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PRESCRIPTION DRUG MONITORING: STRATEGIES TO PROMOTE TREATMENT AND DETER PRESCRIPTION DRUG USE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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PRESCRIPTION DRUG MONITORING: STRATEGIES TO PROMOTE TREATMENT AND DETER PRESCRIPTION DRUG USE

THURSDAY, MARCH 4, 2004

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

The subcommittee met, pursuant to notice, at 1 p.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Greenwood, Whitfield, Norwood, Shimkus, Wilson, Buyer, Ferguson, Brown, Pallone, Stupak, Green, Strickland, and Capps.

Staff present: Patrick Morrisey, deputy staff director; Jeremy Allen, health policy coordinator; Cheryl Jaeger, majority professional staff; Eugenia Edwards, legislative clerk; and John Ford, minority counsel.

Mr. NORWOOD [presiding]. The subcommittee will now come to order. First I want to, and I will do so formally in a minute, but I want to thank our witnesses for being here. Congressman Rogers will be here shortly, and will testify and be questioned first, and then we'll go to the other panel.

I'll recognize myself now for an opening statement.

First, good afternoon to everyone. This, for me, is a very exciting hearing. I'm looking forward to it. There's so much to do and so much we need to learn, but I want to first thank all of you for attending and being part of this today.

As our witnesses are going to testify today, the need for legislation to curb prescription drug abuse is very obvious. It's been obvious to me in my life for about 30 years.

In 2002, the Office of National Drug Control Policy reported that 6.2 million Americans abused prescription drugs, that's 6.2 million. 13.7 percent of youth between the ages of 12 and 17 have abused prescription drugs at least once in their lifetimes, and emergency room visits resulting from narcotic pain relievers abuse has increased 163 percent since 1995.

On Monday, the White House announced the President's strategy for combating prescription drug abuse in an event that included the heads of DEA, FDA, the Drug Czar and the chairman of a committee that doesn't have jurisdiction over this issue. They highlighted the need for expanding prescription drug monitoring programs.

Twenty one States currently operate from some form of prescription drug monitoring program. Maybe it's less, but the President indicated 21 yesterday, but we know it's somewhere between 21 and 15.

The President would like to see this number expanded, and certainly we should consider ways to meet that goal.

Mr. Chairman, welcome.

As we consider how to expand these programs, there are several issues we need to consider in the design of these programs. Should they be State-based or federally centralized? Should they be run out of HHS or DEA? Who should be able to access the data base?

A State like Nevada allows very little access to their data base, while Kentucky has numerous people allowed access.

What schedule of drugs should be covered under a monitoring program? What can we do to protect patient confidentiality, because if we can't be confident that we are protecting patient confidentiality we might not be able to do this.

We also need to be very certain we aren't increasing the liability of anyone through the establishment of monitoring programs.

I look very forward to our witnesses addressing these issues today. The use of drugs to relieve pain is a subject with which I have had significant experience over my life. I experienced it when I was in Vietnam. I've experienced it in my practice as a dentist for 25 years. I experienced it with my friends and family through difficulties they faced in life. I've experienced it personally after a car wreck in 2000. I feel very strongly that we don't do a good enough job in this country to alleviate pain when we can, and morally and ethically we should.

I also know that the drugs that relieve the most severe pain are also usually the most dangerous. The value of drugs in relieving pain may be a double-edged sword, because drugs can create a dependency that makes it difficult for sufferers to wean themselves off these painkillers. And, these painkilling drugs also can be diverted for recreational use by abusers.

This is why we have the Controlled Substance Act. We hold certain drugs to a higher regulatory standard, because we are concerned about how they might be abused. We are faced with a difficult and a complicated task in combating prescription drug abuse. We must be careful that our efforts to stop abuse don't forbid legitimate patients from getting the relief that they need when they need it.

If we come up with solutions that discourage doctors from prescribing appropriate painkillers, pain care in this country will take a serious step backward.

I'd like to close by, again, welcoming all of our witnesses. Chairman Rogers, who has been a pioneer in this field, and, Mr. Chairman, I'm grateful for the work you've done, and I apologize to you that people like me, who are so familiar with this problem, hadn't done something before now. But, thank you for what you've done.

Marcia, Ms. Crosse, of the GAO, who is going to speak to their Report on Monitoring Programs. Danna Droz, did I say that right, Droz, of the great State of Florida, way to go, girl, who is here representing the National Association of State Controlled Substance Authorities. James Holsinger, who runs Kentucky's NASPER pro-

gram, and Doctor Laximaiah Manchikanti, how did I do, got it better, huh, a doctor who understands and has done great work in the treatment and complexities of treating patients in severe pain.

Again, I sincerely thank all of you that are here. We will give the members an opportunity to make an opening statement. I remind the members, your opening statement is 5 minutes. If you wish to waive your opening statement, we'll add 3 minutes to your questioning time, and with that I yield to my friend, Mr. Brown, the ranking minority member of this committee.

Mr. BROWN. Thank you, Mr. Chairman. I want to welcome Doctor Manchikanti and all the distinguished witnesses that have joined us today.

Prescription pain relievers, stimulants and other controlled substances, as we know, play a crucial role in our healthcare. When misused, these same medicines can be enormously disruptive. Some are addictive, some are life-threatening, many are both.

As these medicines proliferate, so, unfortunately, does the risk of misuse. Over the last decade, use of prescription pain relievers has increased by about 200 percent, while the use of stimulants has increased by about 150 percent. 6.2 million Americans misuse prescription medications for non-medical purposes.

In 1999, a quarter of those who took prescription drugs for non-medical purposes were new users. In other words, this problem isn't just growing, it's exploding. Nearly 10 percent of the individuals in drug treatment today are there, not because of a cocaine habit, not because of a heroin habit, not because of a crack habit, they are there to break free of a prescription drug habit.

Physicians and pharmacists too often play an unwitting role in the misuse of prescription drugs. By receiving prescriptions for more than one practitioner, filling these prescriptions in pharmacies unaffiliated with one another, patients can stockpile and mix controlled substances, in which case the whole notion of controlled substance simply loses its meaning.

It's a tragically easy route to drug abuse for vulnerable adolescents and adults. It's an untenable situation for health professionals, whose mission it is to help patients heal. To combat this problem, physicians and pharmacists need information. Fifteen States have implemented drug registries that track the prescribing of certain controlled substances. Two other States are in the process of doing that.

The GAO has studied drug registries and have reinforced the usefulness of these monitoring mechanisms.

This hearing is intended to equip members with the background that we all need as we prepare to consider various legislative proposals intended to expand access to drug registries.

I thank you, Chairman, for giving members the opportunity. I look forward to hearing from all of our witnesses.

Mr. NORWOOD. Thank you, Mr. Brown.

I'd like to recognize my good friend from Kentucky, Mr. Whitfield, who all of us need to thank and congratulate for the work that he has been doing in this particular area of monitoring prescription drugs.

Ed, you are recognized for 5 minutes.

Mr. WHITFIELD. Mr. Chairman, thank you very much for having this hearing, and the issue of prescription drug abuse is a national issue, and is a matter of public health, one of which this committee has jurisdiction, and unless my memory fails me, this may be the first hearing that we've had on prescription drug monitoring programs, which is certainly a very important program.

I was also, like you, Mr. Chairman, pleased to note that President Bush's recent commitment to curbing prescription drug abuse, through the Office of National Drug Control Policy.

We do have a distinguished panel here today, including our colleague, Hal Rogers, who is the Dean of the Kentucky Delegation. He's worked hard to address the problem of prescription drug abuse, specifically, OxyContin, which is prevalent in this district, and has established a program of grants available to States.

I'm also pleased to welcome Doctor James Holsinger, who is the Secretary of the Kentucky Cabinet for Health and Family Services. The Secretary was appointed to his position by our former colleague and member of this committee, Doctor Ernie Fletcher, and I look forward certainly to hearing his testimony as well, Secretary Holsinger's.

I'm also pleased to welcome Doctor Laximaiah Manchikanti, who is President of the American Society of Interventional Pain Physicians. As a physician, he will give us some insight into how physicians are working to identify and treat patients who are addicted to prescription drugs.

When we talk about prescription drug abuse, we are talking about individuals who are using controlled substances in a manner that is inconsistent with their prescribed use. The Federal Government exercises its authority in this area through the Controlled Substances Act of 1970. The Act, of course, classifies drugs into five schedules, based mainly on their potential for abuse.

Although Schedule 1 drugs, such as heroin, are not legally available, Schedule 2 through 5 drugs are. However, the production and distribution of these drugs, such as OxyContin, are regulated by the Drug Enforcement Administration.

I recognize that many people live with chronic pain, or have pain as a direct result of a disease, such as cancer, and know that in many cases relief from their pain comes only from a controlled substance. It is important that these individuals continue to have access to these drugs.

Unfortunately, some people who are prescribed a controlled substance to relieve pain, either on a long or short-term basis, become addicted to them, and many individuals who have not been prescribed these drugs illegally obtain them as an alternative to other drugs.

So, we are all familiar with the problem of prescription drug abuse, but the issue becomes how do we help prevent abuse? And, I believe, along with everyone else in this room, that one way we can effectively combat this problem is through enhancing prescription drug monitoring programs.

Many States, including my own State of Kentucky, have prescription drug monitoring programs, and many people would say that the Kentucky program, which I might add was established by the Dean of our Delegation, Hal Rogers, many people say it is the most

effective program in the state. And so, I think we are all very proud of that.

But, today's hearing, I think, is important because we need to determine where do we move in the future. You can make a strong argument that there should be a strong Federal program, because of the Controlled Substance Act, because of DEA, because of Medicaid that the Federal Government is involved in distributing medicines, because of the new Prescription Drug Benefit Program under Medicare. And, some of us on this committee have actually introduced legislation to do that.

Where, on the other hand, we recognize that there are many people, and we'll hear some testimony today about this, who believe that the most effective way to deal with it is through a State program, and both of them have their weaknesses, and not any program in existence today is doing everything that needs to be done. For example, the State programs deal only with intra State issues, and so there's an inner connectivity problem for patients who go back and forth across States, and maybe one State does not have a program.

So, those are some of the issues that I know we'll be getting into today, and I'm delighted with our witnesses that we have, experts in the field, and all of us will walk away from this hearing better informed than we are now, and I'll yield back my 1 second.

Mr. NORWOOD. Thank you very much, Mr. Whitfield, and thank you for the good work that you do.

I'd like to remind all my colleagues, if you wish to waive your opening statement, you'll pick up 3 minutes on your questioning time, and the only reason I'm suggesting that to you is that Chairman Rogers does have a homeland security thing coming up.

So, with that, Mr. Pallone, you are now yielded 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to say that I'm pleased to be here today to discuss prescription drug monitoring and the various ways that Congress can address the ever-increasing problem of prescription drug abuse throughout the United States.

I want to thank all the witnesses for joining us today, to provide expertise on how best to tackle widespread addiction abuse and illegal marketing of prescription drugs, and particularly, I look forward to hearing from my good friend, Doctor Laximaiah Manchikanti, who has worked tirelessly on the forefront of creating a national prescription drug monitoring data base. And, as a result of Doctor Manchikanti's dedication to improving public health and his contributions to the medical profession, Congressman Whitfield and I introduced legislation, known as the NASPER Bill, H.R. 3015, the National all Schedules Prescription Electronic Reporting Act, and I, along with the bipartisan group of nearly 40 members, who have cosponsored this legislation, feel strongly about a national uniform approach to addressing prescription drug abuse and crime.

And, I also wanted to pay special attention to the contribution of Congressman Bart Stupak, who is a cosponsor and worked very hard on this, and also I think you've included in the record, Mr. Chairman, a letter from the American Association of Physicians of

Indian Origin, which is a group that I work with a lot who also support the legislation.

Everyone here, including the Bush Administration, agrees that rampant prescription drug misuse and abuse is a growing problem. Millions of Americans who take prescription medications take them responsibly. However, reliable data indicates there are also 9 million Americans, including children, teenagers and seniors, who use prescription drugs for non-medical reasons, and this can result from needing various multiple medications and thereby make them vulnerable to misuse, or can result from illegal sales of prescription drugs and prescription forgery.

The NASPER approach is vitally important to ensuring our public health, in my opinion. It would establish a national electronic data bank for practitioner monitoring of Schedule 2, 3 and 4 controlled substances, and allows healthcare practitioners and pharmacists to ensure that they are prescribing and dispensing only necessary medications.

Without such a data bank, practitioners and pharmacists have no way of knowing with any certainty whether a particular patient may be receiving the same or incompatible controlled substances from other practitioners. Patients may be receiving prescriptions for these medications from multiple practitioners, and this is particularly troubling in light of the fact that such controlled substances can be the subject of abuse, misuse and trafficking, and have the potential for dangerous drug interactions.

I think we can all agree, Mr. Chairman, that the unmonitored prescription of these medications poses serious public health issues. A number of States, as has been mentioned already today, including California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Michigan, Nevada, New Mexico, Oklahoma, Texas and Utah, have created prescription data banks for controlled substances. The State programs, however, are neither uniform, nor integrated. Moreover, the misuse of Schedule 2, 3 and 4 substances is a national problem that cannot be effectively addressed, in my opinion, on a State-by-State basis.

And, this proposal, our proposal for a national prescription data bank, I think makes good sense from a public health perspective, and I look forward to hearing from the witnesses and working with my colleagues on this very important issue.

I do want to thank you and the subcommittee, both you, Mr. Chairman, and the ranking member, for having this hearing today. I think it's very important, and I think it's testimony to the fact that you would like to see some kind of legislation passed, and, obviously, we are willing to work toward that goal on a bipartisan basis.

Thank you.

Mr. NORWOOD. Thank you, Mr. Pallone.

I can't imagine how we ought to do a bill that isn't bipartisan in nature, and I can't imagine how we would want to do a bill that we wouldn't have everybody in Congress voting for. This is a very important issue and it's not our last hearing.

I'd like to recognize my friend from New Mexico, Ms. Wilson, you are recognized for 5 minutes.

Ms. WILSON. Thank you, Mr. Chairman, and I don't think I'll take the full 5 minutes, but I did want to highlight what a problem this is, and a growing problem in New Mexico.

New Mexico, we ended or lost our prescription drug monitoring program in 2000, and I read a story that was in the newspaper in November, 2003, about a grandmother who was a child psychiatrist, and she had arthritis, and one of the side effects of her arthritis medicine was depression. So, she started to be treated for the depression, and she was taking anti-anxiety drugs, Xanax and Halcion, and started to need them more and more. She was lying about her need for the them and where she got them. She was receiving identical prescriptions from a family doctor, a rheumatologist and a psychiatrist. If she had a prescription for three a day she'd take nine a day, and eventually she realized that the disintegration of her life, the loss of her job, the loss of her home, her relationships with her grandchildren, disintegration that was happening to her was not because of the arthritis and the depression, but because of the drugs and the drug addiction.

She ended up in a detox center for 6 days, and she's now getting her life back together, but I think what this really tells us is that this can happen, addiction can happen to anyone, and I regret that we do have in place the kind of prescription drug monitoring program that might have picked up the multiple doctors' prescriptions to a single person so that this woman could have gotten help.

In New Mexico, death from overdoses have been slowly and steadily increasing. There was 2.7 per 100,000 population in 1998, and it's now up to 3.8 per 100,000 in 2002. While illegal drug use is on the decline, the abuse of legal drugs and addiction to legal drugs is on the increase. You see it in our poison control center statistics in New Mexico, in our death statistics, and in tragic stories of lives lost or destroyed because of addiction to prescription drugs.

I look forward to the testimony here today, and I look forward to working with my colleagues and with the administration on how we can address this problem so that those who need medicine still have access to it, but that we provide health, support and recognize the potential problem of addiction to those lifesaving and life-changing medicines.

I thank you, Chairman—Mr. Chairman, for holding this hearing today and yield the balance of my time.

Mr. NORWOOD. Thank you very much.

Ms. Capps, you intend to waive your opening statement and you'll get 3 minutes of additional time in your questioning.

I'd like to now welcome our Chairman and offer him time for his opening statement.

Mr. Bilirakis.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Chairman.

Mr. Chairman, I have a statement that I would ask unanimous consent it be made part of the record, and would merely just want to welcome all of our witnesses, and to commend Mr. Whitfield and you for your interest in this subject, and the fact that you have supported that interest by virtue of offering legislation, and, particularly, our colleague, Mr. Rogers, who has been a fighter of this issue for a long, long time. And, Hal, I know you've been in the middle of a pretty darn important hearing in your own committee

that you've headed, and I appreciate your taking time to be here, because we need to hear from you on the issue.

Thank you very much, Mr. Chairman. Thanks for being here on time, but between a Veterans Committee hearing and a very important Veterans Special that I had to do on the floor.

[The prepared statement of Hon. Michael Bilirakis follows:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, CHAIRMAN, SUBCOMMITTEE ON HEALTH

Good afternoon. Today's Health Subcommittee hearing, entitled "Prescription Drug Monitoring: Strategies to Promote Treatment and Deter Prescription Drug Abuse," focuses on an issue that is extremely important to this country's overall health and well-being. I thank you all for coming here today.

Prescription drug abuse is an issue that many Members of the Energy and Commerce Committee have been greatly concerned about, and is also receiving national attention as well. President Bush recently included a plan to increase the number of state prescription drug monitoring programs in his National Drug Control Strategy.

In recent years, the misuse and abuse of prescription medications that are classified as schedule II, III, and IV controlled substances has become a major national concern. A 2001 Drug Enforcement Investigation (DEA) investigation into the abuse of the pain medicine OxyContin found that many drug abusers and dealers illegally obtain prescription drugs by "doctor shopping," a practice whereby they visit a number of physicians in an attempt to maximize the number of drugs they can obtain. Additionally, drug abusers and dealers have illegally obtained prescription drugs from physicians or pharmacists, forged prescriptions, and purchased drugs from Internet pharmacies without a valid prescription.

Prescription drugs that are classified as schedule II, III, and IV are primarily pain-related drugs. These drugs are an important source of treatment for many Americans; however, by nature of their composition, they have the potential for serious abuse. One strategy states have adopted in their attempts to deal with this crisis is the implementation of prescription drug monitoring programs. Currently, 22 states have such programs, and many additional states are considering implementing systems.

We have an excellent panel of witnesses here today that will help Subcommittee members learn more about the problem and what differing notions exist about the proper role of the federal government is in enabling the growth of these prescription drug monitoring programs.

First, I would like to thank our colleague, Congressman Hal Rogers, for taking the time to share his personal experiences with OxyContin abuse in his state of Kentucky with us. Your insight will prove valuable as the Subcommittee moves forward with its work in this area.

I would also like to thank our other witnesses for being here today. Ms. Marcia Crosse, the Director of Health Care for Public Health and Military Health Care Issues at the General Accounting Office is here today to discuss GAO's studies into prescription drug monitoring programs, and how they have helped reduce the illegal diversion of drugs.

Ms. Danna Droz, who recently became the Executive Director of the Boards of Pharmacy and Nursing Home Administrators in my home state of Florida, is testifying before us today to present the views of the National Association of State Controlled Substance Authorities.

Dr. James W. Holsinger, Jr., Secretary of the Kentucky Cabinet for Health and Family Services will share his state's experience with the Kentucky All Schedule Prescription Electronic Reporting program (KASPER). I look forward to hearing about Kentucky's program.

Finally, Dr. Laximaiah Manchikanti, will be representing the American Society of International Pain Physicians, and will discuss his organizations views on prescription drug monitoring systems.

Thank you again for taking the time to join us today. I would now recognize the ranking member, my friend from Ohio Mr. Brown, for an opening statement.

Mr. NORWOOD. I was watching you.

Mr. BILIRAKIS. Oh, were you?

Mr. NORWOOD. Mr. Green, you are now recognized for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman, and I will not take the full 5 minutes, because I know I want to hear from our panel and also Chairman Rogers, and I'll submit my statement for the record.

I appreciate the opportunity to have this panel and also this hearing on the abuse of prescription drugs. I don't think that with what's in the news, whether it be, you know, celebrities or anyone else, it's a problem and I appreciate you calling this hearing so we can call attention to it.

Thank you.

Mr. NORWOOD. Thank you, Mr. Green.

Mr. Shimkus, you are recognized for 5 minutes.

Mr. SHIMKUS. Thank you, Mr. Chairman.

My inaugural visit to the Health Subcommittee, I know it's going to be a short stay, but I'm glad to be on here for a short time.

I, too, want to welcome Congressman Rogers, a well-respected member from Kentucky, and we're glad to have you in our room, and in our midst.

I also want to personally welcome Doctor Manchikanti, who has practiced in my district in Southern Illinois, and just as Doctor Manchikanti can easily venture from Illinois to Kentucky to practice medicine, a drug abuser could travel from my district to Kentucky, Indiana, and even Missouri, to illegally obtain a prescription, I think that's basically what we are here to discuss and debate, and to try to recognize.

I also see Senator Hutchinson in the crowd, and I appreciate his helping educate me on this issue.

And, with that, I'll yield back my time.

Mr. NORWOOD. Mr. Stupak, you are recognized for 5 minutes.

Mr. STUPAK. Mr. Chairman, I have a wonderful opening statement, but with all due respect to our witnesses I'm going to waive it.

It's good to see our colleague, Mr. Rogers, here. I know he's worked on this issue, and, Doctor Manchikanti, I look forward to continuing to work with you.

I waive it, Mr. Chairman.

Mr. NORWOOD. Thank you very much.

I remind all of you, you can waive and pick up extra time in your questioning, so we can get to the panel.

Mr. Buyer, you are recognized for 5 minutes.

Mr. BUYER. Thank you.

Mr. Chairman, I want to thank you, Mr. Bilirakis, for holding this hearing, and, Hal, for you to be here. We are anxious to receive your testimony. I also recognize a former colleague of ours who is sitting out here in the audience, Tim Hutchinson, former U.S. Senator, thanks for being here.

I'm pleased that we are going to address this issue, and I welcome your testimony. Two points I would like to address and, hopefully, you can touch on it in your testimony. One is, we can talk about abuse and illegal use, how serious that is, but there are also issues about over medication. A lot of these people, we have patients who are over prescribed, and we also have patients who are very demanding upon their doctors for immediate relief. And, sometimes we are a little too eager to write scrips, I think. Second is, there's a dark side of the medical practice that nobody likes to talk

about. We can put these monitoring programs in place, but we don't like to talk about the dark side, and that's the illegal use and abuse by doctors themselves, by pharmacists themselves, by dentists themselves, the dark side of medical practice. And so, I welcome your testimony to discuss that today.

We can't just talk about monitoring programs as though the medical profession, yes, they are going to police this system, yet who is policing themselves.

Thank you, I yield back.

Mr. NORWOOD. Thank you very much, Mr. Buyer.

Mr. Strickland, you are now recognized for 5 minutes.

Mr. STRICKLAND. Thank you, Mr. Chairman, and I want to thank you for organizing this hearing today.

I am interested in deterring the prescription drug diversion because of the immense problem of OxyContin abuse in many rural areas.

I note my colleague from Kentucky, who has a district much like mine, and I have witnessed, personally witnessed, doctors coming into my little hometown of Lucasville, Ohio, setting up shop for 2 or 3 weeks, putting a handwritten sign on their door saying, "All doctor's visits $250 cash," not accepting any credit cards, not accepting any checks. They left Lucasville, went to Chilliconte, Ohio, were there for 3 or 4 weeks, then they went to Hanging Rock, Ohio, occupied a place that was a former bar, were there for a few weeks until they were burned out. I don't know if it was an accident or not. The local sheriff told me they were going to be taken care of. Then they went to Jackson, Ohio. They were there for several weeks. I called the FBI. I talked to the county prosecutors. I talked to multiple county sheriffs. I called the Ohio Medical Association. I called the Ohio Licensing Board, to talk about these guys.

And so, this is a real problem that I have personally observed. I receive letters from constituents, whose sons and daughters have died as a result of the overdose of use of OxyContin. These tragedies cannot go unchecked.

I'm sure that OxyContin is not the only prescription drug abused in Appalachia, but it is certainly an example of one of the most tragic abuse situations.

This week, my good colleague, the good Doctor Norwood and I, have introduced H.R. 3870, titled, "The Prescription Drug Abuse Elimination Act." The bill is a comprehensive effort to close loopholes in current law that lead to prescription drug abuse. In addition to creating a prescription drug monitoring program like those we will learn about at this meeting, the bill also seeks to regulate Internet pharmacies, the drug distribution process, and the personal importation of controlled substances.

The bill won't stop all prescription drug abuse, but its passage will be a big step in the right direction. The bill Doctor Norwood and I have introduced will build on existing State prescription monitoring programs, by providing grants through the Department of Health and Human Services for States to establish, operate and update prescription monitoring programs. In addition to meeting some basic requirements, States accepting these grants will be required to ensure that their monitoring systems can share information with other States. That's especially important in a region like

mine. My district borders Pennsylvania, West Virginia and Kentucky.

Aside from these mandates, the States would have the responsibility of determining whether the data base can be queried, and who was allowed to query it. Our intention is to expand and improve current system State monitoring programs without eliminating the work, for example, that Kentucky and Nevada has already done.

I know that one argument against prescription monitoring programs is that they will have a chilling effect on doctors' willingness to prescribe pain medications to patients.

I hope to learn from the witnesses who testify today that this has not been the case in the States that have already established monitoring programs. I believe that drugs like OxyContin are important advances in the treatment of pain and pain management, and we must do everything possible to educate doctors and other health providers in their proper use.

One of the problems that we have in this country is the underutilization of such wonderful drugs in order to control pain. But, prescription monitoring, regulation of Internet pharmacies, the regulation of the drug distribution system, are tools that should, and can be, used to ensure that important drugs like OxyContin are properly prescribed and not diverted or abused.

So, thank you, Mr. Chairman, for this hearing, and I look forward to hearing from our witnesses.

Mr. NORWOOD. Thank you, Mr. Strickland.

Mr. Ferguson, you are recognized now for 5 minutes.

Mr. FERGUSON. Thank you, Mr. Chairman.

I thank you for holding this hearing and, obviously, I'm very, very interested in this issue and will continue to be active in that.

In deference to Chairman Rogers and the rest of our panel, I will waive my opening statement.

Mr. NORWOOD. Thank you very much.

Has everybody made an opening statement that wishes to?

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Mr. Chairman, for holding this hearing today. One of the top priorities of my Chairmanship will be oversight of the Federal agencies under this Committee's jurisdiction. On Monday the President announced his National Drug Control Strategy to examine prescription drug abuse and new federal programs to address the problem. With several key agencies at HHS working on this project, it is imperative that we move forward swiftly to review existing programs and rationalize how to invest resources so that the new projects may be successfully implemented. One of the new projects outlined in the President's plan is the expansion of prescription drug monitoring programs.

When we talk about drug abuse in America, many people automatically assume that the most pervasive problem is contraband drugs. According to the National Survey of Drug Use and Health, following marijuana, the misuse of certain prescription drugs like pain relievers, tranquilizers, stimulants and sedatives is the second most common form of illicit drug use. In some communities, the non-medical use of prescription drugs presents a bigger problem than even cocaine and heroin. The University of Michigan's Monitoring the Future survey for 2003 reports that high school seniors abuse of the prescription drug Vicodin is more than double the abuse of cocaine, Ecstasy, or methamphetamines. This is a serious problem that demands real solutions.

Prescription drug monitoring programs are one way that states have chosen to empower physicians and law enforcement officials alike to deter prescription drug abuse. These programs help physicians better serve their patients because they can review the patient's prescription drug history. Drug interactions can often lead to adverse events for patients, so these monitoring programs serve as an additional safety check.

Unfortunately, less than half of the states have established prescription drug monitoring programs. This matters because several reports indicate that when a state establishes a prescription drug monitoring program, illicit drug use shifts to contiguous states without monitoring programs. Herein lies an appropriate Federal role: strengthening prescription drug monitoring programs so that information is readily available across state lines.

I look forward to the witness testimony and working with Members of this Committee who have expressed an interest in moving legislation to address this issue.

Mr. NORWOOD. Here's how we are going to run this thing. Congressman Rogers is going to testify first. Following his testimony, members are going to have an opportunity to ask Chairman Rogers questions for 3 minutes each. Once the question and answer period has expired on the chairman, we will excuse Mr. Rogers so he can go to his homeland security meeting.

From that point on, then we'll go back to regular order. We will hear, at that point, from all the witnesses and go into our regular questions and answer period.

Mr. Chairman, I, again, want to say before you start how much I appreciate the work, the good work that you've done in this for your district, for your state, and now we need to get this done for the rest of the country.

So, with that, we ask you to give us your testimony.

STATEMENT OF HON. HAROLD ROGERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KENTUCKY

Mr. ROGERS. Well, thank you, Mr. Chairman, and thank you for holding this hearing. It's all important, and you are to be commended for it, that especially, and all of the members of the subcommittee who are here and taking a deep interest. It is well overdue.

Mr. Chairman, I have a written statement that I will submit for the record, and I will attempt to summarize it, if that would please you.

Mr. NORWOOD. Yes, sir.

Mr. ROGERS. Mr. Chairman, the scourge of prescription drug abuse is the most devastating thing that I've ever seen in my more than 30 years of public service. Drugs are tearing families apart, stretching the resources of law enforcement, threatening the takeover of local governments, stretching Social Service agencies to the absolute limit, and killing people, especially young people.

My district in Southern and Eastern Kentucky has become the prescription painkiller capital of America. On a per capita basis, our drugstores, hospitals, and other legal outlets receive more prescription painkillers than anywhere else in the Nation.

From 1998 to 2001, nearly a half a ton of narcotics reached just seven small mountain counties, the equivalent of more than 3,000 milligrams per adult who lives there.

While some of this medication is for legal purposes, too much of it is not. A public defender in Perry County, a small mountain area in my Congressional District, estimated that 95 percent of his cli-

ents either sell or abuse prescription drugs. Because of the drug epidemic, our courts are unable to keep up with the overwhelming pace of new crimes. Eastern Kentucky court dockets are jammed with drug cases—in recent years charges for controlled substances have jumped 348 percent. Our residential drug treatment centers are overwhelmed, admissions tripling in the last 5 years. People are dying.

Nationwide, OxyContin played a major role in 464 overdose deaths throughout the Nation between May of 2000 and February 2002. About a quarter of those occurred in Kentucky and Virginia alone. These deaths are not just statistics, Mr. Chairman, they represent real people.

I'm drawn now to a personal friend, my Sheriff of my County, a long-time personal friend, 15 years Sheriff, won national awards, the Sheriff of the Year in Kentucky, just a model of law enforcement. Some 2 years ago, went to a political picnic out in the county at a volunteer fire department, the bake sale, went to his car to leave and was assassinated by a sniper hiding in the woods a few yards away, an OxyContin addict who was doing the bidding of a competitor candidates for Sheriff, who wanted to take over the Sheriff's office to run the drug business in the county.

I had the obligation to deliver Sam Catron's eulogy to a crowd of 5,000 people, and, Mr. Chairman, I don't want to do that again.

That's how insidious this problem is. Why is it a big problem, it's such a problem in my region, I can't explain that to you, except to say that I believe too much of the product is on the market, both legal and illegal, and finding its way into the hands of the wrong people, unfortunately, so many young people. OxyContin has been over-aggressively marketed to rural physicians as a "safe" alternative for long-lasting pain relief. Most often, these doctors don't specialize or have any expertise in pain management.

Now, I want to say, OxyContin is a miracle drug. It's a wonderful thing, for the right patients, at the right times. I know from personal experience how needed it is in terminally ill cancer patients, for example.

But, it's been defined, and the FDA has ruled, that it can be used for moderate to severe pain. And, consequently, doctors are prescribing it for toothaches, and for broken fingers, and that type of thing, and it really eases the pain, but it's such a dangerous drug, Mr. Chairman, so addictive, and so easily abused, that I wish the FDA, and I've testified before them to request, that they change the ruling so that it can only be used for severe pain, not moderate pain.

Let me give you a couple of examples of what some corrupt doctors are doing in Kentucky. One doctor prescribed more than 2.3 million pills, to more than 4,000 patients, during a span of 101 days. Officials likened his operation to a drive-through prescription service.

Another doctor in Harlan County, who is now serving 20 years on a Federal drug conviction, saw 133 patients a day, even this office had no electricity. Similar, Mr. Strickland.

It's a problem that I've not seen the likes of in my experience, such that we started—I felt compelled in my district, 29 counties, Eastern Kentucky, to start an organization that we are now crank-

ing up called UNITE, Unlawful Narcotics Investigations, Treatment and Education, three prongs to the attack, [1] law enforcement; [2] treatment; [3] education. We divided the region into three pieces. We've secured the appropriations. We are now in the process of setting up law enforcement activities to assist the locals. We'll hire 33 undercover agents, even though the State only has 16 for the whole State. These are pros, they will work for the State.

We are starting—we'll have six new special prosecutors to travel throughout the region, helping prosecutors prosecute. The State Supreme Court Chief Justice is a part of our organization, he has now begun to set up drug courts in every county, every district, which will be an enormous help to us. We will lead the Nation in per capital drug courts when it's concluded.

Our treatment centers are absolutely overwhelmed. You could spend the rest of the dollars you have in America and not have enough treatment capability. So, we are trying to figure ways to better utilize the treatment institutions we have, to engage the faith-based community especially in helping Big Brother and Big Sister people, and we're pushing for a Federal voucher program to allow people who would qualify to use vouchers anywhere, out of state, in state, public, private institutions or the like, to secure treatment.

And, we're going to every school and establishing UNITE clubs, to help young people stay away from the problem. UNITE has a three message approach. To young people we say, get smart, stay away from this stuff. To the user, the addict, the non-criminal addict, we are saying, get help, we'll help you. And, to the pusher, whether it be a doctor or otherwise, we are saying, get out. And, that program now is drawing 200-300 people a county, as we come to those coalition building meetings, a most incredible outpouring of support and fear that I've seen.

Now, UNITE is a new program, but we've, as you say, been working with many of you on this committee on this problem for some time. In 2001, we were able to include in the Federal Appropriations Bill a sum of money to create the State Prescription Drug Monitoring Grant Program. Mr. Chairman, Frank Wolfe graciously provided the money for it. It's administered by the Bureau of Justice Administration in cooperation with DEA, that awards grants to States looking to start a prescription drug monitoring program, or to enhance an existing one. This State-by-State approach is supported by DEA, the National Alliance for Model State Drug Laws, the President and the National Office.

Just this Monday, ONDCP Director Walters announced that this drug monitoring program is one of the cornerstones of the President's new National Drug Control Strategy. To date, we've appropriate $16.5 million for this program, 18 States currently have monitoring programs in place. We expect 22 States to have theirs up and running by the end of the year. $6.5 million has been awarded, nine established grants and seven enhancements.

These State prescription monitoring systems, Mr. Chairman, are having a very positive effect, in curbing the abuse of controlled drugs by clamping down on doctor shopping. A couple of examples. Prior to the implementation of the Kentucky program, State drug control authorities took an average of 101 days to complete their

diversion investigations. That average time now has dropped to 19 days. I want to see it real time eventually.

Nevada reduced their investigation time from 120 to 20 days. Utah, an 80 percent reduction in that time. State systems clearly work as a deterrent to would-be criminals, and help reduce the availability of abuse substances.

GAO, our internal investigative arm, concluded the very same thing in a May, 2002 report. In the States that currently have monitoring systems, investigation times and productivity have dramatically improved, and illegal diversion is down.

One of the hallmarks of this program is the flexibility it provides States in setting up their own prescription drug monitoring program. There is no correct, one-size-fits-all approach in my judgment. Each State sets up the program according to their own unique needs. Kentucky houses its program in the Department of Health. Texas, the Law Enforcement Agency. Both programs are highly successfully.

The ultimate goal is to see that all 50 States have some form of monitoring programs, and that those systems communicate regionally.

So, Mr. Chairman, the decisions you make here in Washington will have tremendous impact on the lives of people, I hope saving many lives. This is a life and death matter, and I salute you and your committee for bringing this matter before us.

[The prepared statement of Hon. Harold Rogers follows:]

PREPARED STATEMENT OF HON. HAL ROGERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KENTUCKY

Thank you for allowing me to testify before you today regarding prescription drug abuse and prescription drug monitoring programs. This subject is of critical importance to me, the people in my district, and the nation as a whole.

The hills and valleys of Southern and Eastern Kentucky are home to some of the most beautiful scenic wonders in the country. Although we have been historically isolated from the rest of the country by the Appalachian Mountains, Eastern Kentuckians are proud of our rich heritage. The area is the birthplace of bluegrass music and is the location of the Cumberland Gap which allowed Daniel Boone and other pioneers to carve their way out west.

Unfortunately, these same remote hills and valleys have not been isolated from the scourge of prescription drug abuse. This is the most devastating thing I've ever seen in my more than twenty years of public service. Drugs are tearing families apart, ruining lives, and stretching the resources of law enforcement and social service agencies to the absolute limit.

The problem has literally reached epidemic proportions in my District. In fact, Southern and Eastern Kentucky has become the prescription pain-killer capital of the United States. An analysis of federal drug data found that, on a per capita basis, our drugstores, hospitals, and other legal outlets received more prescription pain-killers than anywhere else in the nation.

From 1998 to 2001, nearly half a ton of narcotics reached seven small mountain counties—*the equivalent of more than 3,000 milligrams for every adult who lives there.* For reference, a typical pill might contain 10 to 20 milligrams. While some of this medication is for legal purposes—too much of it is not. These drugs are hitting the streets resulting in addiction, crime, and death.

Our courts are unable to keep up with the overwhelming pace of new crimes. A public defender in Perry County, a small mountain area in my Congressional District, estimated that 95% of his clients either sell or abuse prescription drugs. Eastern Kentucky court dockets are jammed with drug cases—in recent years charges for controlled substances jumped 348%. Subsequently cases are delayed for months, if not over a year, before they are brought to trial. These delays can lead to unreasonable plea bargains or dismissal altogether. In either case, justice is not truly served and pill pushers go back to plying their trade.

Additionally, Kentucky's residential drug treatment centers are overwhelmed, with admissions tripling since 1998. A Prestonsburg, KY drug treatment program director reports that the new patients, most hooked on OxyContin, are younger and sicker than clients in previous years. Over half of newly admitted patients to drug treatment centers in Kentucky have identified OxyContin as their drug of choice.

Most tragic of all, our people are dying. Nationwide, OxyContin played a major role in 464 overdose deaths throughout the nation between May of 2000 and February of 2002—**about a quarter of these deaths occurred in Kentucky and Virginia alone.** These deaths are more than just statistics—these numbers represent real people that have been taken away forever.

For me, two of these deaths made an indelible impression, putting a face on the tragic consequences stemming from Oxycontin abuse. In 2001, I invited Pastor Ron Coots to testify before the Commerce, Justice, State Appropriations Subcommittee for a hearing we held on Oxycontin abuse. His son Joshua—a bright young man from a good home with a promising future—had been hooked on OxyContin and sat by his side during the hearing. Joshua had gone to rehab and was clean of OxyContin when he came before our Subcommittee. I'll never forget Pastor Coots telling me about the pain that Joshua's drug problem caused his family but how proud he was that Joshua had confronted his problem and beaten it. Less than a year after that hearing, Joshua got hooked on OxyContin again and died of an overdose.

Another tragic story I want you to share with you is that of Sheriff Sam Catron. Sam was a friend of mine and one of the finest law enforcement officials Kentucky has ever seen. On Saturday, April 13, 2002, Sheriff Catron began the day like any other day putting on the brown and yellow uniform of his proud department. That Saturday happened to be an important day for him as well. He was set to appear on television's America's Most Wanted to help in the search for a fugitive from justice. Up for re-election, Sam also had a candidate's night in Shopville, KY. After meeting with local citizens, he headed to his car in order to travel home - to see himself on TV no doubt. But from the shadows came the shot from a snipers rifle; in an instant, Sam lay dead on the ground. I gave his eulogy later that week.

It turns out that the man who pulled the trigger was an OxyContin addict. He was hired to assassinate Sheriff Catron by Sam's political rival and in his need to buy more OxyContin, he did perform the job. In this case, OxyContin addiction took one life and completely ruined another as the killer will spend the rest of his life behind bars.

Why do we have such a terrible problem with OxyContin abuse in my district? Simply put, too much of this product is on the market and is finding its way into the hands of the wrong people. There is a veritable glut of OxyContin making its way onto our streets.

Purdue Pharma has improperly marketed OxyContin as a "safe" alternative for long lasting pain relief. The truth is *there is no hard epidemiological data to support that claim.* The New York Times reported that Judge Sidney H. Stein of the Federal District Court in Manhattan ruled **that Purdue Pharma's patents for OxyContin were invalid because of misrepresentation.** To win its patents, Purdue Pharma claimed that OxyContin was unique because 90 percent of patients got pain relief by taking very little medicine. In reality, *OxyContin's inventor had done no clinical studies and had no evidence to validate this claim.* Despite acknowledging that this figure was manufactured in the mind of its inventor, *Purdue Pharma executives continued to assert the validity of this claim even though they knew there was no evidence to back it up!*

General practitioners in rural areas became an easy target for Purdue Pharma and its sales force. Family doctors rarely have much formal training in pain management and can be wary of prescribing morphine because of its track record of addiction and abuse. The company invested $500 million into a marketing campaign and its sales representatives enticed doctors with claims that OxyContin was the "safe" alternative to morphine. *In reality, a 1999 Purdue-sponsored study concluded that Oxycontin is nearly twice as potent as an equal amount of morphine.*

Further compounding the problem is the fact that the Food and Drug Administration has approved OxyContin for "moderate-to-severe" pain. Due to the subjective nature of "moderate" pain, OxyContin is far too easy to prescribe and obtain. Many doctors are issuing this powerful medication for everything from a backache to a sore toe. While it is a wonderful drug for terminally ill cancer patients or others suffering from severe chronic pain, the FDA dropped the ball in their initial review of OxyContin by failing to recognize the drugs" potential for widespread abuse. It is clear to me that the FDA should limit the prescribing of this drug to severe pain only.

The moderate indication also makes it much easier for patients to "doctor-shop" and trick unsuspecting practitioners. Moving from doctor to doctor with feigned injuries, scores of patients are putting their hands on these powerful narcotics and either getting high themselves or selling the drugs for a tidy profit. A $6 pill of Oxycontin can sell for $80 while a bottle of 40 milligram pills can fetch $2,000 on the street.

Unfortunately some of the very people sworn to protect life are actually peddling these drugs for their own personal gain. For instance, a doctor practicing in the northern Kentucky region was arrested by federal authorities last September for prescribing drugs without a lawful purpose. On average this doctor was handing out 800 prescriptions a month, which balances out to almost 40 prescriptions each working day.

What is most appalling in this case is that this doctor actually expressed concern after his colleagues gave him grief about the amount of OxyContin he was prescribing. He expressed this concern to his Purdue Pharma sales representative. How did his Purdue Pharma representative respond to one of his top purchasers? The sales representative reassured the doctor by telling him that he was "doing the right thing."

Another doctor in Kentucky prescribed more than 2.3 million pain pills of different varieties to more than 4,000 patients during a span of 101 workdays. Officials likened his operation to a drive-thru prescription service.

Still another doctor in Harlan County, who is currently serving 20 years on a federal drug conviction, saw 133 patients in one day, *even though his office had no electricity.* It was reported that he had been prescribing OxyContin and Viagra to teenage boys. This is just a sampling of the problem from Kentucky; similar stories can be repeated across the nation.

In order to combat the epidemic of drug abuse in my Congressional District, I have initiated a program called Operation UNITE (Unlawful Narcotic Interdiction Treatment and Education) with $16 million in appropriations over the last two fiscal years. There are three main components to the program: Law Enforcement, Treatment, and Community Involvement. The success of this program lies in its ability to bring people together for the greater good. Federal, state, and local officials work alongside members of the community to eradicate the scourge of drug abuse from the region.

Drug abuse has stretched the resources of law enforcement to the breaking point in my area. Operation UNITE addresses this problem by creating 3 regional task forces and hiring 32 law enforcement officers to perform undercover operations, which is twice the number of undercover narcotics street agents currently employed by the entire Kentucky State Police. We are also working to create greater coordination among local, state, and federal law enforcement agencies. As a result of these combined efforts, we expect the number of arrests and prosecutions for street-level trafficking to increase dramatically. Resources will also be provided to overburdened prosecutors so they can effectively convict dealers and keep them off of our streets. The creation of a new forensic drug lab will dramatically decrease the wait for narcotics analyses thereby decreasing the time it takes to bring cases to trial.

Getting dealers and corrupt doctors off the street is one thing—real success lies in getting those hooked on drugs back on track. As I mentioned earlier, our treatment centers are overwhelmed. Operation UNITE will address the issue in three stages. In the short term, treatment resources will be coordinated to maximize their potential, making the most of what we already have today. In the intermediate term, drug courts will be created in all 29 UNITE counties. This two-pronged approach will allow our criminal courts to focus on convicting dealers and the drug courts to sentence those of lesser crimes to the treatment they sorely need. Finally, our long term goal is to create new residential treatment centers and after-care programs in order to reduce the waiting period for those who want help kicking the drug habit.

In the past, a lack of coordination between organizations providing drug treatment services existed so that one hand did not always know what the other was doing. Some areas or segments of the population were over-served while others were completely neglected. The important messages being sent out could become muddled or, worse yet, conflicting. Operation UNITE will coordinate these efforts and everyone will be encouraged to become part of the solution. Local citizens will be empowered to join together. The significant resources and abilities of faith based groups and civic organizations will be tapped. Schools will be a focal point so that students can help fight the problem instead of becoming a part of it.

While Operation UNITE is the latest step in the effort to fight drug abuse in Eastern Kentucky, I have been working to address this problem on a national level for many years. Recognizing that Kentucky's problems with drug diversion do not

simply exist within its geographic borders, I started the national "Hal Rogers Prescription Drug Monitoring Program" in 2001.

This program is managed by the Bureau of Justice Administration in cooperation with the Drug Enforcement Administration and awards grants to states either looking to either start a Prescription Drug Monitoring Program (PDMP) or enhance an existing program. The National Alliance of Model State Drug Laws provides technical assistance for states who seek it. The Alliance also facilitates communication between states that are considering PDMPs and states that already have a program in place to encourage compatibility. The Alliance receives $1 million annually from the Department of Justice through the ONDCP to assist them in their work.

DEA also offers tremendous help to states building PDMP's or those that are working to improve their existing program. The Controlled Substances Act of 1970 gave DEA oversight of doctors and pharmacies for the prescribing and dispensing of federally controlled substances. Since the 1980's the DEA has promoted state PDMP efforts to detect the illegal diversion of drugs. DEA has long served as an important program resource for states seeking assistance in developing PDMPs and provide valuable assistance to states that have questions about promulgating monitoring regulations.

I am pleased to report to this Subcommittee that *this state-by-state approach is working. In fact, just two days ago it was announced that the Hal Rogers Prescription Drug Monitoring Grant program is one of the cornerstones of the President's new National Drug Control Strategy on prescription drug abuse.* To date, Congress has appropriated $16.5 million for this program. By the end of 2004, we expect 22 states to have prescription drug monitoring programs in place with that number possibly reaching as high as 25 pending action from three different state legislatures.

From the late 1930's, when the first prescription drug monitoring program was established in California, until 2001, 15 states had established prescription drug monitoring programs. While it took over 60 years to establish those first 15 programs, 7 new programs will be up and running just three years after the Hal Rogers Prescription Drug Monitoring Program was created. That's nearly a 50% increase in a very short period of time.

In a 2002 report, the GAO found that Prescription Drug Monitoring Programs have helped reduce the availability of abused drugs. In fact, it was found that the institution of a PDMP in a state typically leads to a decrease in diversion while neighboring states without a program find increased diversion. Furthermore, the GAO also found that, "The ability of PDMP's to focus law enforcement and regulatory investigators on suspected drug diversion cases to specific physicians, pharmacies, and patients who may be involved in the alleged activities is crucial to shortened investigation time and improvements in productivity." In Kentucky, for example, drug control investigators took an average of 101 days to complete an investigation prior to the implementation of the KASPER system in 1999. That average has since dropped to 19 days. Nevada reduced its investigation time from 120 days to 20 days. Utah has experienced an 80% reduction in its investigation time.

One of the hallmarks of this program is the flexibility it provides states in setting up their own prescription drug monitoring program. Of the 18 programs currently up and running, each one is unique and set up according to the diversion needs of that particular state. Each state addresses concerns over access and privacy in a manner acceptable to their respective citizens. Some states, like Kentucky, house their program in a health services agency while others, like Texas, house it in a law enforcement agency. Because of this localized approach, each state with a PDMP finds their program to be an unqualified success.

As legislators we all know that a program will only succeed if the entity running it has bought into the system. The federal government must allow states to begin a PDMP when they have the financial, technical, and administrative means necessary to put together a system that works and that will last for the long haul.

While it is essential that this program work on a state-by-state basis, we must continue providing encouragement and assistance for new states to come on line and for existing states to make their programs interoperable with neighboring states. It is my goal to see that all 50 states have some form of a prescription drug monitoring system and that those systems communicate regionally in order to prevent cross border doctor shopping. Although budgets, both federally and locally, are tight, states should also look to incorporate real-time reporting systems. This would enable doctors, pharmacists, and law enforcement to quickly recognize when drugs are falling into the wrong patients' hands.

The problems associated with drug abuse are ones that we as a society do not take lightly. The social, moral, and economic costs are staggering. Families are torn apart and promising lives can be lost when individuals venture down the path of sustained drug abuse. For too long we focused our drug control strategy on illicit

substances like marijuana and cocaine and forgot about the plague that could be hiding behind each of our medicine cabinets. Prescription drug monitoring programs serve as important law enforcement, regulatory, and doctor intervention tools and have proven highly effective in fighting drug diversion. I am gratified that our President has recognized the importance of fighting prescription drug abuse and am honored to be a part of his plan. I am also pleased with the progress Congress has made in helping spread monitoring programs across the country. I look forward to working with each of you to continue these efforts in the years to come.

Mr. NORWOOD. Thank you very much, Mr. Chairman, and all of us again owe you a debt of gratitude for shouldering this burden, really, by yourself for a long time.

My sense of it is the calvary is on the way. I think Congress is fixing to crank up on this.

Mr. ROGERS. I hear the hoof steps.

Mr. NORWOOD. Anybody on our side wish to ask the chairman a question?

Mr. Chairman?

Mr. BILIRAKIS. Just very quickly.

Who is at fault? Who would you say is more at fault in this particular problem?

Mr. ROGERS. You mean the drug abuse problem?

Mr. BILIRAKIS. No, I'm talking about the particular problem—well, the drug abuse problem, but the particular problem in your area, this particular drug, the misuse of it.

Mr. ROGERS. OxyContin.

Mr. BILIRAKIS. Yes.

Mr. ROGERS. It's a tough one to answer. My area has a lot of pain-afflicted people, older population, a lot of coal mining disability retirees, pensioners if you like, people who have need for pain medication. So, there's a sort of a—there's an atmosphere there, I think, particularly, with the susceptibility of this kind of problem.

But then, you know, we've had a few bad-egg doctors who exacerbated the problem. Now, the meth labs are moving in, and OxyConton is sort of, not fading away, but not the predominant problem it was.

But, it's a National problem. I mean, we are not unique in this. It may have started in Eastern Kentucky, OxyContin abuse, but now, of course, it' spread nationwide.

Mr. BILIRAKIS. Well, we'll be hearing from the other witnesses, too, but I just—you know, we can do so many of these things, but sometimes we don't get right to the foundation of the reason for the problem.

Based on what you've told me about a couple of doctors, I know we don't want to put all doctors in that same category, you know, in my mind I've just been wondering if they've been reported to the State Medical Association, are they expressing any concern about this?

Mr. ROGERS. Oh, sure, the State Medical Association has been especially aggressive. These doctors I'm telling you about are in the penitentiary now. The U.S. Attorney has been very aggressive. He's a part of our UNITE campaign, by the way, the U.S. Attorney for the Eastern District, and he's a very aggressive prosecutor of these types of cases.

But, I emphasize again, these are just a few bad-egg doctors that, primarily, are not local people. They came in there, much the same as Mr. Strickland mentioned, to make a buck.

Mr. BILIRAKIS. Not members of the Medical Association of the county, of the state.

Mr. ROGERS. Well, they are, they have to be, but they are not regular people.

Mr. BILIRAKIS. Thank you.

Mr. NORWOOD. And, do we have a jail for them at some point?

Mr. ROGERS. Pardon me?

Mr. NORWOOD. Do we have a jail for them at some point?

Mr. ROGERS. For who?

Mr. NORWOOD. These bad doctors that are over-prescribing and coming through?

Mr. ROGERS. Yes.

Mr. NORWOOD. I mean, that's the worst possible thing I believe that a physician can do, and it blackens the eye of every good doctor in America.

Mr. ROGERS. I could tell you many more instances that would raise the hair on your head. They are in the penitentiary now, we got them.

Mr. NORWOOD. Mr. Brown, do you care to ask a question?

Mr. BROWN. Only, not really a question, but I just wanted to thank Mr. Rogers for portraying this problem so dramatically to us and so effectively. Thank you.

I also, Mr. Chairman, ask unanimous consent, Mr. Towns asked me to submit a statement from the Coalition to Assist Victims of OxyContin.

Mr. NORWOOD. So ordered.

[The statement follows:]

PREPARED STATEMENT OF THE COALITION TO ASSIST VICTIMS OF OXYCONTIN

Mr. Chairman and Members of the Committee: The Committee to Assist Victims of Oxycontin offers testimony today to assert that the prescription drug problem in America is much deeper than it appears at first glance. While it is clearly very important that Congress concentrates on the serious problem of prescription drug abuse—and we applaud this committee for its role in that work—we believe there is an aspect of this issue that has not received the attention it deserves.

The part of this story that hasn't been told is the disturbing number of people who took prescription drugs—really, took *medicine*—exactly as prescribed by their physician and have become *addicted*, or even who have become *abusers* themselves, because neither they nor their doctors knew of the addictive potential of certain prescription drugs. In short, any real effort to address the abuse of prescription drugs must address the problem of *addiction* first.

We are primarily concerned with, for example, the painkiller OxyContin. The American public has been routinely bombarded by headlines and evening news stories about the havoc this drug has has wreaked on our citizens. At this point, we barely raise an eyebrow when we read that another person overdosed, that someone robbed a pharmacy, or that a doctor is being investigated for running a so-called "pill mill." But we rarely, if ever, read a story about someone whose life has fallen apart because of a drug addiction that snuck up on them wihout warning. It is a quiet epidemic, but it is assuredly happening all over America.

Now, Purdue Pharma and its agents and defenders of OxyContin might claim every single incident of addiction is the result of drug abuse. And they have said all the right things about drug abuse and have even provided funding for anti drug abuse efforts across the country. But, with all due respect, American history is rife with tales of large corporations and their "voluntary efforts" to protect the health interests of their customers. We would respectfully assert that such efforts have not been universally sincere or successful. The case of the tobacco companies is the most infamous, but we believe it is safe to assume that Congress should regard assertions

by corporate agents with a degree of skepticism. We do not believe today that everyone who becomes addicted to OxyContin is abusing the drug. We do not believe that every OxyContin addict became addicted by crushing the pills or any of the other activities associated with recreational drug use. We believe that many—too many—are becoming addicted, and may be advancing to abusive behavior because of their addiction. This drug is much more dangerous and addictive than is being disclosed.

But still, we will need objectivity. Many people rely on these medicines, including OxyContin. By all accounts OxyContin is a vital tool in managing certain types of severe pain like that faced by cancer victims and others. Let us be clear that nobody, not even the most vocal critics of OxyContin, assert that the drug should be banned—although they do suggest that perhaps additional precautions should be taken when prescribing it and perhaps doctors have been misinformed about the potential for addiction and eventual abuse.

It is our belief that the OxyContin crisis—and make no mistake—*it is a crisis* in the towns and cities and counties across the nation. It is both a health care crisis and a public safety crisis and it boils down to some very simple issues. First, makers of the drug contended that its time release features would provide pain relief for twelve hours, and this turned out not to be the case 100 percent of the time. OxyContin's time release feature was a critical component of the drug and was one of its rationales for being granted a patent. This raises the question of lying to the federal Patent and Trade office and we understand that at least one federal judge has found, after formal court hearings, that Purdue indeed lied about its drug.

It is also our understanding that the company may have mislead regulators by asserting that fewer than one percent of people using OxyContin get addicted, but indeed had not conducted appropriate clinical trials, or really any studies to back up this assertion. The result of all this is that everyday law-abiding people became addicted because their physicians were misled by a drug company. In turn these people's lives were destroyed.

The allegation of misleading federal regulators becomes even more troubling when we are told that one of the people in the Food and Drug Administration who participated in the approval process for OxyContin went to work for the drug maker very soon after leaving the public payroll.

So, with all these allegations and concerns in mind, we urge this Committee, both today and in its work in the future, to take a hard look at the addiction aspects of our prescription drug abuse problem. Clearly, the addiction of our citizens—an accidental addiction on their part—although perhaps not on the part of the drug manufacturer, cannot be tolerated.

And frankly, we are tired of lumping hard-working, law-abiding citizens who followed the advice of their doctors into the same category with irresponsible recreational drug users, even if that practice is beneficial to the financial interests of those why may very well be responsible for their addiction.

There is a whole population of victims whose suffering has not been the focus of prior efforts by Congress. To date, the focus of Congressional inquiries and the voluntary efforts of Purdue in response to those inquiries has been the issue of OxyContin diversion and abuse by illegal users, resulting in crimes of violence, drug overdoses and deaths, the maintenance of "pill mills" run by unscrupulous doctors and the proliferation of street drug dealing in this medication.

None of these efforts, however, have focused upon the serious public health crisis among persons *lawfully prescribed* the medication by doctors who have unwittingly taken on faith Purdue's aggressive, medically unsound, and patently false representations about the purported non-addictive properties of this drug.

Members of the Coalition are representative of thousands of Americans who became "hooked" on OxyContin after being prescribed and taken the drug as directed, sometimes for problems as minor as a broken bone, dental surgery pain and chronic lower back pain. Many of these individuals have suffered not only the physical and psychological ravages of addiction, but as a consequence have lost their spouses, children, homes, jobs and dignity. For most of these addicted victims there are no affordable therapies: Medicaid and Medicare do not cover detoxification programs, nor do private insurers.

We urge this committee to focus on the addiction problem presented by OxyContin.

Mr. NORWOOD. Mr. Whitfield, any questions?

Mr. WHITFIELD. Thanks, Mr. Chairman, and, Mr. Rogers, we appreciate very much your testifying today.

Since you are really, you are sort of recognized as one of the leaders in this area, because as I said in my opening statement, the

Kentucky program is recognized as being one of the most effective in the country.

And, I know that we've already had a little bit of a discussion about different approaches to this problem, and all of us are committed to trying to solve it.

One question I'd like to ask you, I mean, I think you and I have had enough discussions that you are committed to the State approach, and, of course, the first State program started in 1940 in California, in my understanding, and we've had like $16 million appropriated, and the startup costs in Utah, I've been told, is $50,000. And yet, we only have like 16, or 17, or 18 States with programs.

My question would be, do you feel like that we, at a minimum, should mandate that States take action in this area?

Mr. ROGERS. You know, I haven't studied Chairman Norwood's bill, and I heard it described here, but I've not had a chance to examine it carefully.

But, it sounds intriguing to me that any Federal legislation would not supplant the State-by-State monitoring programs, but would, perhaps, give them some standards by which they operate. That intrigues me. I want to study that very carefully.

But, I think the State-by-State approach is the best way to go, as does the DEA, and the President, and the ONDCP, and many others, the uniform State laws people and the like.

Does it have its shortcomings? Of course, it does, and the lack of uniformity, perhaps, is one of those. But, by the same token, giving each State the capability to design, test and make a system for their special needs I think overrides the detriments that might be involved with it.

I think it's very important that these State systems, and, perhaps, this is where Chairman Norwood's bill would be most important, those State systems need to be shared across the border. That's terribly important to all of us, especially in my region. We border on Tennessee, West Virginia and Virginia. Until recently, none of them had a system, and we would see people living near the State line, cross the border, and escape monitoring. That needs to be part of what they do.

Whether we mandate that, I'm not sure of that yet. I want to study his bill to see just how that works.

It took us 60 years to establish these first 15 monitoring programs, but seven new programs will be up and running just 3 years after the monies we set aside was created. That's nearly a 50 percent increase in a very short period of time. So, I think we are making good progress.

We've got a ways to go, but I'm really nervous about Federal takeover of the program.

Mr. NORWOOD. Mr. Stupak, do you have a question of the chairman?

Mr. STUPAK. Yes. This committee spent, especially oversight investigations, numerous hearings on OxyContin coming in this country, especially through the mail, of tens of thousands of receptacles go through our mail every year. Are you finding that being part of the problem down in Kentucky?

Mr. ROGERS. Well, yes, the Internet purchase of OxyContin is widespread. So, yes, it is a problem, big problem.

Mr. STUPAK. Has you, or anyone from the Kentucky, worked with the FDA to try to crack down on this mail order, Internet sales?

Mr. ROGERS. I'm going to let Doctor Holsinger address that, perhaps, in a few minutes. He would know more of that than, perhaps, I would.

Mr. STUPAK. Okay.

Enjoyed your testimony, it was very graphic. Thanks.

Mr. ROGERS. Thank you.

Mr. NORWOOD. Mr. Chairman, thank you very much for the time that you've give us. All of us want the same thing, we've just got to work out the wrinkles.

Mr. ROGERS. Mr. Chairman, if I could just say in closing how much I appreciate you and your dedication to this problem, and Chairman Bilirakis, and Ed Whitfield, and others of you there, we appreciate the work that you are doing.

And, this is a problem that is not going to go away voluntarily, and I so much appreciate your willingness and this committee to start driving a solution across the whole country.

Mr. NORWOOD. Thank you, sir, and you are excused.

Mr. ROGERS. Thank you.

Mr. BILIRAKIS. You would think that with all the supposed power of this committee that we'd be a little more comfortable up here trying to get up from one seat—it's terrible.

Anyhow, Ms. Crosse, why don't you proceed, please?

STATEMENTS OF MARCIA CROSSE, HEALTH CARE, PUBLIC HEALTH AND MILITARY HEALTH CARE ISSUES, U.S. GENERAL ACCOUNTING OFFICE; DANNA E. DROZ, EXECUTIVE DIRECTOR, BOARDS OF PHARMACY AND NURSING HOME ADMINISTRATORS; JAMES W. HOLSINGER, JR., SECRETARY, KENTUCKY CABINET FOR HEALTH AND FAMILY SERVICES; AND LAXIMAIAH MANCHIKANTI, AMERICAN SOCIETY OF PREVENTIONAL PAIN PHYSICIANS

Ms. CROSSE. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, I am pleased to have the opportunity to testify as the subcommittee considers drug monitoring strategies for deterring prescription drug abuse. I will briefly summarize my written statement.

The increasing diversion of prescription drugs for illegal purposes or abuse is a disturbing trend in the Nation's battle against drug abuse. Diversion activities can include doctor shopping by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, prescription forgery, and purchasing drugs from Internet pharmacies without valid prescriptions. The most frequently diverted prescription drugs are controlled substances that are prone to abuse, addiction and dependence, such as drugs containing opioids, tranquilizers or stimulants.

Some States operate prescription drug monitoring programs as a means to control the illegal diversion of prescription drugs. My remarks today will focus on how State monitoring programs compare in terms of their objectives and operations, and the overall impact

of State monitoring programs on illegal diversion of prescription drugs. My comments are based on our May, 2002 report on State monitoring programs, and their usefulness as a tool for reducing diversion.

In brief, we found that 15 States operated monitoring programs in 2002, as a means to control the illegal diversion of prescription drugs that are controlled substances. In addition, West Virginia resumed operation of a program in 2003, bringing the total of current State programs to 16. Other States have programs in development.

Although these programs are all intended to facilitate the collection, analysis and reporting of information about the prescribing, dispensing and use of controlled substances, they differ in their objectives and operations. They all provide data and analysis to State law enforcement and regulatory agencies. These agencies use the information to assist in identifying and investigating activities potentially related to the illegal prescribing, dispensing and procuring of controlled substances.

Further, some programs can be used by physicians to check a patient's prescription drug history, to determine if the individual was doctor shopping to seek multiple controlled substances.

A few States proactively analyze prescription data collected by programs to identify unusual prescribing or dispensing patterns that could suggest potential drug diversion, abuse or doctor shopping. However, most programs use the prescription data in a reactive manner to respond to requests for information.

The operation of the monitoring programs varies primarily in terms of the specific drugs they cover. Some programs cover only those prescription drugs that are most prone to abuse and addiction, generally, Schedule II drugs, whereas, others provide more extensive coverage.

As Representative Rogers noted, we found that State monitoring programs helped in State efforts to reduce drug diversion. Benefits included improvement in the timeliness of law enforcement and regulatory investigations. Each of the three States we've studied in greater depth, Kentucky, Nevada, and Utah, reduced its case investigation time by at least 80 percent. In addition, law enforcement officials told us that they view the program as a deterrent to doctor shopping, because potential diverters are aware that any physician from whom they seek a prescription may first examine their prescription drug utilization history based on monitoring program data.

For example, as drug diverters became aware of Kentucky's ability to trace their drug histories, they tended to move their diversion activities to nearby non-monitored States.

Although monitoring programs can enhance the ability of States to detect and deter illegal diversion of prescription drugs, the number of States with such programs has grown only slightly over the past 12 years, from 10 in 1992 to 16 in 2004. A lack of awareness of the magnitude of the problem, concerns about confidentiality on the part of patients, physicians, pharmacists, and legislators, and difficulty in accessing funding, have kept the numbers of monitoring programs low.

The operational needs of existing programs may also shift with other changes in the marketplace. As drug marketing practices

have changed, and with the advent of Internet pharmacies, programs may need to be modified to reflect more timely information, initiate more frequent analyses to spot trends, or undertake other program enhancements that may entail additional costs.

Mr. Chairman, this concludes my prepared statement. I'd be pleased to respond to any questions you or other members may have.

[The prepared statement of Marcia Crosse follows:]

PREPARED STATEMENT OF MARCIA CROSSE, DIRECTOR, HEALTH CARE—PUBLIC HEALTH AND MILITARY HEALTH CARE ISSUES

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today and thank you for the opportunity to discuss our work on state prescription drug monitoring programs and their use in addressing the diversion of prescription drugs for illegal use.

The increasing diversion of prescription drugs for illegal purposes or abuse is a disturbing trend in the nation's battle against drug abuse.[1] Diversion activities can include "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, prescription forgery, and purchasing drugs from Internet pharmacies without valid prescriptions. The most frequently diverted prescription drugs are controlled substances[2] that are prone to abuse, addiction, and dependence,[3] such as hydrocodone (the active ingredient in Lortab and many other drugs), diazepam (Valium), methylphenidate (Ritalin), and oxycodone (the active ingredient in OxyContin and many other drugs). According to the Drug Enforcement Administration (DEA), increases in the extent of prescription drug abuse and in emergency room visits related to prescription drug abuse, as well as an increase in the theft and illegal resale of prescription drugs, indicate that drug diversion is a growing problem nationwide.

Some states operate prescription drug monitoring programs as a means to control the illegal diversion of prescription drugs. My remarks today will focus on (1) how state monitoring programs compare in terms of their objectives and operation and (2) the overall impact of state monitoring programs on illegal diversion of prescription drugs. My comments are based on our May 2002 report on state monitoring programs and their usefulness as a tool for reducing diversion.[4] For that report we reviewed information from DEA and the National Alliance for Model State Drug Laws on the features of existing programs. To gain a more in-depth understanding of these programs and the challenges they face, we also studied the programs in Kentucky, Nevada, and Utah. We selected these three states because at the time they had the most recently established programs.

In brief, we found that 15 states operated monitoring programs in 2002 as a means to control the illegal diversion of prescription drugs that are controlled substances.[5] Although these programs were all intended to facilitate the collection, analysis, and reporting of information about the prescribing, dispensing, and use of controlled substances, they differed in their objectives and operation. They all provided data and analysis to state law enforcement and regulatory agencies in order to assist in identifying and investigating activities potentially related to the illegal prescribing, dispensing, and procuring of controlled substances. Further, some pro-

[1] Office of Drug Control Policy, "U.S. Drug Prevention, Treatment, Enforcement Agencies Take on 'Doctor Shoppers', 'Pill Mills'," Mar. 1, 2004, www.whitehousedrugpolicy.gov (downloaded Mar. 2, 2004).

[2] Under the Controlled Substances Act, which was enacted in 1970, drugs are classified as controlled substances and placed into one of five schedules based on their medicinal value, potential for abuse, and safety or dependence liability.

[3] According to the National Institute on Drug Abuse, addiction is a chronic, relapsing disease, characterized by compulsive drug seeking and use and by neurochemical and molecular changes in the brain, whereas physical dependence is an adaptive physiological state that can occur with regular drug use and results in withdrawal symptoms when drug use is discontinued.

[4] For more details on these programs, see U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion,* GAO-02-634 (Washington, D.C.: May 17, 2002).

[5] The 15 states were California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Nevada, New York, Oklahoma, Rhode Island, Texas, Utah, and Washington. In 1998, West Virginia terminated its monitoring program, but began operating a program again in 2003, bringing the total of state programs to 16. In addition, Virginia began operating a pilot program in the southwestern part of the state in fall 2003.

grams could be used by physicians to check a patient's prescription drug history to determine if the individual may have been doctor shopping to seek multiple controlled substances. Some programs also offered educational programs for the public, physicians, and pharmacists regarding the nature and extent of the problem and medical treatment options for abusers of diverted drugs. The operation of the monitoring programs varied primarily in terms of the specific drugs they covered and the type of state agency in which they were housed. Some programs covered only those prescription drugs that are most prone to abuse and addiction, whereas others provided more extensive coverage. In addition, most programs were administered by a state law enforcement agency, a state department of health, or a state board of pharmacy.

We found that state monitoring programs realized benefits in their efforts to reduce drug diversion. These included improving the timeliness of law enforcement and regulatory investigations. Each of the three states we studied reduced its investigation time by at least 80 percent. In addition, law enforcement officials told us that they view the programs as a deterrent to doctor shopping, because potential diverters are aware that any physician from whom they seek a prescription may first examine their prescription drug utilization histories based on monitoring program data. For example, as drug diverters became aware of Kentucky's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states.

BACKGROUND

The diversion and abuse of prescription drugs are associated with incalculable costs to society in terms of addiction, overdose, death, and related criminal activities. DEA has stated that the diversion and abuse of legitimately produced controlled pharmaceuticals constitute a multibillion-dollar illicit market nationwide. One recent example of this growing diversion problem concerns the controlled substance oxycodone, the active ingredient in over 20 prescription drugs, including OxyContin, Percocet, and Percodan. OxyContin is the number one prescribed narcotic medication for treating moderate-to-severe pain in the United States.[6] Currently, a single 20-milligram OxyContin tablet legally selling for about $2 can be sold for as much as $25 on the illicit market in some parts of Kentucky.

Combating the illegal diversion of prescription drugs while ensuring that the pharmaceuticals remain available for those with legitimate medical need involves the efforts of both federal and state government agencies. The Controlled Substances Act of 1970[7] provides the legal framework for the federal government's oversight of transactions involving the sale and distribution of controlled substances at the manufacturer and wholesale distributor levels. The states address these issues through their regulation of the practice of medicine and pharmacy.

Controlled Substances Act

The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances.[8] Controlled substances are classified by DEA into five schedules on the basis of their medicinal value, potential for abuse, and safety or dependence liability. Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD and PCP—have a high potential for abuse and no currently accepted medical use. Schedule II drugs—including methylphenidate (Ritalin) and opiates such as hydrocodone, morphine, and oxycodone—have a high potential for abuse among drugs with an accepted medical use and may lead to severe psychological and physical dependence. Drugs on schedules III through V have accepted medical uses and successively lower potentials for abuse and dependence. Schedule III drugs include anabolic steroids, codeine, hydrocodone in combination with aspirin or acetaminophen, and some barbiturates. Schedule IV contains such drugs as the antianxiety medications diazepam (Valium) and alprazolam (Xanax). Schedule V includes preparations such as cough syrups with codeine. All scheduled drugs except those in schedule I are legally available to the public with a prescription.[9]

Under the act, DEA provides legitimate handlers of controlled substances—including manufacturers, distributors, hospitals, pharmacies, practitioners, and research-

[6] U.S. General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem,* GAO-04-110 (Washington, D.C.: Dec. 23, 2003).

[7] Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. No. 91-513, §§ 100 *et seq.*, 84 Stat. 1236, 1242 *et seq.*).

[8] Section 201, classified to 21 U.S.C. § 811.

[9] Some schedule V drugs that contain limited quantities of certain narcotic and stimulant drugs are available over the counter without a prescription.

ers—with registration numbers, which are used in all transactions involving controlled substances. Registrants must comply with a series of regulatory requirements relating to drug security and accountability through the maintenance of inventories and records. Although all registrants, including pharmacies, are required to maintain records of controlled substance transactions, only manufacturers and distributors are required to report their transactions involving schedule II drugs and schedule III narcotics, including sales to the retail level, to DEA. The data provided to DEA are available for use in monitoring the distribution of controlled substances throughout the United States, in identifying retail-level registrants that received unusual quantities of controlled substances, and in investigations of illegal diversions at the manufacturer and wholesaler levels. Although data are reported to DEA regarding purchases by pharmacies, the act does not require the reporting of dispensing information by pharmacies at the patient level to DEA.

State Regulation of the Practice of Medicine and Pharmacy

State laws govern the prescribing and dispensing of prescription drugs by licensed health care professionals. State medical practice laws generally delegate the responsibility of regulating physicians to state medical boards, which license physicians and grant them prescribing privileges.[10] In addition, state medical boards investigate complaints and impose sanctions for violations of the state medical practice laws. States regulate the practice of pharmacy based on state pharmacy practice acts and regulations enforced by the state boards of pharmacy. The state boards of pharmacy are also responsible for ensuring that pharmacists and pharmacies comply with applicable state and federal laws and for investigating and disciplining those that fail to comply. According to the National Association of Boards of Pharmacy, all state pharmacy laws require that records of prescription drugs dispensed to patients be maintained and that state pharmacy boards have access to the prescription records.

STATE MONITORING PROGRAMS VARIED IN OBJECTIVES AND OPERATION

State prescription drug monitoring programs varied in their objectives and operation. While all programs were intended to help law enforcement identify and prevent prescription drug diversion, some programs also included education objectives to provide information to physicians, pharmacies, and the public. Program operation also varied across states, in terms of which drugs were covered and how prescription information was collected. Which agency, such as a pharmacy board or public health department, was given responsibility for the program also varied across states. Additionally, methods for analyzing the data to detect potential diversion activity differed among state programs.

State monitoring programs are intended to facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of prescription drugs within a state. The first state monitoring program was established in California in 1940, and the number of programs has grown slowly. We reported that the number of states with programs has grown from 10 in 1992 to 15 in 2002; the number of programs stands at 16 in 2004.

We found that state programs varied in their objectives. All states used monitoring programs primarily to assist law enforcement in detecting and preventing drug diversion, and but some also used the programs for educational purposes. Programs assisted law enforcement authorities both by providing information in response to requests for assistance on specific investigations and by referring matters to law enforcement officials when evaluations of program data revealed atypical prescribing or dispensing patterns that suggested possible illegal diversion. The programs evaluated prescribing patterns to identify medical providers who may have been overprescribing and inform them that their patterns were unusual. They also identified patients who may have been abusing or diverting prescription drugs and provided this information to practitioners. For example, the programs in Nevada and Utah sent letters to physicians containing patient information that could signal potential diversion activity, including the number and types of drugs prescribed to the patient during a given time period and the pharmacies that dispensed the drugs. Monitoring programs have also been used to educate physicians, pharmacies, and the public about the existence and extent of diversion, diversion scams, the drugs most likely to be diverted by individuals, and ways to prevent drug diversion.

[10] The types of practitioners who prescribe drugs and may be monitored by a state program vary among states. Physicians are the majority of covered practitioners, but in most states many nonphysicians who also have prescribing authority may be covered, including physician assistants, dentists, optometrists, podiatrists, veterinarians, and certain types of nurses, such as nurse practitioners and advanced practice nurses.

Monitoring programs also differed in operational factors, some of which have cost implications. These factors included the choice of controlled substance schedules monitored, approaches to analyzing and using data, computer programming choices, number and type of staff and contractors, turnaround times and report transmittal methods, and number and type of requests for information.

State programs varied in the controlled substances they covered, in part because of differences in available resources and other state-specific factors such as level of drug abuse. Two of the states we studied—Kentucky and Utah—covered schedules II through V. These states' program officials told us that covering those schedules allowed them flexibility to respond if drugs on other schedules became targets for diversion. Most experts agree that covering all controlled substance schedules prevents drug diverters from avoiding detection by bypassing schedule II drugs and switching to drugs in other schedules.

States used different approaches to analyze the prescription information they received. A few states used a proactive approach, routinely analyzing prescription data collected by the programs to identify individuals, physicians, or pharmacies that had unusual use, prescribing, or dispensing patterns that could suggest potential drug diversion, abuse, or doctor shopping. Trend analyses were shared with appropriate entities, such as law enforcement, practitioners, and regulatory and licensing boards. In contrast, most state programs generally used the prescription data in a reactive manner to respond to requests for information. These requests may have come from physicians or from law enforcement or state officials based on leads about potential instances of diversion. According to state program officials, most programs operated in a reactive fashion because of the increased amount of resources required to operate a proactive system.

Some state programs had electronic reporting systems, while others were paper-based. If data are reported electronically, there are ongoing computer maintenance and programming choices and their attendant costs. Similarly, some state programs engaged private contractors to collect and maintain the data, while others did so in-house. If a private contractor collects the raw data from dispensers and converts them to a standardized format, the program pays annual contracting costs for database maintenance. Kentucky and Nevada privately contracted with the same company to collect data for their program databases. Utah, in contrast, collected and maintained drug dispensing data in-house, using its own software and hardware.

The number and type of staff a state chose to operate its monitoring program also varied. In 2002, Kentucky's program employed four full-time and four part-time staff to help ensure the accuracy of its reports, including a pharmacist-investigator who reviewed each report before it was sent. Nevada's program operated with one employee because a private contractor collected the data. In contrast, in 2002 Utah's program, with three full-time employees and no private contractor, had one program administrator who collected all dispensing data, converted them to a standardized format for monitoring, and maintained the database. The two other staff answered requests.

If the program seeks to provide more timely responses to report requests, such as same-day responses, the costs involved in returning the response to the requester may increase. For example, in 2001 Kentucky spent up to $12,000 in 1 month for faxing reports. Monitoring program officials from Kentucky, Nevada, and Utah told us in 2002 that they estimated 3- to 4-hour turnaround times for program data requests, and all mainly used faxing, rather than more costly mailing, to send reports to requesters. Same-day responses may be preferable for physicians who want the prescription drug history for a patient being seen that day and for law enforcement users who need immediate data for investigations of suspected illegal activity.

As users become more familiar with the benefits of monitoring program report data, requests for information and other demands on the programs may increase. In Kentucky, Nevada, and Utah, use had increased substantially, mostly because of an increase in the number of requests by physicians to check patients' prescription drug histories. In Kentucky, these physician requests increased from 28,307 in 2000, the first full year of operation, to 56,367 in 2001, an increase of nearly 100 percent. Law enforcement requests increased from 4,567 in 2000 to 5,797 in 2001, an increase of 27 percent. Similarly, Nevada's requests from all authorized users also increased—from 480 in 1997, its first full year, to 6,896 in 2001, an increase of about 1,300 percent.

Additionally, as drug marketing practices change and monitoring programs mature, the operational needs may shift as well. For example, states face new challenges with the advent of Internet pharmacies, because they enable pharmacies and physicians to anonymously reach across state borders to prescribe, sell, and dispense

prescription drugs without complying with state requirements.[11] In addition, if users want program reports to reflect more timely information, dispensing entities would have to report their data at the time of sale, rather than submitting data biweekly or monthly, to capture the most recent prescription dispensing. If users want to be alerted if a certain drug, practitioner, or pharmacy may be involved in a developing diversion problem, programs would have to initiate periodic data analysis to determine trends or patterns. Such program enhancements would entail additional costs, however, including costs for computer programming, and data analysis.

States that are considering establishing or expanding a monitoring program face a variety of other challenges. One challenge is the lack of awareness of the extent to which prescription drug abuse and diversion is a significant public health and law enforcement problem. States also face concerns about the confidentiality of the information gathered by the program, voiced by patients who are legitimately using prescription drugs and by physicians and pharmacists who are legitimately prescribing and dispensing them. Another challenge states face is securing adequate funding to initiate and develop the program and to maintain and modify it over time.[12]

STATE MONITORING PROGRAMS HAVE HELPED SHORTEN INVESTIGATION TIMES AND MAY REDUCE ILLEGAL DRUG DIVERSION

We found that states with monitoring programs have experienced considerable reductions in the time and effort required by law enforcement and regulatory investigators to explore leads and the merits of possible drug diversion cases. We also found that the presence of a monitoring program in a state may help reduce illegal drug diversion there, but that diversion activities may increase in contiguous states without programs.

The ability of the programs to focus law enforcement and regulatory investigators who are working on suspected drug diversion cases on specific physicians, pharmacies, and patients who may be involved in the alleged activities is crucial to shortened investigation time and improvements in productivity. States that do not have programs must rely on tips from patients, practitioners, or law enforcement authorities to identify possible prescription drug abuse and diversion. Following up on these leads requires a lengthy, labor-intensive investigation. In contrast, the programs can provide information that allows investigators to pinpoint the physicians' offices and pharmacies where drug records must be reviewed to verify suspected diversion and thus can eliminate the need to search records at physicians' offices and pharmacies that have no connection to a case.

In each of the three states we studied, state monitoring programs led to reductions in investigation times. For example, prior to implementation of Kentucky's monitoring program, its state drug control investigators took an average of 156 days to complete the investigation of alleged doctor shoppers. Following the implementation, the average investigation time dropped to 16 days, or a 90 percent reduction in investigation time. Similarly, Nevada reduced its investigation time from about 120 days to about 20 days, a reduction of 83 percent, and a Utah official told us that it experienced an 80 percent reduction in investigation time.

Officials from Kentucky, Nevada, and Utah told us in 2002 that their programs may have helped reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increased number of program reports were being used by physicians to check the prescription drug use histories of current and prospective patients when deciding whether to prescribe certain drugs that are subject to abuse. Law enforcement officials told us that they view these drug history checks as initial deterrents' a front-line defense—to prevent individuals from visiting multiple physicians to obtain prescriptions, because patients are aware that physicians can review their prescription drug history. For an individual who may be seeking multiple controlled substance prescriptions, the check allows a physician to analyze the prescription drug history to determine

[11] For more details on Internet pharmacies, see U.S. General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight,* GAO-01-69 (Washington, D.C.: Oct. 19, 2000).

[12] Federal grants are available to states to establish new monitoring programs and to enhance existing programs under the Harold Rogers Prescription Drug Monitoring Program. DEA's Office of Diversion Control, in collaboration with the Department of Justice's Bureau of Justice Assistance, provides grants to states to establish new programs and to enhance existing monitoring programs through the Harold Rogers Prescription Drug Monitoring Program. The fiscal year 2003 grantees are Alabama, Florida, Maine, New Mexico, and Wyoming for new programs, and California, Idaho, Nevada, and New York for enhanced programs. The grantees in fiscal year 2002 were Ohio, Pennsylvania, Virginia, and West Virginia for new programs, and California, Kentucky, Massachusetts, Nevada, and Utah for enhanced programs.

whether drug treatment appears questionable, and if so, to verify it with the listed physicians. In Kentucky, a physician could request a drug history report on the same day as the patient's appointment, and usually received the report within 4 hours of the request. In 2002, Kentucky's program typically received about 400 physician requests daily, and provided data current to the most recent 2 to 4 weeks.

The presence of a monitoring program may also have an impact on the prescribing of drugs more likely to be diverted. For example, DEA ranked all states for 2000 by the number of OxyContin prescriptions per 100,000 people.[13] Eight of the 10 states with the highest numbers of prescriptions—West Virginia, Alaska, Delaware, New Hampshire, Florida, Pennsylvania, Maine, and Connecticut—had no monitoring programs, and only 2 did—Kentucky and Rhode Island. Six of the 10 states with the lowest numbers of prescriptions—Michigan, New Mexico,[14] Texas, New York, Illinois, and California—had programs, and 4—Kansas, Minnesota, Iowa, and South Dakota—did not.

Another indication of the effectiveness of a monitoring program is that its existence in one state appears to increase drug diversion activities in contiguous states without programs. When states begin to monitor drugs, drug diversion activities tend to spill across boundaries to states without programs. One example is provided by Kentucky, which shares a boundary with seven states, only two of which had programs in 2002—Indiana and Illinois. As drug diverters became aware of the Kentucky program's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states. OxyContin diversion problems worsened in Tennessee, West Virginia, and Virginia—all contiguous states without programs—because of the presence of Kentucky's program, according to a 2001 joint federal, state, and local drug diversion report.[15]

CONCLUDING OBSERVATIONS

Although monitoring programs can enhance the ability of states to detect and deter illegal diversion of prescription drugs, the number of states with such programs has grown only slightly over the past 12 years from 10 in 1992 to 16 in 2004. A lack of awareness of the magnitude of the problem; concerns about confidentiality on the part of patients, physicians, pharmacists, and legislators; and difficulty in accessing funding have kept the numbers of monitoring programs low. Cooperative efforts at the state and national levels are seeking to overcome these challenges and increase the number of states with programs.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have.

Mr. BILIRAKIS. Thank you. Thank you very much, Ms. Crosse.

Let's see, Doctor Droz, and from my own State of Florida, Tallahassee, welcome to Washington.

STATEMENT OF DANNA E. DROZ

Ms. DROZ. Thank you very much, Chairman Bilirakis, members of the subcommittee, ladies and gentlemen, I want to tell you how much I appreciate the opportunity to be here today speaking to you about this timely issue, but one that is hardly new.

First of all, let me tell you just a little bit about my background. I am the President of the National Association of State Controlled Substance Authorities. I'm also the Executive Director of the Florida Board of Pharmacy. I just assumed that position in January. Prior to that, I worked in Kentucky with the Drug Enforcement in the Professional Practices Branch, and it was the highlight of my career there to be very involved in the implementation and development of the KASPER program.

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[13] OxyContin, Hearings Before the Subcommittee on the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies, House Committee on Appropriations, 107th Cong. Part 10., pp. 21, 22 (2001) (Statement of Asa Hutchinson, Administrator of the Drug Enforcement Administration).

[14] New Mexico's monitoring program was terminated in June 2000.

[15] Appalachia High Intensity Drug Trafficking Area Investigative Support Center, with the assistance of the National Drug Intelligence Center, *The OxyContin Threat in Appalachia* (London, Ky.: Aug. 2001).

The National Association of State Controlled Substance Authorities, which we abbreviate as NASCSA, is a non-profit educational organization in its 20th year. Our members are State agencies or State regulators who have an interest in regulating controlled substances, but we also have a number of associate members, Federal agencies, the drug manufacturers, trade associations and others, who meet with us annually in an open forum to discuss ways to address the problem of prescription drug abuse, but yet make sure that these drugs are available to patients.

Since its inception, NASCSA has recognized the importance of prescription monitoring programs, which as Congressman Rogers alluded to, has a long history. The first program began in 1939 and 1940 in California. It was what we referred to as a triplicate prescription program, paper-based, of course, being in that time period. The physician wrote a prescription, he kept a copy, the pharmacy kept a copy, and a copy went to the State. There the data could be used for analysis.

Over the next 40 years or so, several other States developed these triplicate prescription programs. But, because of the nature of the paper, they were limited to Schedule II, and they were primarily law enforcement-based programs.

In 1991, Oklahoma wanted to develop a similar program, but they recognized that pharmacies were using computers, not only to keep records, but also for billing purposes. They sensed that there was an opportunity to do something different here, and so they developed the first electronic program. Physicians wrote the prescriptions, and the pharmacies submitted the data to the State, not on paper, but electronically. This made it much easier for physicians to prescribe the Schedule II drugs that the patients needed, and also it was much easier for the pharmacies to record. So, a virtually transparent process evolved.

Over the next 10 years, that paved the way for many other States to develop these electronic programs. Today, all of the programs in the country collect the data electronically. Now, some of them still have special forms that physicians use for other purposes, such as preventing forgery, but the paper is not used to collect the data.

In 1995, NASCSA, along with the Alliance of States With Prescription Monitoring Programs, developed the first Model Prescription Drug Monitoring Program Act. The purpose of this was to provide guidance to States who wanted to develop a program to set some standards so that there would be some commonality among these programs.

The members of NASCSA recognized that the drugs involved are approved to treat medical conditions. While they have the potential to produce abuse or even addiction, they are absolutely necessary to alleviate pain and treat certain other medical conditions.

Because of the importance of pain management, between 1998 and 2001 NASCSA passed three resolution supporting the educational programs for practitioners, pharmacists and other healthcare providers to increase their awareness and their ability to appropriately use controlled substances.

In 2002, NASCSA and the Alliance again collaborated on a new prescription monitoring program model act. The need for this pro-

gram was because of changes in technology, more State pat programs, there were more issues to be addressed. But yet, the goals of the monitoring programs remained the same.

And, I want to tell you what those goals are, but now remember that not every State has all of these goals. States focus their programs and their goals depending on their individual needs.

Education and information is one of the goals of prescription monitoring programs. Healthcare practitioners, as a group, receive very little training about the appropriate use of controlled substances, but prescription monitoring programs provide an ideal platform for providing more education to these groups to enable them to provide better treatment for patients.

The States that use their program primarily for education and information for healthcare practitioners report that the most of the users are physicians. When I was in Kentucky, 85 percent of all the requests for information that we got came from physicians, and they reported to us that this information was absolutely essential to them. It gave them a sense of regaining control over their practice. It enabled them to do some things in a much more efficient manner than they had previously. A couple of physicians told me that they hired a person in their office to do nothing but contact pharmacies and check on various patients' prescription drug histories. With KASPER, they were able to get this information much more quickly, and much more efficiently, and cover a much wider area.

Kentucky, Nevada, and Utah are recognized as the States that tend to focus more on healthcare practitioners than some of the others, and all three of those States report very high use by physicians.

Mr. BILIRAKIS. Please summarize, if you would, Ms. Droz.

Ms. DROZ. Yes, sir.

The other goals are public health initiatives, such as analyzing the data, allowing physicians to intervene and prevent drug abuse and addiction in patients, and then also providing a tool for investigations and enforcement to use when patients or physicians do things that are against the law.

The States always recognize the importance of maintaining confidentiality. The variability in State programs is recognized by the members of NASCSA, but the key is balance. It's possible to create a program that will absolutely prevent all diversion, but if you do that patients will suffer. It's possible to make drugs so accessible that patients can get everything that they need but diversion will be rampant.

Mr. BILIRAKIS. I'm sorry, your time is well up, but yet I know you have more. But, I think during the questions and answers you'll be able to get a few of those points across. I apologize for that.

Ms. DROZ. I apologize profusely. As you can tell, this is one of my passions, and I'm normally speaking for much longer than this, and I'm having trouble. I apologize again.

Mr. BILIRAKIS. And, if it were Doctor Norwood giving your presentation, as slowly as he speaks, it probably would have taken an extra 2 minutes.

Mr. NORWOOD. You are talking about these girls from Tallahassee, I grew up in Austin.

[The prepared statement of Danna E. Droz follows:]

PREPARED STATEMENT OF DANNA E. DROZ, PRESIDENT, NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCE AUTHORITIES

NASCSA supports the Harold Rogers Grants for Prescription Monitoring programs and recommends continued financial support and consideration of a federal mandate for states to develop prescription monitoring programs.

Chairman Bilirakis, members of the Subcommittee, Ladies and Gentlemen, good afternoon. Thank you for the opportunity to speak with you today about topics that are very timely but hardly new, particularly to our members—abuse of prescription drugs and prescription monitoring programs.

I represent the National Association of State Controlled Substance Authorities (hereinafter NASCSA). NASCSA is a non-profit educational organization, celebrating its twentieth anniversary this year. Currently we have 42 member states, although many other people and organizations are associate members or otherwise active in the organization. The primary purpose is to provide a continuing mechanism through which state agencies, federal agencies, the regulated industries and professions, and others can work to increase the effectiveness and efficiency of state and national efforts to prevent and control drug abuse, yet provide mechanisms to make the class of drugs known as controlled substances reasonably available to those persons who have a true medical need for these drugs. This is accomplished by providing a neutral forum during the fall conference of each year, for the exchange of ideas, information, and views on legal and regulatory issues relating to the controlled substances.

The issue of prescription monitoring programs has been a focus of NASCSA since its inception. Some of the first conferences of NASCSA in the early 1980's included sessions on prescription monitoring, a practice that continues to this day.

Abuse of prescription drugs and efforts to monitor those drugs has existed almost as long as prescription drugs. In 1939-1940, California implemented the first prescription monitoring program by requiring that any physician who wrote a prescription for a Schedule II drug, such as morphine or Demerol(had to use a special three-part form. The physician retained a copy, the pharmacy retained a copy and one copy was sent to the state. The information was then available for analysis to determine if physicians or patients might be misusing or abusing these drugs. Over the next 40 years or so, several other states adopted similar programs which were often referred to a "triplicate prescription programs."

In 1991, Oklahoma developed a similar program. However, instead of collecting data on paper, they recognized that the pharmacy industry was using computers to transfer prescription information for billing purposes. Sensing an opportunity, the state officials developed the first electronic prescription monitoring program. The same data was collected but no pieces of paper were involved. This made it much easier for physicians to prescribe Schedule II controlled substances and for pharmacists to report the required information to the state. A virtually transparent process evolved. Over the next ten years, several more states developed electronic monitoring programs and expanded from schedule II only to all controlled substances. The states that formerly required triplicate prescription blanks have now converted to electronic data collection of prescription information. (Note: Some of the states still utilize special or state-issued prescription blanks but not for data collection purposes.)

In 1995, NASCSA and the Alliance of States with Prescription Monitoring Programs (hereinafter Alliance of States), a sister organization, developed and adopted the first Model Act for Prescription Monitoring Programs. This document served to guide states in developing new programs but allowed sufficient latitude for each state to make modifications to address various state-specific needs. Today we have about 22 states with programs in operation or currently being implemented.

The members of NASCSA have always recognized that prescription controlled substances are first and foremost, prescription drugs that are approved to treat medical conditions. While they inherently possess the potential to be abused or produce addiction, these drugs are absolutely necessary to alleviate pain and treat certain other conditions. Recognizing the importance of appropriate pain management, between 1998 and 2001, NASCSA members adopted three different resolutions reiterating their support for the appropriate use of controlled substances and encouraging increased education for practitioners, pharmacists, and other health care providers surrounding the appropriate use of prescription controlled substances for treating patients with legitimate medical conditions.

In 2002, NASCSA and the Alliance of States again collaborated on a new model act, the "Prescription Monitoring Program Model Act of 2002." This document ad-

dressed many of the changes in technology and needs recognized by states with current programs. However, the goals of prescription monitoring programs remained the same:

- Education and information—Health practitioners, as a group, receive very little training about appropriate use of controlled substances. Prescription monitoring programs provide an excellent platform for various groups to offer educational opportunities for such learning.

  Practitioners in those states that have programs report that the additional information about patients' drug histories is invaluable in evaluating medical conditions where the prescribing of controlled substances is being considered.
- Public health initiatives—Analyzing trends and sudden changes in prescribing or dispensing patterns can provide valuable information that may alert officials to potential diversion before it becomes an epidemic.
- Early intervention and prevention—Physicians and pharmacists who review a patient's history of prescription controlled substances have an opportunity to recognize the warning signs of abuse or addiction. These patients can be steered into intervention programs or referred to treatment programs earlier in the abuse/addiction disease process, possibly saving thousands of health care dollars that would otherwise be required.
- Investigations and enforcement—Crimes involving prescription drugs require very different investigative and evidence gathering techniques than those used to investigate street drug crimes. The information available from a prescription monitoring program can be a tool for gathering evidence by allowing an officer to focus his/her investigation on locations where evidence is most likely to be located. Please note that data from a program does not replace the investigation; it merely decreases the time required to gather evidence.
- Protection of confidentiality—Every state with a prescription monitoring program has very strict parameters about who can get access to the data, the purposes for which it can be used, and with whom the information may be shared. While the parameters vary from state to state, each one recognizes the confidential nature of the information and the necessity of minimal disclosure.

It is worth noting that NASCSA members recognized the importance of patient privacy long before HIPAA required it. A person's prescription information should be available only to those persons with a legal need-to-know.

Today the variability in state programs is significant. Each program is developed and implemented because of specific needs, interests, and compromises within the individual state. Yet each program also works because it meets many, but not all, of the needs of the agencies and persons who utilize the program. While it would be possible to develop a program that absolutely prohibited misuse or diversion, many legitimate patients would be denied access to the drugs that make their lives worth living. On the other hand it would be possible to make prescription controlled substances easily available to every person who might potentially benefit from their use. Yet such a system would be fraught with drug diversion. The key is balance. Prescription Monitoring Programs attempt to strike the appropriate balance between making drugs available for patients and limiting drug diversion.

I'd like to review the various programs currently in place or being implemented across the country.

Schedules of drugs monitored—Many of the states that initially had paper-based programs using state-issued prescription blanks monitor only schedule II drugs such as Demerol®, Dexedrine®, morphine, OxyContin®, Percocet®, Ritalin®, Tylox®, and all of their generic equivalents. Other states have expanded to Schedules II, and III, which would cover the Lorcet®, Lortab®, Tylenol® with codeine and Vicodin® and equivalents. Those states that monitor Schedules II, III, and IV include all of the above mentioned drugs plus many of the diet pills like Adipex® and the anti-anxiety agents like Valium® and Xanax®. Three states, Kentucky, Michigan, and Utah, monitor *all* the controlled substances. While the use and abuse of schedule V drugs is not nearly as voluminous as in Schedules II, III, and IV, it does occur. Those states feel that it is very difficult for a state, having once implemented a limited program, to amend its laws to expand it. Furthermore, one never knows what new drug will appear in the marketplace and how it will be scheduled. Often the abuse potential is not recognized at the outset. Some of you may recall that many of our problem drugs of today were hailed at product launch as having no abuse potential. Even some of our over-the-counter drugs are being abused and causing deaths in young people.

What agency operates the program—Some states house their prescription monitoring program in a health program agency, some in a law enforcement agency and some in a pharmacy board or similar licensing agency. Where the program is located is often a function of the types of people that utilize the data and what pur-

pose the program was implemented to address. Those states that house the program in a health agency generally use the data for health purposes such as providing information to physicians or pharmacists who are treating patients or health licensing boards that are investigating complaints against health care practitioners. If the program is housed in a law enforcement agency, the state tends to focus on prescription forgery, "doctor-shopping", or other patient focused crimes.

How frequently is data updated—Currently all states utilize a reporting process called batch reporting. States require pharmacies to report the prescriptions for controlled substances on a regular basis ranging from every week to every month. While everyone recognizes the limitations of batch reporting, it is still the most cost-effective way to collect this type data. Of course real-time reporting is preferable but there are significant hurdles to overcome, not the least of which is cost. It is also important to note that Oklahoma used real-time reporting when their program was initially implemented. However, they abandoned it in favor of batch reporting because they found that its limited value was not worth the cost. In addition, there were technological problems that prevented the data from entering the database as quickly as they had hoped. *At this point in time,* real-time reporting of prescription data is a simple concept, but it is very difficult to implement. While I was working in Kentucky, we worked with groups of physicians as well as law enforcement officers. The consensus was that batch reporting of data will meet 85-90% of their needs. In the words of Dr. Steve Davis, my former supervisor, we have to make sure "the juice is worth the squeeze."

Who has access to the information—States have different concepts of who has a need for patient-specific prescription information. Some states limit access to this information to a specific law enforcement agency, some to only law enforcement agencies, some to health care providers, including pharmacists, and some to only physicians. Access by licensing boards that discipline health care practitioners are sometimes considered law enforcement and sometimes health care.

Sharing across state lines—All NASCSA members recognize that prescription drug abuse has no boundaries. Patients and providers alike frequently cross state lines for a multitude of reasons, most of them legitimate. Some states are able to share the information contained in prescription monitoring program data bases while others are not. The 2002 Prescription Monitoring Program Model Act supports the appropriate sharing of information between states. Many of the states, who cannot share information at the present time, are seeking to amend their laws to include this capability.

In 2003, NASCSA convened a workgroup composed of representatives from states with prescription monitoring programs, DEA's Drug Diversion group, pharmacies, third party payers and drug manufacturers. The goal of this group was to develop standards for reporting prescription information to such programs. The group felt that if every state required the same information to be reported, it would facilitate:

(a) sharing information from one state to another and
(b)compliance by corporations with pharmacies in multiple states.

These reports, as well as other documents that I have referred to in my testimony are available on NASCSA's website at www.NASCSA.org.

In summary, NASCSA members support the concept of prescription monitoring programs and recognize the problems associated with a state-by-state implementation process. However, there are significant issues associated with a national data base for prescription monitoring purposes. Therefore NASCSA has passed a resolution both in 2002 and 2003 supporting the Harold Rogers Grant programs for states seeking legislation for a prescription monitoring program, implementing a new program or enhancing an existing program. It is the position of NASCSA that a federal program would be duplicative of the states efforts, have the unintended consequence of providing a disincentive to states to continue their programs, and limit the ability of the states to address unique problems. NASCSA members believe that prescription monitoring programs would be more effectively supported by Congress' financial support and possibly a mandate for all states to develop such programs with standard features that would facilitate sharing data among the states.

We would like to thank members of this committee for permitting me to testify on behalf of NASCSA on this very important issue which our members have been working on collectively for years. We look forward to collaborating with Committee members and your staff on this issue. Since many of our members have years of experience in the issue of prescription drug abuse and prescription monitoring programs, we believe we are uniquely qualified by this experience to serve as a vital voice in this debate. I would be happy to answer questions you might have.

Mr. BILIRAKIS. Doctor Holsinger.

STATEMENT OF JAMES W. HOLSINGER, JR.

Mr. HOLSINGER. Well, Mr. Chairman, it's a real pleasure once again to be in front of you at a committee hearing. It's been over a decade since we've had a chance to do this, and I really appreciate the opportunity to be here. It's amazing how fast time flies.

It's also a great pleasure for me to have been able to sit at the same witness table with the Dean of the Congressional Delegation from Kentucky, Congressman Hal Rogers, who, as you know, has worked diligently in the Commonwealth of Kentucky and across the country here in Congress to reduce the abuse of prescription drugs, and, obviously, I want to thank Congressman Ed Whitfield for all of his support, as he has also been passionate about reducing the abuse of prescription drugs.

I think it's rather interesting, if you look at this witness table, I'm not quite sure where Ms. Crosse has been in her career, but if she's been in Kentucky it's an all Kentucky cast. This is a group of people that have one time or another throughout the past few years been intimately involved in dealing with this particular issues.

I'd like to tell you briefly about KASPER. KASPER is the acronym for the Kentucky All Schedule Prescription Electronic Reporting program. This system automated the processing of data to support the tracking and sharing of information in accordance with existing statutes governing controlled substance prescriptions.

It was enacted into law during the 1998 legislative session following the recommendation of a task force that was chaired by Dr. Rice Leach, Commissioner for Public Health for the Commonwealth of Kentucky, and made up of representatives of many groups in the State with a stake in controlled substance diversion issues. Even today KASPER is considered in our Commonwealth to be a public health initiative.

In addition to authorizing KASPER, the 1998 legislation made other changes to the controlled substance act including permission for the cabinet to share prescription information with providers and law enforcement agencies under specific circumstances, the mandatory use of security prescription blanks for all controlled substance prescriptions, and the theft of a security prescription blank became a felony offense.

KASPER did not add any authority the State did not already have to monitor scheduled drug prescriptions. KASPER's purpose, like that of any tool, is to increase productivity of individuals with the task of administering the controlled substance act.

A comprehensive program like KASPER, in conjunction with Kentucky's other controlled substance statutes, is necessary because the diversion of controlled substances is at epidemic levels. Since individuals involved in drug diversion cover large geographic areas to obtain drugs, the agencies charged with controlling the problem needed a tool that would add value to their investigative efforts.

The two main goals of the statutes that created KASPER are first, to be a source of information for physicians and pharmacists and to be an investigative tool for law enforcement. KASPER is the tool that enables this information to be collected, analyzed, and shared rapidly.

KASPER allows the State to capture dispensing information on Schedules C-II, III, IV, and V drugs electronically in a relational data base.

Data gets into the relational data base as dispensers transmit prescription data to our data collection agent by modem, diskette or tape. The data collection agent then verifies, compiles and sends the data to the Drug Enforcement and Professional Practices Branch in the Department for Public Health to be loaded onto the secure KASPER server.

Very high security procedures protect access to the data, with only Branch personnel having access to information within the KASPER data base. Report requesting by authorized individuals also undergoes a high level of scrutiny. Release of data to anyone not authorized by Kentucky statute is a class D felony.

Kentucky's KASPER statute allows a report to be obtained by a grand jury subpoena, by a prescriber for medical treatment, by a pharmacist for pharmaceutical treatment, by law enforcement officers with a bona-fide investigation, by professional licensing boards investigating a license, and it's important to realize that, and by Medicaid programs for a recipient and by a court order from a judge of competent jurisdiction.

As a result of KASPER, State reporting productivity, as has been already mentioned, has rather dramatically, 30 fold, originally, the first year there were only 3,000 reports requested, but now there are 110,000 reports that are requested annually, and 85 percent, as mentioned earlier by Ms. Droz, are from physicians. The investigative productivity has improved 5 fold in 5 years. Prior to KASPER, the drug enforcement officers took about 100 days to complete an investigation, now it is less than 20.

Many of the clinicians in the State were skeptical when KASPER was initiated. They felt the scrutiny implied by a monitoring program would interfere with their practice. In actuality, they have found that by utilizing the program to monitor their patients chronically utilizing controlled substances they have documentation to prove they are treating these patients judiciously.

Even the Kentucky Board of Medical Licensure has included the use of KASPER reports in its standards of practice guidelines for chronic pain management.

Prior to the ready availability of KASPER reports, law enforcement personnel would receive a complaint, then use a very detailed process in order to spread out and come to a conclusion as to where the problem was arising from. The information from KASPER, though, has drastically improved the investigative routine for law enforcement officers. They receive a complaint, request a KASPER report, they know immediately whether prescriptions were filled and the physician that wrote the prescription.

The results generated by the KASPER data have been so well received the State legislature saw fit to make funding available to enhance the program. In an effort to address the biggest complaint with KASPER, which was a 4-hour report turnaround time, the enhanced system will be web based allowing requesters to receive a majority of their reports within 15 minutes, with the ultimate goal of becoming a real-time program. These and other additional en-

hancements are also being studied as funding for these projects becomes available.

I want to thank the chairman and committee members for allowing me today to come and tell you about a program that we believe is a model for the Nation, KASPER.

Thank you.

[The prepared statement of James W. Holsinger, Jr. follows:]

PREPARED STATEMENT OF JAMES W. HOLSINGER, JR., SECRETARY OF THE CABINET FOR HEALTH AND FAMILY SERVICES, COMMONWEALTH OF KENTUCKY

Chairman Bilirakis, members of the Committee, thank you for allowing me the opportunity to come and testify this afternoon. I also want to thank and recognize Congressman Hal Rogers, who we affectionately refer to as the Dean of the Kentucky delegation, for all of his hard work to reduce the abuse of prescription drugs. I also want to thank Congressman Ed Whitfield who is passionate about wanting to work towards reducing the abuse of prescription drugs in the Commonwealth and beyond.

KASPER is the acronym for the Kentucky All Schedule Prescription Electronic Reporting program. This system automated the processing of data to support the tracking and sharing of information in accordance with existing statutes governing controlled substance prescriptions.

KASPER was enacted into law during the 1998 legislative session following the recommendation of a task force chaired by Dr. Rice Leach, Commissioner for Public Health for the Commonwealth, and made up of representatives of many groups in the state with a stake in controlled substance diversion issues. Even today KASPER is considered a public health initiative.

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KASPER allows the state to capture dispensing information on schedules C-II, III, IV, and V drugs electronically in a relational database.

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Kentucky's KASPER statute allows a report to be obtained by a grand jury subpoena, by a prescriber for medical treatment, by a pharmacist for pharmaceutical treatment, by law enforcement officers with a bona-fide investigation, by professional licensing boards investigating a licensee, by Medicaid programs for a recipient and by a court order from a judge of competent jurisdiction.

As a result of KASPER, state reporting productivity has increased 30 fold* and investigation productivity has improved 5 fold** in 5 years.

Many of the clinicians in the state were skeptical when KASPER was initiated. They felt the scrutiny implied by a monitoring program would interfere with their

practice. In actuality they have found that by utilizing the program to monitor their patients chronically utilizing controlled substances they have documentation to prove they are treating these patients judiciously.

Even the Kentucky Board of Medical Licensure has included the use of KASPER reports in its standards of practice guidelines for chronic pain management.

Prior to the ready availability of KASPER reports, law enforcement personnel would receive a complaint, then use a "spiral out" approach visiting pharmacies to determine if the suspect had purchased controlled substances at that location. When they found a number of records they would then visit the physicians involved to get statements. In a highly populated area this could involve a large number or pharmacies. In rural areas this could involve going to several counties.

The information available from KASPER has drastically improved the investigative routine for law enforcement officers. They receive a complaint, request a KASPER report and know immediately where the prescriptions were filled and the doctor that wrote the prescription.

The results generated by the KASPER data have been so well received the state legislature saw fit to make funding available to enhance the program. In an effort to address the biggest complaint with KASPER, which was a four hour report turn around time, the enhanced system will be web based allowing requestors to receive a majority of their reports within 15 minutes with the ultimate goal of becoming a real-time program. These and other additional enhancements are also being studied as funding for these projects becomes available.

I want to thank the Chairman and Committee members for allowing me to come and testify.

Mr. BILIRAKIS. Thank you very much.

Doctor Manchikanti.

STATEMENT OF LAXIMAIAH MANCHIKANTI

Mr. MANCHIKANTI. Mr. Chairman, members of the committee and staff, I would like to thank you on behalf of the American Society of Interventional Pain Physicians for giving us this opportunity to present our views.

ASIPP is an organization representing interventional pain physicians and other professionals involved in interventional pain management. Interventional pain management is a discipline of medicine devoted to the diagnosis and treatment of pain related disorders, principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment. As interventional pain physicians, our members are involved extensively in prescribing controlled substances.

I have provided the committee with a great deal of information on a multitude of issues facing substance abusing generally and prescription drugs in particular. During the next few minutes, I would like to discuss personal experiences on specific issues relating to chronic pain and prescription drugs.

Today, chronic pain requiring some type of treatment is estimated in 15 to 30 percent of the population. Psychotherapeutic drugs, which include pain relievers, tranquilizers, stimulants, and sedatives, were the second leading category of illicit drug use in 2002, following marijuana.

However, what is not appreciated is that misuse of these drugs in the chronic pain population, recent surveys have shown that approximately 18 percent to 24 percent of the chronic pain patients in well-managed settings with medical necessity assessment, controlled substance agreements, KASPER and random drug testing do abuse these drugs.

In addition, illicit drug use among this population ranges from 14 percent to 32 percent. This, essentially, translates into an additional 5 to 10 million persons misusing prescription drugs or using illicit drugs.

While pharmaceuticals can be diverted in multiple ways, the most popular form of diversion and point of prevention is doctor shopping. The most alarming form of drug abusing was, not only Schedule II drugs, but also Schedule III and IV drugs.

State monitoring programs are extremely useful in preventing the drug diversion—that is at the doctor's office or at the pharmacy. KASPER is a helpful program for Kentucky physicians. However, if a patient is not from Kentucky, or not purchasing drugs in Kentucky, KASPER is not useful.

As an example, I had a patient from Illinois. He was a Vietnam veteran, had five back surgeries, and, obviously, needed medical treatment. He presented all the right information, we were very diligent, and we did a random drug testing, which was appropriate. However, we were not able to get a past drug information on him because he was from Illinois.

After a few minutes, I was just walking by the operating room, one of the other patients asked me to talk to him. He told me that this patient that I referred to previously has been selling OxyContin and has been bragging about it, that he was making $10,000 a month by selling these drugs.

So, I went and confronted him. He denied everything, of course.

We contacted the pain center, and the dramatic information was that they were not giving him OxyContin, but they were giving him morphine.

So, we contacted four other offices, at that time we found that one of the physicians was giving OxyContin, 80 milligrams three times a day. The same patient, in this process, we found that went and had another block at another office just a month before, so that he could get the medicine.

As you know, I cannot get information if a patient is from a different State. For example, in Kentucky we evaluate 1,000 patients in my practice, we were not able to get information on 26.6 percent of the patients.

If they were from Kentucky it was 10 percent, but if they were from Illinois, Tennessee or Missouri, it was much higher.

National drug control policy is going to spend over $12 billion in 2005 on this issue. Medicaid is expected to spend almost $9 billion to purchase these drugs for recipients, because it is ideal and in the best interest of the public to have a comprehensive strategy to control drug abuse that it is ordering by appropriate monitoring systems, by means of either NASPER or the regional system which will have access to data for physicians from all the surrounding States.

A good prescription monitoring program will enable physicians to provide optimal care and the patient will receive appropriate and timely care. This is exemplified by the fact that in the past we used to inquire of our patients drug history by calling each doctor's office in Kentucky, now we just get a KASPER report and look at it and provide the proper care.

If we do not have the proper information, we won't be able to provide the same quality of care. The same thing still happens with Illinois, Tennessee and Missouri patients. I have had instances where I was forced to send patients home, while awaiting on a reliable drug profile.

Thank you.

[The prepared statement of Laximaiah Manchikanti follows:]

-PRESCRIPTION DRUG MONITORING: STRATEGIES TO PROMOTE TREATMENT AND DETER PRESCRIPTION DRUG ABUSE

Statement of:

LAXMAIAH MANCHIKANTI, M.D.

PRESIDENT AND EXECUTIVE DIRECTOR
AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS

Before:

Subcommittee on Health
House Energy and Commerce Committee

March 4, 2004

The American Society of Interventional Pain Physicians is an organization representing interventional pain physicians and other health care professionals involved in interventional pain management. Our membership is 2,600 at the present time. It is estimated that there are 6,500 interventional pain physicians across the country practicing interventional pain management. Interventional pain management, as per NUCC, is defined as – "the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment." As interventional pain physicians, our members are involved extensively in prescribing controlled substances, even though not to the same extent as non-interventional pain physicians whose mainstay of treatment of chronic pain is controlled substances.

1. The management of pain is becoming a high priority in the USA

- Chronic pain is prevalent in 15% to 30% of the population.
- In the last several years, health policy-makers, health professionals, regulators and the public have become increasingly interested in the provision of better pain therapies.

2. Controlled substance abuse and diversion is becoming a high priority

- Non-medical uses of psychotherapeutics as described in multiple surveys include non-medical use of any prescription type:
  - Pain relievers
  - Tranquilizers
  - Stimulants
  - Sedatives

  This category does not include over-the-counter substances.
- This interest in managing chronic pain has led to the increased prescription of controlled substances, fueled by:
  - Pharmaceutical companies providing marketing and gifts.
  - Numerous organizations providing guidelines and standards.
  - Patient advocacy groups demanding opioids for benign pain.
  - Enactment of patient's Bill of Rights in many states.
  - JCAHO regulations mandating monitoring and appropriate treatment of pain.
  - Patient's right to pain relief.
- While the true extent of prescription drug abuse and diversion is unknown, estimates from a national survey indicate that the principle drug of abuse for nearly 10% of U.S. patients in treatment is a prescription drug.
- The most commonly abused drugs include oxycodone (Percodan, Percocet, Roxicet, Tylox, OxyContin), hydrocodone (Vicodin, Vicoprofen, Lorcet, Lortab), hydromorphone, morphine (Astramorph, Duramorph, MS Contin, Roxanol), codeine, clonazepam (Klonopin), alprazolam (Xanax), lorazepam (Ativan), diazepam (Valium) and carisoprodol (Soma).[1]

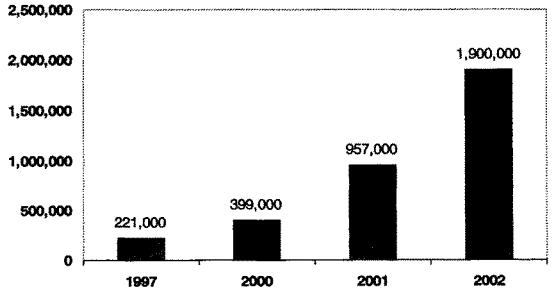
[1] 2002 National Survey on Drug Use and Health (NSDUH). Results from the 2002 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services.

- Prescription drug abuse ranks second behind marijuana.
- John Walters, Director of the White House Office of National Drug Control Policy, said "the non-medical use of prescription drugs has become an increasingly widespread and serious problem in this country, one that calls for immediate action".
- Emergency room visits resulting from the abuse of narcotic pain relievers have jumped 163% since 1995.
- The proposed 2005 budget from the White House for prescription drug diversion control will increase by $20 million to $138 million. Most of the funds will be directed at reducing the non-medical use of prescription drugs, mainly opioids.

3. Drug abuse and diversion as a national problem

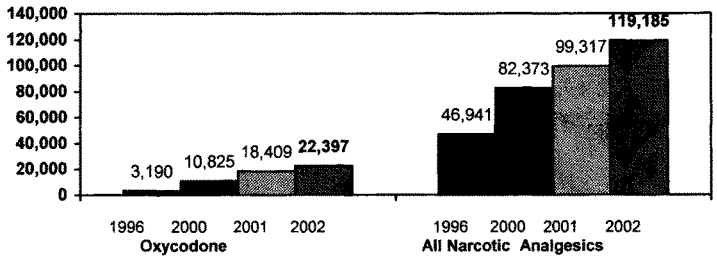
Results from the 2002 National Survey on Drug Use and Health showed the following:

- Non-medical pain reliever abuse prevalence among youths age 12 to 17 in increasing lifetime prevalence in 2002 was 11.2% from 9.6% in 2001.
- Among young adults aged 18 to 25, the lifetime non-medical pain reliever abuse rate increased from 19.4% in 2001 to 22.1% in 2002.
- The young adult rate had been 6.8% in 1992.
- Among the adult age group from 18 to 25 years, illicit drug use was as follows: marijuana - 17.3%, non-medical use of prescription drugs – 5.4%.
- Among 12 or 13-year olds, non-medical use of prescription drugs – 1.7%, marijuana – 1.4%, inhalants – 1.4%.
- In 2002, approximately 1.9 million persons age 12 or older had used OxyContin non-medically at least once in their lifetime.



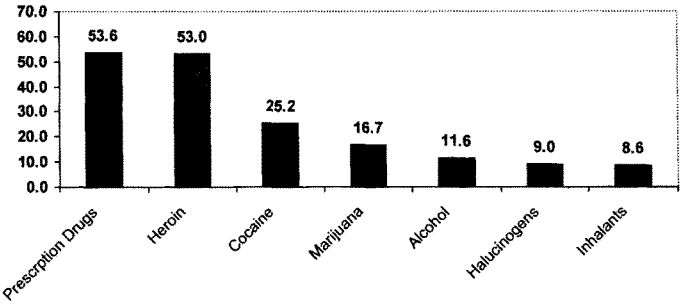
Non-Medical use of OxyContin

- Estimated number of emergency department mentions for total coterminous United States from 1996 to 2002 increased substantially.



Estimated number of Hydrocodone and Oxycodone Emergency Department (DAWN ED) mentions for total coterminous United States: 1996-2002

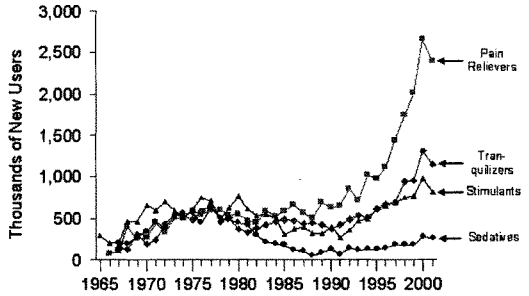
- Dependency or abuse of specific substances among past year users of substances is high for prescription drugs.



Percent of users with Dependence or Abuse of Specific Substances
Source: 2002 National Survey on Drug Use and Health (NSDUH). Results from the 2002 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services

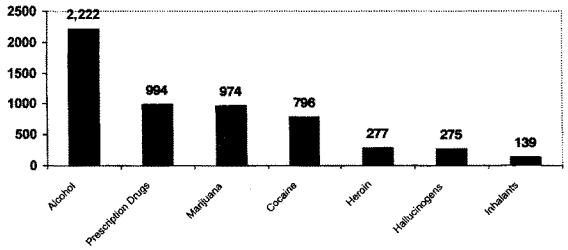
- *Drug abuse in chronic pain management is common.*
  - Substance abuse in chronic low back pain patients has shown to be 19%.
  - Substance abuse in interventional pain management settings has been shown to be 18% to 24%.
  - With prevalence of chronic pain ranging from 15% to 30% in the United States (25 to 45 million persons), the prescription drug abuse or misuse is seen in 18% to 24% (Approximately 5 million to 9 million persons).
  - *The illicit drug use among patients in chronic pain receiving controlled substances has been shown to be 14% to 32%.*

- New non-medical users of psychotherapeutics have been increasing steadily since 1965 to 2002.



Source: 2002 National Survey on Drug Use and Health (NSDUH). Results from the 2002 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services

- The following shows substances for which persons aged 12 or older received treatment in the past year based on 2002 survey.



Numbers (in Thousands) Receiving Treatment for Specific Substances
Source: 2002 National Survey on Drug Use and Health (NSDUH). Results from the 2002 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services

- Prevalence of mental illness is almost double in patients with drug abuse.

4. Management of abuse and diversion of controlled substance is a public health issue

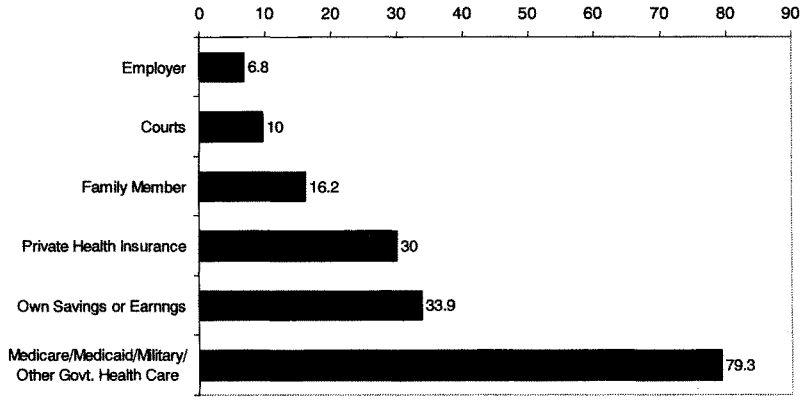
- The diversion and abuse of prescription drugs are associated with incalculable costs to society in terms of addiction, overdose, death, and related criminal activities. The DEA has stated that the diversion and abuse of legitimately produced controlled pharmaceuticals constitute a multi-billion dollar illicit market nationwide[2]. As of February 2002, OxyContin has been involved in 464 deaths from prescription drug abuse, as reported by DEA on the basis of medical examiners autopsy findings for 2000 and 2001 from 32 states.

[2] Drug Enforcement Administration and the National Alliance for Model State Drug Laws, *A closer Look at State Prescription Monitoring Programs* (http://www.deadiversion.usdoj.gov/pubs/program/prescription-monitor/summary.htm

- Patients may be receiving Schedule II, III, and IV prescriptions from multiple practitioners who are unaware of the potential for drug interactions or of the potential for abuse, and diversion of certain medications.

- Drug spending is skyrocketing. Significant amounts of Medicaid funds are spent on abused drugs. Drug spending in some states has increased by 65% in 2003.

- Source of payment for specialty treatment or drug abuse and addiction treatment is highest for federal funds:



Percent Source of Payment for Treatment

(Note that the estimates of treatment by source of payment include persons reporting more than one source.)
Source: 2002 National Survey on Drug Use and Health (NSDUH). Results from the 2002 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services

- Projected economic cost of drug abuse for 1998 through 2000 has been shown by Levin group as 143.4 billion for 1998, 152.5 billion for 1999, and 160.7 billion for 2000.

5. Current state of affairs dictate the need for prescription monitoring programs

- The increasing diversion of prescription drugs for illegal use is a disturbing trend in the nation's battle against drug use and abuse.

- Prescription drug diversion is the channeling of pharmaceuticals for illegal purposes or abuse. It can involve activities such as "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, and prescription forgery.

- States have recognized the need for monitoring of controlled substances since 1940 with implementation in California followed by Hawaii in 1943 (***Table I***).

Now, 15 states have such programs, which include California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Nevada, New York, Oklahoma, Rhode Island, Texas, Utah, and Washington State.

- Florida and Virginia are actively pursuing such programs.

- GAO in its May 2002 report of state monitoring programs concluded that:

  - They indeed provide an efficient tool for stemming the growing problem of illegal diversion of prescription drugs.
  - They offer quick access to comprehensive information on drugs most likely to be abused and deter abusers from doctor shopping within the state.
  - Incidences of drug diversion, however, are on the rise in neighboring states, indicating the problem is proliferating or shifting to states without monitoring programs.
  - The programs have helped reduce availability of abused drugs in Kentucky, Nevada, and Utah.

- State prescription monitoring programs reduce expenses to healthcare officials, pharmacists, and law enforcement officials.

- State programs have helped shorten investigation time and reduce illegal drug diversion.

6. Problems facing physicians

- Every day a physician has to consider:

  - Litigation for failure to treat pain
  - Litigation for undertreatment
  - Criminal charges for abuse, addiction, or death
  - Numerous federal regulations
  - State Board of Medical Examiners
  - Drug Enforcement Agency
  - State Bureau of Narcotics
  - State Board of Pharmacy

- Case Study: Kentucky
  - Almost half a ton of prescription narcotics reached six counties in Eastern Kentucky from 1998-2001, equating to .75 pound for every adult in those counties.
  - On a per capita basis, Eastern Kentucky drugstores, hospitals, and legal outlets receive more prescription painkillers than anywhere else in the United States.

- The Escalating Problem: Hydrocodone

- Nationally, emergency room visits for hydrocodone overdoses increased 500 percent from 1990-2000
- Three Eastern Kentucky counties had enough Lortab, Lorcet, and Vicodin pills in 2001 to provide every adult in those countries with 156 pills
- OxyContin sells on the street for about $40/pill;
  Lortab sells for $20/pill and Lorcet for $9/pill

♦ The Consequences

- From 1997-2001, Eastern Kentucky court cases involving possession and trafficking in controlled substances increased 348 percent.
- In 2000, three Eastern Kentucky counties had more DUIs related to drugs than to alcohol.
- One 21-bed substance-abuse residential house in eastern Kentucky recently reported that all of its beds were occupied by recovering prescription-drug addicts. The number of people in Eastern Kentucky seeking residential treatment for prescription drug addiction tripled from 1998-2001.

♦ Options for Physicians

- Referral to Pain Medicine Clinics
  - Clinics with mainstay treatment of opioids
  - Very limited resource
  - Rare option for Interventional Pain Specialists

- Refuse to Prescribe Controlled Substances
  - Not an option for many practices
  - Inadequate treatment of pain lawsuits
  - Litigation for addiction
  - Criminal charges of murder

- Surrender Schedule II DEA License
  - Lose many patients
  - Lose hospital privileges
  - Lose all insurance patients
  - Not an option for interventionalists

♦ Benefits for Physicians:
- NASPER could alert physicians about patients who are drug shopping.
- Physician can make more informed decisions on prescribing, leading to less risk for medical license.
- Decreased hassle factor with
  DEA
  Medical Board
  US Attorneys

7. Problems facing patients

- Undertreatment of pain
- Suspicion may not be resolved
- KASPER
  - Information not available (of 1000 patients on controlled substances)

Total	26.6%
Kentucky residents	9.7%
Illinois residents	73.9%
Tennessee residents	80.4%

2-4 weeks delay in reporting

- Patients who are drug shopping will benefit from physician intervention

- Patients who are not drug shopping will benefit from physician ability to feel more comfortable in prescribing medicines they need

- Benefits for Patients:
  - Improved access
  - Stable patient – physician relationship

"Honest patients receive appropriate treatment"

8. The need for a comprehensive strategy to control drug abuse and diversion is increasing

While state programs have been effective, the following deficiencies have been noted.

- From 1940 to 1999, states have been able to establish only 15 functioning programs. The number of states with prescription drug monitoring programs has grown only slightly over the past decade, from 10 in 1992 to 15 in 2002.

- The White House estimates to increase drug monitoring programs by 10 next year.

- The nationwide number of prescription drug monitoring programs has been changing. West Virginia terminated its program in 1998, but enacted legislation in 2002 to create a new program. New Mexico terminated its program in 2000 (Figure 1).

- Even though the 15 programs have a common goal of reducing prescription drug diversion and abuse, they vary in their objectives, design, and operation.

- The major purpose of the state programs is to help law enforcement identify and prevent prescription drug diversion.

- Education objectives to provide information to physicians, pharmacies, and the public is a secondary objective.

- Very few states are proactive to the extent that physicians can access the

information proactively to reduce or prevent abuse and diversion.

- Program design also varies across states, in terms of which drugs are covered, how prescription information is collected and which agency is given responsibility for the program.

- Methods for analyzing the data to detect potential diversion activity also differ among states.

- Only 4 of 15 states monitor Schedule IV drugs and only 5 of 15 monitor Schedule III drugs which are the subject of major controlled substance abuse.

- Challenges exist in establishing and expanding state programs, due to lack of awareness of the extent to which prescription drug abuse and diversion in a significant public health and law enforcement problem.

- Extent of diversion in abuse is not always recognized by the states.

- National efforts have focused only on providing guidance and technical assistance.

- **Incidents of drug diversion, however, are on the rise in neighboring states, indicating the problem is proliferating or shifting to states without monitoring programs**.

9. Federal versus state control of controlled substances

Federal

- Controlled Substances Act. The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designed as controlled substances.

- FDA regulations of prescription drugs. The FDA is responsible for ensuring that all new drugs are safe and effective.

- The DEA's regulation of controlled substances. The DEA is the primary federal agency responsible for enforcing the Controlled Substances Act. The DEA has the authority to regulate transactions involving the sale and distribution of controlled substances at the manufacturer and wholesale distributor levels.

- Guidelines for marketing drugs to healthcare professionals. In April 2003, HHS's Office of Inspector General issued voluntary guidelines for how drug

companies should market and promote their products to federal healthcare programs. Federal funds are spent through Medicare/Medicaid military health and other assistance programs spent by patients in acquiring drugs and also in drug treatment.

- Federal funds utilized for management diversion.

Thus, drugs are mostly controlled by federal agencies rather than state agencies.

State

- The state's regulation of practice of medicine and pharmacy and role in monitoring illegal use and diversion of prescription drugs. State laws govern the prescribing and dispensing of prescription drugs by licensed healthcare professionals.

- Multiple state agencies have responded to reports of drug abuse. However, complete information is not available from the directors of state Medicaid fraud control units in Kentucky, Maryland, Pennsylvania, Virginia, and West Virginia. They stated that drug abuse and diversion of OxyContin is a problem in these states.

- State Medical Licensure Boards have also responded to complaints about physicians who were suspected of abuse and diversion of controlled substances, but like the Medicaid Fraud Control Units, the Boards generally do not maintain data on the number of investigations that were involved.

  - Although Medical Boards may be tough, they can't always catch the bad apples
  - Kentucky's Board of Medical Licensure ranked fifth in the nation for disciplining physicians in 2001
  - Board reacts to complaints and can't statutorily look for problems on its own

In contrast, the DEA has statistics available on drug abuse and diversion.

Overall, federal control and responsibility outweighs states.

10. A national program is feasible and cost-effective

- The cost of the program in each state varies according to differences in their design and operational factors.

- Confidentiality appears to be a major concern. Both physicians who legitimately prescribe prescription drugs and patients who legitimately use them are concerned that the information collected, maintained, and monitored by state programs may be used inappropriately or compromised.

  - **All states, regardless of whether there is a state prescription monitoring program or not, have the authority under their laws to conduct investigations of the records of individuals**

alleged to be involved in prescription drug diversion and abuse, including the records of prescribing physicians and dispensing pharmacies.

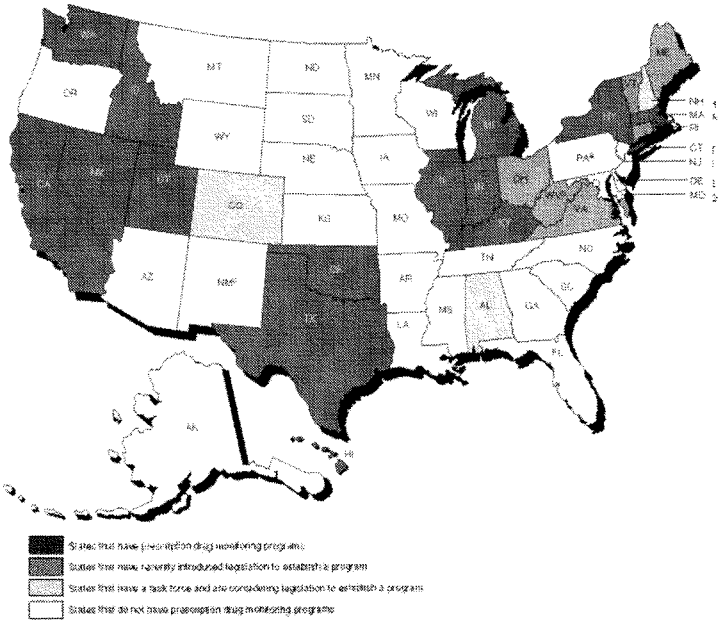
- According to GAO, securing program funding is a critical challenge. The 2002 report states that according to officials from the National Alliance for Model State Drug Laws, the National Association of Drug Diversion investigators, and the DEA, securing program funding is a critical challenge faced by states that choose to develop, maintain, or expand a prescription drug monitoring program.

- A national or a regional comprehensive program with uniform data collection dispersion and ability for physicians to access the data will reduce drug abuse and diversion and at the same time, provide appropriate pain management. A national program has to capture data. There are approximately 60,000 pharmacies across the United States covering half a million prescriptions per year.

- A national program will be cost effective. However, a regional program with availability of data to all bordering states is feasible with data collection and in reducing drug diversion and abuse. However, the cost of such a program is not known. ***Table 2*** shows the contiguous states for each of the 50 states.

- As per the available data from the 2002 GAO report, describing key features of selected state prescription drug monitoring programs as shown in ***Table 3***, the set of funding was $415,000 in Kentucky, $134,000 in Nevada, and $50,000 in Utah. The annual operating costs consecutively for the 3 states was $500,000, $112,000 and $150,000.

Figure 1: Status of Prescription Drug Monitoring Programs, by State, April 2002



*Pennsylvania does not have a PDMP, but requires pharmacies to submit data to the state attorney general's office.

*West Virginia terminated its PDMP in 1999 and has enacted legislation in 2002 to create a new program.

*New Mexico terminated its PDMP in 2000.

Source: National Alliance for State Model Drug Laws, 2002, and discussions with officials in New Mexico, Pennsylvania, and West Virginia.

Table 1. *Characteristics of state prescription drug monitoring programs*

State	Year Implemented	Controlled substance schedule(s) monitored	Type of monitoring system	Administrative Agency
California[a]	1940	II	Electronic and triplicate form[b]	Pharmacy and law enforcement
Hawaii	1943	II	Electronic	Law enforcement
Idaho	1967	II, III, and IV	Electronic	Pharmacy board
Illinois	1961	II	Electronic	Public health
Indiana	1995	II	Electronic	Law enforcement
Kentucky	1999	II, III, IV and V	Electronic	Public health
Massachusetts	1992	II	Electronic	Public health
Michigan[c]	1989	II	Single form	Commerce
Nevada	1997	II, III, and IV	Electronic	Pharmacy board and law enforcement
New York[d]	1977	II	Electronic	Public health
Oklahoma	1991	II	Electronic	Law enforcement
Rhode Island	1979	II, III	Electronic	Public health
Texas[e]	1982	II	Electronic	Law enforcement
Utah	1997	II, III, IV, and V	Electronic	Commerce's Licensing Division
Washington[f]	1987	Determined by disciplinary authority	Triplicate form[b]	Public health

[a]California is currently testing an electronic monitoring program for Schedule II controlled substances. Until the pilot program is completed on July 1, 2003, pharmacies will also have to continue submitting copies of the triplicate forms to the state monitoring agency.

[b]A triplicate prescription form is a paper prescription form issued by the state to prescribers, who must use it when writing prescriptions for covered controlled substances. The prescriber keeps one copy after writing the prescription, and the pharmacist keeps a copy when the prescription is filled and sends the third copy to the state PDMP.

[c]In 2001, Michigan enacted legislation to convert its PDMP to an electronic monitoring program. Until the new electronic system is implemented, the program will continue to require pharmacies to submit copies of state-issued official prescription forms for schedule II controlled substances.

[d]As of January 1, 2002, New York switched to an electronic monitoring system from a paper-based system using a triplicate form. The new electronic system is supplemented by a state-issued, single-copy prescription form that includes a number of security features to prevent counterfeits.

[e]Beginning in September 1999, Texas permitted pharmacies to submit prescription data electronically rather than submitting paper copies of prescription forms. In March 2002, Texas switched from triplicate to single-copy forms with a number of security features to prevent counterfeits. The requirement to submit prescription forms to the state agency will continue until the electronic system is fully implemented.

The Washington program applies only to licensed practitioners whose prescribing practices require monitoring because of the past drug abuse or inappropriate prescribing. The drugs the program covers vary, depending on the prescriber, from one controlled substance to all prescriptions.

Source: National Alliance for Model State Drug Laws. Information is current through February 4, 2002.

Table 2. *Shows the contiguous states for each of the 50 states*

State	Surrounding States
Alabama	Florida, Georgia, Mississippi, Tennessee
Alaska	None
Arizona	California, Colorado, New Mexico, Nevada, Utah
Arkansas	Louisiana, Missouri, Mississippi, Oklahoma, Tennessee, Texas
California	Arizona, Nevada, Oregon
Colorado	Arizona, Kansas, Nebraska, New Mexico, Oklahoma, Utah, Wyoming
Connecticut	Massachusetts, New York, Rhode Island
Delaware	Maryland, New Jersey, Pennsylvania
Washington DC	Maryland, Virginia
Florida	Alabama, Georgia
Georgia	Alabama, Florida, North Carolina, South Carolina, Tennessee
Hawaii	None
Idaho	Montana, Nevada, Oregon, Utah, Washington, Wyoming
Illinois	Iowa, Indiana, Kentucky, Missouri, Wisconsin
Indiana	Illinois, Kentucky, Michigan, Ohio
Iowa	Illinois, Minnesota, Missouri, Nebraska, South Dakota, Wisconsin
Kansas	Colorado, Missouri, Nebraska, Oklahoma
Kentucky	Illinois, Indiana, Missouri, Ohio, Tennessee, Virginia, West Virginia
Louisiana	Arkansas, Mississippi, Texas
Maine	New Hampshire
Maryland	District Of Columbia, Delaware, Pennsylvania, Virginia, West Virginia
Massachusetts	Connecticut, New Hampshire, New York, Rhode Island, Vermont
Michigan	Indiana, Ohio, Wisconsin
Minnesota	Iowa, North Dakota, South Dakota, Wisconsin
Mississippi	Alabama, Arkansas, Louisiana, Tennessee
Missouri	Arkansas, Iowa, Illinois, Kansas, Kentucky, Nebraska, Oklahoma, Tennessee
Montana	Idaho, North Dakota, South Dakota, Wyoming
Nebraska	Colorado, Iowa, Kansas, Missouri, South Dakota, Wyoming
Nevada	Arizona, California, Idaho, Oregon, Utah
New Hampshire	Massachusetts, Maine, Vermont
New Jersey	Delaware, New York, Pennsylvania
New Mexico	Arizona, Colorado, Oklahoma, Texas, Utah
New York	Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont
North Carolina	Georgia, South Carolina, Tennessee, Virginia
North Dakota	Minnesota, Montana, South Dakota
Ohio	Indiana, Kentucky, Michigan, Pennsylvania, West Virginia
Oklahoma	Arkansas, Colorado, Kansas, Missouri, New Mexico, Texas

Oregon	California, Idaho, Nevada, Washington
Pennsylvania	Delaware, Maryland, New Jersey, New York, Ohio, West Virginia
Rhode Island	Connecticut, Massachusetts
South Carolina	Georgia, North Carolina
South Dakota	Iowa, Minnesota, Montana, North Dakota, Nebraska, Wyoming
Tennessee	Alabama, Arkansas, Georgia, Kentucky, Missouri, Mississippi, North Carolina, Virginia
Texas	Arkansas, Louisiana, New Mexico, Oklahoma
Utah	Arizona, Colorado, Idaho, New Mexico, Nevada, Wyoming
Vermont	Massachusetts, New Hampshire, New York
Virginia	District Of Columbia, Kentucky, Maryland, North Carolina, Tennessee, West Virginia
Washington	Idaho, Oregon
West Virginia	Kentucky, Maryland, Ohio, Pennsylvania, Virginia
Wisconsin	Iowa, Illinois, Michigan, Minnesota
Wyoming	Colorado, Idaho, Montana, Nebraska, South Dakota, Utah

Table 3. *Key features of selected state prescription drug monitoring programs*

Key features	Kentucky	Nevada	Utah
Census 2000 population	4.04 million	1.99 million	2.23 million
Year operational	1999	1997	1997
Start-up funding	$415,000 in federal start-up grant funds	$134,000[a] in state funds	$50,000 in one time state funds
Controlled substance schedules monitored	II, III, IV, V	II, III, IV	II, III, IV, V
Electronic data collection and reporting	Yes	Yes	Yes
Private contractor receives dispensing information and creates database	Yes	Yes	No
Annual operating costs (estimate)	$500,000	$112,000	$150,000
Staff	4 full-time (1 licensed pharmacist investigator, 2 pharmacy technicians, 1 data entry operator) and 4 part-time	1 full-time with all administrative duties	3 full-time including manager and 2 support staff
Number of pharmacies reporting dispensing data (estimate)	1,300	387	375
Number of daily data requests received (estimate)	400	20	130 to 150
Report turnaround time to requestor (estimate)	4 hours	4 hours	3 hours
Penalty for unauthorized use or disclosure of PDMP data	Class D felony[b]	PDMP statue has no penalty	Third-degree felony[c]

[a]Nevada received $265,000 for the first 2 years of its program's operations, including 2-year grants from two pharmaceutical companies and the state board of medical examiners.
[b]Kentucky law defines a class D felony as one carrying a sentence of at least 1 year, but not more than 5 years in prison.
[c]Utah law defines a third-degree felony as one carrying a sentence of not more than 5 years in prison.

Source: GAO interviews with PDMP administrators.

Mr. BILIRAKIS. Thank you very much, Doctor.

Doctor, you are the President and Executive Director of the society, right?

Mr. MANCHIKANTI. That's correct.

Mr. BILIRAKIS. Society of Interventional Pain Physicians.

You also practice medicine in the pure sense, by that I mean you have an office?

Mr. MANCHIKANTI. Yes, an active practice.

Mr. BILIRAKIS. Active practice.

You can tell us then, I think, if there is a drug monitoring system and implementation, are there additional requirements on physicians, an additional burden to physicians?

Mr. MANCHIKANTI. No.

Mr. BILIRAKIS. There are not?

Mr. MANCHIKANTI. None.

Mr. BILIRAKIS. How often do you request prescription drug histories of your patients?

Mr. MANCHIKANTI. We request close to—from our Paducah office, which is in Kentucky, about 6,000 of them every year.

Mr. BILIRAKIS. All right. Well, does that mean you request it of every one of your patients?

Mr. MANCHIKANTI. Yes, and every 6 months.

Mr. BILIRAKIS. Every 6 months.

Mr. MANCHIKANTI. That's correct.

Mr. BILIRAKIS. I see.

Is that—how does that compare with the way most physicians, in your opinion, practice?

Mr. MANCHIKANTI. It all depends on individual experiences, but most physicians are becoming very careful. I'm also a member of Kentucky Board of Medical Licensure, so we are seeing more and more physicians adapting the same principle.

Mr. BILIRAKIS. Is the information that you are acquiring from the patients generally accurate?

Mr. MANCHIKANTI. Ninety percent of the time it is accurate.

Mr. BILIRAKIS. What, again, and I'm not trying to simplify the problem, because God knows it isn't simple, but who is at fault here? I realize that, you know, people are in pain, and who is at fault? Why is this such a big problem?

Mr. MANCHIKANTI. Well, I had a section in there, pharmaceutical companies are providing marketing and—There are numerous organizations providing guidelines and standards that our patient advocacy groups are demanding opiates for benign pain. Everybody looks at Internet and comes and says, oh, I can have that medicine.

Then, enactment of patients' bill of rights in many States—or regulations mandating monitoring in the proper treatment of pain, and patients think they have the right to pain relief.

Mr. BILIRAKIS. Doctor Holsinger. I'd like to have maybe all of you answer that.

Mr. HOLSINGER. Well, I think, Mr. Chairman, that the fault, perhaps, lies rather broadly across our society. I think that we are bombarded by television with advertising for substances, drugs, pharmaceutical agents. We have physicians that are constantly barraged by information about new pharmaceutical agents. There's such a huge number of pharmaceutical agents, and I suspect that

very few of us physicians adequately use more than 30 to 40 different pharmaceutical agents in their practice.

I mean, you just can't know the medications that well, that's why we turn to our friends, the clinical pharmacists, to provide us assistance. In fact, today, I think if I were in a private practice of medicine I wouldn't practice without a clinical pharmacist as part of my practice team. I need that kind of support in order to be able to deal with the pharmaceutical agents that we are constantly dealing with.

And, I think that it's a multi-faceted problem, and our best hope is to deal with it on a multi-faceted approach. I think KASPER, NASPER, some form of effort to deal with the diversion of controlled substances is helpful. It helps to deal with the front door, in a sense, getting them out of the system and onto the street, but I think that it's going to take a lot of work on everyone's part to really make a dent in it.

Mr. BILIRAKIS. Ms. Droz.

Ms. DROZ. It's a very complex problem, and I think Doctor Holsinger and Doctor Manchikanti have covered the range of causes.

Mr. BILIRAKIS. Ms. Crosse, do you have anything to add?

Ms. CROSSE. I believe they talked about the difficulties.

Mr. BILIRAKIS. Well, there are two pieces of legislation here that we are talking about. Mr. Whitfield introduced his, and Doctor Norwood, more recently. There are some differences there, and I'm sure when their opportunity comes they will ask you the questions.

But, very quickly, does anyone have anything significant you may want to say regarding those pieces of legislation?

Mr. MANCHIKANTI. Well, I'm in support of NASPER, and Congressman Ed Whitfield is from—I'm in his district, and Doctor Shimkus, Mr. Shimkus.

We came up with this idea because KASPER was working so well, but we were not able to obtain information from other States. So, the next step was the NASPER, having a national program. So, the fundamental thing is, we need a workable program, which will be able to share the data when a physician inquires about a patient when I'm in Kentucky, he goes to California, Florida, or Georgia, wherever he gets the medicines, a physician should have access to that.

If that is achieved, and the program is mandated so it is uniform across the States, then they more or less need to have a minimum standard that is acceptable. There should not be any difference whether it's a State or national program.

Mr. BILIRAKIS. Thank you, Doctor.

My time is up.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

I'd ask unanimous consent to enter in the statement of Mr. Dingell, into the record, both his statement and some letters that were actually sent to him.

Mr. BILIRAKIS. Without objection that is the case, and, of course, the opening statements of all members of the subcommittee, I imagine probably Doctor Norwood put them into the record.

Mr. BROWN. Again, thank you, Mr. Chairman, Secretary Holsinger, I would like to start with you.

In listening to testimony from all of you, and reading and listening over the last couple years about this whole issue, it's pretty clear that there is some significant amount of misuse, it's an interstate problem.

Talk to us, if you would, about what programs are in place to help States communicate with each other and jointly monitor patients, given that each State program, including yours, each State program has its own unique structure.

Mr. HOLSINGER. I think as Doctor Manchikanti said, that's one of the major difficulties that we have in Kentucky. We have not historically had surrounding States with programs, so that we were unable to actually contact back and forth. I think any State that has a program, providing their State legislation allows them to share that information with us, we could do that.

In the case of Kentucky's KASPER program, I think that should there be surrounding programs and interest in other States, and having data from those, we could rapidly get legislative approval to share data.

The problem right now is that not every State has a program, and depending on what your particular regional situation is, there's no one to share data with.

Mr. BROWN. Doctor Manchikanti, you obviously bring a unique perspective to this panel, you are a practicing physician, you contend with these issues just about every day. Are more patients being directed into intervention programs as a result of monitoring these programs, and if so, how is that accomplished while preserving HIPAA medical privacy protections?

Mr. MANCHIKANTI. All the programs do follow the HIPAA regulations, and under the NASPER they are not asking for anything more than what is available already in the KASPER or any other program.

Whether it is a national program, State program, whether they monitor one drug, four drugs, they all have certain regulations, and they all are accessible to law enforcement.

The only thing we are trying to do is, we want, the physicians want the same information which is available to law enforcement officials, so we want to prevent it rather than after something happens. We don't want to go to jail, but just provide the proper care.

Mr. BROWN. Tell us, run through a scenario, how you direct it, if you see a problem with a patient because of these monitoring programs, maybe either of you could answer this, Doctor Holsinger or Doctor Manchikanti, how do you actually direct a patient into one of these—into some kind of intervention program? What do you exactly do?

Mr. MANCHIKANTI. Well, each person has their own guidelines, each practice can have their guidelines, and the States have their own guidelines. But, in my practice, if I see a patient abusing controlled substances, I remind them that they already have a narcotic controlled substance from me, they can't be going to other physicians and obtaining them.

So, we give them a warning, and if they are willing to follow it, and the mistake is not huge, we go ahead and give them the prescription. We continue to follow them every visit.

Meanwhile, we'll also start doing random drug sampling on them. If somebody's tested positive for an illicit drug, then it all depends on what illicit drug it is. If it is cocaine, I will not provide any further drugs for them. If it is marijuana, I do provide them at that point, and if they test positive next time I will stop providing them. If they are on heavy drugs, and they can't just stop it immediately, we try to send them to the drug rehab program.

Does that answer the question?

Mr. BROWN. Yes, good, thank you.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Whitfield to inquire.

Mr. WHITFIELD. Thank you, Mr. Chairman.

You know, we could stay here all afternoon, and we could talk about confidentiality issues, we could talk about which department of Government would be the appropriate department to administer a program, we could talk about which schedule of drugs should be monitored, we could talk about who would have access to the information, all those things, but the bottom line is this, the first program started in 1940, we are 64 years later, we have 16 programs, and we could work out all of those previous things that I talked about.

And, I notice that, Ms. Droz, in your testimony you said that the group that you represent, the National Association of State Controlled Substance Authorities, are opposed to a Federal program because it would be duplicative of the States' efforts.

But, when you consider that we already have a Controlled Substance Act, we have the DEA involved, we have the Medicaid program, and now we are going to have a prescription drug program through Medicare, and we have 64 years in which States have not taken action, why should the Federal Government not take action and at least mandate the States, or at least implement a Federal program?

Ms. DROZ. My organization is very supportive of prescription monitoring programs, and we believe there is a role for the Federal Government. However, our position is merely that one size does not fit all.

We would support Federal legislation to mandate that States have programs, and set some common parameters that would allow States to share information, but as far as—but we believe that States should be allowed to make some modifications to address particular States' needs.

Mr. WHITFIELD. And, Utah has a program that evidently was started on $50,000, and I don't know all the details of it, but it would sound like it's a pretty minimal program.

If you had a Federal program that provided some minimum guidelines, and then required every State to provide information to it, the bill that we have, for example, even allows States to continue their program that's already in existence, or even form a program, but the data would have to be transferred to the Federal Government, so that that data would be available there. I mean, would you be opposed to that kind of an approach?

Ms. DROZ. Representative Whitfield, the fear of the members is that with that kind of approach that our State legislators would say, well, if the Feds are going to fund those programs there's no longer any need for us to continue our State program.

Mr. WHITFIELD. Doctor Holsinger.

Mr. HOLSINGER. I think it's interesting, the KASPER program in Kentucky began with an appropriation from the State legislature for $425,000 for the first year of operations. It went up to $500,000, and then up to $725,000 a year, which is what it's at now. So, for less than $1 million we operate this program a year. It's all on State general funds.

We did have, at one time, $150,000 in the first 2 years from a Federal Department of Justice grant, to help get it started, but in general this has been a program that's been underwritten by the taxpayers of the Commonwealth of Kentucky, because there's a real interest on the part of, not only our legislature, but our Governor and the rest of us, that we work to control the problem.

Mr. WHITFIELD. So, a real concern is that the States have been putting in money, primarily, and without that you would not have a program. But, I thought that Congressman Rogers indicated that over $16.5 million had been appropriated for grants to help start these programs, is that correct?

Ms. DROZ. Yes, that's correct. There were two separate appropriations to allow States to implement new programs or enhance current programs, and this goes a long way.

A number of the States that have implemented new programs and passed their laws is because of the money that's been available from Congressman Rogers' grant program.

Mr. WHITFIELD. Yes.

Mr. HOLSINGER. And, in point of fact, in Kentucky, as we move forward to enhance KASPER and take it to a real-time operation, we intend to be applying for grant funds from those as well.

Mr. WHITFIELD. So, at least I sense that you would not oppose mandates, and if the Federal Government were able to come forth with the money, more than likely these differences on approaches could probably be worked out. Would that be incorrect or would that be correct?

Ms. DROZ. That is absolutely correct.

Mr. WHITFIELD. Thank you.

Mr. BILIRAKIS. Mr. Pallone to inquire.

Mr. PALLONE. Thank you, Mr. Chairman.

Mr. Chairman, can I just request that, this is at the request of Mr. Stupak, because he had to go back home, if we could submit written questions to the panel?

Mr. BILIRAKIS. As we do customarily.

Mr. PALLONE. Thank you.

Mr. BILIRAKIS. You know, we always ask witnesses to make themselves available for written questions. By all means.

Mr. PALLONE. Thank you.

I just wanted to ask two questions, I guess, of Doctor Manchikanti, but, you know, just listening to the comments, I was glad—of the questions that were asked of Ms. Droz, because in your statement you say that you would support a mandate for all States to develop programs with standard features. So, I know that

there's a difference between the bill that I support, which would have a Federal program, versus a State mandate. But, it's clear that you would support a mandate, and some kind of Federal guidelines, correct?

Ms. DROZ. Yes, sir.

Mr. PALLONE. Okay.

The problem, of course, and Doctor Manchikanti, basically, raised it, is that—and so did Mr. Whitfield, is that, you know, it would be nice if we could rely on the States to do this, and, of course, Kentucky is the best example of a State that has, and even funds it, but, you know, after so many years we only have about 15 or 16 States that have moved in that direction. And, without a national program, or at minimum a State mandate, a Federal mandate, I think the likelihood is that we are not going to get that many more States to do this.

And, both, I think, Doctor Manchikanti and Ms. Crosse, stressed the fact, and the GAO report stresses the fact, that the diversion, in other words, because of the fact that some States don't have monitoring you have diversion of these practices and illegal practices by the States.

So, I just wanted to ask Doctor Manchikanti first, you indicated that a number of the surrounding States from Kentucky do not have a monitoring program, and I just wanted you to tell us a little more about how this regional patchwork impacts your ability to treat your patients. I know you talked about that a little bit, if you could develop it a little more.

Mr. MANCHIKANTI. Actually, there are two States, according to the list, who do have programs, that is Illinois and Indiana. This really exemplifies the differences. Indiana and Illinois monitor only Schedule II drugs, and there are, basically, law enforcement issues. But, as KASPER in Kentucky is public health, they are helping the patients and the physicians, mainly the patients.

So, I really have problem. We have an Illinois office, and we are really improving the practice there. I just had to hire another nurse, so she can collect information on the patients who are presenting to Illinois office, by making all the phone calls to the office. So, it is just costing me one extra nurse, just to get the information on these patients.

Sometimes we have to call ten, 12 doctors offices to get the information. But, as in Kentucky, we don't have to do that if the patient is from Kentucky.

Mr. PALLONE. And then a second question, but it's along the same lines. As we mentioned, in the last 60 years, you know, less than 20 States have fully implemented a prescription drug monitoring program, and, of course, your organization has doctors from all over the country, and has worked on this at every level. But, absent a national approach, which obviously you and I support, do you think that individual States will enact a drug monitoring program, and how the State approach will impact your ability to treat your patients. In other words, you know, on the one hand we'd like to see a national bill, on the other hand Ms. Droz has said, you know, we could have a Federal mandate linked with Federal guidelines. But, I mean, absent something, my impression is that we are not going to make much progress.

And so, I just wanted you to say, you know, tell us without this national approach, what do you think is going to happen, and how is that, you know, continuation of this State-by-State approach going to impact your ability to treat your patients?

Mr. MANCHIKANTI. Well, with all the hoopla about 21, 20 programs, actually, there are only 15 functioning programs, if you include West Virginia, that makes it 16. I really do not know where these other five programs are coming from, what they have to offer or anything.

Out of these 16 programs, only five programs monitor Schedule III and IV drugs. That is where most of the abuse is going to be imputed, with all the crackdown on OxyContin, Schedule III and IV are going to be extremely important.

In Kentucky, hydrocodone is the most abusive drug, that is Schedule III drug. So, that is being monitored only in 4 or 5 States. So, the remaining 11 programs, they have to make radical changes, so the only programs which are functional are 4 or 5, so short of national approach or mandated approach for every State, with data sharing, there is no solution. We will be talking the same thing after 20 years, and my children will be talking the same thing, and people will be much more serious.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. So, do you all, basically, agree with Doctor Manchikanti, if I may follow up on Mr. Pallone, that, basically, without some sort of a mandate or some sort of a Federal type of a program that a lot of the States are just not going to do the job? Do you have any opinions on that?

Ms. CROSSE. We don't have an opinion, GAO doesn't have a position on whether or not a Federal program or a mandated State program, or a State initiative program is preferable.

Clearly, there are problems right now that occur because of the patchwork of coverage, with some States having monitoring programs and other States having no program.

As to the number of States that are coming on line, with the Rogers funding from the Department of Justice, there are a few States that are in the early stages of developing programs. Virginia has a pilot program in a few counties in southwestern Virginia. New Mexico will be able to resume it's program. It hopes to bring that back on line later this year.

There is some startup funding available in some other States, Alabama, Florida, Maine, and Wyoming, they have bills under consideration in their legislatures, but it's not clear whether that legislation will pass and those programs will go into implementation. But, they've also received funding.

Also Ohio and Pennsylvania have received some funding, because they've had legislation under consideration, but none of those programs are ready to go. So, it's not clear how quickly other States will be able to implement programs.

Mr. BILIRAKIS. Okay.

Well, if you have any—do you have any opinion on this, Ms. Droz?

Ms. DROZ. Yes, Chairman, I do.

I believe that the statements are very accurate, that without a Federal mandate and Federal funding we will continue to see this patchwork, because there's a lot of interest in this program in every State, but there's not the will to put them in place in every State. So, absent some action by the Federal Government, by Congress, I think we'll continue to have problems.

Mr. BILIRAKIS. Doctor Holsinger, I think you've already testified to that fact.

Mr. HOLSINGER. Right, I think that certainly in the Commonwealth of Kentucky, we would consider it to be extremely helpful to know what's happening in surrounding States, and to be able to share data certainly within the confines of particular requirements.

There's a question that hangs out there, though, that you all will need to wrestle with, and that's who is going to be the enforcer of such a program, whether it's State mandates or a Federal program. We certainly know—the reason I say that, I think we certainly know that in our Commonwealth our law enforcement officers are extremely interested in this program. It has made life tremendously better for them. They've allowed them to deal with these cases in a much more efficacious way, and a much more effective way, so I'm sure that they would want to be at the table in any of those kind of discussions.

But, I think it would be fair to say that the administration's position in the Commonwealth of Kentucky is that whatever system, you as the national policymakers decide is the right way to go, we will work within that, and be happy to do so.

Mr. BILIRAKIS. Doctor Manchikanti, we've already heard from you on that, so I think that your feeling is that there's got to be some sort of a mandate or something of that nature.

Mr. MANCHIKANTI. That is correct, workable.

Mr. BILIRAKIS. Yes, workable.

Doctor Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman.

I want to work on the record here just a little bit. First of all, Ed and I have two separate bills, and Mr. Pallone and Mr. Strickland, and they really are different. Ed's bill is a monitoring bill, State—I mean, federally mandated, ours is a State monitoring bill with a Federal floor and the dollars put to it.

Also, our bill goes a lot further. We are after stopping the misuse of Class II, III and IVs, not just simply having a monitoring program. Now, it's a little misleading to say, well, gosh, we've had 63 years and nobody has been involved.

As Chairman Rogers pointed out, it seems to me States are starting to get involved the more money he puts into it. We had 15, five more coming on line, there's a simple answer to that, that's because money is available.

Kentucky has done a fabulous job. I do nothing, Doctor Holsinger, but give you credit. You ain't funding that program, you put some money into it in 2004, but you are fortunate to have a great Member of Congress who is on Appropriations who has funded the program. And, what we're saying is, that States ought to have at least a bottom line to which they must do, I believe very strongly States will fall right into this thing as soon as we put the dollars to it, and then it actually does work.

The reason you don't have States around you that have monitoring programs, in my opinion, is that Congressman Rogers has slowly but surely added more money to it and more States will come in line.

Now, let me just ask a couple of quick little questions now that we've got that straight.

If we were to pass a law, you got it all, Mr. Pallone, it isn't exactly like nobody has been paying attention, if we were to pass a law today outlawing the manufacture of OxyContin, nobody can make it, it's against the law, you go to prison if you make it in the United States, what would happen, Doctor Holsinger, to your monitoring program? Would you get to go out of business then?

Mr. HOLSINGER. Oh, heavens no. We monitor Class II, III and IV drugs, and OxyContin is only the fourth largest prescribed medication, we have 90 percent. We still have a problem, as you heard from Doctor Manchikanti, that's not our biggest problem today.

Mr. NORWOOD. Well, that's it, I just needed to hear you say that, because I believe that, too. This is not something new. We act like this is something that just started last week. This has been going on a long, long time, and we're finally getting to, hopefully, dealing with the problem and, hopefully, Georgia will do it as well as Kentucky is doing it.

Let's say your monitoring program works so great, it absolutely, and should, put a stop to doctor shopping. Can you go out of business now?

Mr. HOLSINGER. No, because our physicians rely upon this program in Kentucky in order to be able to practice quality medicine as far as pain medications are concerned.

Mr. NORWOOD. I agree, that's different though. That is not exactly the same thing as stopping the illegal use of these drugs.

Mr. HOLSINGER. Right, but I believe that we have a program that plays a major role, according to our physicians, in the care of their patients in a quality way. For that reason alone, I'd continue the program.

Mr. NORWOOD. I would, too, don't misunderstand me, I would, too.

Mr. HOLSINGER. I recognize that we are on the same side.

Mr. NORWOOD. But, what I'm getting at here is, that if you stop doctor shopping, if you absolutely bring it to an end, and I hope to God to put everyone of them in jail, if you do that, there are still other ways to get to the drugs, and we can't ignore that if our goal is to try to prevent the misuse of opiates. Would you tend to agree with that?

Mr. HOLSINGER. I would.

Mr. NORWOOD. It's also my impression that pharmaceutical companies that market directly to patients, as opposed to marketing to physicians, who, you know, they have a position of I'd like to sell my product, I put it on the back of the physician, the dentist, whatever, they need to make the right call about what's used, but it concerns me about companies that market directly to patients out there, that make them want some of these drugs.

Now, does anybody know if the maker of OxyContin markets directly to patients? Because if that's going on, we need to revise our bill. Does anybody know the answer to that?

Yes, ma'am.

Ms. CROSSE. We recently completed a study of OxyContin's marketing, and we did not find that they have a program aimed at direct marketing to patients. They have activities marketing to physicians that have included some videos that physicians could use to show to patients that would provide information about pain relief drugs.

Mr. NORWOOD. Well, that's——

Ms. CROSSE. But, it's not in direct consumer type of advertising that you would see with advertisements on television or advertisements in the popular press. It is rather through physicians that they are providing information to patients.

Mr. NORWOOD. Real quickly, real-time information, I think that's very important.

Doctor—any of you, do you agree with that?

Mr. HOLSINGER. Correct.

Mr. NORWOOD. How much trouble are you having, and I'm having to hurry, how much trouble are you having with privacy? I'm very concerned about that, and hear people talking about that, you have a lot of people that can access your program, I'm just wondering what the experience is.

Mr. BILIRAKIS. Let's do it, but quickly.

Mr. HOLSINGER. I think we've not had a real problem with issues around leakage of information.

Mr. BILIRAKIS. Anybody else, any comments regarding that question?

Are you satisfied, Doctor Norwood?

Mr. NORWOOD. For that round.

Mr. BILIRAKIS. Mr. Strickland to inquire.

Mr. STRICKLAND. Thank you, Mr. Chairman.

It seems to me that States may not implement this program for, basically, three reasons, money, awareness of the need, or privacy concerns.

Quite frankly, from where I'm coming from, if a State decides that the privacy concerns can't be overcome then they can choose to opt out. But, I agree with Doctor Norwood, that if you provide the money, I find it unlikely that States are going to not move forward and implement these programs.

I also agree that there are lots of ways that these medicines can be diverted and abused, the Internet, the misuse of the law allowing personal use of medication to be brought into the country.

And, the bill that Doctor Norwood and I have been working on, I think will approach these things in a comprehensive manner. But, just let me ask you your personal opinion.

If we were to make available $25 million for startup costs to States, and if we were to make available $10 million to carry forth this activity, do you think the States would likely ignore this opportunity, or do you think the States would more likely, in fact, choose to undertake this activity? I'm just asking for your personal opinion.

Mr. HOLSINGER. I think that my sense would be that the likelihood is that States would be more likely to come on line. I think, though, that there are two or three States that have very far advanced programs, like Kentucky, and that with a probably reason-

ably minor amount of money in the greater scheme of things we could bring the system into real-time operation, and that could be, in turn, offered to other States as a way of being able to move forward more rapidly and with less cost.

I think rather than inventing 50 different wheels, we ought to look at two or three that are really good and see which one we think would be the best national model, and to let that one be, you know, worked to fine tuning it, and then make it available to other States, you know, with only the cost of implementation. I think you could save a lot of money.

Mr. STRICKLAND. I have here a statement, Mr. Chairman, I'd like to make reference to. It's from the American Medical Association. They point out that they support a State-based rather than a federally based program for a variety of reasons. They point out what some States have already done, mentioning Kentucky, Nevada, and Utah, for example. And then, they point out these things.

Whenever a drug problem—wherever a drug problem lies, the States are better positioned than the Federal Government to have incite into how best to address their own unique problems.

Another reason that they think it ought to be State-based is that medicine itself has been, and should remain, regulated by the States physicians, pharmacists and other healthcare providers are all licensed by the State in which they practice.

And so, it seems to me that the concern that we not have a mandate will result in States not choosing to proceed here, because 60 years have passed and we have not yet done it, as Doctor Norwood points out. I think there's a reason for that, awareness being one, and we are probably more aware than we have been, but certainly resources. If the Federal Government provides the money, it is my judgment that the States will, in fact, take advantage of that opportunity and develop these programs.

So, I would return the balance of my time, Mr. Chairman. Thank you for the opportunity to ask questions.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Buyer to inquire.

Mr. BUYER. Thank you.

Earlier in my opening statement, I made some comments and referred to dentists, and I said to my colleague, Doctor Norwood, I was not casting aspersions upon your profession, because my father is a dentist, my grandfather is a dentist, my brother is a dentist, my sister is a dentist, my cousin is a dentist, my uncle is a dentist, and you chose to follow halitosis and so did they. I chose not to, but I respect your profession, Doctor.

Mr. NORWOOD. Well, I was going to tell them all what you said.

Mr. BUYER. Okay, I thought I'd beat you to it.

I will say this, though, Doctor Norwood, and to others, I really didn't know a lot about this issue until my sister, who was then the—Doctor Diane Buyer, was the Editor of the Indiana Dental Journal, and she wrote an article that became very controversial at the time, but she went into the issue about the profession themselves prescribing these controlled substances for each other, their colleagues, and abuse of themselves. And, actually, it turned out to be positive, because it got the profession talking about it and beginning to police themselves.

So, I want to turn to you and ask about these monitoring programs, and I call it the dark side of the profession, it's not just dentistry, it's all the professions, and if one does it, then it makes them all look bad.

So, do these monitoring programs at all address what occurs in the professions, in terms of the doctors we have here?

Mr. MANCHIKANTI. Yes. I am a member of the Kentucky Board of Medical Licensure. Our investigations have gone up substantially. So far, medical boards can be as tough as you want, we can stop everyone, but they won't be able to catch every person. Plus, there has to be a complaint filed on a physician. Unless there is a complaint, medical board cannot inquire.

They are punishing them strictly, and there was just an article in Jeffersonville, one of the newspapers, how many doctors are losing their licenses because of controlled substances. Kentucky ranks fifth in the Nation for disciplining physicians. Sixty to 70 percent of the disciplines are related to the controlled substance prescription patterns. Kentucky has the guidelines for that purpose.

Mr. BUYER. All right, thank you.

Are other States doing this, including it in their programs? GAO?

Ms. CROSSE. Most of the States are like Kentucky, in that they are reactive if there is a complaint, if there is some other evidence that would lead to an investigation of a practitioner, then the data would be available through the program. But, very few States are using it to monitor individuals in a proactive way, to look for problems just arising out of the data.

Mr. BUYER. I'll have further questions as this bill goes forward, and I look forward to working with the authors of the bill.

The other point, if I could—I'll work with you on that—the other issue I have is, in the face of an over litigious bar, the trial lawyers, we have this sort of trend in our American society whereby we don't want to accept personal responsibility, and if we can blame something on someone else that's wonderful. At the same time, we have a victim of a particular crime, and these trial lawyers are then looking for deep pockets and being very creative.

So, my question is, have there been any lawsuits against—have there been any lawsuits, or is there a potential of liability to a State monitoring program that has not done its job, or has been alleged negligence, brought into party to a lawsuit against a drug manufacturer? Has that occurred yet?

Mr. MANCHIKANTI. To the best of my knowledge, no.

Mr. BUYER. GAO, did you see any evidence of this in your study?

Ms. CROSSE. Well, there are a number of lawsuits that have been filed against the manufacturer or OxyContin, alleging that the patient was misled about the drug, and was inappropriately treated with it, and are now physically dependent or addicted to the drug.

Mr. BUYER. Do you see it possible that a State could be brought in as a party to a lawsuit if the State did not adequately fund a particular program and, therefore, they were negligent in their monitoring, and are subject to liability just as the manufacturer?

Mr. HOLSINGER. We would claim sovereign immunity, I believe, in the Commonwealth of Kentucky.

Mr. BUYER. You claim immunity.

Mr. HOLSINGER. Sure. We have a very strong sovereign immunity in the Commonwealth of Kentucky, which has just in the last 5 years been reiterated by the State Supreme Court, over a case involving the University of Kentucky Hospital, which is a State-owned hospital, which has sovereign immunity as well.

Mr. BILIRAKIS. I think you'll find that probably that exists in every State in a variety of ways.

Mr. Greenwood to inquire.

Mr. GREENWOOD. Thank you, Mr. Chairman.

First, let me say to the GAO, thank you for the report that responded to the request of Congressman Wolfe, Rogers and myself. It's pretty well done.

Let me, from my experience, and I got into this years ago when we had a doctor in Bucks County, my district, who was—his name was Palino, and he was—had an operation, he had actually lost his license, but when the DEA got down and investigated him he was—he was turned in by a pharmacist who saw all these people coming in with their prescriptions. His waiting room was a room fool of zombies, and his parking lot was a parking lot full of zombies, and they were basically going in and giving him $60 for what he was writing down as a routine examination, and just handing out scripts for OxyContin.

As I've looked into this issue, my vision of what would work is something like this, and I'd like your response. My vision is, every pharmacist in the country, when they fill a prescription for one of these scheduled drugs, goes onto a web site and enters in the details about the doctor, and then the patient, and the drug, and the dosage and so forth, and that that information then would be downloaded to one secure—it would go to the State, but also it would simultaneously go in real time to a secure server in Washington, either HHS or DEA, and that the software at the recipient servers, State and Federal level, would do real-time printouts of—or at least lapsed-time printouts that would indicate individuals who were getting prescriptions from multiple doctors. So, we'd have that information. And then, you would also have doctors who were prescribing over some threshold, so you would see the outliers among the physicians, and you could eventually alter the system so that you would not continuously kick out the big pain centers and so forth, and try to get to the places, the anomalies would be those doctors and areas that would not be expected to be prescribing so heavily.

And that then, law enforcement would have the opportunity to focus in on both the individuals, who are doctor shopping, and the doctors who are patient shopping, and over prescribing.

Now, what I'd like to ask you is just, how do you react to that? Is that sort of pie in the sky, or does that make sense, because what it involves is real time, both State and Federal access to the information, receiving the information, having access to it, and a proactive law enforcement approach as opposed to information being in 50 different data sources, and if they get around to it there is—the DEA, for instance, getting around to getting information and acting on it if they have the personnel.

Ms. DROZ. If I might respond. That sounds perfect. However, in brief, there are a number of technological problems with doing that, and at some later time I'd be happy to discuss those at length.

Mr. HOLSINGER. I think that, you know, we've got one of the three advanced systems, and yet we work on a 2-week delay as far as the data, and right now we are working on a 4-hour turnaround, going to 15 minutes, going to real time for the turnaround information.

But, to be able to have all the physicians offices, and all of the pharmacies in the country, hard wired, if you will, and wired into a real-time system is huge undertaking.

Mr. GREENWOOD. Well, is it using—taking advantage of the worldwide web, having an Internet site, a secure Internet site, and we are not talking about new wires and new——

Mr. HOLSINGER. Well, you know, that's correct, but we in Kentucky do not necessarily have every physician office on line in the Commonwealth, and we also don't necessarily have every physician office with a computer.

Mr. GREENWOOD. Well, I understand that, but my guess is we are in the 90's somewhere, and it would seem to me that accomplishing this with 90 percent would be quite an accomplishment, and you could certainly—there certainly ought to be ways to fill in the gaps eventually. But, I would hate perfect to be the enemy of could have.

Mr. HOLSINGER. Ms. Droz was in Kentucky at the time a lot of this was being worked on, but I think one of the most significant issues that we had to overcome was the issue of the feeling of intrusiveness into this, both into the physicians's practice, which we overcame, but also the concern about what happens if the data is not secure.

And, I think one of the biggest issues we'll have is the issue of secure data.

Mr. GREENWOOD. My time is expired, but I would look at those as challenges to be overcome, rather than barriers.

Mr. BILIRAKIS. I would hope that you two gentleman, will see each other during these many years, will be able to sit down and get things worked out. The important thing is that we do something about this subject.

You know, I'm not admonishing you, but you are both close friends, but if we are going to stick in a hard-headed way to our particular position we are not going to get anything done, and then have the committee doing a mark-up.

Mr. NORWOOD. We discussed that today already, Mr. Chairman, while you were fighting out concurrently, we talked about that just a little bit, and everybody tends to agree on what the policy, basically is, the problem is. There's no excuse for this committee not having a unanimous vote on a bill that would solve this problem.

Mr. BILIRAKIS. I am not going to go a second round, but I would say that if anyone—I'm just going to maybe extend 2 minutes to members here to maybe close or whatever the case might be.

I'll go over to this side to Mr. Pallone, 2 minutes.

Mr. PALLONE. I'm not going to—I just have one question, and it's about the funding. I know that there's been statements made by Mr. Strickland and Mr. Norwood about, you know, how money was

given from the Federal Government to the States that start their programs, but I know that we already have this existing fund from the Hal Rogers program, and my notes say that in fiscal year 2003 $10 million was awarded, while in fiscal year 2004 $7 million in grants were given. Are these grants being utilized, and part of the question also, Doctor Manchikanti, is, you talked about how the national program would be very cost effective and really wouldn't cost that much, so if you could just comment a little on to what extent the existence of money now is being used by States without a mandate, and to what extent, what the cost would be of a cost effective——

Mr. BILIRAKIS. You know, and I might add, as I understand it, those funds haven't even been authorized. It's been a case of appropriation.

Mr. PALLONE. Oh, well you know those appropriators, they are bad.

Mr. BILIRAKIS. But, the money, of course, has been appropriated.

Mr. PALLONE. Doctor?

Mr. MANCHIKANTI. Well, to my knowledge, and Doctor Holsinger can confirm, but the Kentucky program really started with Kentucky tax dollars, not from Federal funds, and you may confirm or deny that.

So, other programs I'm not sure why they are not starting, like West Virginia, which is a major problem for Kentucky. In 1998, that is when Doctor—Mr. Rogers program started, at the same time they dropped their program because of the funds, lack of funds. After 3 years they restarted, I don't know how effective their program is.

So, I'm a little bit skeptical on that issue, and I was reading an article in U.S.A. Today, the other day, it said that States really don't have any incentive to control their Medicaid spending because for every $1 they spend they get $3 Federal. My calculations show that on abuser drugs, Medicaid funds are spent about $9 to $10 million, so States are in one way benefiting, even though they are trying to control the problem.

Mr. PALLONE. Well, is there any indication——

Mr. BILIRAKIS. The gentleman's time is up.

Mr. PALLONE. Okay, I'm sorry. Forgive my rudeness.

Mr. BILIRAKIS. Mr. Whitfield, 2 minutes.

Mr. WHITFIELD. Mr. Chairman, thank you. I want to thank you also for allowing us to have this hearing on a particularly important subject matter, and in the spirit of further record clarification I would like to state that as far as I know the American Medical Association has not endorsed or officially opposed either of these bills, is my understanding. In fact, the only bill that has support of an organization that I know of is our bill, which does have the support of the Interventional Pain Management Association and the American Association of Physicians of Indian Origin.

However, this is such an important matter, I hope that the will is in the Congress to provide the funding to provide the mechanism to get this in place around the country, and I do firmly believe that you can make a strong argument for a strong Federal program, because the Federal Government is involved in the largest portion of healthcare in our country today, and with the prescription drug

program under Medicare it's going to be even more so, and so I think physicians need to have access, we need to have it available for law enforcement, we need it for educational purposes, and I do believe you can make a strong argument.

However, we also know, and I know this very well, and anybody that's served in Congress knows it, you don't get anything done in Congress, you don't accomplish anything without being willing to compromise on it, and I'm not—so I look forward to working with all of our cohorts in trying to deal with this issue, and with that, having clarified the record, I will stop talking.

Mr. BILIRAKIS. Doctor Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Say the same thing, will you?

Mr. NORWOOD. In the spirit of comedy, and the spirit of working this out, I won't respond to some of that, but I think that it is important, it is really very important, Doctor Holsinger, you understand the startup cost of KASPER was $415,000, that your great appropriator from Kentucky sent to Kentucky, and that's how the program got started, and that's how the State programs have started.

Doctor Lax, I love that first name, Lax, tell me this, you are on the State Board of Medical Examiners in Kentucky, am I correct?

Mr. MANCHIKANTI. Yes, sir.

Mr. NORWOOD. Yes, and you can't really inquire unless someone brings a complaint to the State board.

Mr. MANCHIKANTI. We can start April 1. They have changed the State law, now we can go randomly check physicians and prescription patterns, or even patient interception patterns, and who is prescribing what. But, at the same time then we will have these problems with money and personnel.

Mr. NORWOOD. And lawyers.

Mr. MANCHIKANTI. Lawyers.

Mr. NORWOOD. But, mostly what I'm trying to find out is, can you—can a red flag come up on your monitoring system, can that be enough for you to inquire?

Mr. MANCHIKANTI. After April 1 we can.

Mr. NORWOOD. Great, that is an extremely important part, in my opinion, of this whole monitoring system.

I've observed, just over some years being on the State board and different things, many physicians who are writing prescriptions, who have no business in writing prescriptions for the reasons they are writing them for, are addicted themselves. There seems to be, at least in Georgia, and I've watched this over some years, there seems to be a correlation with that in our State, that healthcare providers that are addicted to something tend to be the ones that more frequently are writing bad prescriptions. Is that true in Kentucky?

Mr. MANCHIKANTI. Yes, probably it is true throughout the country. We had a witness, one physician, we had an emergency order to take his license away, he brought about three high-powered attorneys, and his statement was, none of them knew the hell we were doing. He was the only one who knew, because he had two back surgeries, he hurts, he knows how patients feel.

Mr. NORWOOD. Mr. Chairman, that makes this even more important, because it's not just the misuse of prescription drugs, it's the bad doctors.

Mr. BILIRAKIS. That's for sure. Thank you, Doctor Norwood.

And, to close, Mr. Brown.

Mr. BROWN. I will be well under 2 minutes, thank you, Mr. Chairman.

As a supporter of the Whitfield-Pallone bill, I do believe, in fact, that we can figure this out and work out a solution, and I am very hopeful that we do, and equally hopeful that we find the funding for this.

Unfortunately, you know, we've spent the surplus we had, we have this deficit, and, unfortunately, way too often, Mr. Chairman, tax cuts, all the decisions we make around here, made it harder to come up with funding for health issues that the chairman and I both support. And, I hope that even though this is a lot of dollars, compared to other programs, that it's something that we can figure out how to do and make the right fiscal decisions and the right healthcare decisions.

So, I yield back my 1 minute and 18 seconds, Mr. Chairman.

Mr. BILIRAKIS. All right.

The hearing is over, but we will have these written questions to you. Please, respond to them in a timely fashion. You know, I don't like to put a particular date on them, but, hopefully, within 2 or 3 weeks, whatever.

When we get these two gentlemen and their co-sponsors to be able to sit around the table to work out something in the interest of time here, I'll just say getting your responses will be important in that regard.

Thank you very much, it was a good hearing. We appreciate it.

[Whereupon, at 3:23 p.m., the subcommittee was adjourned.]

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