The time spent by them with a patient is much less, and there is much less energy spent to addressing the larger issues of a person's life. One variable here is that most insurance companies strictly limit any psychiatric benefits, so many people have to go elsewhere for treatment.

Over the years only a very few of my patients have not been honest with me. Eventually the dishonesty becomes evident and I have been forced to ask them to leave my practice. This usually follows if they refuse to accept the reality of what they are doing, or if they refuse to modify or seek the needed treatment for the associated problems unpinning the dishonesty or the improper use of medications. This is a very small percentage. I would like to offer the committee a pie graph reflecting this statistic, but in absence of a graph, I would estimate that I have had only 1-2% of all my chronic patients not be honest with me or who attempted to misuse my willingness to treat their pain with opiates. The reason for this is that I try to spend time with them and to get to know them.

Concern has been voiced that the opiate producing pharmaceutical companies have over-promoted the use of their products, which in turn allegedly fostered some of the improper use of the medications. While in fact the company does have a sales force, the vast majority of physicians simply listen to the drug representatives as a source of information

and then apply that information to their patient's clinical needs. A prescription follows only if it is appropriate to those needs.

In the recent Ft Lauderdale Sun-Sentinel series called "Drugging the Poor" the reporter addressed the improper use of medications. He listed doctors and pharmacies that were very high prescibers of narcotics. He spoke about the tremendous costs of providing this care to the Medicaid system. There was very little in the piece about the real benefits of these medications. There was not enough emphasis that the medication costs to the state are the product of the pharmaceutical industry's prices. Indeed much of the cost factors would be diminished if the medications simply cost less money. The implication was clearly made that anyone properly involved in the use of these medications was also, somehow, motivationally similar to the prescribing doctors, pharmacies and patients who were abusing Oxycontin's availability. The reporter emphasized the problems with those doctors and pharmacies (and indeed some real problems existed) without adequate attention to the fact that perhaps some, if any, of the patients under the care of those doctors, did in fact properly benefit from pain relief under their care.

I would offer the following recommendations:

1. Recognize that chronic pain is a real and is often under treated in our country. The reason for this is mostly fear and lack of knowledge on the doctor's part. The benefits won over the last several decades must not be lost in an effort to stop the relatively few who are improperly capitalizing on the more accepting environment for pain treatment. This accepting environment is actually the acceptance of the use of opiates.
2. Allow schedule 2 medications to be sent electronically to a pharmacy. Patients would be required to use only one pharmacy. This would eliminate all fraudulent scripts. Sufficient internet security exists to encrypt the prescriptions. No written prescription would be given except for small amounts (such as after a tooth is pulled) or in a one time emergency.
3. A computerized monitoring system should be established to follow narcotic prescriptions. When a prescription is presented to a pharmacy, the pharmacy's computers will compare it to a data base. If some question about dosing changes, refills or other irregularities appear, then the data base will notify the pharmacist who can then call the doctors for clarification. The data base would tell the pharmacist from which doctor the patient was also getting prescriptions for narcotics. I do not think this data base needs to be open to law enforcement since I believe it will self-police the use of narcotics. It would simply be impossible for someone to get multiple prescriptions or to forge a prescription. I believe Purde Pharma has offered to fund such a program in Florida.
4. The above recommendations will do little to prevent inappropriate prescription use if the same doctor is giving a continuous supply to an inappropriate patient. This is a much more difficult problem to address. The telling factor cannot be merely the quantity of medication used. Proof that legitimate pain is being treated must be available. An unbiased but experienced committee may be needed to review the case. Care must be made not to assume too early on in the doctor-

patient relationship that improper medication use exists – it may take time for the patient to find a balance between pain control and getting their life in order. This may allow for some inappropriate use to continue for a while. Issues of patient-doctor confidential y will arise. The central issue for any judgment on a potential misuse situation will be on how the medciation is affecting a person's life over time. That must be reflected in the clinical notes. Treatment must be followed over sufficient time for the patient's life and dose to stabilize, as well giving enough time for the patient to learn to live with the pain, the establishment of coping skills, and other interventions to better control the pain and it's impact on their lives. Pain treatment is a time consuming process. High dose chronic pain patients may have to accept the knowledge that their medical charts may be reviewed. Additional levels of confidentially protection may be needed if a psychiatric process is also occurring. This is the problem with dual diagnosis treatment – a patient with pain and perhaps history of substance abuse deserves treatment for the pain, but this combined treatment approach must be done by those able to do so. Any potential for a formalized outside review of the treatment plan must be carefully tooled so as to not chill a patient's comfort in being honest and addressing the more intimate aspects of his life and problems with his doctor.

5. I believe that the availability of Oxycontin did not in and of itself create new onset narcotic abusers. The propensity to misuse the medication existed before hand. Some of the abusers were narcotic addicts who benefited from a pharmaceutical grade drug supply, and it was certainly medically and legally safer to get the medciation from a doctor and pharmacy than on the street. This applied to using not choosing to use other narcotics as well, such as heroin. I'm certain that a certain percentage of Oxycontin users were recreational or experimental drug users. I'm also certain that some people use it because of the socially lax, dangerously permissive and attractive attitude that exists in our culture about drug use. The psychology, biochemistry and sociology of substance abuse is complex, massive and still not able to prevent substance abuse. But I would recommend that programs be given to teenagers and young adults for jobs and schools, and to make them integrated parts of a community. We need to study and learn from those cultures which have less of a substance abuse problem, and we have to be willing to adopt some of the lessons from those cultures.
6. Many substance abusers may also need long term mental health care, but many have no or limited access to it – this needs to be changed. Likewise, little can be done to prevent a physician or other person from willfully choosing to practice improper medicine. The Medical Boards must address this problem. Physicians should be required to take pain management courses for license renewal.
7. For the most part this is not a problem whose solution lies in law enforcement outside of removing those who intentionally capitalize in the trade of improper prescriptions. Law enforcement can work with health care and educational resources. Ultimate y scaring people with legal consequences to substance abuse has failed – the number of people incarcerated for drug problems shows this approach has failed. We feel good too easily by sending law enforcement officers but historically this approach has never worked. If we had as many social workers as police officers, then perhaps we might have a chance to correct the problem.

8. I also recommend that additional funds be allocated into research for new pain treatment modalities, into more research on substance abuse, and into providing additional money for proper substance abuse treatment. I also recommend that monies be given to schools to provide after school clubs and activities to give young people a sense of emotional connection and importance to their community and in their families.

The beauty of a cliché is that contains truth. The cliché in this situation is this: Oxycontin is not the problem. Oxycontin reflects the problem.

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February 10, 2004

Honorable Mark Souder
Congress of the United States
House of Representatives
Fax: 202 225-1154

Ref. Subcommittee on Criminal Justice, Drug Policy
And Human Resources

Dear Representative Souder,

I would like to thank you for your assistance in helping to hold the "To Do No Harm: Strategies For Preventing Prescription Drug Abuse" hearing this past Monday in Winter Park.

I am a chronic pain patient for over nine plus years and I was extremely surprised and disappointed that there was no representation on one of the panels from someone such as my self. Certainly there are a **small** percentage of doctors that have made the decision along the way to try and make a bundle of money illegally. And yes, there are patients that abuse the medication that is given to them for pain relief. I'm sure that some of these patients do "doctor shop" in order to relieve their pain.

Success in relieving pain is a tremendous problem in this country. The field of pain management has certainly made many advances in dealing with this problem. Then a series of newspaper articles is published possibly pushing us backwards in time treating chronic pain patients by instilling fear in both the medical community and their patients.

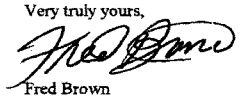
While it is extremely sad hearing of the deaths that were reported in the Sentinel articles, I find it more amazing that thousands of people die each year in auto accidents from the

use of alcohol and very little is reported on this and I certainly don't see state and federal congressional hearings being formed.

It is imperative that I take care of myself. I will do what is needed to try and stay as stable as possible and to have access to medications that let me function every day. I feel that I am proactive with my illness and as long as my health permits, I will be a patient advocate and do whatever I can to make sure that those medications such as Oxycontin are available, not only to myself but also any patient that needs them for severe chronic pain.

If I can answer any further questions to you or other committee members, please do not hesitate in letting me know.

Very truly yours,



Fred Brown
Severe Chronic Pain Patient

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

May 24, 2004

The Honorable Mark Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions posed to Mr. Thomas W. Raffanello, Special Agent in Charge of the Miami Division of the Drug Enforcement Administration, following Mr. Raffenello's appearance before the Subcommittee on February 9, 2004. The subject of the hearing was: "To Do No Harm: Strategies For Preventing Prescription Drug Abuse."

We hope that you will find this information helpful. If we may be of additional assistance, we trust that you will not hesitate to call upon us.

Sincerely,

William E. Moschella
Assistant Attorney General

Enclosure

cc: The Honorable Elijah Cummings
Ranking Minority Member

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY & HUMAN RESOURCES

"TO DO NO HARM: STRATEGIES FOR PREVENTING PRESCRIPTION DRUG ABUSE"

FEBRUARY 9, 2004

FOLLOW-UP QUESTIONS FOR THE RECORD FOR
MR. THOMAS W. RAFFANELLO
SPECIAL AGENT IN CHARGE, MIAMI DIVISION
DRUG ENFORCEMENT ADMINISTRATION

1. During the hearing you testified that the laws against illegal distribution of controlled substances over the Internet are very vague. What changes in the current federal laws would DEA like to see made? What new steps can Congress take to assist your law enforcement efforts to combat the illegal distribution and use of prescription drugs?

DEA is moving aggressively to enforce existing prohibitions against the illegal dispensation of controlled substances. At the same time, DEA and the Justice Department have been reviewing Federal law to determine whether changes need to be made. We look forward to working with the Congress on this issue.

2. From newspaper reports discussed at the hearing, it is clear that a relatively small number of doctors are prescribing very large amounts of oxycodone and other controlled substances in Florida. This information was based on data maintained by the Medicare/Medicaid system. Does the DEA monitor Medicare/Medicaid information and if so, how? How is this information used for law enforcement purposes?

Although the DEA does not monitor Medicare or Medicaid databases, information is routinely exchanged among the agencies. In Florida for example, DEA Special Agents and Investigators exchanged case related information directly with the Medicaid Fraud Control Unit.

3. What other kinds of information does DEA keep track of in its efforts to stop illegal diversion of prescription drugs? What factors go into a decision by DEA to open investigations into illegal use or distribution of prescription drugs?

The DEA monitors emerging drug trends through the Automation of Reports & Consolidated Orders System (ARCOS), an electronic reporting system for all manufacturers and distributors of Schedule II and Schedule III narcotic controlled substances. DEA is able to analyze the reported transactions and determine unusual purchasing patterns. DEA investigations focus on large scale trafficking organizations of pharmaceutical controlled substances that have a significant international, national, or regional impact.

4. Does the number of conditions for which a drug is approved by the US Food and Drug Administration impact the illegal use of the drug? In other words, if the number of approved uses increases, does that increase the potential for the drug to be diverted or misused? Should drugs like OxyContin be approved for use in treating moderate or even lesser levels of pain? Does the number of conditions for which a drug is approved by the FDA impact the illegal use of drugs?

The more approved uses there are for a particular drug results in more prescriptions written, which often equates to a higher frequency of diversion. For example, stocks in pharmacies are larger so robberies will cull a greater amount of a particular drug to be used illicitly. High-dose, single entity products like OxyContin® are ideal for patients who are or become opiate tolerant and need 24-hour coverage for an extended period of time for severe pain management. For moderate pain, other immediate release products will alleviate the pain. High-dose products are highly desirable for use as a heroin substitute by narcotic addicts. As has been publicly stated in the past, the DEA believes OxyContin® should only be used for severe pain management.

5. On February 15, 2004, the Washington Post reported that "top officials" at DEA were working to reclassify hydrocodone combination products (i.e., drugs that are made up of hydrocodone and another medicine, as opposed to pure hydrocodone) as Schedule II drugs). What is the status of this reclassification effort? What potential impact would it have on DEA's ability to combat the diversion and abuse of these drugs?

The DEA has received a petition to reschedule hydrocodone combination products, such as Vicodin® and Lortab® from Schedule III to Schedule II of the CSA. We are currently in the initial phase of gathering available data to be forwarded to the Department of Health and Human Services for review. We do not anticipate imminent action to reschedule hydrocodone products. Schedule II controls would prohibit prescription refills, eliminate call-in prescriptions, and provide greater security and oversight of these drugs. It also would put doctors on notice that these products have been extensively abused and more careful prescribing is needed.

6. During the hearing, the Subcommittee discussed several proposals for the creation of a database or databases to monitor the distribution and prescription of controlled substances. What form should such a database take, and who should create and maintain it? Should a single federal database be created? Or should each state create its own database? If the latter, how would we ensure that they would be linked and capable of sharing information with each other?

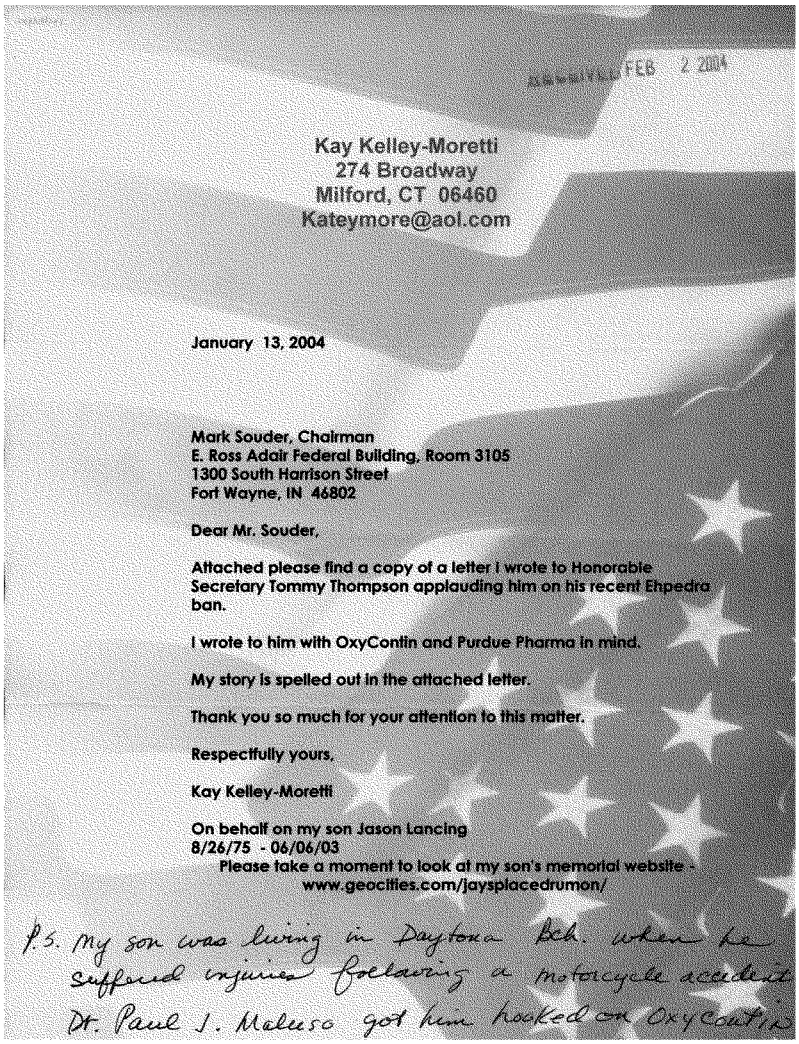
The Prescription Monitoring Programs (PMPs) offer the best approach to monitoring prescription use and abuse. Federal funding has been available for the states to initiate and improve PMPs through a grant program known as the Harold Rogers Prescription Drug Monitoring Program. Since fiscal year 2002, Congress has appropriated $16.5 million to the Department of Justice for PMPs. Twenty-two states, representing approximately 50 percent of the practitioners and

pharmacists registered with the DEA, currently operate PMPs.

A state by state approach to developing these programs provides the states with a high degree of flexibility in the design and implementation of the programs. The DEA and the National Association of State Controlled Substance Agencies are coordinating their approaches in order to capture basic data from each PMP in an effort to develop procedures for State officials to identify and track questionable substances between states.

7. Approximately what percentage of DEA's time and resources is expended in connection with illegal distribution of prescription drugs? How does that compare to the agency's efforts with respect to illegal drugs such as marijuana, cocaine and heroin?

Last year, the DEA expended 5.4% of its total work hours in connection with the illegal distribution and use of prescription drugs and 83.6% of total work hours combating illegal opiates, cocaine, cannabis, and other dangerous drugs.



RECEIVED FEB 2 2004

Kay Kelley-Moretti
274 Broadway
Milford, CT 06460
Kateymore@aol.com

January 13, 2004

Mark Souder, Chairman
E. Ross Adair Federal Building, Room 3105
1300 South Harrison Street
Fort Wayne, IN 46802

Dear Mr. Souder,

Attached please find a copy of a letter I wrote to Honorable Secretary Tommy Thompson applauding him on his recent Ehpedra ban.

I wrote to him with OxyContin and Purdue Pharma in mind.

My story is spelled out in the attached letter.

Thank you so much for your attention to this matter.

Respectfully yours,

Kay Kelley-Moretti

On behalf on my son Jason Lancing
8/26/75 - 06/06/03
Please take a moment to look at my son's memorial website -
www.geocities.com/jaysplacedrumon/

P.S. My son was living in Daytona Bch. when he suffered injuries following a motorcycle accident. Dr. Paul J. Maluso got him hooked on OxyContin.

Kay Kelley-Moretti
274 Broadway
Milford, CT 06460
Kateymore@aol.com

January 3, 2004

Honorable Secretary Thompson,

I am writing on behalf on your recent conquest; ie, your painstaking measures to hav Eph dra banned. Now I implore you to take a long hard look at the OxyContin epidemic, which has swept across our country and has left behind hundreds and thousands of deaths.

My son, Jason Lancing Kelley, age 27 was one of the many left without a voice. He died of an Accidental OxyContin overdose on June 6th, 2003. He was prescribed the drug following a motorcycle accident and his injuries were not chronic, were not severe and were healing quit well. His doctor knew this and continued to prescribe the drug until it killed him.

This drug found it's way into the marketplace in 1996 and has left a trail of deaths and shattered families and broken hearts... It took the death of a major leagu bas ball player to bring the Ehpedra problem to the surface.... why is this? My son was a talented musician and good Christian young man with dreams and aspirations... So many of our lost loved ones were accomplished people. There is a stigma that Purdue Pharma, Stamford CT, mak r of the drug OxyContin, has tried to implant in people's minds that only "Addicts" die from this drug. Only those who abuse it, die ! This is not true. They try to rectify the problem by spending thousands on educating people on the dangers of addiction, but the source of th problem is the drug itself.. It is a known fact that there is a malfunction in the time released mechanism of the drug and Purdue Pharma is well aware of this.... In fact, the head of the research and development department of Purdue Pharma, brought this to the attention of th CEO and president and he was demoted and subsequently fired. He now has a major legal battle pending against Purdue Pharma.

In your interview on Fox News a few days ago you said "I take my job very seriously". Now, Honorable Thompson, I am asking you to take this "OxyContin" situation seriously... as seriously as you dealt with the Ephedra problem.

Without your help, we are left broken hearted, childless, widowers, widows, fatherless, moth rless, etc. This OxyContin epidemic must be addressed and I am writing to you in good faith..I know you will look into this matter and "take this seriously".

If you would like a good education on how this drug has left an indelible mark on many lives, please go to www.oxyabusekills.com and read of the many lives "gone too soon" and the shattered hearts left behind.

Why it has taken so long and so many fatalities to stop this epidemic is beyond me, but I am hoping that YOU will delve deeply into this problem...

Respectfully yours,

Kay Kelley-Moretti
On behalf on my son Jason Lancing
8/26/75 - 06/06/03
Please take a moment to look at my son's memorial website -
www.geocities.com/jaysplacedrumon/

Assisted Recovery Centers of America
Centers for the Treatment of Addictive Disorders

April 5, 2004 for Subcommittee

VIA FACSIMILE
To: Congressman Mark Souder

Re: Comments on Drug Treatment

Dear Congressman Souder,

I watched with great interest the hearings by your subcommittee on Treatment of Drug Addiction. I was impressed by your very incisive questions to the panel of experts from the government and private agencies. I will begin by just three questions that sum up the problem besetting the treatment community resulting in shockingly poor outcomes:

- **Why are medications rejected in the treatment of the 'disease' of addiction?**
- **Why only highly addictive drugs are heavily promoted in the treatment of addictions?**
- **Why are non-addicting drugs approved by the FDA rejected or ignored by the treatment community and Federal agencies like NIDA?**

Although alcoholism and drug addiction is a major public health issue the treatment community has rejected all advances in the field of neurosciences on the grounds that addictions are caused by moral weakness, lack of will power or a personality flaw.

Addicting medications are very helpful in the detoxification process but have a huge problem if used chronically. Yes, sometimes they have to be used, but with great caution and discretion. A perfect example of this problem is the treatment of heroin addiction and now the near epidemic of addictions to pain medications like OXYCONTIN and VICODIN. The NIH realized way back in the 1970's that getting people off methadone is very difficult and therefore, developed a medication completely free of any addictive liability. The drug is called naltrexone. Naltrexone does not produce a 'high' is non-scheduled and is not addictive or have any abuse liability. Pharmacologically it is the complete opposite of methadone. Yet, NIDA ignored this drug on the grounds of poor compliance. Compliance is a problem with any chronic disease and particularly with addictive disorders. It takes special training to motivate patients to take a medication that does not produce a high, yet the agencies have not done anything to provide the psychosocial counseling to motivate patients to take non-addicting medication.

Naltrexone is so old that it is now a generic drug and it is the only drug that is approved both for the treatment of opioids and alcoholism. Yet few have heard about it.

6651 Chippewa St., Suite 224 St. Louis, MO, 63109 *Phone: 314-645-6840 Fax: 314-645-6847* *Email: contactus@arcamidwest.com Web: www.arcamidwest.com*

Naltrexone was the first of the non-mood-altering medications developed. Most of the newer medications that are awaiting FDA approval or look promising to treat alcoholism or drug addictions belong to this category. Some of the drugs include Acamprosate, Baclofen, Topiramide, Vigbatrin, Ondansetron etc. Yet little is being done to train therapists and counselors on using these types of medications in conjunction with relapse prevention counseling.

The major fallout of promoting only highly addicting and abusable drugs for the treatment of addictions greatly contributes to the stigma associated with the disease. Moreover, we open ourselves to pressures to legalize addicting drugs like marijuana, cocaine as a way to reduce drug addiction. We are all too aware about millions of dollars being spent on ballot initiatives in many states to legalize drugs. You talked about the problems Vancouver is experiencing with legalized drugs.

I sincerely believe that unless we make a major shift and incorporate the significant advances made in the field of neuroscience, we will end up wasting billions of dollars as has happened in the past.

I am not supported by any organization or company and would be honored to offer a different perspective on the use on non-mood-altering drugs in the treatment of alcoholism and drug addictions.

Yours respectfully,

Percy Menzies, M. Pharm.
President

H. LEE MOFFITT Cancer Center & Research Institute
The End Of Cancer Begins Here.
A National Cancer Institute Comprehensive Cancer Center
At the University of South Florida

The Honorable Mark Souder, Chairman
Committee on Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515

Re: February 9th Federal Field Hearing on Abuse of Prescription Medications, Winter Park, FL

Dear Mr. Chairman:

As a pain management advocate and a pain management clinician, I am greatly concerned about the ongoing negative press coverage of opioid analgesics and their abuse. Unfortunately, such coverage significantly impacts the ability of patients in our state to find a provider who can adequately assess and pharmacologically manage pain. Published data continues to demonstrate that the under-treatment of pain continues to be an epidemic in our country and in our state. Just recently, the Florida Pain Initiative (FPI) released survey data demonstrating that nearly four of five households in Florida have at least one member who suffers from pain on at least a monthly basis. Although I agree that abuse and diversion are problematic, the under-treatment of pain is a much larger issue. The continued under-treatment of pain in this state will only lead to greater socioeconomic costs (e.g., disability, lost productivity) and greater problems. As a pain clinician, an advocate for pain patients, and the president of the Florida Pain Initiative, I have seen many patients mismanaged by providers due to fear of scrutiny and fear of opioids. Opioids are definitely not always appropriate, but when needed, these medications can drastically improve quality of life, reduce anxiety, fear and depression, optimally control pain, and improve functionality. In fact, I've seen many patients who have failed other therapies dramatically improve on opioid therapy, returning to work and become functioning members of our society. Strangely enough, most state and national data suggest that addiction continues to be a problem in up to 10% of our population - a significantly lower number than the 75% of patients in our state with regular persistent pain. Addiction is not a drug-induced disorder and is defined by the American Society of Addiction Medicine as a "primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations." Although the media in our state and parents of drug-abusing children insist that the problem of addiction is actually a direct result of the medication, the manufacturer marketing, or provider prescribing, there is no evidence that this is the case. Furthermore, all published literature regarding addiction describes this disorder as a complex syndrome that has much more to do with underlying psychiatric disorders than one or two drugs. Furthermore, I am having a difficult time comprehending why our state is blaming pain providers and manufacturers for criminal activity and the increased prevalence of adolescents (or adults) using prescription controlled substances without a prescription. While I believe any death from a drug overdose is a tragedy, I believe our state is misplacing the blame and avoiding the fact that this is criminal activity. If a criminal wishes to abuse a prescription controlled substance, they will find a way. No evidence from any state has ever suggested that changes in provider prescribing or

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regulation of specific classes of opioids makes any difference in actual rates of abuse and diversion. Furthermore, most data suggests that opioid-related deaths are a result of polysubstance (i.e., multiple substance) abuse, including illegal substances such as cocaine and heroin and "licit" substances such as alcohol. In comparison, if many patients or criminals took 20 aspirin this morning (i.e., abused it) and bled to death as a result, I doubt our state would be making such an issue of it. Either way you cut it, this is still abuse (aspirin or an opioid). Our state would be better served by spending its money on improved education of the public regarding abuse, education of providers on appropriate opioid prescribing and the under-treatment of pain, education of healthcare providers regarding appropriate screening for substance abuse or patients at risk for substance abuse, and earlier intervention when abuse is identified.

As a pharmacist, a pain management clinician, a pain patient advocate, and the president of the FPI, I would like to request time to testify at the February 9th Hearings in Winter Park, Florida. Hopefully, my testimony will provide some balance to the issue.

Please do not hesitate to contact me at the following phone numbers if you have any questions.

Sincerely,
Jennifer Strickland

Jennifer M. Strickland, PharmD, BCPS
President, Florida Pain Initiative
Clinical Pharmacist, Pain and Palliative Care Service
Director, Specialty Pharmacy Residency in Pain and Palliative Care
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