NASPER: WHY HAS THE NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING ACT NOT BEEN IMPLEMENTED?

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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NASPER: WHY HAS THE NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING ACT NOT BEEN IMPLEMENTED?

WEDNESDAY, OCTOBER 24, 2007

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

The subcommittee met, pursuant to call, at 10:05 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives DeGette, Green, Schakowsky, Pallone, Whitfield, Murphy, and Burgess.

Staff present: Kristine Blackwood, Joanne Royce, Scott Schloegel, Kyle Chapman, Alan Slobodin, and Karen Christian.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. The subcommittee will come to order. Today we have a hearing on "NASPER: Why Has the National All Schedules Prescription Electronic Reporting Act Not Been Implemented?" Each Member will be recognized for a 5-minute opening statement. I will begin.

More than 2 years ago, with wide-spread support in both the House and Senate, Congress passed the National All Schedules Electronic Reporting Act, otherwise known as NASPER. NASPER established a grant program at the Department of Health and Human Services to foster the development of prescription drug monitoring programs in every State. These drug monitoring programs will provide a safe, comprehensive, and balanced approach to stop the growing epidemic of prescription drug abuse by detecting and preventing doctor shopping for addictive drugs.

I was pleased to join with my good friends, Ed Whitfield, ranking member of this subcommittee, full committee Chairman John Dingell, Ranking Member Mr. Barton, as well as Congressman Pallone, chairman of our Health Subcommittee, to work and have Congress pass this comprehensive program to provide the tools necessary to the physicians, pharmacists, and law enforcement for fighting prescription drug abuse. In passing NASPER, Congress recognized that prescription drug abuse cannot be fought only by law enforcement. It is not enough to simply prosecute pill mills and drug addicts to solve this complex problem. Identifying the pill mills and prosecuting dealers occurs after the pill pushers have

been in business for months or years, spreading the devastation to the addicts, their families and communities.

Congress passed NASPER because we understand that, in addition to putting drug dealers behind bars, we must ensure that physicians, pharmacists, and public health officials have the resources they need to identify and stop drug addiction before it begins. NASPER would enhance that so physicians have immediate access to patients' prescription drug history. NASPER would give pharmacists the ability to thwart doctor shopping by patients and drug dealers. NASPER would ensure that patients are not being overprescribed pain medicine or taking dangerous combinations of prescription drugs. NASPER would ensure that public health officials could review prescribing patterns, educate, and warn physicians about medication risk. At the same time, NASPER ensures that law enforcement will have access to prescription drug data to support their investigations and prosecutions.

In short, NASPER recognizes that prescription drug addiction is both a law enforcement, medical, and a public health problem. Congress granted HHS oversight of the NASPER Program because we believe that the program fits best within HHS's public health mission. NASPER calls upon the Secretary of HHS to issue regulations with public input to ensure uniformity among the States' prescription drug monitoring programs. If drug monitoring programs receive real-time and uniform electronic data, States can share critical drug data abuses while effectively protecting patient privacy. The NASPER Program will benefit from HHS expertise and experience in addition to prevention, treatment, and medical privacy law, health information, and e-prescribing technology. Moreover, NASPER can be integrated with the prescription drug benefit programs run by Medicaid and Medicare programs and help the Food and Drug Administration to monitor the post-market effect of prescription drugs.

This administration has failed to provide any funding to implement the NASPER Program. Instead, the administration has promoted and funded a drug addiction program at the Department of Justice that was never authorized by Congress, a program that emphasizes the law enforcement aspect of prescription drug epidemic at the expense of public health concerns.

The purpose of today's hearing is to determine why the will of Congress has been ignored. We will hear from three distinguished witnesses this morning. First we will hear from Dr. Leonard Paulozzi. Am I saying that correct, sir?

Dr. PAULOZZI. It is Paulozzi.

Mr. STUPAK. Paulozzi, from the Centers of Disease Control and Prevention in Atlanta, and he is a nationally recognized expert on prescription drug abuse trends. Dr. Paulozzi's testimony will provide troubling evidence that the epidemic of prescription drug abuse is getting worse, not better. Next, we will hear from Dr. Westley Clark, the Director of the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration of HHS. Dr. Clark is an expert in addiction treatment and prevention and leads the Agency's effort to provide effective and accessible treatment to Americans with addictive disorders. Our third witness will be Dr. Andrea Trescot, the president of the

American Society for Interventional Pain Physicians, or ASIPP. In addition to her leadership role with ASIPP, Dr. Trescot is a Director of Pain Fellowship Program at the University of Florida. Dr. Trescot will provide the physician's perspective on the importance of implementing NASPER.

Let me advise members that we are setting up a meeting with the Office of Management and Budget. This subcommittee requested that OMB testify before us to gain a better understanding of the administration funding goals. Unfortunately, Director Nussle could not make it, but he will be meeting with us at 3:30 p.m. Thursday. Let me be clear. This subcommittee and this committee are committed to carrying out the NASPER Program, and we hope the administration will join us. I thank the witnesses for appearing today, and I look forward to their testimony.

Next, let me yield to my friend and one of the advocates of the NASPER Program, Mr. Whitfield from Kentucky, for an opening statement, please.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KENTUCKY

Mr. WHITFIELD. Chairman Stupak, thank you very much. I want to thank you for convening this important hearing.

Back in 2005, many members of the Energy and Commerce Committee co-sponsored legislation, the NASPER legislation, which was passed by the House of Representatives under the suspension calendar, and about 3 days later passed the U.S. Senate, and then President Bush signed NASPER into law on August 11, 2005. NASPER was the product of strong bipartisan support. It was passed by the committee by voice vote after hearing testimony about the epidemic of prescription drug abuse in this country. The members of this committee and the House and Senate felt compelled to create a Federal prescription drug monitoring program to reinforce the State programs and to ensure that these programs were interoperable, that information could be shared, that the NASPER law also provided a basic guideline and had mandates in it so that every program had to meet certain specifications. It allows physicians to obtain information about their patient so that they can identify and treat a possible addiction. It also allows law enforcement to access prescribing information so that they can build investigations against doctors and patients who abuse the healthcare system by improperly prescribing or obtaining prescription drugs.

Yet almost 2 years after NASPER was signed into law by the President, not a single dollar has been requested by the administration, by OMB, and I am not sure, Dr. Clark, that even HHS has asked for any dollars for this program when you compiled your budget requests and sent them to OMB. As Chairman Stupak said, we have talked to OMB, we invited OMB to come and testify, and they said they would like to meet with us privately on this issue. But I would like to stress what Chairman Stupak said. The only program in existence today is a non-authorized program that the Appropriations Committee decided that they would fund without any hearings, without any checks and balance on the system. They simply provided the money, and the first year after NASPER was

signed, we all sat in a room, appropriators and Energy and Commerce people, and Chairman Barton was very emphatic in that meeting that NASPER was going to be funded. We agreed to fund NASPER to the tune of $5 million, and the Department of Justice system was funded for $5 million, but due to the continuing resolution, funding for NASPER was never appropriated. And we asked Chairman Dingell to get involved in this issue because it does go to the jurisdiction of this committee. We have jurisdiction over this issue, but more important than that, more important than jurisdiction, is which program is the best program?

The DOJ program is focused on law enforcement. NASPER is focused on providing information for physicians so that they can best treat their patients, who may be suffering from drug addiction, and we know that drug addiction is a serious problem around the country. And I know that Dr. Paulozzi will talk about that in his testimony. And I also noted that, Dr. Clark, we are glad you are here today, but I noticed in your testimony you don't mention anything about NASPER. You are talking about the DOJ program, but the DOJ program was not authorized by anyone, and appropriators don't have jurisdiction over the program. We have jurisdiction.

And so I look forward to the testimony today, because this is a program passed by Congress, signed by the President, and someone has the responsibility and obligation to fund this program, not because this committee passed it, but because it is the best program, the one most likely to succeed. So, with that, Mr. Chairman, I will yield back the balance of my time.

Mr. STUPAK. I thank the gentleman. I ask for unanimous consent to enter Chairman Dingell's statement in the record, and that statement of all members will be entered in the record, whether they appear or if they just provide a statement.

[The prepared statements of Messrs. Dingell, Barton, and Pallone follow:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding this hearing on implementation of the National All Schedules Prescription Electronic Reporting Act (NASPER).

The NASPER legislation was passed by the 109th Congress and signed into law by the President in 2005. Although the NASPER Program was enacted 2 years ago, this administration has done virtually nothing to implement it and has failed to include any money for the program in its annual budgets. It is vitally important to our system of government that when Congress establishes national policy by passing laws, those laws are not simply ignored by the executive branch. Today, I hope we learn more about the benefits of this program as well as the reason for the administration's failure to seek funding for it.

In order to solve the problem of prescription drug abuse, we need a multi-pronged approach. We cannot solve the complex problems associated with abuse and addiction with criminal enforcement alone. We need to enlist physicians, pharmacists, and other healthcare professionals in the fight. A robust, nationwide system of prescription drug monitoring programs will help medical professionals prescribe responsibly. Strong monitoring systems can allow physicians to promptly identify patients at risk for addiction and get them into treatment, and avoid patients who are "doctor shopping" to feed their own addiction or to sell their drugs to other addicts.

NASPER would provide a strong monitoring tool to help not only law enforcement but also the medical community stop the "pill-pushing" and "doctor shopping" that has devastated so many of our communities over the last decade. Especially in rural areas, where isolated physicians and pharmacies can easily be manipulated by addicts who travel from community to community to get their fix for illegal pharmaceuticals, NASPER would ensure that these healthcare providers know what drugs

their patients have recently obtained or have tried to obtain in other communities including those across State lines.

As you know, Mr. Chairman, our State of Michigan has a strong prescription drug-monitoring program. Ninety-five percent of the requests Michigan's program receives are from doctors and pharmacists seeking to ensure that patients are getting the medicine they need for genuine medical purposes, not medicine that will be used for illicit purposes. I am interested in hearing from our witnesses how Michigan's program compares with others around the Nation and how NASPER could enhance these programs.

I commend Ranking Member Whitfield for his leadership on this issue, and I thank our witnesses for their testimony today.

PREPARED STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Chairman Stupak and Ranking Member Whitfield, for holding this hearing on the status of the National All Schedules Prescription Electronic Reporting Act.

NASPER is the result of broad, bipartisan and bicameral cooperation of the kind that we don't see much anymore. It passed this committee over 2 years ago by voice vote. The House passed it as a suspension bill, and the Senate passed it by unanimous consent. The President signed NASPER into law on August 11, 2005.

NASPER was so successful as legislation because its purpose was so transparent and simple. The law created grants to help fund state prescription drug monitoring programs. The idea, as I noted 2 years ago when we passed NASPER, is that States be able to work with each other to stop the abuse of prescription drugs. NASPER starts the States on the road to cooperation by making certain that they each collect the same information. So instead of 50 separate monitoring programs with 50 different data sets that don't jibe, States collect the same data and then share it. Real interoperability means we can detect illicit prescription-drug operations when the drug dealers shift across state lines. Without NASPER, unfortunately, drug abusers and their dealers can still prescription-shop in some States because some information isn't being shared. That's a problem, and we're here today to start fixing it.

The Energy and Commerce Committee was also concerned about protecting the privacy of Americans whose information is held in the prescription drug databases. NASPER establishes strict criteria governing the use and disclosure of the information that states must meet in order to receive funding. Without NASPER, there are no minimum standards to protect the personal information held in prescription drug monitoring program databases.

Despite these positive features, NASPER has not yet been funded. Although the President signed the bill, funding for this important program was not included in the President's budget. On January 10, 2006, several of us on the committee—including Chairman Dingell, Mr. Whitfield, Mr. Stupak, Mr. Deal, and Mr. Pallone—wrote to then-director of the Office of Management and Budget Joshua Bolton, requesting the inclusion of $15 million in the administration's fiscal year 2007 budget for NASPER. To get NASPER launched, there has to be a budget request. At the February 6, 2007 full committee hearing on the HHS fiscal year 2008 budget, HHS Secretary Michael Leavitt testified that HHS supported the program, but that OMB decided not to include a budget request for it. I understand that we have not even received a reply to the January 10, 2006 letter.

We had hoped to have a witness from the Office of Management and Budget here today to explain OMB's reluctance. Instead, I understand that OMB Director Jim Nussle has agreed to meet with Mr. Whitfield and other members of this subcommittee in the near future to discuss the status of NASPER's funding. I hope that Director Nussle can finally answer the question we put to two of his predecessors: Why hasn't the administration included a request to fund NASPER in its budgets? The problem of prescription drug abuse doesn't seem to be curing itself, and it isn't as if the issue is either partisan or even mildly controversial. We are here today to find out why nothing has happened.

I am committed to ensuring that NASPER is funded. Last year, I raised a point of order to the appropriations bill for the Commerce, Justice, and State Departments because funding was included in that bill for an unauthorized prescription drug monitoring program at the Justice Department while no appropriations were provided for NASPER. I trust now that they are in the majority, Committee Chairman Dingell and Subcommittee Chairman Stupak will continue to make this committee's concerns about the lack of funding for NASPER known to our colleagues here in the House and to the Administration. I suspect I can count on it, in fact.

Thank you, again, Chairman Stupak and Ranking Member Whitfield. I yield back the balance of my time.

PREPARED STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Thank you, Mr. Chairman, for holding this hearing and allowing me to participate. I am pleased to be here today to discuss the importance of prescription drug monitoring. The bipartisan legislation we are reviewing today was signed into law by President Bush in 2005, But today, more than 2 years later, it has still not been funded. As the only program authorized in statute to assist states in combating prescription drug abuse, it is crucial that we work to ensure the Act receives the funding needed for implementation.

At the time this legislation was passed, members on both sides of the aisle agreed that rampant prescription drug misuse and abuse was a growing problem. And now, 2 years later, it is still a growing problem. In fact, the diversion of prescription drugs is one of the fastest growing areas of drug abuse in our Nation today. It is a problem that is blind to geographic regions, blind to age, and blind to income-levels. And according to the data, it affects 9 million Americans.

In my home State of New Jersey alone, 4.1 percent of our residents have abused prescription drugs in the past year. The per capita retail distribution of the pain medication oxycodone increased 181 percent between 2000 and 2005. For hydrocodone, another pain medication, it increased 66 percent during that same timeframe.

Some States have already begun developing the means to stop this escalating trend, and Congress agreed back in 2005 that the NASPER Act was the best way to aid States in their efforts to ensure that prescription drugs are only being used for medical purposes, in the correct way, and that they are not getting into the hands of people who would abuse them.

The solution presented through NASPER is to create a better monitoring and tracking system for prescription drugs. And studies have shown these types of programs to be very effective. The five States with the lowest number of oxycodone, specifically OxyContin prescriptions per capita, have long-standing prescription monitoring programs and report no significant prescription drug diversion problems. While at the same time, the five states with the highest number of OxyContin prescriptions per capita do not have prescription monitoring programs and have reported severe abuse problems.

This data strengthens the argument that health care practitioners and pharmacists desperately need electronic monitoring systems to ensure that they are prescribing and dispensing Schedule II, III, and IV Controlled Substances that are medically necessary. And NASPER assists them in this area.

As passed in 2005, NASPER would provide grants to help States develop or expand a prescription drug-monitoring program that has the ability to communicate with monitoring programs in other States. Any Controlled Substance II, III, or IV that is prescribed would be electronically reported by the physician or pharmacist to the State's primary monitoring authority. Upon certified request, physicians and law enforcement can access the information in these databases, in an effort to prevent prescription drug addiction and to crack down on bad actors who are contributing to the problem.

Without these interconnected databanks, practitioners and pharmacists have no way of knowing with any certainty whether a particular patient has received the same drug or another incompatible controlled substance already from another practitioner.

This is particularly troubling in light of the fact that physicians are increasingly more hesitant to prescribe these medications out of fear that they will be the ones to take the fall if a patient is in fact "doctor shopping" and abusing these substances. More and more patients have to suffer from intense pain because doctors are overly cautious in prescribing the medications they need. A program like the one we are discussing today would protect the innocent provide them with the information they need to make the correct decisions for their patients.

The NASPER bill passed Congress and was signed into law in August 2005. Thanks to its passage, I firmly believe that we will move one step closer in providing a strong and effective approach to addressing prescription drug abuse and crime. But our fight is not over, just because the bill has passed. Now we need to get the program funded so we can provide the necessary money to States.

Because of the strict timetable set forth in NASPER, it is vital that funding be included in fiscal year 2008 to ensure that HHS is able to promulgate regulations and seek public input, thereby allowing grants to be awarded this year.

My colleague from Kentucky, Ed Whitfield, and I are busy working towards achieving that goal. We have sent a letter to appropriators requesting $15 million in funding for NASPER in fiscal year 2008. I have the letter here, Mr. Chairman, and would like to submit it for the record. We have also been speaking with members of the appropriations committee urging them to fulfill our request.

And I would like to thank you again, Mr. Chairman, for having this very important hearing today. I am hopeful that we will be able to get this program funded this year. I would also like to thank all the witnesses for joining us and I look forward to your testimony.

Mr. STUPAK.With that, next I would move to Mr. Green for opening statement, please.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for ordering this hearing on prescription drug monitoring programs and the NASPER Program, which Congress enacted in 2005. High-ranking member Mr. Whitfield was the author of the National All Schedules Prescription Electronic Reporting Act, and I was proud to be a co-sponsor and support it when it went through both our committee and both the 108 and 109th Congress. The need for NASPER is clear to us, being on both the law enforcement level and a drug safety level. With State prescription drug monitoring programs sporadic and not interoperable, it was relatively easy for individuals who abuse prescription drugs to doctor shop for controlled substances or obtain the prescription drugs illegally with little detection from physicians or law enforcement.

The Texas prescription drug monitoring program, called the Texas Prescription Program, was established more than 25 years ago, in 1981. Each year the Texas Prescription Program collects 3.3 million prescriptions and monitors Schedule II prescription drugs. During the first year of the Texas Prescription Drug enactment, the number of Schedule II prescriptions filled in the State fell by 52 percent. The program helped the State crack down on pill mills and forged prescriptions, but it is clearly a law enforcement program and housed at the Texas Department of Public Safety. Without question, prescription drug monitoring programs offer significant benefits for law enforcement. They should go hand in hand with the drug safety and public health benefits. It is disturbing that the administration doesn't recognize these dual needs and implement the NASPER Program.

Mr. Whitfield, this committee purposely housed NASPER with the Department of HHS to strike the appropriate balance between law enforcement activities and public health safeguards. In fact, the criteria for grant awards ensured a certain level of interoperability, timely reporting by pharmacies, and assurances for patients of privacy. By giving physicians access to the data compiled by prescription drug monitoring programs, NASPER would also help physicians coordinate care and reduce the number of contraindicated drugs prescribed to patients. The administration's refusal to implement this program suggests it is only interested in law enforcement aspects of prescription drug monitoring programs.

Secretary Leavitt supported this conclusion when he appeared before this committee earlier this year and cited OMB's decision to review these programs as law enforcement tools, while the administration's synthetic drug control strategy and drug monitoring program is at the Department of Justice. The problem is, neither the administration's synthetic drug control strategy nor the DOJ grant program ever has been authorized by Congress. My State received the welcomed grant funding through the DOJ programs, but the DOJ programs only provide half a loaf. Within the DOJ program, there is no real strategy for interoperability, which is critical if we want to stop folks from hopping across State lines to obtain prescription drugs illegally and escape detections from their home State monitoring programs. The DOJ programs also have none of the safeguards for patient privacy and pay little to no attention to public health ramifications.

Like my colleagues, I wish OMB Director Nussle would have appeared before us today and explained the administration's rationale for failing to implement NASPER. However, I am pleased that he has agreed to meet with our Chair and ranking member to discuss the important issue. I hope that Mr. Nussle, as a former member of this chamber, will be able to understand the frustrations we feel when the administrations ignore Congressional intent. And I would like to thank the Chair and the ranking member for holding this hearing and needed oversight over the administration's inaction on this issue and shed light on the administration's missed opportunity to address the problem of prescription drug abuse in an effective manner. And again, I am glad our witnesses are here.

Mr. Chairman, I yield back my time.

Mr. STUPAK. Thank you, Mr. Green. Mr. Burgess, for an opening statement, please.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman, and I appreciate very much you holding this hearing today. Back in my home State of Texas, in the city of Dallas, the Dallas Morning News ran a series of several articles, 2003, 2004, 2005, on a physician who ran a pill mill. And it seems that everyone knew about the pill mill. He didn't make appointments, but he saw a lot of patients, and the patients were seen, I guess you would call it kind of a modified wave method of making appointments. The patients would sleep in the parking lot so they would be the first in line to get in the door the next day, and in fact sometimes the clinic had to hire off-duty police officers to kind of keep order in the parking lot before the clinic opened. The doctor would see 200 patients a day. They were mostly Medicaid and Medicare beneficiaries. In fact, this office was the source for the largest single source of Diazepam prescriptions for Medicaid prescriptions in the State of Texas. Now, at least 11 of his patients died, and they died of drug overdoses or drug complications, and after a very long investigation, culminating just a few weeks ago, this doctor received probation. I think, had this program, had NASPER been up and running and functioning, I think he certainly could have been contained much earlier, and I think

some patients and their families could have foregone some needless suffering, and perhaps we could have even avoided loss of life.

Now, when NASPER was signed into law, August 11, 2005, it was the only congressionally authorized program to assist State prescription drug monitoring programs. The previous program established by the Department of Justice was created with a lack of adequate Congressional oversight and appropriate administration by the Justice Department. Both parties agreed that such a program should have strict guidelines and that Health and Human Services is better suited to administer such a program than the Department of Justice. So NASPER must be funded, especially to guard against scenarios such as this that has been well documented in my papers back home.

Well, Chairman Stupak, I thank you and ranking member Whitfield for holding the appropriators accountable, and I join in asking them to make the Appropriations Committee aware and to fund this program.

And NASPER could allow doctors to find out what medications a patient is currently taking and what he or she has taken in the past. Without a database in place for doctors to track patient history, doctors have no way of knowing who is really in pain and who is looking to abuse the system, and I speak of this with some authority because I was a practicing physician back in Texas for 25 years, and I certainly know. I got caught in similar situations. I do have some questions. I have some questions about how this is affected by our current HIPAA laws, and then, going further, how is the law that we recently passed, the Genetic Information Non-Discrimination Act, how is that going to affect the sharing of information, because that bill was fairly broadly constructed and I think may have more of an effect on this that will curtail the sharing of data. Now a database is extremely powerful, extremely powerful in helping to manage a patient's care and helping to provide information to caregivers about a patient's status.

We had a situation in Dallas right after Hurricane Katrina landed in New Orleans 2 years ago. A lot of folks were taken from the Superdome in Louisiana and delivered to the parking lot outside Reunion Arena in Dallas. Many of these people were patients who were on multiple medications. Many of them had been without their medications for several days, and some were just a few steps away from getting into serious trouble with their underlying illness. One of the chain pharmacies set up a mobile unit right outside Reunion Arena, and doctors were able to quickly access the database, get information about the patients. Obviously Charity Hospital didn't have electronic medical records up online, but this data was available to the doctors who were receiving those patients and triaging those patients in the parking lot of Reunion Arena, and within a very short period of time were able to accommodate those patients' needs. And I think out of the many, many thousands of people who were transferred from New Orleans to Dallas, only a few required hospitalization, because they got timely treatment and timely recognition on the night of their arrival. So it just underscores how powerful a database can be if used appropriately.

Mr. Whitfield alluded to how important it is to have interoperability of databases, and I certainly think that is key if we are

going to have two side-by-side systems. Clearly they need to be able to communicate with each other in efficient fashion. But realistically if we could have a single system that worked and was funded, I think that is the preferable route to go.

With that, Mr. Chairman, I will yield back the balance of my time.

Mr. STUPAK. Thank you. Next opening statement, Ms. Schakowsky, please.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. This is an important hearing for a couple of reasons. First, we all know that prescription drug abuse is rising and that accidental deaths from overdose have increased dramatically. But in addition, we know that over 2 years ago this Congress passed, and the President signed into law, aimed at fighting this growing problem. And yet to date, as people have said, but I think it bears repeating, no funds have been included in the President's budget for the implementation of this bipartisan bill, the NASPER.

Without a doubt, there is a need for a tool to reduce prescription drug abuse. For many of our communities, this is an ever-growing problem that has resulted in the death of too many friends and neighbors and family members. According to this committee's records, when HHS Secretary Michael Leavitt testified before this committee on the President's 2008 budget, he stated that the Department supported the program and that it was a program that he would gladly administer. Yet, when pressed further, he deferred to the OMB, stating that it was up to them to make a final decision. And meanwhile, over the past several years, the Department of Justice has made annual grants to a number of States for the purpose of establishing or strengthening a prescription drug monitoring program. These grants have been supported both through Congressional earmarks and the President's budget requests, so the question I look forward to answering today is why NASPER has yet to be implemented or funded despite administration support for the prescription drug monitoring. Additionally, I look forward to hearing from our witnesses regarding what appears to be this administration's preference to house the prescription drug tracking program at a law enforcement agency, as opposed to the Department of Health and Human Services. I have concerns about what this means for patient privacy and preserving the relationship between patients and their physicians.

It is also important that we examine the disadvantages of relying on the DOJ grant program, a competitive grant program which has yet to reach all States. Furthermore, State PDMPs have remained largely incompatible. If our best interests lay in exposing bad actors within the prescription drug arena, our system must be interoperable and attainable for all States. So I look forward to getting some answers from our witnesses, and I thank them all for being here today, and I yield back.

Mr. STUPAK. I thank the gentle lady. Mr. Pallone was here, and he had to step out, but unfortunately Mr. Pallone is not a member of the subcommittee, so he may not be allowed to make an opening

statement but may be back to ask questions. But it should be noted, as I noted in my opening statement, it was Mr. Pallone, as ranking member of the Health Subcommittee, who helped push this legislation through and critical in getting it passed and signed into law. We appreciate his continued interest, and hopefully he will be able to make it back in time for questions. With that, Mr. Murphy, for an opening statement, member of the subcommittee.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman, and thank you for holding this important hearing. In particular because we are all very concerned about the abuse of prescription drugs, it should be noted that high school students in the United States and college students are declining in their abuse of illicit drugs for consecutive years, but there is an increasing level of the abuse of prescription drugs among youth and adults. And it is cause for concern, and it is an area that we need to closely monitor. And what we are considering today is a mechanism by which we can do this.

I would like to quote briefly from an article that appeared in the Pittsburgh Post Gazette earlier this year, in March, where in reference to an interview with a Dr. Neil Capretto of the Gateway Rehabilitation Center in Pittsburgh, he said, "There has been a growing non-medical addictive use of prescription drugs, particularly opioid drugs like Oxycontin, codeine, morphine, Percocet, Vicodin, and Dilaudid. Opiates possess more properties characteristic of opioid narcotics like heroin and morphine but are not derived from opium poppy." He went on to say, "The good news is, we are treating pain better than we did 10 years ago. The bad news is, there are more people abusing and misusing prescription drugs. Unfortunately, from our end, I am really afraid it is going to get worse before it gets better."

As of 2003, 6.3 million Americans used prescription drugs for non-medical purposes. In 2002 almost 30 million people had used prescription pain relievers for non-medical purposes. Prescription medications are now involved in close to 30 percent of drug-related emergency room visits. The most recent monitoring, the Future Report from University of Michigan, found that 5.5 percent of all high school seniors abuse Oxycontin. Oxycontin abuse has increased 26 percent since 2002 among 8th- and 9th- and 12th-graders. The abuse of prescription drugs cuts across gender, race, and virtually all groups.

As we look at programs like NASPER, it is disappointing that it has not been funded, and that is why we are here today. The Appropriations Committee continues to fund a program out of DOJ that focuses solely on enforcement. Although we are pleased that DOJ has this program, and I don't necessarily have a problem with the DOJ program, but we have rules in place for a reason. Why should we fund an unauthorized program when we have an authorized program that accomplishes the same mission? With that said, we do agree on the mission, to prevent prescription drug abuse. In my many years of practice as a psychologist, I saw the wretched examples of drug abuse first-hand. And as we look at this, my questions will be, how can we make these programs work together?

How can we make them be effective and efficient, not redundant or exclusive? How can we gather and share data and databases so we can work with law enforcement officials, we can work with drug treatment programs, and we will work with effective funding here in Congress?

I don't believe there is anybody here who does not consider it a high mission of this Congress to make sure we do all we can to reduce prescription drug abuse and all drug abuse, for that matter. Because people understand how they can doctor shop, because databases are not clear, it stands as a barrier to enforcement. It stands as a barrier to treatment, and unfortunately it is the system that the drug abuser has figured out how to get around for now. We have to close those doors if we are going to help people. And again, reflecting on the statistics I read earlier, about 8th- and 9th- and 12th-graders, it would be a real tragedy if we did not work to make this program work, to make this program and the Department of Justice program find a way of working together so that our goal of Justice and our goals in Congress of reducing and eliminating prescription drug abuse are met.

I look forward to hearing the testimony of this hearing of how we can reach those goals, and I yield back my time, Mr. Chairman.

Mr. STUPAK. Thank you. Ms. DeGette, for an opening statement, please.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, Mr. Chairman. Mr. Chairman, I will submit my full statement for the record, but I just want to say that a couple of months ago I read one of those articles that really opens your eyes in the New York Times Magazine—about patients who truly have chronic pain that affects their whole ability to conduct their lives. And these patients are really stuck in a whipsaw, because on the one hand they are trying to get medications that will help solve their pain, and there are many legitimate doctors now who say that patients like these really do need very high doses of pain medication. But these patients are caught because they are identified as abusers of these medications. And, at the same time then, you have people who really are abusers of these medications, and they are illegally obtaining these drugs. I think that NASPER would really help to bring some sense to this situation and allow the legitimate patients to get the drugs that they need, so that they can get pain relief while at the same time giving law enforcement the tools to track and identify both the abusers of these drugs and the physicians who are participating in some of the abuses. So I think it is a real shame on behalf of the patient and on behalf of law enforcement that we haven't funded NASPER, and I know that talks are continuing. I would hope that the administration would really put some funding behind this very important program.

With that, Mr. Chairman, I will yield back.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Mr. Chairman, let me begin by thanking you for holding this hearing on the National All Schedules Prescription Electronic Reporting Act, a vital tool for ensuring public health and safety.

Sadly, drug abuse has become an all-too-familiar issue, whether it be illicit drugs or drugs prescribed for pain relief. Chronic pain, for example, is a legitimate concern with legitimate treatment options, yet prescription pain killers are often abused. We need a way to allow patients access to such drugs when they are appropriate, while at the same time adequately controlling access and identifying patients who are at risk of addiction or are so-called "doctor shoppers." We passed NASPER and signed it into law in 2005 for exactly these reasons, yet nothing has come of the program to date.

NASPER would give law enforcement personnel access to drug monitoring data that relates to illegal prescribing, dispensing, or procurement of controlled substances, while also providing reliable data to doctors in the form of "prescription histories" for their patients. Prescription histories not only help to identify doctor shoppers, but also help doctors identify patients who might at risk of addiction and would therefore be better-suited to an alternative, less addictive drug. Just as importantly, it would enable doctors and patients to avoid potentially deadly drug interactions that occur when patients see multiple doctors for different conditions but neglect to inform the doctor of other prescriptions they may be taking.

NASPER does all this while providing privacy safeguards for patient protection and without placing pressure on doctors to avoid prescribing medicine that is legitimately needed.

NASPER has the potential to be of immense value, yet because the Administration has failed to provide funding for it, it has not been able to help a soul.

In fact, the administration has instead funded a different, unauthorized prescription drug monitoring program through the Department of Justice. This does not make much sense to me, especially given that the DOJ program lacks some of NASPER's key components.

For example, the DOJ program lacks interoperability requirements that would allow States to share data—a key problem that we are seeing repeatedly with current Health Information Technology initiatives. NASPER, on the other hand, includes such interoperability provisions.

Mr. Chairman, I would like to know why the administration is yet again dismissing Congress' authority—by not only failing to fund NASPER, but by instead funding an unauthorized program.

I yield back the balance of my time.

Mr. STUPAK. Thank you. That concludes the opening statements by members of the subcommittee.

We have our first panel before us. On our first panel we have Dr. Westley Clark, Director of the Center of Substance Abuse Treatment within the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, SAMHSA, as we call it, and Dr. Len Paulozzi, a medical epidemiologist at the Centers for Disease Control and Prevention. It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses, under the rules of the House, have the right to be advised by counsel during testimony. Do either of you gentlemen wish to be advised by counsel during your testimony?

Dr. PAULOZZI. No.

Dr. CLARK. No.

Mr. STUPAK. Both indicate they do not. Therefore I will ask, since it is tradition to take testimony under oath, please rise, and raise your right hand to take the oath.

[Witnesses sworn]

Mr. STUPAK. Let the record reflect both witnesses replied in the affirmative. You are now under oath. We will begin with your open-

ing statements. Dr. Paulozzi, would you like to go first for 5 minutes for an opening statement, please, and thank you again for appearing.

TESTIMONY OF LEN PAULOZZI, M.D., MEDICAL EPIDEMIOLOGIST, DIVISION OF UNINTENTIONAL INJURY PREVENTION, NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. PAULOZZI. Good morning, Chairman Stupak, Ranking Member Whitfield, and distinguished members of the subcommittee. My name is Dr. Leonard Paulozzi, and I am a medical epidemiologist at the Centers for Disease Control and Prevention. I am here on behalf of the CDC Director, Dr. Julie Gerberding. My remarks will focus on drug poisoning involving prescription drugs in the United States as a public health problem. Can I have the second slide?

[Slide]

By way of background, this figure shows the leading causes of unintentional or, if you will, accidental injury death in the United States in 2004. The green bar is motor vehicle deaths. The yellow bar in the center is poisoning, which ranks as the second-leading cause of unintentional injury death, with approximately 20,000 deaths from this cause in the year 2004, of which 95 percent of these poisoning deaths are drug overdoses. Next slide.

[Slide]

The problem here is this upward trending line. This is drug poisoning death rates in the United States from 1970 through 2004. You can appreciate the trend line and the dramatic increase in the 1990's and the first years of this decade. We can explain some of the earlier blips with black-tar heroin or crack cocaine, but the problem was explaining what happened in the later years of the 1990's. Next slide.

[Slide]

We did a study which looked at the death certificates to identify the drugs that were listed there as causing these deaths. We broke it down into three types, heroin in white, cocaine in yellow, and the red line at the top, pointed by my marker, is the opioid analgesic category. You can see it is going up dramatically. It outnumbers either heroin or cocaine by the year 2004. And this opioid analgesic category, of course, is the narcotic painkillers like Oxycontin and Vicodin that you have heard so much about. Next slide, please.

[Slide]

Again, this is the drug mortality death rate line that you saw before. I have paired it with opioid sales, shown here in green. These are sales per capita, shown from 1997 on. From 1997 to 2004, the opioid sales increased six-fold, and the line closely tracks the death rate in drug poisoning. The other thing to note is that, 2005 and 2006 sales continued to go up, so we expect further increases in the drug poisoning death rate in 2005 and 2006. Indeed, preliminary information from 2005 suggests that the death rate did rise in 2005. Next slide, please.

[Slide]

This shows the drug poisoning death rates in the United States. The dark States are those with the top third of death rates. I would

like to point out that we have traditionally high rates in the Southwest. Louisiana, Maine, are also high, but we have a band of States, Appalachian States, from Tennessee to Pennsylvania, with some of the highest rates in the country. And as late as 1990, these same Appalachian States had some of the lowest rates in the country. So this has really affected rural States more than urban States in this particular prescription drug problem. Next slide.

[Slide]

Well, death certificates don't tell you circumstances of the death. So how do you know whether these are accidents of people taking too many pills, or are these abuse? We think that these are primarily related to misuse and abuse of prescription drugs, for three reasons. People dying of the prescription drugs are largely middle-aged males: the same groups who died of heroin and cocaine in earlier years. Surveys from SAMHSA have annually shown steady increases in prescription drug misuse, non-medical use rates in the United States. And lastly, studies done by medical examiners have found that the decendents from prescription drug deaths typically or commonly will have a history of substance abuse. Next slide.

[Slide]

How can the problem be addressed? Obviously this is a multi-factorial, complicated problem, and solving it depends upon input from multiple Federal and State agencies. CDC will continue to respond to this problem, as it has, through surveillance activities, epidemiological work, and through evaluation of potential interventions. In the next year, CDC will focus on a study of prescription drug deaths and poisoning victims. We will also start an evaluation of prescription drug monitoring programs, and we are working with the Association of State and Territorial Health Officials to look at State-specific policy responses to this problem.

Thank you for the opportunity to appear here today to make you aware of the serious health consequences of this growing misuse of prescription drugs in the United States, and I will be happy to answer any questions you may have.

[The prepared statement of Dr. Paulozzi follows:]

Testimony
Before the Subcommittee on
Oversight and Investigations
Committee on Energy & Commerce
United States House of Representatives

Trends in Unintentional Drug Poisoning Deaths

Statement of
Leonard J. Paulozzi, M.D., M.P.H.
Medical Epidemiologist
Division of Unintentional Injury Prevention
National Center for Injury Prevention & Control
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

CDC
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For Release on Delivery
Expected at 10:00 a.m.
October 24, 2007

Good morning Chairman Stupak, Ranking Member Whitfield, and distinguished members of the Subcommittee. My name is Dr. Leonard Paulozzi, and I am a medical epidemiologist with the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you on behalf of CDC to discuss our Agency's research and prevention activities addressing unintentional poisoning deaths. Thank you also for your continued support of CDC's goal of healthy people throughout all stages of their lives.

Today, our nation and the world are focused on threats such as pandemic influenza, natural disasters, and terrorism. While these threats require and deserve our immediate attention, we cannot lose sight of the pressing realities of public health issues that we face every day, such as unintentional poisonings, which are now the second leading cause of unintentional injury death, exceeded only by motor vehicle fatalities.

Definitions

A poison is any substance that is harmful to your body when ingested (eaten), inhaled (breathed), injected, or absorbed through the skin. Any substance taken in excess, including a prescription drug, can be a poison. Therefore, the CDC categorizes drug overdoses as drug poisonings. Drug poisoning does not include adverse reactions to medications taken in the correct amounts.

Drug poisonings can be intentional or unintentional. Intentional poisoning is the result of a person taking or giving a drug with the intention of causing harm. Suicide using drugs falls into this category. If the person taking a drug did not mean to cause harm, it is considered an unintentional poisoning. Unintentional poisoning includes the use of drugs for recreational purposes in excessive amounts. It also includes the unintentional exposure of a toddler to drugs, or a confused person taking too much medication. When the intent of the person taking a drug resulting in death is unclear to a coroner or medical examiner, as is sometimes the case despite a thorough investigation, the label of undetermined poisoning may be applied.

Today, my remarks will pertain to unintentional drug poisonings. I will focus on *fatal* drug-related poisonings because such events are extensively investigated, coded in a standardized way, and available for analysis in annual mortality files created by CDC's National Center for Health Statistics (NCHS). I will discuss data through 2004, the latest year for which mortality statistics are available for the United States in this extensive level of detail.

Historical Trends in Mortality Rates

The mortality rates from drug poisoning (not including alcohol) have risen steadily since the early 1970s. Over the past ten years they have reached historic highs.

Rates are currently more than twice what they were during the peak years of crack cocaine mortality in the early 1990s, and 4 to 5 times higher than the rates during the year of heroin mortality peak in 1975. This upward trend has continued through 2004.

Trends in Mortality Rates: 1990-98

During most of the 1990s, the categorization of drug poisoning deaths did not allow easy distinction between deaths caused by prescription drugs and deaths caused by street drugs. Major data categories included opiates, cocaine, other drugs, and unspecified drugs. During this time period, rates rose in all major categories, including opiates and cocaine. The label "opiates" did not distinguish between heroin and prescription opiates (also known as opioid analgesics) so it was difficult to determine how much of the change in opiate deaths was attributed to heroin and how much to prescription opioid analgesics. Prescription drugs used for psychotherapeutic purposes (including sedatives and antipsychotic drugs) also caused an increasing number of deaths during the 1990s, but such deaths represented a much smaller share of the total than deaths attributed to opiates.

Trends in Mortality Rates: 1999-2004

Beginning with 1999 data, a new coding protocol was introduced that combined heroin, prescription opioids, and cocaine into one category called "narcotics," and

combined "other" and unspecified drugs into another category. Sedatives and other psychotherapeutic drugs continued to be tracked separately. Increases in death from these categories of drugs, as seen during the 1990s, continued from 1999 through 2004. By 2004, at least 20,000 unintentional drug poisoning deaths occurred annually in the United States. By comparison, just over 17,000 homicides occurred that year.

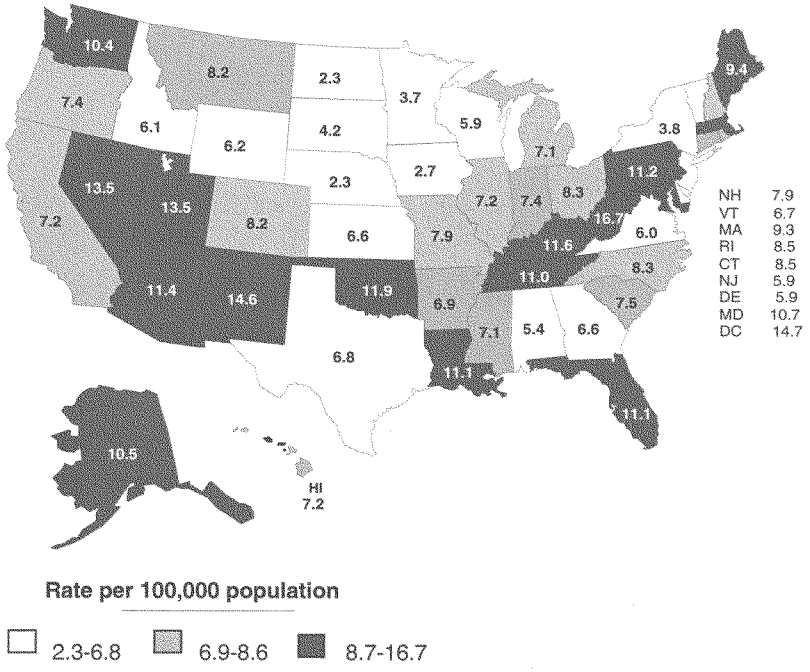
The new coding protocol also allowed researchers to determine specifically which drugs were involved in these deaths by allowing disaggregation of the "narcotics" and "other/unspecified" categories into their 3 largest components: opioid analgesics, cocaine, and heroin. Opioid analgesics include derivatives from opium, such as oxycodone or hydrocodone, as well as synthetic drugs with similar action, such as methadone. Analysis of these data, published last year, showed that the slow increase in cocaine-related mortality seen earlier continued after 1999, while the number of deaths involving heroin stabilized. In contrast, the number of deaths involving prescription opioid analgesics increased from roughly 2,900 in 1999 to 7,500 in 2004, an increase of 160% in just 5 years.[1] By 2004, opioid painkiller deaths numbered more than the total of deaths involving heroin and cocaine. For the first time, it became apparent that prescribed controlled substances were driving the upward trend in drug poisoning mortality.

[1] Paulozzi, LJ, Budnitz, DS, Xi, Y. Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Saf* 2006; 15: 618-627. (originally published last year and recently updated)

Characteristics of Those Dying from Drug Poisoning

This rapid increase in prescription drug poisoning has changed the epidemiologic patterns of drug poisoning. A map of the United States shows that the highest unintentional drug poisoning mortality rates in 2004 were in the Appalachian states, the Southwestern states, and New England.

Figure. Unintentional and undetermined drug poisoning mortality rates per 100,000 population by state, 2004; map generated using Centers for Disease Control and Prevention's WONDER online mortality data query system, available at wonder.cdc.gov (accessed 22 March 2005)



In contrast, 1990 rates in rural states were some of the lowest in the nation.[2] In a paper published in the *American Journal of Prevention Medicine* last year, CDC showed that there was a statistically significant correlation between state drug poisoning rates and state sales of prescription opioids.[3] There was almost a four-fold difference among states in their use of opioid analgesics. States with the highest distributions tended to be those with the highest drug poisoning mortality rates.

Drug poisoning rates were twice as high for men than for women in 2004. The group at highest risk for drug poisoning death is middle-aged men, the same demographic group that historically has had high rates of fatal heroin overdoses. Rates were higher for whites (7.2 per 100,000) than for African Americans (6.6 per 100,000). The highest rate was among those aged 35-44 years. Rural areas now have rates comparable to those in urban areas as a result of greater rate increases in rural counties than in urban counties since 1999. These patterns also hold true when studying deaths involving prescription opioid analgesics.

Why are Deaths Occurring?

There are certainly exceptions, but most unintentional drug poisoning deaths are not "accidents" caused by toddlers or the elderly taking too much medication.

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[2] There are about 3,000 undetermined deaths and 20,000 unintentional drug deaths per year. The map includes data for both because medical examiners in some states report all drug overdoses as undetermined intent.

[3] Paulozzi, LJ, and Ryan, GW. Opioid analgesics and the rates of fatal drug poisoning in the United States. *Am J Prev Med* 2006; 31: 506-511.

Mortality statistics suggest that these deaths are largely due to the misuse and abuse of prescription drugs. Such statistics are backed up by studies of the records of state medical examiners. Such studies consistently report that a high percentage of people who die of prescription drug overdoses have a history of substance abuse.

These findings are consistent with annual surveys from HHS's Substance Abuse and Mental Health Services Administration (SAMHSA) that have reported increasing rates of nonmedical use of prescription drugs, especially opioid analgesics, during the same time period when mortality was rising. "Nonmedical use" was defined as use without a prescription of the individual's own or simply for the experience or feeling that the drugs caused. The 2006 SAMHSA National Survey on Drug Use and Health found that 2.1 percent of the U.S. population age 12 or older had used prescription pain relievers such as opioid analgesics for nonmedical purposes in the past month. That amounts to 5.2 million nonmedical users in a typical month. However, the change in the rate of current nonmedical use of pain relievers between 2005 and 2006 (1.9 and 2.1 percent, respectively) was not statistically significant. Interestingly, by comparison, CDC's National Health and Nutrition Examination Survey found that about 9 million Americans reported use of opioid analgesics for medical purposes in a typical month.

Projection of Trends during 2005-2007

Because the process of death certificate completion, collection, correction, and computerization for 2.4 million deaths annually is laborious and time-consuming, final information on mortality for the nation as a whole is only available through 2004. However, the overall drug poisoning mortality trend closely tracked the rapid rise in sales of opioid analgesics per capita recorded by the Drug Enforcement Administration (DEA) from 1997 through 2004. And sales of opioid analgesics rose in 2005 and 2006. Therefore, we are likely to see additional increases in the drug poisoning mortality rate during 2005 and 2006. Indeed, preliminary information from NCHS indicates that the unintentional poisoning rate, which largely tracks the unintentional drug poisoning mortality rate, did increase in 2005. Moreover, rates of nonfatal emergency department visits for poisoning from the National Electronic Injury Surveillance System show an upward trend from 2004 to 2006, although NSDUH data from 2006 does not show a statistically significant increase from 2005 to 2006.

What Can Be Done

Addressing the problem requires better epidemiologic information on the patterns and predictors of prescription drug use as well as better information on what specific drugs pose the greatest risk. Data from prescription drug monitoring programs on the patterns and trends in use of specific drugs in local jurisdictions is one source of such epidemiologic information. Such programs may contribute to solving this problem if active use is made of the information they collect.

Based on what we know now, possible interventions could include:

1) Using insurance mechanisms to modify the behavior of patients using dangerous amounts of prescription drugs. A number of states use information about drug use collected on their Medicaid populations to identify high-volume users. They have options such as "locking in" such users to a single provider and a single pharmacy to reduce the likelihood of "doctor shopping," a term used to describe prescription abusers who visit multiple doctors until they get the desired amount of narcotics.

2) Educating physicians and pharmacists to more closely monitor patients who are taking opioid painkillers on a long-term basis. Existing literature describes how this can be done, including the use of doctor-patient contracts and pill counts. This is difficult in some settings such as emergency departments, where there may be no long-term doctor-patient relationship. Unfortunately, about 40% of the prescribing of opioid analgesics in outpatient settings is done in emergency departments.

3) Using opioid analgesics more judiciously, e.g., reducing the use of strong painkillers when weaker ones would suffice, and following proper prescribing practices for FDA-approved indications versus "off label" uses of these drugs.

4) Modifying the drugs themselves so they are more difficult to crush and dissolve in preparation for injection, a mode of use favored by some opioid abusers.

CDC Activities

This coming year, CDC is planning to examine the prescription histories of persons who died of prescription drug overdose in one state to see whether their prescription histories vary from the typical histories of others using the same class of drugs. We expect to see that the decedents have markers of inappropriate prescription drug use, such as multiple, overlapping prescriptions. Such markers may help identify people at risk of fatal drug overdoses in prescription drug monitoring program records. CDC is also conducting a study that will evaluate prescription drug monitoring programs (PMPs) nationwide. The study will compare changes in prescription drug sales and overdose rates in states starting PMPs with changes in states not initiating such programs. Information obtained on program characteristics associated with effectiveness could be used to enhance the effectiveness of PMPs nationwide.

Recently, CDC staff conducted a field investigation of drug overdose deaths in West Virginia, the state with the highest drug poisoning mortality rate in 2004. We will be publishing information about the characteristics of those deaths and

the implicated drugs. Part of this investigation involved examining PMP records that had been obtained by the state medical examiner for these decedents. Those records will help characterize the prescription history of people dying from prescribed drugs. This investigation will support the critical need for more detailed information about how the people misusing these drugs are obtaining them.

Finally, CDC is working with the Association of State and Territorial Health Officials to survey a sample of state health officers about their state policy responses to this problem. Their experience with such preventive measures may be useful to other states.

Conclusion

Unintentional drug poisonings are a significant and worsening public health problem. CDC continues to respond to this problem through state surveillance activities, epidemiologic research and evaluation of potential interventions.

Thank you for the opportunity to discuss this important public health issue today. Thank you also for your continued interest in and support of CDC's unintentional poisoning activities. I will be happy to answer any questions.

Prescription Drug Overdoses: A Public Health Threat

Leonard J. Paulozzi, MD, MPH
Medical Epidemiologist

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

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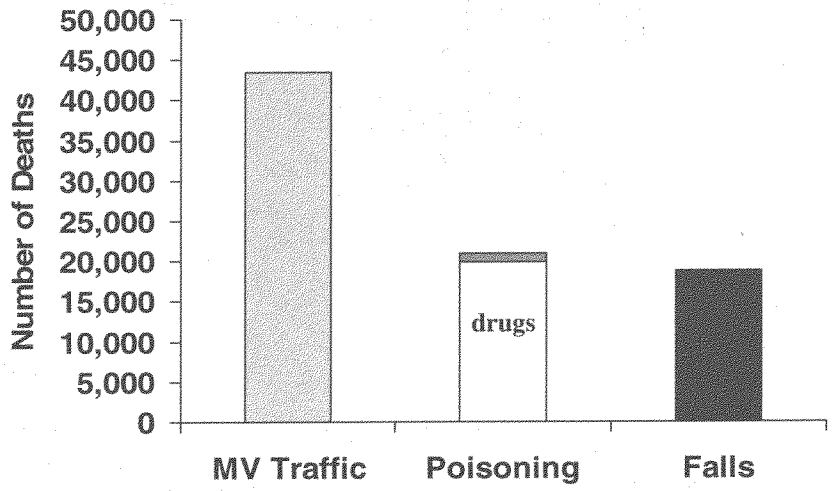
Leading causes of unintentional injury death, US, 2004



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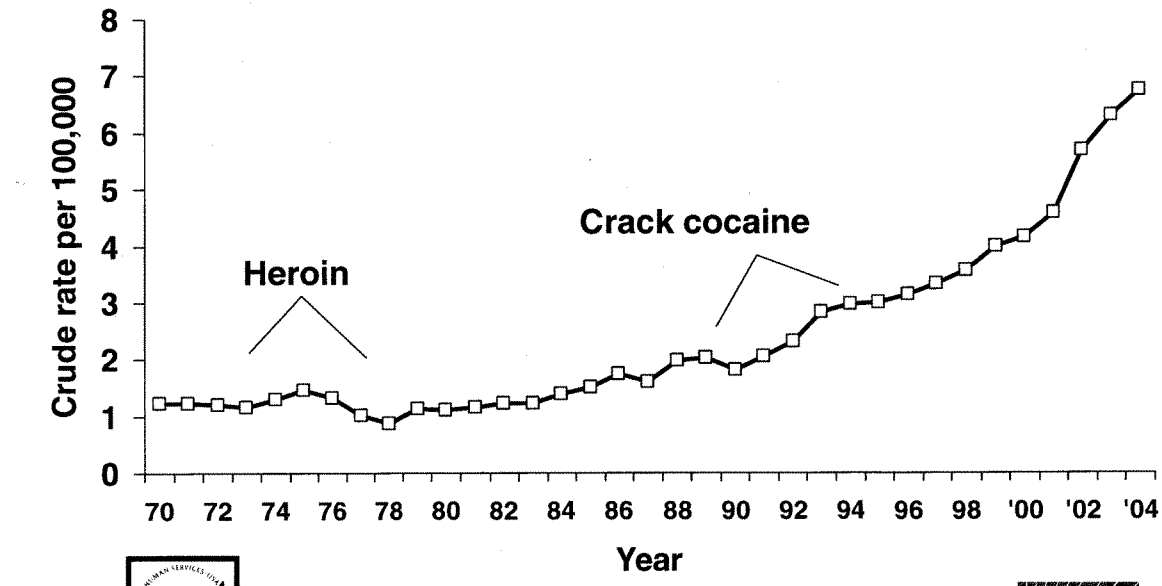
Unintentional drug poisoning death rates, US, 1970-2004



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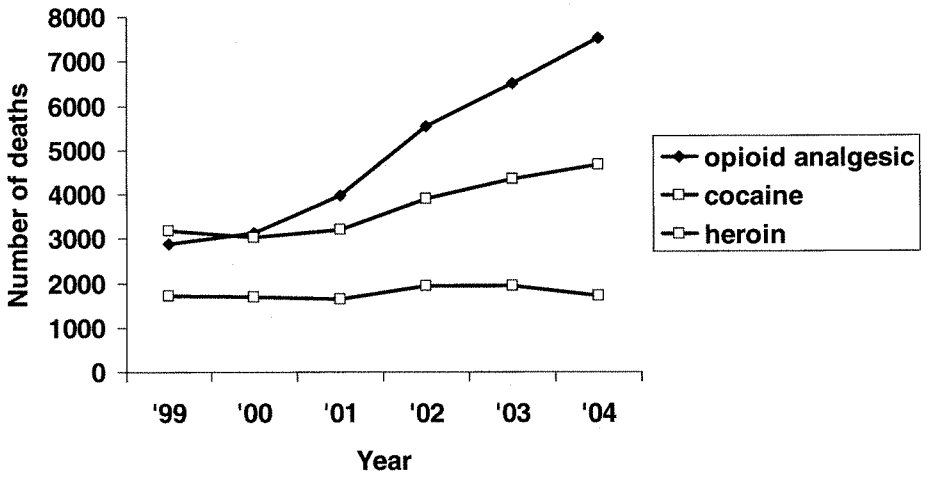
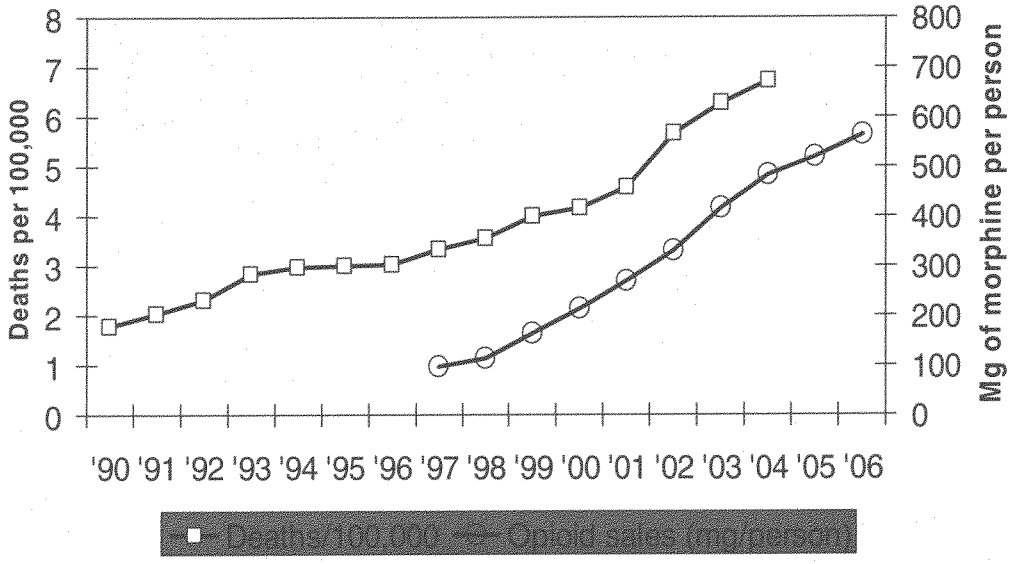
Unintentional drug poisoning deaths by type of drug, US, 1999-2004



Unintentional drug poisoning death rates and sales of opioid analgesics by year in the U.S.



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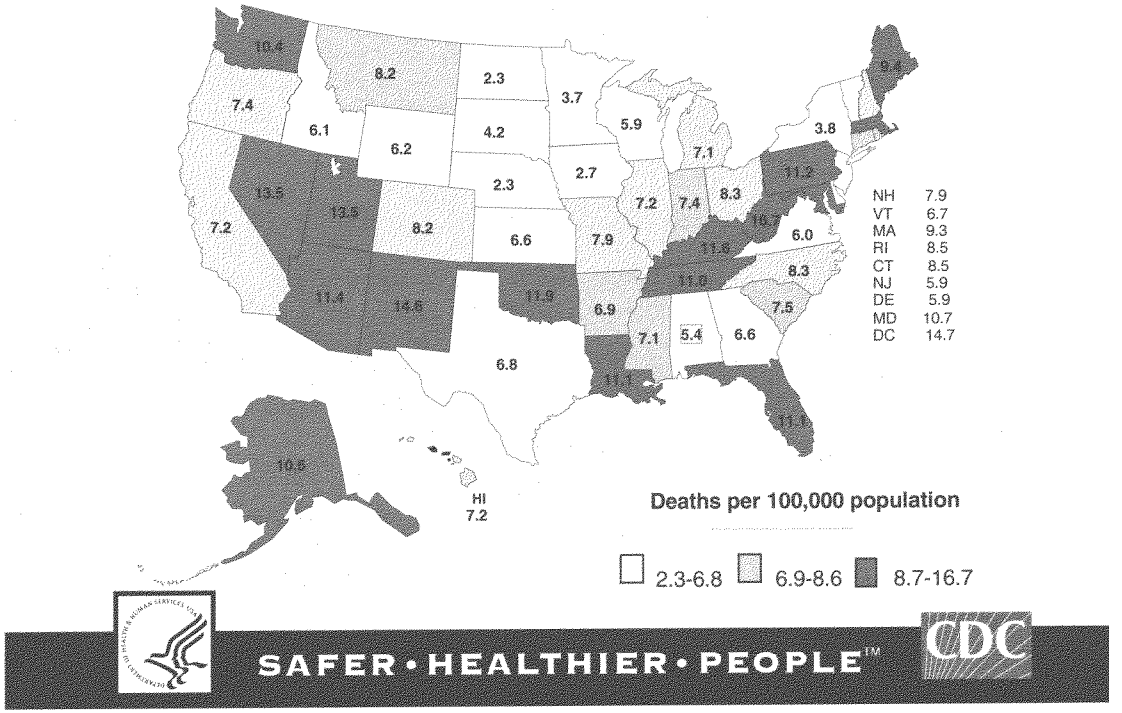
Unintentional and undetermined drug poisoning death rates by state, 2004



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Are these deaths mistakes or the results of misuse and abuse?

- These deaths primarily represent drug misuse and abuse because:
  - People dying of prescription drug overdoses are mostly middle-aged men, the same group that historically abused street drugs.
  - Surveys suggest corresponding increases in nonmedical/recreational use of these drugs.
  - Medical examiners commonly find a history of substance among these victims.

How can this problem be addressed?

- CDC will continue to respond to this problem through surveillance activities, epidemiologic research, and evaluation of potential interventions.
- In the next year, the CDC will focus on
  - A study of the prescribing patterns of drug poisoning victims
  - An evaluation of state prescription drug monitoring programs,
  - A review of state policy responses to the problem to date.

Mr. STUPAK. Thank you, Dr. Paulozzi. Dr. Clark, your opening statement, please, sir.

TESTIMONY OF H. WESTLEY CLARK, M.D., DIRECTOR, CENTER FOR SUBSTANCE ABUSE TREATMENT, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. CLARK. Mr. Chairman, members of the subcommittee, my name is Dr. H. Westley Clark, and I am the Director of the Centers for Substance Abuse Treatment, within the Substance Abuse and Mental Health Services Administration, an agency of the U.S. Department of Health and Human Services. I am testifying on behalf of our Administrator, Terry Cline, Ph.D., who was not able to be here. I am a board certified psychiatrist with added qualification in addiction and psychiatry.

According to SAMHSA's National Survey on Drug Use and Health, combined data from the reports from 2002 to 2006 indicate that an average of 4.7 percent of persons age 12 and older, an estimated 12.6 million people, used prescription pain relievers nonmedically in the 12 months prior to the survey. 2006, 2.1 percent of persons age 12 and older used a prescription pain reliever nonmedically in the month prior to the survey. Among persons 12 and older, 2.2 million initiated non-medical use of prescription pain relievers within the past year, and that is about the same as the estimated number of initiates for marijuana.

Where do people obtain their drugs? The 2006 National Survey on Drug Use and Health also revealed where the people were obtaining their prescription drugs. Nearly 56 percent of the patients who had non-medical use of prescription pain relievers obtained the drugs free of charge from a friend or a relative, 19.1 percent from a single doctor; 14.8 percent bought or took them from a relative or a friend; 3.9 percent bought from a drug dealer or other stranger; 1.6 percent got them from more than one doctor; less than 1 percent reported getting them from the Internet; and 4.9 percent got them from other sources, including a fake prescription, or stole them from a doctor's office, clinic, or hospital pharmacy. As a result, it is clear that what we need is a coordinated response.

The emerging challenge of prescription drug abuse and misuse is a complex issue that requires epidemiologic surveillance, distribution chain integrity, intervention, more research by both the private and the public sectors. We also need to be concerned about the issue of the appropriate use of prescription drugs. We know that there are some 75 million people who are suffering from severe pain. Some 50 million people suffer from chronic pain, and some 25 million people suffer from acute pain. So the Federal Government needs to work with medical partners, public health administrators, State legislatures, international organizations, are all needed to collaborate and cooperate through educational outreach and other strategies targeted to a wide swath of distinct populations, including physicians, pharmacists, patients, both intended and inadvertent, educators, parents, high school and college students, high-risk adults, the elderly, and many others. Outreach to physicians and their patients and pharmacists needs to be complemented by edu-

cation, screening, intervention, and treatment for those misusing or abusing prescription drugs.

Beginning fiscal year of 2002, Congress appropriated funding to the Department of Justice to support prescription drug monitoring programs. Since the inception of the Department of Justice program, called the Harold Rogers Prescription Drug Monitoring Program, this funding opportunity has resulted in 21 States receiving new program grants and 13 States netting planning grants. There are now 25 States operating prescription drug monitoring programs and eight States with legislation in place to establish a program.

In addition to the prescription monitoring programs of the DOJ, the Federal Government has a number of other activities involving prescription drugs. We are promulgating guidelines for the appropriate disposal of prescription drugs. These guidelines urge Americans to take unused, unneeded, or expired prescription drugs out of their original containers and dispose of them appropriately by mixing the prescription drugs with undesirable substances like coffee grounds or kitty litter to throw them away in the trash. We also are addressing the issue of prevention and treatment. We have drug-free communities, and on behalf of ONDCP we administer grants to communities across the country to form local anti-drug coalitions. We have spent $1.76 million for our substance abuse prevention and treatment block grant, $504 million in prevention and treatment discretionary grant, including our Access to Recovery, our ATR grant. We also have a screening and brief intervention grant. Furthermore, the National Institute of Drug Abuse has initiated a research program looking at the use of Buprenorphine for the treatment of prescription opioid abuse.

As I stated earlier, the emerging challenge of prescription drug abuse and misuse is a complex issue that requires epidemiologic surveillance, distribution chain integrity, intervention, and more research by private and public sectors. It requires a concerted effort by many, and electronic monitoring systems are a key part of the response, along with treatment and prevention programs that include outreach and education. SAMHSA is committed to allowing programs to give States and the local authorities the flexibility they need to deal with the issue and meet the challenge. Our strategy of prevention and treatment is essential to that.

Thank you for the opportunity to present this information to you.

[The prepared statement of Dr. Clark follows:]

Testimony
Before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

The Use and Utility of Prescription Drug Monitoring Programs

Statement of
H. Westley Clark, M.D., J.D., M.P.H.
Director
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

For Release on Delivery
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Mr. Chairman and members of the Subcommittee, my name is Dr. H. Westley Clark, and I am the Director of the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS). I am testifying on behalf of our Administrator, Terry Cline, Ph.D., who was not able to be here.

I am here to talk about electronic monitoring systems and how these systems have helped States and the Federal Government address non-medical use of prescription drugs.

Non-medical Prescription Drug Use

In February, John Walters, the Director of the White House's Office of National Drug Control Policy (ONDCP) stated, "Millions of Americans benefit from the tremendous scientific achievements represented by modern pharmaceutical products. But, when abused, some prescription drugs can be as addictive and dangerous as illegal street drugs."

Combined data from the Reports for 2002 to 2006 of SAMHSA's National Survey on Drug Use and Health (NSDUH) indicate that an annual average of 4.7 percent of persons aged 12 or older (an estimated 12.6 million persons) used a prescription pain reliever non-medically in the 12 months prior to the survey. In 2006, 2.1 percent of persons aged 12 or older (about 5.2 million persons) used a prescription pain reliever non-medically in the month prior to the survey. Current non-medical use of pain relievers between 2005 and 2006 was statistically unchanged. In the survey, "non-medical use" of these drugs was defined as use without a prescription of the

individual's own or simply for the experience or feeling the drugs caused. The 2006 survey found that males were more likely than females to have used a prescription pain reliever non-medically in the past year (6.1 vs. 4.3 percent). Young adults aged 18 to 25 had the highest rate of past year non-medical use, at 12.4 percent, compared to 7.2 percent for ages 12 to 17, 7.4 percent for ages 26 to 34, and 2.7 percent for ages 35 and above.

In addition, the NSDUH reported that in 2006, among persons aged 12 or older, 2.2 million **initiated** non-medical use of prescription pain relievers within the past year. That is about the same as the estimated number of initiates for marijuana.

Where are People Obtaining Their Drugs?

The 2006 NSDUH also revealed where people were obtaining their prescription drugs. Nearly 56 percent of the past year non-medical users of prescription pain relievers obtained the drugs free of charge from a friend or relative, 19.1 percent from a single doctor, 14.8 percent bought or took them from a relative or friend, 3.9 percent bought them from a drug dealer or other stranger, 1.6 percent got them from more than one doctor, less than 1 percent reported getting them from the internet, and 4.9 percent got them from other sources, including a fake prescription, or stole them from a doctor's office/clinic/hospital/pharmacy.

SAMHSA is responding, along with other agencies across the government, to address the non-medical use of prescription drugs, which now ranks second, only behind marijuana as the Nation's most prevalent illegal drug.

According to SAMHSA's Treatment Episode Data Set (TEDS), treatment admissions for abuse of opiates other than heroin, such as morphine, oxycodone, and hydrocodone, represented approximately 16,000 of all primary opiate admissions in 1995 and rose to about 68,000 in 2005. Opiates other than heroin represented 21 percent of all primary opiate admissions in 2005, up from 7 percent in 1995.

The emerging challenge of prescription drug abuse and misuse is a complex issue that requires epidemiological surveillance, distribution chain integrity, interventions, and more research by the private and public sectors. Thus, no organization or agency can address the problem alone; a coordinated response is required. The Federal Government, medical partners, public health administrators, State legislators, and international organizations all are needed to implement educational outreach and other strategies targeted to a wide swath of distinct populations, including physicians, pharmacists, patients (both intended and inadvertent), educators, parents, high school and college students, high risk adults, the elderly, and many others. Outreach to physicians and their patients and pharmacists needs to be complemented by education, screening, intervention, and treatment for those misusing or abusing prescription drugs.

Prescription drug monitoring programs (PDMPs) are among the most important components of government efforts to prevent and reduce controlled substance diversion and abuse. Prior to Fiscal Year (FY) 2002, there were 15 States operating PDMPs. Beginning in FY 2002, Congress appropriated funding to the Department of Justice (DOJ) to support PDMPs.

Since the inception of the DOJ program, called the Harold Rogers Prescription Drug Monitoring Program, (Rogers PDMP or Rogers Program), this funding opportunity has resulted in 21 States receiving new program grants and 13 States netting planning grants. There are now 25 States operating PDMPs and 8 States with legislation in place to establish a program. Nearly all of the 33 States have received funding through the Rogers Program. (Rhode Island has never applied for funding.) Out of the States that have enacted PDMP legislation, 24 States have legislative authority to provide reports to physicians or prescribers, 26 to licensing boards, 21 to pharmacies, and 29 to law enforcement. Currently, six States have established agreements with other States. As these programs mature, the number of States who are sharing information with other States continues to grow. It should be noted that some States collect more than only controlled substances information, and some States have different substances in their schedules than those set out in the Controlled Substances Act.

Although PDMPs vary from State to State, the majority of these types of programs are administered by a law enforcement agency in conjunction with a state board of pharmacy or through professional licensing boards. All States receiving Rogers PDMP funding are encouraged to exchange data. Collaboration is an important aspect of these activities, and grantees must develop a team of law enforcement and health care professionals and collaborate with other public and private agencies and organizations.

The Bureau of Justice Assistance (BJA) within DOJ's Office of Justice Programs administers the Rogers Program along with DEA's Office of Diversion Control and ONDCP. The National Alliance for Model State Drug Laws provides technical assistance to states that

either have a PDMP or intend to establish one. Every PDMP that receive funding through the Rogers Program must provide performance data on: reducing the rate of "inappropriate use of prescription drugs"; reducing the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit (i.e., "doctor shopping"); and increasing coordination among PDMP partners (e.g., regulatory, health, law enforcement agencies).

All share the following common objectives:

- To educate and inform practitioners and the public;
- To develop and advance public health initiatives;
- To facilitate early identification and intervention in cases of drug misuse or abuse;
- To aid investigations and law enforcement; and
- To safeguard the integrity and access to the programs database.

Education and Information A major goal of many PDMPs is the provision of information and feedback to practitioners and the public. For example, data gathered through these systems is used to identify and analyze prescribing trends within geographic regions, medical specialties or drug classes permitting agencies to provide appropriate information or training at the right time.

Public Health Initiatives States use the information obtained from the review and analysis of monitoring data in the development of public health initiatives. Information on trends in prescribing and dispensing can be used to assist in addressing problems such as under- and over-utilization and inappropriate prescribing. Some States use monitoring information as the basis for initiation of education and prevention programs, formulation of laws and regulations,

development of controlled substances policies, and establishment of practice and treatment guidelines. One advantage of prescription drug monitoring is that initiatives can be targeted to selected subsets of healthcare practitioners.

Early Intervention and Prevention Another goal of these monitoring programs is early intervention and prevention of drug misuse. PDMPs can help physicians detect patients who may be abusing prescriptions sooner than would be possible with other forms of information gathering.

Investigations and Enforcement Existing DOJ-funded State programs have demonstrated a strong track record of assisting law enforcement and regulatory agencies to identify and respond to some illegal activity associated with prescription drugs. The systems make prescription records accessible at a single site, often computerized database, and thereby facilitate the gathering of evidence with minimal or no intrusion on practitioners and pharmacies. Similar to public health agencies, law enforcement can use information on trends in prescribing and dispensing to assist addressing problems such as identifying online Internet sales or finding suspicious prescribing patterns which may merit further investigation.

Confidentiality It is imperative that confidentiality protections are strictly enforced, so as to protect the patient, and that the systems work in conjunction with Health Insurance Portability and Accountability Act security and privacy provisions.

In recognition of the importance of the systems and the need for education and information, recently, the BJA within DOJ collaborates with SAMHSA through a multi-year grant to the SAMHSA-funded National Addiction Technology Transfer Center for an Educational Collaborative for Prescription Drug Monitoring Program Initiative. This initiative was created to enhance the linkages between the DOJ Prescription Drug Monitoring Programs and State-funded and -licensed addiction treatment systems. The goal of the project is to:

- create electronic profiles between the PDMPs and the State-funded treatment system;
- develop a guide for family practice physicians and pharmacists describing the signs and symptoms of prescription drug abuse;
- develop a guide for family practice physicians outlining the skills for screening, intervening and referring individuals to treatment for prescription drug use disorders; and
- develop a marketing plan to assure dissemination of these products and resources.

Although we do not yet have results from this grant, we are hopeful that the goals of the project will be met and will help with future efforts around establishing and enhancing PDMPs. Recognizing the fact that electronic monitoring systems are not the only answer, focus has expanded to the proper use of prescription drugs. Many individuals who receive prescriptions for pain because of surgeries, dental work, or back pain leave the drugs in their medicine cabinets or other places in the house for extended periods of time. The Federal Government in February of this year issued guidelines for proper disposal of prescription drugs. These guidelines urge Americans to:

- Take unused, unneeded, or expired prescription drugs out of their original containers;
- Mix the prescription drugs with an undesirable substance, like used coffee grounds or kitty litter, and put them in impermeable, nondescript containers, such as empty cans or sealable bags, further ensuring that the drugs are not diverted or accidentally ingested by children and pets;
- Throw these containers in the trash;
- Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs it is safe to do so; and
- Return unused, unneeded or expired prescription drugs to pharmaceutical take-back locations that allow the public to bring unused drugs to a central location for safe disposal.

SAMHSA also works with ONDCP to provide outreach and disseminate educational materials efforts to various sectors of our society that encounter this class of drugs. On behalf of ONDCP, we administer grants to communities across the country to form local anti-drug community coalitions that coordinate prevention and intervention efforts. These coalitions bring together community leaders and professionals in health care, law enforcement, and education to provide local, grassroots solutions to the challenges drug and alcohol abuse pose to their neighborhoods.

The President's Fiscal Year (FY) 2008 budget request for SAMHSA includes $1.76 billion for the Substance Abuse Prevention and Treatment Block Grant, of which 20 percent is a mandatory set-aside for substance abuse prevention. These funds are directed to specialty

treatment providers, many of whom provide treatment for abuse and dependence of prescription drugs. The President's FY 2008 budget also includes nearly $504 million in prevention and treatment discretionary grants, including Access to Recovery (ATR) and Screening, Brief Intervention, Referral and Treatment (SBIRT) programs.

The Access to Recovery program was launched in August 2004 with the announcement of grants to 14 States and one tribal organization. Since then, more than 170,000 people with substance abuse problems have received treatment and/or recovery support services, exceeding the three-year target of 125,000 people. In September 2007, 24 new Access to Recovery grants were awarded to 18 States, five tribal organizations, and the District of Columbia to increase access to clinical treatment and recovery support services for an estimated 160,000 individuals over the three-year grant period.

The Screening, Brief Intervention, Referral and Treatment program was established to engage health professionals in the identification, counseling, referral, and ongoing medical management of persons with substance abuse disorders. Through SBIRT, States, territories, and tribal organizations are eligible to receive grants to provide effective early identification and observation in general medical settings. This program is based on research showing that by simply asking questions regarding future unhealthy behavior and conducting brief interventions, patients are more likely to avoid the behavior in the future and seek help if they believe they have a problem.

Conclusion

As I stated earlier in my testimony, the emerging challenge of prescription drug abuse and misuse is a complex issue that requires epidemiological surveillance, distribution chain integrity, interventions, and more research by private and public sectors. It requires a concerted effort by many, and electronic monitoring systems are a key part of the response along with treatment and prevention programs that include outreach and education. SAMHSA is committed to allowing its programs to give States and local authorities flexibility in meeting drug-related challenges their communities face, including the mounting problem of prescription drug abuse. Our strategies in prevention and treatment of prescription drug abuse are both targeted specifically to the prescription drugs themselves and to programs that enable prevention, intervention, and treatment of addictions, which can have a significant long-term impact on prescription drug abuse and misuse.

Thank you for this opportunity to present this information to you. I would be pleased to answer any questions you may have.

Mr. STUPAK. Thank you, and thank you for your testimony. We will begin questions. We will go 5 minutes. If need be, we can go back and forth. Dr. Clark, in your testimony you never mentioned the NASPER Program. Why is that?

Dr. CLARK. At this particular point in time, the NASPER Program has not been funded, but the components of NASPER are—we are actively engaged in addressing some of those components and working——

Mr. STUPAK. Well, if it hasn't been funded, how can you be actively engaged in addressing the components?

Dr. CLARK. We are involved in the issue of collecting data on prescription drug abuse.

Mr. STUPAK. Why didn't you fund NASPER or the program that you have then to help inform doctors of the problems of the prescription drug abuse?

Dr. CLARK. Well, we understand that the funding process is complex. It is my understanding that, through the appropriations process, Congress has chosen to fund these activities within DOJ and not HHS.

Mr. STUPAK. Well, as Mr. Whitfield said, there was $5 million for the NASPER Program brought on approximately 2 years ago. What ever happened to that $5 million for the NASPER Program then?

Dr. CLARK. To my knowledge, we never got $5 million.

Mr. STUPAK. Has SAMHSA ever asked for money for the NASPER Program?

Dr. CLARK. I am not in a position to discuss the internal deliberations that occur in——

Mr. STUPAK. I am not asking for internal discussions. I am asking if you ever made a request of the appropriators for the NASPER Program. That is nothing internal. Did the Department ever ask for funding for the NASPER Program? That is a public statement. Did you ever do that?

Dr. CLARK. Asking for funds for specific programs is an internal process that we use, and we follow the internal processes to achieve that.

Mr. STUPAK. Why is the budget then published every year, if it is an internal process? It is a public process. The President sends his budget to Capitol Hill, and then we discuss whether or not to do it, whether or not to fund certain programs. Has the Department ever made a request to fund NASPER?

Dr. CLARK. To my knowledge, no.

Mr. STUPAK. From a public health perspective, what do you believe are the most important features of NASPER as distinguished from the unauthorized grant program at the Department of Justice?

Dr. CLARK. I think one of the most important things is that we want to be able to educate and inform practitioners, and we get that from the Department of Justice program. We want to make sure that there is this balance between the appropriate use of pain medications and the inappropriate use of pain medications. As I mentioned, there is some 75 million people who suffer from severe pain in the United States. So the concerted strategy that we are working with in the Federal Government, we believe, will assist us in addressing these issues in a cost-conscious environment.

Mr. STUPAK. Well, those two that you pointed out, to inform and educate the doctors who prescribe prescriptions, and also the use of pain medication, that is not found in the Rogers program in the Department of Justice, is it?

Dr. CLARK. I am not the best person to comment about the elaborate components of the Department of Justice programs.

Mr. STUPAK. Well, you testified on the Department of Justice program, so why can't you comment on the Department of Justice programs?

Dr. CLARK. I think the Department of Justice programs, in order to speak with the extreme authority, I think it would be best for the Department of Justice to comment. We do know that the Department of Justice is very much interested in advancing the public health component of theirs and not simply to aid in investigation and law enforcement. We know that they are——

Mr. STUPAK. Well, let me ask you this one, then. Let me ask you this. Last night at 8 o'clock, your Agency gave our investigators, 8 o'clock last night, a study required by the NASPER legislation. The study was supposed to be presented to Congress. That was supposed to be done 6 months after the bill was signed into law, which would have been August 2005, so early 2006 we should have received that report. We never saw the report until last night at 8 p.m. So why was this study a year and a half late? And when was this study completed?

Dr. CLARK. The study was released yesterday. It required extensive deliberation. We have discovered——

Mr. STUPAK. When was the study completed? I know you released it last night at 8 o'clock. When was it completed?

Dr. CLARK. The study was completed after it was approved, and I think part of the——

Mr. STUPAK. When was it completed, after it was approved?

Dr. CLARK. It was approved yesterday, sir.

Mr. STUPAK. So it took you 18 months to approve this study?

Dr. CLARK. Yes, sir.

Mr. STUPAK. How long did it sit in the Department, trying to get its final approval?

Dr. CLARK. I think the Department acted upon the report with dispatch and due deliberation, so it is not possible for me to comment on where it was after it left, because we have been exchanging comments and deliberations on it. So we have been actively involved in addressing the specifics of the report.

Mr. STUPAK. So you are telling me under oath here today that you have been actively and specifically going over this report for the last 18 months?

Dr. CLARK. Well——

Mr. STUPAK. Isn't the real answer was, you knew you were called up before this committee, so therefore you released your report last night? You haven't been actively engaged in this report. I can tell that just by looking at the report we saw last night, and I am reminding you, you are under oath. I am not trying to give you a bad time, but when we ask for things and you come here and you say you have been actively engaged in this thing for the last 18 months, studying it, and that is why it just got released last night, that is a bunch of bull. There is no other way to put it.

Ms. DEGETTE. Mr. Chairman, if I may. I always say there is a good reason to have a hearing. You get so much information the minute you schedule the hearing, so this is just yet another example of it.

Mr. STUPAK. So, do you want to revise your answer on that last one? Or are you going to stick with actively engaged for the last 18 months?

Dr. CLARK. Oh, we were pursuing the report as expeditiously as we could, and the final deliberations of the report were completed when the report was released.

Mr. STUPAK. Mr. Whitfield for questions, please.

Mr. WHITFIELD. Thank you, Chairman Stupak. Dr. Clark, you mentioned in responding to Mr. Stupak that HHS did not request any funding for NASPER. Is that correct?

Dr. CLARK. Yes, sir.

Mr. WHITFIELD. And how was that decision made?

Dr. CLARK. Again, I am not at liberty to discuss the internal deliberations that occur every year during the preparation of our annual budget.

Mr. WHITFIELD. Well, Secretary Thompson came and testified before this committee and said they supported NASPER, that it would be helpful to them in dealing with this problem. Secretary Leavitt came to this committee, testified to this committee, that NASPER would be helpful to them to solve this problem. And you are testifying this morning that you all did not request any money from OMB in your budget request. Is that correct?

Dr. CLARK. I am testifying that I am not at liberty to discuss the internal deliberations that occur——

Mr. WHITFIELD. No, but I thought you said you did not request any funds for this program.

Dr. CLARK. In the public, published budget.

Mr. WHITFIELD. All right. Now, Secretary Leavitt also said that it was OMB's decision not to fund this program. Can you make a comment on that?

Dr. CLARK. I will defer to Secretary Leavitt's comments.

Mr. WHITFIELD. Well, the point that I would make is that it is quite obvious from the charts that Dr. Paulozzi has mentioned here and has shown us that the unintentional drug poisoning death rate continues to increase. And which would indicate that this program at DOJ maybe is not being as effective as it could be. Now, the reason that we were excited about NASPER was that the first prescription drug monitoring program in America was established in 1939 in California. And today there are 25 States that actually have operational programs. So, from 1939 until 2007, only 25 States have operating programs. NASPER mandated that States do certain things to get these programs up and operational, and as we stated earlier we had a lot of hearings on this issue. We didn't just run an appropriation bill, and put it in an earmark to establish a program. We had extensive hearings, a lot of testimony, and the thought was that this program is much more comprehensive, has guidelines and so forth, and would be much more effective. Now, let me ask you, has HHS or SAMHSA taken any steps to prepare for administering NASPER in the event that funding is provided?

Dr. CLARK. We have had internal discussions. We have worked with the medical groups. We have sent staff to the various meetings on prescription monitoring programs, and in fact we also have an internal working group on electronic health records, which we believe would be a component of this. We understand that electronic prescribing is a concept that is being promoted, and we believe that, should this issue mature, we would need to be able to address that. So, yes, we have been addressing some of the collateral issues that we think are essential to prescription monitoring.

Mr. WHITFIELD. I might also say that we feel like in NASPER there are standards in there protecting patient privacy, which we think are superior to the DOJ program. I would also say that NASPER requires that dispensers like pharmacies report each dispensing of a controlled substance no later than one week after the date the drug was dispensed, and I don't think that is required on the DOJ program. And as far as interoperability of these programs, I mean, it is quite obvious that under the DOJ program not all these States are able to share information with each other. And I would just ask Dr. Paulozzi, how often do you all work with HHS? You are at the Centers for Disease Control. Do you all have a continuing dialogue with HHS on specific programs to address this unintentional drug death issue?

Dr. PAULOZZI. Well, Congressman Whitfield, we have had ongoing discussions with various staff at HHS. We worked with them very closely on the Fentanyl-heroin contamination issue of a year or two ago, and subsequently I have been keeping in touch with Dr. Hoffman at SAMHSA on various issues. But our conversations have not focused on the prescription drug monitoring program.

Mr. WHITFIELD. Thank you. My time has expired.

Mr. STUPAK. Ms. Schakowsky, for questions, please.

Ms. SCHAKOWSKY. I noticed that you said that you are testifying on behalf of your Administrator, Terry Cline, who was not able to be here. What I am also noticing as a consequence, you are not really able to talk about the funding issues, and I am disappointed in that because that is really at the center of what this hearing is about. We are trying to really get at why it is that NASPER has not been implemented within HHS. Do you think you are the best person, and, believe me, I am not challenging your role as a psychiatrist and your role at SAMHSA, but do you think you are really the best person that can explain what this committee is trying to get at?

Dr. CLARK. I think the committee is going to be meeting with the director of OMB, and you have already met with the Secretary on this topic, so I think those are the best people who can comment on this issue.

Ms. SCHAKOWSKY. Well, we are going to do our best. The study that was presented to our staff last night, HHS states that there is no evidence of negative impact on patients' access to pain treatment, particularly access by children to medicines they need. That is under the current system, which is the DOJ grant program system. I wonder if you could elaborate on that and if there is a chilling effect on physicians because of the current system?

Dr. CLARK. One of the things that the report does acknowledge is that there is a paucity of general information. However, based

on the modeling that was done, it does appear that the prescription modeling programs do have a chilling effect on practitioner behavior. One of the reasons a comprehensive strategy would be helpful, we are able to provide feedback to practitioners real time so that, in fact, you don't have children and adolescents denied care when that care is legitimate. Massachusetts——

Ms. SCHAKOWSKY. But, can I just interrupt for 1 second? Do you think the fact that it would be this program, to the extent that it is implemented, with the prescription drug monitoring programs in selected States, but the fact that it is housed in a law enforcement agency, do you think that would add any additional negative impact?

Dr. CLARK. Our hope is that it would not.

Ms. SCHAKOWSKY. What do you mean?

Dr. CLARK. Well, if in fact we are able to establish the linkages between the DOJ program, the HHS programs, and clinical practice, then we would not have a chilling effect.

Ms. SCHAKOWSKY. Does the DOJ program provide for this coordination of agencies?

Dr. CLARK. I think the DOJ is attempting to achieve that.

Ms. SCHAKOWSKY. So, so far there has not been any coordination. Do they coordinate with your agency?

Dr. CLARK. Not on a routine basis.

Ms. SCHAKOWSKY. It appears that most States with these PDMPs, would the PDMP legislation choose to have their program in health agencies rather than in their law enforcement agencies? I wonder if you could comment on that.

Dr. CLARK. From the public health point of view, it appears that in a number of jurisdictions most of the people requesting information are actually prescribers. For instance, Kentucky's program, the group requesting reports tends to be, 92 percent were prescribers, three percent pharmacists, three percent law enforcement, 1 percent licensing board. So the issue is, how do we help physicians make proper decisions in the care of their patients? And we have got a system that allows for real-time exchange of information. We are able to facilitate that.

Ms. SCHAKOWSKY. Thank you. I yield back.

Mr. STUPAK. Mr. Murphy, for questions, please.

Mr. MURPHY. Yes, Mr. Chairman, just a couple quick ones. This Department of Justice program, how long has it been going on, Dr. Paulozzi? My understanding is, about five years or so?

Dr. PAULOZZI. Are you referring to the Harold Rogers Program, Congressman?

Mr. MURPHY. Yes.

Dr. PAULOZZI. I am sorry. I don't really know when that program began.

Mr. MURPHY. My understanding, it was first funded around 2002. When I think of the slides you were showing us, it appears that during that time we have seen some pretty dramatic increases in drug poisoning and death rates.

Dr. PAULOZZI. That is correct, Congressman.

Mr. MURPHY. And on your slide you were also indicating that—I am not sure if it is saying it is a correlation, or it is cause and

effect that, with regard to the increase in the use of these opioids and other analgesics?

Dr. PAULOZZI. The trend lines parallel, which is consistent with a causal relationship. It certainly doesn't prove one.

Mr. MURPHY. And in the breakdowns in the testimony today, there is several factors that relatives may give the drugs away, some sell it, a small percentage are stolen from doctors' offices and prescriptions, but generally we trace it with these drugs. My question is this, is the Department of Justice program working?

Dr. PAULOZZI. Congressman Murphy, it is difficult to tell, without a formal evaluation of that process. It is hard to know what the rates would have been without interventions in prescription drug monitoring programs in selected States.

Mr. MURPHY. Sure. A good point. I appreciate that. What I am wondering here is, when I look back on some testimony that Secretary Leavitt had here, and it was actually in response to some questioning from my colleague, Mr. Whitfield, in reference to the NASPER Program he says, "It is a program we support. It is a program we would gladly administer." He went on to say that it was OMB that recommended it be in the law enforcement program. My question is, to each of you, is there a value in doing the NASPER Program, even from the point of an armchair analyst, since it is not that it has been tried and found wanting, it has been unfunded and left untried, it seems to me. Am I correct in that assessment, that without the funding we don't know if it works, but we clearly know that the DOJ program is, during the time that that is in place, we are seeing an increase in these deaths? I would like both of you to answer that, too, if you could respond, please. You can point at each other. That is fine.

Dr. PAULOZZI. As I say, it is difficult to determine what the impact is of Harold Rogers or without a formal evaluation or rigorously-done evaluation to determine what the impact of NASPER could be. As I say, I think it is difficult to infer evidence of effectiveness or lack of effectiveness from the information we have here.

Mr. MURPHY. Will CDC be doing that kind of evaluation, to find out if it is working or has a value?

Dr. PAULOZZI. We actually do plan a study to look at the impact of the initiation of prescription drug monitoring programs of all kinds on the drug fatality rates in the States that implement them.

Mr. MURPHY. Dr. Clark?

Dr. CLARK. Should it be decided that NASPER should be funded, I think Secretary Leavitt's comments would answer your concerns. So I will defer to Secretary Leavitt's comments on this matter. Clearly, the Department is pursuing a number of initiatives which would envelope the NASPER issues and would allow an aggressive participation and monitoring of what is going on without sacrificing patient care.

Mr. MURPHY. Well, and I would hope we are all on the same page with this, so all I am trying to find is the most effective, most efficient way, and it seems to me when we team up with people who are involved with law enforcement and those who are involved with healthcare delivery monitoring, we could have some value here. I mean, when we are looking at even such things as electronic medical records, with which one can track who is doing the

doctor shopping and getting duplicate drugs, it is a question that the physician can actually bring up with the patient in the confidential realm of the doctor's office, not necessarily waiting for the law enforcement officials, but to say, Mr. Jones, I think you have gone to several doctors here, and you are taking an awful lot of Oxycontin here. I am very concerned. And I don't know if the DOJ program allows that to happen. Is it? I mean, by design, does the DOJ program allow that? Do the physicians have access to that kind of information when they are seeing a patient?

Dr. PAULOZZI. My understanding is that there is nothing blocking their access to that information, but I would defer to people who know more about it than I do.

Mr. MURPHY. I am referencing, and there was an article that appeared a couple weeks ago in a newspaper in Pennsylvania, in Kittanning, Pennsylvania, Armstrong County, which is not in my district, but I was reading here a quote from a law the Armstrong County district attorney, Scott Andreassi. He said, "What is not happening now is monitoring things like doctor shopping. We need to take this program a step further and involve the pharmacies and virtually everyone involved with prescriptions every step of the way. We are going to discuss it in the future as to how we are going to talk to one another, exchange information on prescription drugs and so on." And it makes me wonder, unless there is a misunderstanding of these programs, I am wondering if we are getting the right information to the right people who can really do the right thing for patient care? And I would think that those are under the jurisdiction of HHS and CDC, that we are concerned about people abusing drugs, doctor shopping, illicit prescriptions, et cetera, and looking at these together. I would hope that from the comments that both of you made you are going to help this committee get that information and can bring it to the committee's attention in the future. I yield back.

Mr. STUPAK. Thank you. Ms. DeGette, do you have questions?

Ms. DEGETTE. Thank you, Mr. Chairman. Dr. Clark, in your prepared testimony, you say, "Our strategies in prevention and treatment of prescription drug abuse are both targeted specifically to the prescription drugs themselves and to programs that enable prevention, intervention, and treatment of addictions, which can have a significant long-term impact on prescription drug abuse and misuse." That is your conclusion. So my question is to you, if those are your strategies, don't you think it would be really helpful to have NASPER to help you achieve those strategies?

Dr. CLARK. Clearly, having access to the electronic matrix where information is shared real-time between pharmacists and physicians and patients, through their physicians or healthcare provider, we would be in a much better position to assess the appropriateness of a particular prescription. As a physician, I used to work for the VA, and we had electronic records. And so when a patient would come in, I could pull up those records, and I could see what medication the patient was on, and I could deal with the issues of synergism, multiple prescriptions, and appropriate——

Ms. DEGETTE. And that is part of what NASPER does, correct?

Dr. CLARK. That is part of what NASPER does, yes.

Ms. DEGETTE. So I guess your answer would be, yes, that would assist you in these important goals of your agency.

Dr. CLARK. Yes.

Ms. DEGETTE. Dr. Paulozzi, I just have a question. I was interested to look at your slide that shows that these incidences of deaths from overuse of these drugs, both in my area of the country, the southwestern United States, and also in Appalachia, are greater, and I was wondering if you have any indication of why that might be. Is it a systems breakdown? Is it for cultural reasons? What might the reasons be?

Dr. PAULOZZI. Well, thank you for that question, Congresswoman DeGette. New Mexico used to have the highest drug poisoning mortality rates in the country for many years. And it was thought to be related to the black-tar heroin, some of it coming in from Mexico, also related to maybe the cultural practices of use of heroin in that community. Some of the neighboring States to New Mexico's rates have gone up, though, in the last 10 or 15 years as well, so it is not clear to what extent that is prescription drugs and to what extent it is illicit drugs. But that has really historically been the focal point for drug poisoning, in the Southwest.

Ms. DEGETTE. And we don't really know why exactly?

Dr. PAULOZZI. No, I would have to say that there are speculations about illicit drugs and type of heroin use in cultural practices.

Ms. DEGETTE. In your testimony you mentioned a variety of surveillance and examination activities that the CDC will undertake this year, such as looking at prescription histories. This is one of the things NASPER does. It gives doctors and officials access to patient histories. So wouldn't it make sense to use the NASPER Program for this, and especially since it has already been authorized?

Dr. PAULOZZI. Yes, absolutely, Congresswoman. The information collected by prescription drug monitoring programs could be very useful to people like myself or State health departments, public health researchers at all levels, to look at the prescription histories of people suffering overdoses, to look at the trends in distributions, in county-by-county distributions across the State. I think it is an invaluable tool.

Ms. DEGETTE. And you have reported unintentional deaths from prescription drug abuse is now the second cause of accidental deaths in this country, second only to traffic accidents. If NASPER is implemented by HHS, how would the data from PDMP programs help medical researchers engaged in public health research, like you?

Dr. PAULOZZI. Well, the data would be very helpful, Congresswoman, in terms of telling us what is happening with distributions of drugs and trends in sales of drugs. We currently don't have a good source of information about that. Proprietary information is available, but working in the public sector, we can't afford to buy it. In addition, the people doing studies, and medical examiners, just looking at the deaths of individuals, could benefit from being able to see what their prescription history has been in terms of helping to determine what led to their death. So there are multiple applications.

Ms. DEGETTE. And one thing I was just sitting here thinking about, like with my question to you about why are the deaths high-

er in certain regions of the country, if you had that data you could actually see, is the use or abuse of these prescription drugs greater in these areas, or is it really illicit drugs, a fact that you can only speculate on right now? Correct?

Dr. PAULOZZI. Yes, that would be an additional tool. There are some survey data, though, that are broken down by State, collected by SAMHSA, about substance abuse that may be useful in that regard.

Ms. DEGETTE. And, Dr. Clark, you were shaking your head. You think this could be helpful as well, I assume?

Dr. CLARK. Yes.

Ms. DEGETTE. Thank you. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you. Dr. Paulozzi, if I may, Ms. DeGette asked you about, you mentioned New Mexico and Colorado and the Appalachian States, and in a map of the States you have the highest drug poisoning rates in the country. And again, in your opinion, if the prescription drug monitoring programs in those States had interoperable capabilities, like they would under NASPER, do you believe that would help decrease the drug poisoning in those States?

Dr. PAULOZZI. Well, Mr. Chairman, I believe that the prescription drug monitoring programs are promising tools for that purpose. They would provide a lot more information in a timely way, both to regulators, people in public health, and also to physicians in trying to manage care for patients. So there are a lot of reasons to believe that they would be effective in preventing overdoses, managing care of people with chronic pain better.

Mr. STUPAK. Your data that you used in your study came from coroners and medical examiners as to the cause of death. How do coroners and medical examiners determine what types of prescription drugs were involved in these accidental deaths?

Dr. PAULOZZI. Yes, Mr. Chairman. The coroners and medical examiners do complete the death certificates, which are filed, and then those become the source of the studies that we have done. They determine the cause of death by a variety of means. They look at the death scene investigations to see what prescription vials are there and whether there are syringes that were used to inject drugs. They also, of course, do toxicologic testing to look for the drugs found in the decedents' bodies after death. They will ask questions about the person's history, and they may even get the record from the prescription drug monitoring program, if there is one in their State, about the person's prescription history, to look for signs of abuse of drugs.

Mr. STUPAK. If we had NASPER, that would provide that information readily available to those coroners and others, would it not?

Dr. PAULOZZI. Yes.

Mr. STUPAK. About the prescription drugs?

Dr. PAULOZZI. Yes, Mr. Chairman, it would.

Mr. STUPAK. Thanks. In your testimony you mentioned that there is a significant correlation between State drug poisoning rates and State sales of prescription drugs. If you were in charge of creating a drug monitoring program such as NASPER, would you choose to house it in a health agency which has jurisdiction

over prescription drugs or a law enforcement agency like DOJ, and why?

Dr. PAULOZZI. Well, that is a complicated question, and I am not sure I really understand fully the ramifications of those two different choices. I can say on the one hand that there is a lot of use made of prescription drug monitoring program data by law enforcement. On the other hand, there should be use of NASPER-type data by physicians. I would hope for a system that would be accessible to everyone who needed access to it, with the appropriate protections of patient privacy, and not have the use be dictated by the location of the program.

Mr. STUPAK. Thank you. Dr. Clark, in the study you gave to our staff last night, and SAMHSA spent 18 months massaging it, let me ask you this. In there, it states that there is evidence of a negative impact on the patient's access to pain treatment. Are you saying that the Harold Rogers program is negatively impacting patients' ability to seek proper treatment on legitimate pain diseases?

Dr. CLARK. No, what we are saying is, looking at controlled substance monitoring programs generally so that comment is not targeted toward the Harold Rogers Program. It is saying that when jurisdictions implement controlled substance monitoring programs, there is an unintended consequence of practitioners altering their clinical decision-making because of the existence of such programs.

Mr. STUPAK. The Rogers prescription drug monitoring program has been around since 2002. Congress has spent $43.5 million. Has anyone ever assessed the success of that program, if it has been successful in reducing unintentional deaths in drugs, Mr. Clark?

Dr. CLARK. I don't think so.

Mr. STUPAK. All right. In your testimony you say that no organization or agency can address the program or the problem alone. A coordinated response is required. Does the Rogers program provide this coordination of agencies?

Dr. CLARK. I think under the one-government paradigm we should be operating with that level of coordination. It hasn't happened.

Mr. STUPAK. So the Rogers program doesn't support coordination amongst agencies, then?

Dr. CLARK. I can't articulate the explanation for the Rogers program's activity in that area.

Mr. STUPAK. Well, let me ask you this. Does HHS support the NASPER Program?

Dr. CLARK. You have heard from Secretary Leavitt. I will defer to his position on this matter.

Mr. STUPAK. Has Secretary Leavitt seen this report that you handed to us last night?

Dr. CLARK. That report has been cleared by HHS. I can't say whether Secretary Leavitt himself has seen the report.

Mr. STUPAK. Mr. Whitfield, for questions.

Mr. WHITFIELD. Just a couple more. Obviously on an issue as serious as this issue, it is important that the programs, that they be effective and that there be a way to measure their effectiveness and that there be adequate oversight. And I would make the argument that, when you do an earmark on an appropriation bill, generally there is no follow-up report to examine its effectiveness at

all. In NASPER, there is a requirement that after three years of operation that HHS conduct a study and determine how effective the program is. So I think that is one big difference in these programs. The second difference is that, under the existing DOJ program, it relies on the States to determine who has access to the information. And, for example, Indiana and Pennsylvania will not allow physicians access to the information. The NASPER Program allows physicians access to the information, allows law enforcement access to the information, and sets guidelines for privacy protection concerns. So when you look at these programs, I think the more balanced program overall certainly is NASPER and I must say that it is frustrating that the President signs this bill, and still there is no funding for this program. And it is more important than just jurisdiction. It is about addressing a serious problem in the country, and that is really what this hearing is all about. Now, Dr. Clark, let me ask you one question. When you all work with OMB on your budgetary needs, who, what is the name of the individual at OMB that you work with? I mean, I know that Leavitt can call Jim Nussle on the phone, or he can call Rob Portman on the phone, but at the staff level, who works with who? Between HHS and their budget requests and OMB?

Dr. CLARK. As I recall, the staff person is an individual named Patricia Smith.

Mr. WHITFIELD. Patricia Smith? And then, at the White House, who is the White House liaison with HHS?

Dr. CLARK. I don't have that information.

Mr. WHITFIELD. Thank you very much.

Mr. STUPAK. Seeing no members with further questions, I would like to thank this panel for their testimony today. Dr. Paulozzi and Dr. Clark, thank you for being here.

Dr. CLARK. Thank you.

Dr. PAULOZZI. Thank you.

Mr. STUPAK. We will call up our second panel. We have one witness on our second panel, and that is Dr. Andrea Trescot, president of the American Society of Interventional Pain Physicians, and she is also the director of Pain Fellowship at the University of Florida. We will give you just a minute, Dr. Trescot, and then we are ready to go. It is the policy of this subcommittee to take all testimony under oath. Please be advised that the witness has the right, under the rules of the House, to be advised by counsel during their testimony. Do you wish to be represented by counsel, doctor?

Dr. TRESCOT. No, sir, I do not.

Mr. STUPAK. The witness testifies that she does not, then raise your right hand and take the oath.

[Witness sworn]

Mr. STUPAK. Thank you. Let the record reflect the witness has answered in the affirmative. She is now under oath. Dr. Trescot, if you would, please, just give an opening statement, and then you may submit a longer statement for inclusion in the record, and we look forward to questions and answers. Doctor?

TESTIMONY OF ANDREA M. TRESCOT, M.D., PRESIDENT, AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS; DIRECTOR, PAIN FELLOWSHIP

Dr. TRESCOT. Thank you. Distinguished Chairman, ranking member, Members of Congress, and staff, my name is Dr. Andrea Trescot. I am very grateful for this invitation to speak before you regarding a critical issue, prescription drug abuse. I am an interventional pain physician with nearly 20 years of private practice experience, and earlier this year I left private practice to join the University of Florida and the Gainesville VA as Director of the Pain Fellowship Program. I am currently the president, as you said, of the American Society of Interventional Pain Physicians, ASIPP, a professional society with over 4000 providers. But it is in my role as a physician, treating patients in agonizing pain, that I come to you today requesting your help.

Opioid or narcotic use and misuse is a huge and growing problem in the United States. As you have heard, Americans make up only 4 percent of the world's population, but they consume nearly 80 percent of the global supply of pain medicines, 99 percent of the global supply of hydrocodone, one of our very easily obtained opioids, and two-thirds of the world's illegal drugs. Despite billions of dollars thrown at this problem we have not been able to reduce the Nation's substance abuse and addiction.

The number of Americans abusing controlled substance drugs has jumped from 6.2 to 15.2 million in the last 10 years. Among chronic pain sufferers who receive opioids, one in five abuse those medications. The number of teen users, who somehow view prescription medicines as being safer, has more than doubled, but the highest use of pain relievers, non-medically, has been in the 18- to 25-year group. An undercover surveillance video I viewed last week of a pill mill showed nearly 100 people standing in a doctor's waiting room, waiting to pick up their narcotics. I was stunned by how much it looked like a bar scene and then realized it was because virtually person in the waiting room was under the age of 30. Unfortunately, the elderly are also at risk because of their multiple medications and potential drug interactions and their multiple degenerative joint changes. Though this population may have significant and legitimate opioid needs, they are at risk for diversion of their medications, sold for income supplementation or stolen by caregivers and family members.

Approximately 75 to 90 percent of drug abusers have obtained their medications legally, and most through a prescription. We feel, therefore, that the most effective way of controlling this epidemic is to control the end of the pen, or in other words, how the medicines are prescribed. The White House Office of National Drug Control Policy, focusing on stopping use before it starts, healing drug users, and disrupting the market, has spent over $10 million a year since its enactment in 1988, with no demonstrable curb in drug abuse or addiction. And yet, almost a quarter of a trillion dollars of the Nation's yearly healthcare bill is attributed to substance abuse and addiction.

We feel strongly that NASPER is a major weapon against prescription drug abuse. Unfortunately, the ONDCP's budget of $13 million doesn't include funding for NASPER, which is arguably the

most effective program. To fight drug abuse before the drug is prescribed would require about $10 million, which is less than 1 percent of the current budget and could provide as much as 30 percent reduction in prescription drug abuse. Now NASPER was based, as you have heard, on a successful program in Kentucky, KASPER, which has been effective but limited because Kentucky has seven border States, allowing patients to take the prescriptions across State lines to avoid monitoring. One of the most important features of NASPER was the information sharing across State lines, but that requires each State to have a monitoring program in place. In this day of unfunded mandates, the States have been slow to enact legislation, most of which was inadequately funded and not designed to share information.

I live in north Florida, an hour away from the Georgia border. Although Florida passed a bill that was named FLASPER, suggesting that it was part of the NASPER Program, the eventual legislation was castrated into a voluntary program of electronic prescribing. We are convinced that, had the funding for NASPER been in place, the law in Florida would have conformed to the national recommendations, which would have prevented Florida patients from obtaining narcotics from multiple doctors, whether they were day laborers or syndicated radio columnists. By identifying those patients who are doctor shopping, physicians will be able to intervene early with patients who are misusing and abusing their medications, legitimate pain patients will receive access to care they truly need, and we can shut down the most obvious avenue for obtaining fraudulent prescriptions.

It is clear the prescription monitoring programs are effective specifically when they are proactive, and we feel NASPER is just such a program. We at ASIPP also feel that, since less than 40 percent of physicians receive any kind of training regarding pain evaluation in medical school, the White House should facilitate the dissemination of pain and addiction information to the general medical community. I have provided the committee with a copy of such an education tool, published last year by the Florida Medical Association.

In closing, the White House has declared a total global war on terrorism, with a budget of $145 billion. We are asking for only a tiny fraction of that to battle an insidious and just as deadly internal threat to the welfare of this great Nation. Please help us in that battle by providing funding for NASPER as one of the major tools we have in this critical battle. Thank you very much, and I look forward to answering any questions you might have today and in the future and perhaps providing additional insight to some of the questions asked today.

[The prepared statement of Dr. Trescot follows:]

Oral Testimony

NASPER:
Why has the National All Schedules Prescription Electronic Reporting Not Been Implemented?

Andrea M. Trescot, MD

Andrea M. Trescot, MD
President
American Society of Interventional Pain Physicians
Director, Pain Fellowship
University of Florida
3401 NW 98th Street
Gainesville, FL 32606
Phone: (352) 376-1611
Fax: (352) 271-4541
amt57@aol.com

Distinguished Chairman, Ranking Member, Members of Congress and staff, my name is Dr. Andrea Trescot. I am very grateful for this invitation to speak before you about a critical issue, prescription drug abuse. I am an Interventional Pain Management physician with nearly 20 years of private practice experience. Earlier this year I left private practice to join the University of Florida Faculty as the Director of the Pain Fellowship Program. I am currently the President of the American Society of Interventional Pain Physicians, a professional society with over 4000 providers. It is in my role as a physician treating patients in agonizing pain that I come to you today requesting your help.

Opioid or narcotic use and misuse is a huge and growing problem in the United States. Americans make up only 4.6% of the worlds population, but they consume 80% of the global supply of pain medicines, 99% of the global supply of Hydrocodone (one of the most abused of our readily available pain medicines) and 2/3rds of the world's illegal drugs. Despite the billions of dollars thrown at this problem, we have not been able to reduce the nation's substance abuse and addiction.

The number of illegal drug users is rising. The number of teen illegal drug users has more than doubled, and the number of Americans abusing controlled prescription drugs has jumped from 6.2 to 15.2 million in the last ten years. Among the patients suffering with chronic pain and receiving opioids, 1 in 5 are abusing those prescription-controlled medications and approximately the same number of patients are also using illicit drugs.

The National Drug Control Strategy from the White House spent over 10 billion dollars a year since its enactment in 1988 with no demonstrable results in curbing drug abuse or addiction. And, specifically, there has been no change in prescription controlled substance abuse. Yet, almost a quarter of a trillion dollars of the nation's yearly healthcare bill is attributed to substance abuse and addiction.

Some of the increase in opioid abuse is occurring with teenagers, who view prescription medications as not only "safer," but also the "cool" drugs to use. Prescription medications are the most commonly used drugs to get high among teenagers, and teenagers represent almost a third of the prescription drugs abused in the country. These medicines have come from friends, from stealing the medications from their family members, and occasionally from the internet. Over 90% of drugs were obtained by legitimate prescriptions.

In addition, the highest use of pain relievers non-medically was in the 18-25 year group. I was struck by an undercover surveillance video I viewed last week, which showed nearly a hundred people standing in a doctor's waiting room as they waited their turn to pickup their narcotic prescriptions. I was stunned by how much it looked like a "bar seen" and then realized it was because virtually every person in the waiting room was under the age of 30. This pill mill was catering to the young.

Unfortunately the elderly are also at risk, because of their multiple medications (and potential drug interactions), and their multiple degenerative joint changes (such as hip, knees and back). And yet, though this population may have significant and legitimate opioid needs, they are at risk for diversion of their medications, either actively (selling them for income supplementation) or passively (with their medications stolen by caregivers and family members).

Approximately 75-90% of drug abusers have obtained their medications legally, and most likely through a prescription. Doctor shopping is one of the most common methods of obtaining prescription drugs for personal and illegal use. We feel therefore strongly that the most effective way of controlling this epidemic is to control the "end of the pen" or, in other words, the way the medications are prescribed.

The White House Office of National Drug Control Policy, which focused on stopping use before it started, intervening and healing drug users, and disrupting the market, is pending approximately 13 billion dollars per year. Unfortunately, the ONDCP budget does not include funding for NASPER which is arguably the most effective program. To fight drug abuse before the drug is prescribed would require 10 million dollars, which is less than 1% of the budget. This 1% would provide as much as 30% reduction in prescription drug abuse. We feel strongly that the National All Schedules Prescription Electronic Act (NASPER), which was signed into law August 11, 2005, is a major weapon against prescription drug abuse.

NASPER was based on a successful program in Kentucky, KASPER, which has been effective but limited by the fact that Kentucky has 7 Border States and patients can therefore take their prescriptions across state lines and thwart the ability of Kentucky physicians to monitor that narcotic use. One of the most important features of NASPER was the information sharing across state lines, but that requires each state to have a monitoring program in place. However, in this day of unfunded mandates, the states have been slow

to enact legislation, most of which are inadequately funded, and are not designed to share information.

By identifying those patients who are doctor shopping, legitimate physician will be able to identify and intervene early with patients who are misusing and abusing their medications. In addition, the ability to identify legitimate pain patients will increase the access to care for those patients who truly need the medication and shut down the most obvious avenue for obtaining fraudulent prescriptions.

As an example, I live in North Florida, an hour away from the Georgia border. Although Florida passed a bill that was named FLASPER, suggesting that it was the state response to the NASPER bill, the eventual legislation, which was passed in July of this year was castrated onto a voluntary program of electronic prescribing.

We are convinced that had the funding for NASPER been in place, the law in Florida would have conformed to the national recommendations. This would have prevented Florida patients from visiting multiple doctors regardless of whether they were day laborers or national syndicated radio columnists.

It is clear the prescription monitoring programs are effective specifically when they are proactive. NASPER would allow communication among states. We in ASIPP also feel that since less than 40% of physicians receive any training regarding pain evaluation in medical school, the White House should organize events to facilitate the dissemination of pain and addiction information to the general medical community. I have provided to the committee a copy of such an education tool, published last year by the Florida Medical Association.

We also feel that controlled substance education must be mandated in medical schools, residency training programs and supported by continuing education every year. That training should be accredited and approved and could be monitored by the DEA or the State Boards of Medical Licensure.

There are a growing number of pain professionals who feel that pain management should be a separate residency. ASIPP is doing its part by providing a training program and examination leading to a clinical competency in controlled substance prescribing.

In closing, the White House has declared a global war on terrorism with a budget of $145 billion dollars. We are asking for a tiny fraction of that to battle an insidious and just as deadly internal threat to the welfare of this nation. Please help us in this battle by providing funding for NASPER, one of the major tools we have in this crucial battle.

Thank you.

I will be happy to answer any question you might have.

Written Testimony

National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies

Laxmaiah Manchikanti, MD

Reprinted and revised from Pain Physician journal.

From: Pain Management Center of Paducah, KY.

Dr. Manchikanti is CEO of the American Society of Interventional Pain Physicians, Medical Director of the Pain Management Center of Paducah, KY, and Associate Clinical Professor of Anesthesiology and Perioperative Medicine, University of Louisville, Louisville, KY.

Address Correspondence:
Laxmaiah Manchikanti, MD
2831 Lone Oak Road
Paducah, Kentucky 42003
E-mail: drm@apex.net
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Joseph A. Califano, Jr., Chairman and President of the National Center on Addiction and Substance Abuse at Columbia University (CASA), on May 7, 2007 issued a press release on the state of the affairs of illicit drug use and the diversion and abuse of controlled prescription drugs in the United States (1). Califano, a former U.S. Secretary of Health, Education, and Welfare, called for a major shift in American attitudes about substance abuse and addiction and a top to bottom overhaul in the nation's healthcare, criminal justice, social service, and education systems, in awakening the power of parenting, to curtail the rise in illegal drug use and other substance abuse. He called substance abuse and addiction a chronic disease of epidemic proportions with physical, psychological, emotional, and spiritual elements that require continuing and holistic care (1,2).

Americans, constituting only 4% of the world's population, consume 80% of the global supply of opioids, 99% of the global supply of hydrocodone, and two-thirds of the world's illegal drugs (1-4). Consequently, the sum of all the measures on the current war on drugs has not been able to reduce the nation's substance abuse and addiction.

Califano, also in a July 2005 editorial on the diversion and abuse of controlled prescription drugs in the United States (5) noted the following:

"While America has been congratulating itself in recent years on curbing increases in alcohol and illicit drug abuse and in the decline in teen smoking, abuse and addiction of controlled prescription drugs - opioids, central nervous system depressants and stimulants - have been stealthily, but sharply, rising. Between 1992 and 2003, while the US population increased 14%, the number of people abusing controlled prescription drugs jumped 81% - twice the increase in the number of people abusing marijuana, 5 times the number abusing cocaine and 60 times the increase in the number abusing heroin. Controlled prescription drugs like OxyContin, Ritalin, and Valium are now the fourth most abused substances in America behind only marijuana, alcohol, and tobacco."

Consequently, as in prior years, multiple surveys of non-prescription drug abuse (6-10), emergency department visits for prescription controlled drugs (11-15) and unintentional deaths due to prescription controlled substances (16-20) have been steadily rising.

Further, the activities of the White House Office of National Drug Control Policy (21-23), numerous hearings held by Congress, the Administration, and various agencies at the federal and state levels (4,24,25) reiterate the growing problem of illicit drug use and prescription controlled substance abuse. Yet, the number of prescriptions for controlled substances continue to soar along with arguments for undertreatment of pain and education for increased prescription and availability of controlled substances with continued funding for numerous programs whose effectiveness have not been proven yet.

Figure 1 illustrates the increase of controlled substances abuse from 1992 to 2003, in comparison to US population and prescriptions written for controlled substances, but, newer statistics are even more impressive. From 1992 to 2005, the US population increased 15%, whereas, during this period adults abusing controlled substances increased 98%. The 2005 NSDUH Survey showed 6.4 million persons or 2.6% of the population 12 years or older in the United States used prescription type psychotherapeutic drugs nonmedically in the past month (6). Nonmedical use of psychotherapeutic drugs in the past year increased to 15.172 million or 6.2% of the US population of 12 years or older (6). Similarly, lifetime nonmedical use of psychotherapeutics increased to 48.709 million persons or 20% of the United States population of 12 years or older. Further, in the past year, initiation of substance use among persons aged 12 or older, nonmedical use of psychotherapeutics, was 2.526 million. The only silver lining is that nonmedical use of therapeutic drugs among 12-17 year olds decreased in 2005 compared to 2002 and 2003, whereas it significantly increased for 18-25 year olds from 2002 to 2005.

The National Institute on Drug Abuse (NIDA) on the eve of unveiling its first consumer publication to

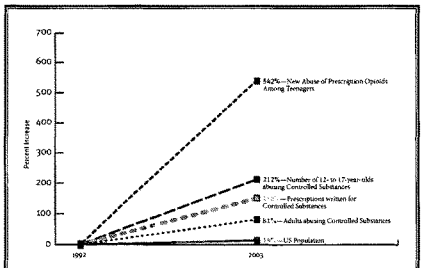


Fig. 1. *Increase of controlled substance abuse from 1992 to 2003, in comparison to US population and prescriptions written for controlled substances.*

explain the signs of addiction on March 5, 2007, reported that abuse and addiction to alcohol, nicotine, and illegal substances costs Americans upwards of half a trillion dollars a year (26).

The National Center on Addiction and Substance Abuse at Columbia University in an update published in 2006, its third report (27), concluded that prescription controlled drugs continue to be as easy to buy over the Internet as candy, and anyone, including children, can readily obtain, without a prescription, highly addictive controlled substances from Internet drug pushers as long as a person has a credit card. Califano once again reiterated that not surprisingly, controlled prescription drug abuse is on the rise, today, with more adults and teens having reported abusing these drugs than having abused all other illicit drugs combined except marijuana.

Even then pain is considered as undertreated by some, while opioid prescriptions are soaring (3). In recent medical news and perspectives of JAMA, it was shown that by far the most commonly used prescription analgesic in the United States is hydrocodone with acetaminophen which has been the most prescribed medication of any category for at least the past 5 years, with more than 100 million prescriptions in 2005, far exceeding the number of prescriptions for the second and third most prescribed medications-cholesterol-lowering atorvastatin with about 63 million prescriptions, and the antibiotic amoxicillin, with about 52 million prescriptions. In addition, in 2004, the United States used 99% of the global supply of the opioid hydrocodone, according to the 2005 report from the International Narcotics Control Board (3). Between 2000 and 2004, medical use of hydrocodone increased 60% domestically.

In a recent letter to Members of Congress titled "Prescriptions Drugs: An Emerging Threat," John P. Walters, Director of White House Office of National Drug Control Policy, expressed his deep concern that America's leadership be aware of this burgeoning problem so that they can inform their communities about the dangers of prescription drug abuse (28).

The National Drug Threat Assessment 2007 by the National Drug Intelligence Center US Department of Justice (29) reported that rates of pharmaceutical drug abuse exceeded that of all other drugs except marijuana resulting in a high number of pharmaceutical overdose deaths annually.

Despite the alleged undertreatment of pain, based on the present statistics, it appears that opioids are overprescribed. Widely quoted literature about the undertreatment of pain, pertains to terminal illness, malignancy, post-operative pain and AIDS. Opioid prescriptions have increased substantially from 1997 to 2005, with increases in methadone prescriptions of 933%, oxycodone prescriptions of 588%, and hydrocodone prescriptions of 198% (Table 1). The increase in the legitimate use of opioids has been paralleled by a rise in abuse of these drugs with a 62.5% increase in opioid deaths during the 5-year period from 1999 to 2004 (16,17). Further, in pain management settings, as many as 90% of patients have been reported to receive opioids for chronic pain management (30,31). Multiple investigators (32-49) have shown prevalence of drug abuse around 20% and as high as 58% in the patients receiving opioids for chronic pain. Unfortunately, a significant proportion of chronic pain patients also tend to use illicit drugs, with proportions increasing based on concurrent abuse of prescription controlled substances (32-49). The explosion of opioid use and abuse along with illicit drug use in chronic pain patients is sadly coupled with a lack of evidence of their long-term effectiveness in these patients.

Our national drug control strategy, with billions of dollars spent each year, is not working. As Califano stated, "All the huffing and puffing of the current war on drugs has not been able to blow down the nation's house of substance abuse and addiction." Note the following glaring and startling facts (1,2):

- The number of illegal drug users, which had dropped from a high of 25.4 million in 1979 to a quarter century low of 12 million in 1992, has risen to 20 million in 2005.

Table 1. *Retail sales of opioid medications (grams of medication 1997–2005*

	1997	2005	% of Change
Methadone	518,737	5,362,815	933%
Oxycodone	4,449,562	30,628,973	588%
Fentanyl Base	74,086	387,928	423%
Hydromorphone	241,078	781,287	244%
Hydrocodone	8,669,311	25,803,544	198%
Morphine	5,922,872	15,054,846	154%
Meperidine	5,765,954	4,272,520	-26%
Codeine	25,071,410	18,960,038	-24%

Source: http:www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.htmo

- The number of teen illegal drug users, which had dropped from its 1979 high of 3.3 million to a low of 1.1 million in 1992, has more than doubled to 2.6 million in 2005.
- From 1995 to 2005 the number of Americans abusing controlled prescription drugs jumped from 6.2 to 15.2 million.
- One in 4 Americans will have an alcohol or drug problem at some point in their lives.
- Among the patients suffering with chronic pain and receiving opioids, 1 in 5 abuse prescription controlled substances and approximately the same number of patients also use illicit drugs.

Thus, the consequences of this epidemic are severe (1,2):

- Almost a quarter of a trillion dollars of the nation's yearly health care bill is attributable to substance abuse and addiction.
- The national drug control strategy from White House spent over $10 billion dollars a year since its enactment in 1988 with no demonstrable results in curbing drug abuse and addition, specifically prescription controlled substance abuse.
- The National All Schedules Prescription Reporting Act of 2005 signed into law by President Bush on August 11, 2005, has not been funded. Instead, an incoherent program by the DEA has been appropriated over the years.
- While education about the undertreatment of pain, prevalence of pain and increasing levels of comfort among physicians prescribing opioids has fueled increased prescriptions of opioids with parallel growth in the unintentional consequences of misuse, abuse and deaths, the education of physicians and the public with reference to deleterious effects of opioids, non-opioid management of chronic pain, abuse and addiction, hasnot been implemented.
- Majority of prescription controlled substances for nonmedical use are obtained for free from a friend or relative (60%), purchased from a friend or relative (8%), taken from a friend or relative without asking (4%) and from prescriptions from one doctor (17%).

Consequently, a mounting revolution is essential to control this problem. Changes are needed not only in the healthcare system, but also justice, social service, and education. This review will focus on the problem of prescription drug abuse and relevance of the National Drug Control Policy and will discuss multiple facts and fallacies, along with proposed solutions.

State of Illicit Drug Use

The 2005 National Survey on Drug Use and Health (NSDUH), an annual survey sponsored by the Substance Abuse and Mental Health Services Administration provided the following statistics about the state illicit drug use in the United States (6). The survey considered current use of an illicit drug during the month prior to the survey interview.

- In 2005, an estimated 19.7 million Americans aged 12 or older or 8.1% of the population were current illicit drug users.
  - Illicit drugs include marijuana/hashish, cocaine including crack, heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics used nonmedically.
  - The rate of current illicit drug use in 2005 was slightly higher than the rate in 2004 (8.1% vs 7.9%), but similar to 2003 and 2002 (8.2% and 8.3%).
  - The rates of current illicit drug use among youths aged 12 to 17 in 2005 was 9.9% similar to the rate in 2004, but significantly lower than 2002 (11.6% in 2002, 11.2% in 2003, 10.6% in 2004).
  - There were no significant changes in past month use of any illicit drugs among adults aged 18 to 25 between 2004 and 2005, except for cocaine use which increased from 2.1% to 2.6%.
- Marijuana was the most commonly used illicit drug with 14.6 million past month users with a 6% population.
  - The rates remained same as in 2004 (6.1%), 2003 (6.2%) and 2002 (6.2%).
  - The rate of current marijuana use among youths aged 12 to 17 declined from 7.6% in 2004 to 6.8% in 2005.
- The current cocaine use was reported in 2.4 million Americans aged 12 and older or 1% of the population.
  - Current use of cocaine in 2005 was slightly higher than 2004 (1% vs 0.8%), however, was not statistically significant.
- The current use of hallucinogens was by 1.1 million or 0.4%.
  - This included 0.2% who had used ecstasy and the estimates were similar to the corresponding estimates for 2004.
- The current use of methamphetamine (0.2%) and past year use of 0.5%, did not change between 2004 and 2005, but the lifetime rate changed in 2005.
  - Even though, the lifetime rate declined from 4.9% in 2002 to 4.3% in 2005, the number of methamphetamine users who are dependent on or abused some illicit drug did rise significantly during this

Table 2. *Types of illicit drug use in past year among persons aged 12 or older from 1995 to 2005 (numbers in thousands).*

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Non-medical use of Psychotherapeutic drugs	6,166 (2.9%)	6,652 (3.1%)	6,111 (2.8%)	5,759 (2.6%)	9,220 (4.2%)	8,761 (3.9%)	11,102 (4.9%)	14,680 (6.2%)	14,986 (6.3%)	14,643 (6.1%)	15,172 (6.2%)
Marijuana	17,755 (8.4%)	18,398 (8.6%)	19,446 (9.0%)	18,710 (8.6%)	19,102 (8.6%)	18,589 (8.3%)	21,086 (9.3%)	25,755 (11.0%)	25,231 (10.6%)	25,451 (10.6%)	25,375 (10.4%)
Cocaine	3,664 (1.7%)	4,033 (1.9%)	4,169 (1.9%)	3,811 (1.7%)	3,742 (1.7%)	3,328 (1.5%)	4,186 (1.9%)	5,902 (2.5%)	5,908 (2.5%)	5,658 (2.4)	5,523 (2.3%)
Total or Any Illicit Drug usage	22,662 (10.7%)	23,182 (10.8%)	24,189 (11.2%)	23,115 (10.6%)	25,402 (11.5%)	24,535 (11.0%)	28,409 (12.6%)	35,132 (14.9%)	34,993 (14.7%)	34,807 (14.5%)	35,041 (14.4%)

Source: www.samhsa.gov

period from 164,000 in 2002 to 257,000 in 2005.

- There were 6.4 million (2.6%) persons who used prescription-type psychotherapeutic drugs nonmedically in the past month.
- The estimates were similar to the corresponding estimate for 2004.

Epidemic of Non-medical Prescription Drug Abuse

The National Survey on Drug Use and Health (NSDUH) of 2005 (6) provided rather startling statistics as shown in Table 2. The type of illicit drugs used in past year among persons aged 12 or older from 1995 to 2005 increased for nonmedical use of psychotherapeutic drugs and overall use of any illicit drug, but decreased slightly for marijuana and cocaine (6).

In 2005, there were 6.4 million or 2.6% of persons aged 12 or older who used prescription-type psychotherapeutic drugs nonmedically in the past month. Of these 4.7 million used pain relievers, 1.8 million used tranquilizers, 1.1 million used stimulants including 512,000 using methamphetamine, and 272,000 used sedatives (Fig. 2). The current nonmedical use of prescription-type drugs among young adults aged 18 to 25 increased from 5.4% in 2002 to 6.3% in 2005 (6). The majority of the increase was seen in pain reliever use which was 4.1% in 2002 and 4.7% in 2003, 2004, and 2005.

In a report of patterns and trends in nonmedical prescription pain reliever use from 2002 to 2005 (50), NSDUH reported that nonmedical use of prescription pain relievers among persons aged 12 or older remained relatively stable between 2002 and 2005 (nonsignificant increases were seen), 4.8% of the

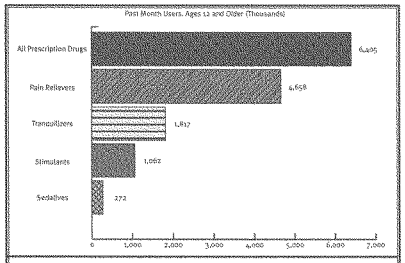


Fig. 2. *Pain relievers account for the largest portion of nonmedical use of prescription drugs. Source: SAMHSA, 2005 National Survey on Drug Use and Health (Sept. 2006).*

population or 11.4 million persons used a prescription pain reliever nonmedically in the 12 months prior to the survey and 57.7% of persons who first used pain relievers nonmedically in the past year used hydrocodone products and 21.7% used oxycodone products.

As shown in Figure 3, the highest use of pain relievers nonmedically was in the 18 to 25 age group with males more likely than females to have used a prescription type pain reliever nonmedically in the past year (5.2% vs 4.4%). However among youths aged 12 to 17, females were more likely than males to have used pain relievers nonmedically in the past year (7.9% vs 6.8%) whereas males aged 18 to 25 and males aged 26 to 34 at higher rates than their female counterparts. Among adults aged 35 to 49 and those aged 50 or older, males and females had similar rates

of nonmedical use prescription pain relievers.

In another report released by the Office of National Drug Control Policy with an analysis of recent trends on the emerging drug threat among teens (51), the following was included:

- Next to marijuana, prescription medications are the most commonly used drugs among teens to get high.
  - Teens are turning away from street drugs and using prescription drugs to get high. Indeed, new users of prescription drugs have caught up with new users of marijuana.
- For the first time, there are just as many new abusers of prescription drugs as there are marijuana abusersamong teens (6).
- Among 12- to 17-year-olds, the gap between new marijuana users and new prescription drug users is shrinking (Fig. 4).
  - Between 2003 and 2005, the gap closed by 5.9%.
  - In 2005, the estimated number of 12- to 17-year-olds who started using prescription drugs in the 12 months prior to the survey was 850,000, compared with 1,139,000 marijuana initiates.
  - In 2003 the estimates were 913,000 for prescription drugs, compared to 1,219,000 marijuana initiates (6,7)
- Three percent, or 840,000, teens ages 12-17, reported current abuse of prescription drugs in 2005, making this illegal drug category the second most abused drug next to marijuana (7%) (6).
- In 2005, 2.1 million teens abused prescription drugs, almost one-third of prescription drugs abused in the country. Teens aged 12-17 have the second-highest annual rates of prescription drug abuse after young adults aged 18-25 (Fig. 5).
  - For young adults 18-25, past month nonmedical use of prescription-type drugs increased from 5.4% in 2002 to 6.3% in 2005, whereas, it decreased among the 12-17 age group (Fig. 5).
- Prescription drugs are the most commonly abused drug among 12- to 13-year-olds (6). Teens aged 12-17 and young adults aged 18-25 were more likely than older adults to start abusing prescription drugs in the past year (6).
- Teens (12-17) in western and southeastern states are more likely to abuse prescription pain relievers.
  - Arkansas (10.3%), Kentucky (9.8%), Montana (9.6%), Oregon (9.3%), Oklahoma (9.1%), Tennessee (8.9%), and West Virginia (8.9%).
- Teens are abusing prescription drugs because they

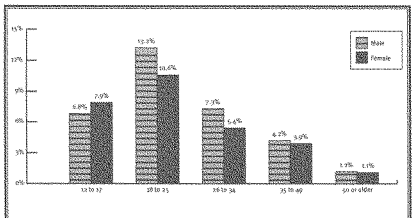


Fig. 3. *Percentages of past year nonmedical pain reliever use among persons aged 12 or older, by age group and gender: 2002-2005.*

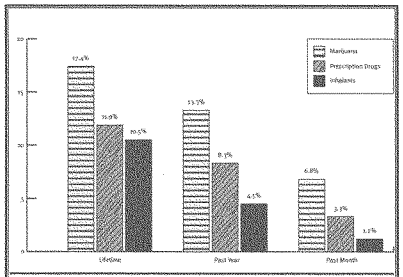


Fig.4. *Types of illicit drug use among teens aged 12-17 (percentage). Source: SAMHSA, 2005 National Survey on Drug Use and Health (Sept. 2006).*

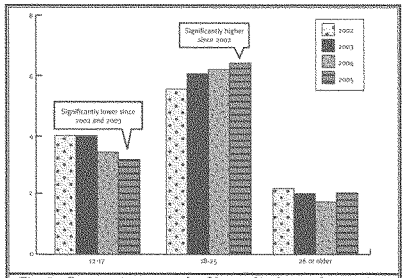


Fig. 5. *Current (past month) Nonmedical use of prescription drugs among various age groups (percentage). Source: SAMHSA, 2005 National Survey on Drug Use and Health (Sept. 2006).*

believe the myth that these drugs provide a medically safe high (51).

- Monitoring of the Future Study from the University of Michigan in 2006 (52) showed among 12th graders in the past year, marijuana was used by 31.5%, while a 2006 Partnership for a Drug America survey showed nearly 1 in 5 teens (19% or 4.5 million) report abusing prescription medications that were not prescribed to them (53).
- A dangerous trend is developing among the teens where they admit to abusing prescription medicine for reasons other than getting high, including to relieve pain or anxiety, to sleep better, to experiment, to help with concentration, or to increase alertness (54).
- Further, when teens abuse prescription drugs, they often characterize their use of the drugs as "responsible," "controlled," or "safe," with the perception that the prescription drugs are safer than street drugs (55).
- In addition, more than one-third of teens say the feel some pressure to abuse prescription drugs, and 9% say using prescription drugs to get high is an important part of fitting in with their friends.

- In its 17th Annual National Study of Teen Drug Abuse, the Partnership for a Drug-Free America reported that an alarming number of teenagers are abusing a variety of prescription and over-the-counter medications to get high and classified them as generation RX.
- Approximately 1 in 5 teenagers has abused a prescription painkiller to get high, and 1 in 11 has abused OTC products, like cough medicine.
- Figure 6 shows an emerging category of substance abuse: 18% of teens trying Vicodin, 10% OxyContin, and 10% Ritalin and Adderall. In contrast, crack cocaine was used by 9% and marijuana was used by 37%. Meth and ketamine were also used but to a lesser extent.
- Thus, 50% of teens tried psychotherapeutic drugs alone or in combination.

Epidemic of Medical Prescription Drug Abuse

Supply

In response to the alleged undertreatment of pain as a major health problem in the United States, numerous initiates were developed (3,4,25,30). Multiple patient advocacy groups, professional organizations, Federation of State Medical Boards and its constituent boards, and even DEA have fueled explosion in use of therapeutic opioids (4). Consequently, use of therapeutic opioids in the United States is responsible for over 80% of the global supply of all opioids and 99% of hydrocodone. In fact, sales of hydrocodone increased 198% from 1997 to 2005, whereas methadone usage increased 933% and oxycodone increased 588% (Table 1 and Fig. 7). Estimated number of prescriptions filled for controlled substances increased from 222 million in 1994 to 354 million in 2003.

Increasing Deaths

Paulozzi et al (16) reported unintentional drug poisoning morality rates increased on average 5.3% per year from 1979 to 1990 and 18.1% per year from 1990 to 2002 and at-

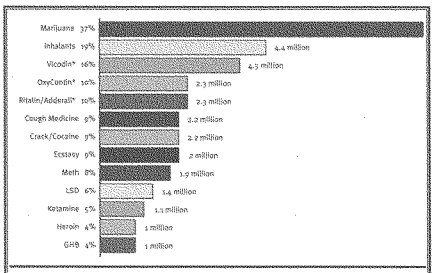


Fig. 6. *Generation Rx, emerging category of substance abuse among teens (percentage and number (in millions) of teens who have ever tried).*

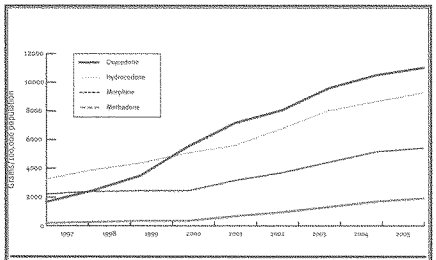


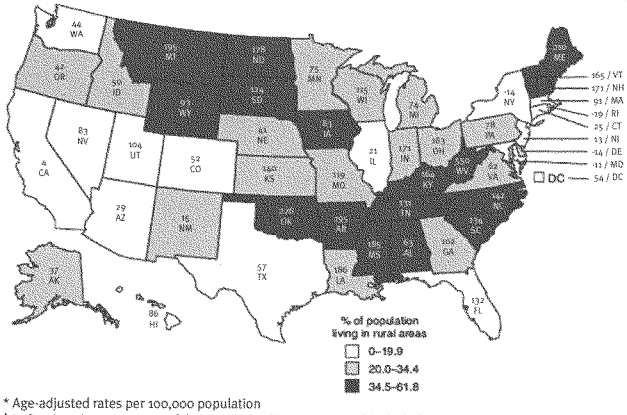
Fig. 7. *The increase in therapeutic opioids use in the United States (grams/100,000 population).*
Source: Based on data from US Drug Enforcement Administration, Automation of Reports and Consolidated Orders System (ARCOS); www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

tributed the rapid increase during the 1990s to narcotics and unspecified drugs. Between 1999 and 2002, the number of opioid analgesic poisonings on death certificates increased 91.2%, while heroin and cocaine poisonings increased 12.4% and 22.8%, respectively. By 2002, opioid analgesic poisoning was listed in 5,528 deaths – more than either heroin or cocaine. The increase in deaths generally matched the increase in sales for each type of opioid.

In a morbidity and mortality weekly report by Paulozzi in February 2007 (17), in 2004, unintentional drug poisoning was second only to motor-vehicle crashes as the cause of death from unintentional injury in the United States. The number of unintentional poisoning deaths increased from 12,186 in 1999 to 20,950 in 2004. The annual age-adjusted rate increased 62.5%, from 4.4 per 100,000 population in 1999 to 7.1 in 2004. The highest rates in 2004 were among persons aged 35-54 years, who accounted for 59.6% of all poisoning deaths. Rates also varied based on the states from 1999 to 2004, rates increased by less than one-third in the Northeast and West but more than doubled in the South and nearly doubled in the Midwest. States with the largest relative increase were West Virginia (550%), Oklahoma (226%), Maine (210%), Montana (195%), and Arkansas (195%). Increases of 100% or more occurred in 23 states (Fig. 8).

Fingerhut (19) from the Office of Analysis and Epidemiology evaluated methadone-related deaths from 1999 to 2004. She reported that the number of all poisoning deaths increased 54% to 30,308 over the 1999-2004 period, while the number of poisoning deaths mentioning methadone increased 390% to 3,849. Poisoning deaths mentioning methadone increased from 4% of all poisoning deaths to 13% of all poisoning deaths. Most recently, it was also shown that all poisoning deaths increased 6% from 2003 to 2004, whereas those mentioning methadone increased 29%. The absolute number of poisoning deaths mentioning methadone was less than the number of deaths mentioning heroin, cocaine or other opioids (Table 3). Age specific rates of methadone death were higher for persons aged 35-44 and 45-54 years than for those younger or older. The largest increase, however, was noted for young persons 15-24 years; the rate in 2004 was 11 times that in 1999.

Methadone-related unintentional poisoning deaths from 1999 to 2004 and ratio of deaths in 2004 to deaths in 1994 by state-by-state showed greater than ratio of 15 in West Virginia (24.8), Ohio (17.4),



* Age-adjusted rates per 100,000 population

† Defined as the percentage of the population living in census blocks below a certain population density, based on U.S. Census data for 2000.

Fig. 8. *Percentage change in unintentional poisoning mortality rates *by rural status of state † United States, 1999 - 2004 (17).*

Table 3. *Number of poisoning deaths in which specific narcotic substances are mentioned, 1999 to 2004.*

Substance	1999	2000	2001	2002	2003	2004	1999-2004	2003-2004
							Percent change	
Poisoning by narcotics and psychodysleptics, all	9,955	10,173	11,480	14,247	15,731	16,735	68.1	6.4
Opium	4	2	5	3	4	1	-75.0	-75.0
Heroin	1,964	1,846	1,782	2,091	2,080	1,881	-4.2	-9.6
Other opioids	2,757	2,932	3,484	4,431	4,877	5,242	90.1	7.5
Methadone	786	988	1,456	2,360	2,974	3,849	389.7	29.4
Other synthetic narcotics	732	784	962	1,301	1,406	1,668	127.9	18.6
Cocaine	3,832	3,565	3,840	4,612	5,212	5,461	42.5	4.8
Other narcotics	2,902	2,880	2,881	3,143	3,117	2,761	-4.9	-11.4
Cannabis	37	41	37	50	61	99	167.6	62.3
LSD	3	3	2	0	1	1	-66.7	0.0
Other	9	8	7	5	6	5	-44.4	-16.7

Note: Substance-specific data are not addictive because a death certificate could have multiple drugs listed.
Source: National Center for Health Statistics, National Vital Statistics System Ref. (19)

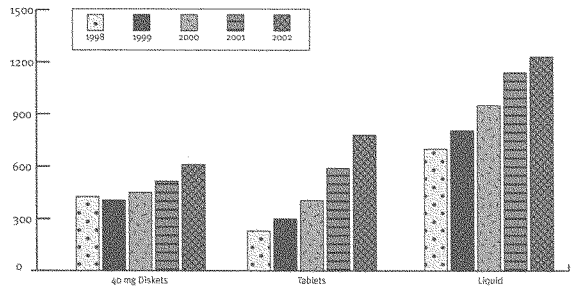


Fig. 9. *Methadone distribution by formulation (grams per 100,000 population)*
Source: Adapted from DEA ARCOS-2 data provided by June E. Howard, Methadone-associated mortality from a report of a national assessment.

Louisiana (16.0), Kentucky (15.1) and New Hampshire (14.5); whereas ratios between 10 and 14 were seen in Florida (13.8), Oregon (13.6), Pennsylvania (12.6), Tennessee (12.4), Wisconsin (10.5) and Maine (10.4).

As shown in Figure 9, the available data for methadone by formulation from 1998 to 2002, grams per 100,000 population, shows consumption of liquid has increased substantially and was higher than diskettes and tablets. However, for prescription availability, tablets are the only source for physicians and rarely liquid. Diskettes and liquids are prescribed by methadone clinics. Thus, the combined dispersion of diskettes and liquids was higher when compared to tablets. If this is combined with methadone tablet seizures, which increased 133% between 2001 and 2002, it appears that illegally obtained methadone and methadone

clinics have contributed more to methadone deaths than prescription methadone by physicians, contrary to popular opinion (18).

Emergency Department Visits

The Drug Abuse Warning Network (11) showed in 2005, there were 816,696 emergency department visits involving an illicit drug. Nonmedical use of pharmaceuticals contributed to 598,542 visits involving nonmedical use of prescription or over-the-counter pharmaceuticals or dietary supplements, with majority of these visits (55%) involving multiple drugs. Central nervous system agents (51%) and psychotherapeutic agents (46%) were the most frequent drugs reported in the nonmedical-use category of emergency department visits. Among the CNS agents the most frequent drugs were opiate/opioid analgesics (33%). Methadone, oxycodone, and hydrocodone were the most frequent opioids.

- Hydrocodone/combinations in 51,225 ED visits (CI: 37,416 to 65,033),
- Oxycodone/combinations in 42,810 ED visits (CI: 30,672 to 54,948), and
- Methadone in 41,216 ED visits (CI: 29,249 to 53,184).

Overall narcotic analgesic emergency department visits were 160,363 in 2005 compared to 42,857 in 1995. Among the psychotherapeutic agents, the anxiolytics (anti-anxiety agents, sedatives, and hypnotics) were the most frequent, occurring in 34% of visits associated with the nonmedical use of pharmaceuticals. DAWN estimated that 172,388 ED visits were associated with the nonmedical use of pharmaceuticals involving benzodiazepines in 2005, compared to 71,609 in 1995. Figure 10 illustrates emergency department visits resulting from narcotic analgesics and benzodiazepines from 1995 to 2005.

Is Pain Undertreated?

Considerable controversy exists about the use of opioids for the treatment of chronic pain of a non-cancer origin (30). Inadequate treatment of pain has been attributed to a lack of knowledge about pain and pain management options, inadequate understanding of addiction, or fears of investigation or sanction by Federal, State and local regulatory agencies. It has been alleged that pain is undertreated and it is a major problem in the United States. Consequently, multiple initiatives have been developed to address the alleged barriers responsible for the undertreatment of pain however, widely quoted literature pertains to pain management in terminal illness, malignancy, post operative pain, and AIDS. Thus far, there is no single, reliable objective report of the undertreatment of chronic, non-cancer pain.

The prevalence of pain also has been over-reported. The prevalence of chronic pain in the adult population ranges from 2% to 40%, with a median point prevalence of 15% (30). However, persistent pain was reported with an overall prevalence of 20% of primary care patients, with approximately 48% reporting back pain (56). Thus, chronic persistent pain may be much less than advocacy organizations report which is as high as 50-60% of Americans. It is stated

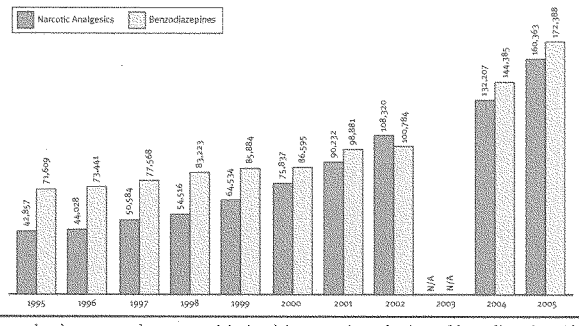


Fig. 10. *Drug abuse related emergency department visits involving narcotic analgesics and benzodiazepines (data from 2003 not available). Source: DAWN data (11-13).*

that alleged undertreatment and prevalence of pain has been expected to worsen as the population ages, with increasing rates of arthritis, cancer, back pain, and other conditions. Thus, both the undertreatment of pain and high prevalence of pain represent inflated statistics from patient self reports which are unreliable and may even indicate drug abuse rather than undertreatment.

Are Opioids Overprescribed?

As shown in Table 1 between 1997 and 2005 methadone prescriptions increased 933% whereas oxycodone prescriptions increased 588% compared to increase of hydrocodone prescriptions of 198%. Kuehn (3) wrote that in addition to an increased awareness of the importance of pain control, pain experts attribute the overall increases in prescription pain medication use to a variety of factors, including support and requirements for appropriate pain control from state medical boards and advances in the science of pain control. In spite of lingering concerns surrounding prescription pain medications, which are overblown, many physicians have become more comfortable using these drugs as they have learned more about them (3).

State and national organizations also are emphasizing the importance of managing pain. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued unproven, mandatory standards for pain management in January 2001. Many state health care licensing organizations have followed JCAHO. While these widely applied policies are meant only for acute pain and postoperative pain, they have been argued for application in all settings including chronic non-cancer pain.

In many states, medical, pharmacy, and nursing boards are issuing joint statements emphasizing the need to use these drugs in appropriate circumstances while taking steps to avoid abuse and diversion (3). The Federation of State Medical Boards has crafted a model policy, adopted by many states, regulating the use of controlled substances, which emphasizes adequate pain control and that physicians should periodically monitor patients to prevent abuse (3,57).

In pain management settings, as many as 90% of patients have been reported to receive opioids for chronic pain management (30,31). In addition to promotion of undertreatment, promotion of breakthrough pain will also increase or explode the use of opioids in managing chronic non-cancer pain (58).

Are Controlled Substances Abused by Chronic Pain Patients?

While opioids are by far the most abused drugs other controlled substances such as benzodiazepines, sedative-hypnotics, and central nervous system stimulants, though described as having less potential for abuse, are also of major concern. Multiple investigators (30-49,59,60) have shown a prevalence of drug abuse in 18% to 41% in patients receiving opioids for chronic pain. In a recent systematic review (49) of opioid treatment for chronic back pain, the prevalence of lifetime substance use disorders ranged from 36% to 56%, and the estimates of the prevalence of current substance use disorders were as high as 43%. Aberrant medication-taking behaviors ranged from 5% to 24%.

Are Illicit Drugs Used by Chronic Pain Patients?

It has been shown that patient's in chronic pain on prescription controlled substances also use illicit drugs. Prospective evaluations (34,43) have shown illicit drug use in 22% of the patients which reduced to 16% with enhanced adherence monitoring.

What Is the Evidence of Effectiveness?

Multiple reviews have been published to evaluate the effectiveness of opioid therapy in chronic pain (49,61-66). Short-term trials provide favorable results where treatment lasts for 32 weeks and moderate doses of opioids were administered with 180mg of morphine or morphine equivalent per day.

The real question, however, when embarking on a course of opioid treatment for chronic pain is whether analgesic efficacy is maintained over time (66). A review of the open-label follow-up studies has shown that 56% of patients abandon the treatment because of a lack of effectiveness or side effects (62). One meta-analysis directly comparing the effectiveness of efficacy of different opioids demonstrated a non-significant reduction in pain from baseline (66). In another systematic review (61) it was concluded that there was insufficient and poor evidence to prove the safety or effectiveness of any opioids. In another systematic review of effectiveness and safety (62), the mean decrease in pain intensity in most studies was at least 30% and only 44% of the patients continued treatment between 7 and 24 months. In an analysis of effectiveness and side effects (65), it was concluded that strong opioids were more effective with pain relief and functional outcomes, however, drop-out rates averaged 33%. Ballantyne and Mao (63) and Ballan-

tyne (66) concluded that a cautious approach must be used in using opioids.

A recent epidemiological study from Denmark (67), where opioids are prescribed liberally for chronic pain, demonstrated worse pain, higher healthcare utilization, and lower activity levels in opioid treated patients compared to a match cohort of chronic pain patients not using opioids, suggesting that even if some patients benefit, the overall population does not when opioids are prescribed liberally.

Overall the evidence supporting the long-term analgesic efficacy is weak based on the present evidence. Epidemiological studies are less positive with regards to function and quality of life and report failure of opioids to improve quality of life in chronic pain patients.

What Are Side Effects?

Common and well known side effects are related to nausea, sedation, euphoria or dysphoria, constipation, depression, and itching. However long-term opioid therapy results in hyperalgesia or increased pain, negative hormonal and immune effects, addiction and abuse.

Where Do These Drugs Come From?

Most of diversion of prescription drugs from their lawful purpose to illicit use can happen at any point from the pharmaceutical manufacturing to distribution and consumption by the intended lawful individual. The diversion of prescription drugs among adults is typically one or more of the following: doctor shopping, illegal Internet pharmacies, drug theft, prescription forgery, or illicit prescriptions by physicians.

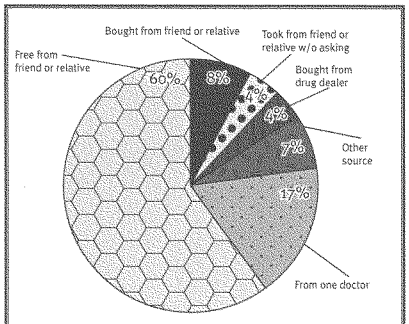


Fig. 11. *Source of pain relievers for most recent non-medical use among past year users. Source: Ref (6)*

In contrast, youths typically acquire drugs by stealing them from parents or relatives, buying them from classmates who are selling legitimate prescriptions, or buying them from illegal Internet pharmacies or vendors.

Based on a 2005 NSDUH survey (6), nearly 60% of non-medical prescription drug users say that they received the prescription drug from a friend or a relative for free (Fig. 11). This study also showed that other methods of acquiring prescription drugs for non-medical use include doctor shopping, traditional drug dealing, theft from pharmacies or homes, and illicitly acquiring the prescription drugs over the internet. Among these, 17% reported that they received it from one doctor, 8% reported that they bought from friend or relative, 7% from other sources, 4% took from a friend or relative without asking, with another 4% buying from a drug dealer.

Thus, approximately 77% to 89% obtained the drugs legally, most likely through a prescription. Consequently, providing a controlled substance prescription drug to a person who is not the intended recipient of the prescription, whether freely given, shared, or offered for sale, is not only dangerous but also illegal.

A report of National Drug Threat Assessment 2007 from the National Drug Intelligence Center US Department of Justice (29) concluded that the availability of diverted pharmaceutical drugs is high and increasing, fueled by increases in both the number of illegal online pharmacies and commercial disbursements within the legitimate pharmaceutical distribution chain. The rates of past year use for pharmaceuticals are stable even though at very high levels. The report also found that demand for prescription narcotics may decline as some users switch to heroin, particularly in areas where law enforcement efforts curb the diversion and availability of prescription drugs.

Doctor Shopping

Doctor shopping is one of the most common methods of obtaining prescription drugs for legal and illegal use (4). The majority of physicians perceive "doctor shopping" as the major mechanism of diversion (5). The persons practicing doctor shopping may be targeting physicians who readily dispense prescription without a thorough examination or screening (68-70). It has been reported that individuals may collect thousands of pills during a one-year period and sell on the street (70). Further, some individuals collect pills and give them to others to whom they perceive need the pills whereas some supplement Social Secu-

rity check income by selling part or all of their prescriptions (71).

Since 1999, illegal Internet pharmacies have provided a convenient alternative for individuals wishing to fill their prescriptions (25,27,72-76). In a June 2006 CASA report (27), the Internet was found as a growing source of drugs with increased prescription drug abuse. They also found that an emergent trend was "online consultation" whereas there were no controls blocking sale to children and substantial shipments were from within the United States. Table 4 illustrates Internet availability of controlled prescription drugs by class whereas Table 5 illustrates Internet sites advertising or selling controlled prescription drugs. The startling fact is that a staggering 89% of sites selling controlled prescription drugs have no prescription requirements, down slightly from 94% in 2004. However, the total number of sites selling drugs that do not require a prescription has increased each year with 147 in 2004 compared to 152 in 2005 and 165 in 2006. Of the 11% of the sites stating that they require a prescription, 70% only require that a prescription be faxed-allowing a customer to easily forge prescription or fax the same prescription to several Internet pharmacies. Table 6 illustrates Internet pharmacy prescription requirements.

Drug Theft

Drug theft is another problem which is on the rise, largely due to vast increases in prescription drug abuse and high street prices (55,75,77-83). In addition, prescription forgery is also fairly common, either by altering the prescriptions, stealing blank prescription pads in order to write fake prescriptions, or calling pharmacies for prescriptions without authorization from the physician.

Improper Prescribing and Sharing

Similarly improper prescribing and sharing among family and friends is also very common (Fig. 11). Diversion and abuse of methadone is a special issue (Fig. 9).

Thus, multiple causes and reasons leading to abuse include increasing supply and demand, advertising and advocacy availability, Internet availability, Internet sales, increasing street value, motivation for use, perceived safety, lack of perception of risks, lack of knowledge of prescription drug abuse liability, lack of knowledge about non-opioid techniques, lack of eduction, wasted efforts on war on drugs, non-evidence based practice guidelines, and finally incoherent and ineffective prescription drug monitoring programs.

Table 4. *Internet availability of controlled prescription drugs by class*

	2004	2005	2006
Benzodiazepines	92% (144)	146 (91%)	84% (155)
Opioids	66% (103)	74% (118)	68% (126)
Stimulants	30% (47)	21% (34)	8% (14)
Barbiturates	1% (2)	3% (4)	1% (2)
Total sites	157	160	185

Source: The National Center on Addiction and Substance Abuse. (27) www.casacolumbia.org/pdshopprov/files/you_ve_got_drugs.pdf

Table 5. *Internet sites advertising or selling controlled prescription drugs*

	2004	2005	2006
Sites selling drugs (anchor sites)	32% (157)	40% (160)	54% (185)
Sites advertising drugs (portal sites)	68% (338)	60% (242)	46% (159)
Total sites	498	402	344

Source: The National Center on Addiction and Substance Abuse. (27) www.casacolumbia.org/pdshopprov/files/you_ve_got_drugs.pdf

Table 6. *Internet pharmacy prescription requirements*

	2004	2005	2006
Sites not requiring prescription	94% (147)	95% (152)	89% (165)
No prescription needed	44%* (64)	36%* (55)	30%* (50)
Online consultation	52%* (77)	57%* (87)	60%* (99)
No mention of prescription	4%* (6)	7%* (10)	10%* (16)
Sites requiring prescription	6% (10)	5% (8)	11% (20)
Patient faces	70%# (7)	12%# (1)	70%# (14)
Patients mails	30%# (3)	63%# (5)	15%# (3)
Doctor contacted	0	25%# (2)	15%# (3)

*of sites not requiring prescription
# of sites requiring prescription
Source: The National Center on Addiction and Substance Abuse. (27) www.casacolumbia.org/pdshopprov/files/you_ve_got_drugs.pdf

National Drug Control Strategy

The White House Office of National Drug Control Policy (ONDCP), a component of the Executive Office of the President, was established by the Anti-drug Abuse Act of 1988. The principle purpose of ONDCP is to establish policies, priorities, and objectives of the nation's drug control program. The goals of the program are to reduce illicit drug use, manufacturing, trafficking, drug-related crime and violence, and drug-related health consequences. The national drug control strategy directs the nation's anti-drug efforts and establishes a program, a budget, and guidelines for cooperation among Federal, State and local entities.

The National Drug Control Strategies focus around 3 issues: 1) stopping use before it starts, 2) intervening and healing drug users, 3) disrupting the market. The budget for fiscal year 2007 was $13.128 billion, an increase of $0.129 billion over the FY 2006 enacted level of $12.999 billion (Fig. 12). For fiscal year 2008 the proposed budget totals $12.961 billion, which is a decrease of $0.167, or 1%. However, for fiscal year 2008 the administration is also separately requesting $266.1 million in additional spending for emergency designations associated with drug-related operations, principally in Afghanistan.

Stopping Use Before It Starts

The fiscal year 2008 budget includes federal resources totaling $1.6 billion or 12% (Fig. 13) supporting a variety of education and outreach programs aimed at preventing the initiation of drug use. The Department of Health and Human Services (HHS) contributes a 60% share of these resources ($937.4 million) to fund prevention activities through its Programs of Regional and National Significance. As shown in Figure 13, $17.9 million is spent on Student Drug Testing, $59.0 million is spent on Research-Based Grant assistance to local educational agencies, $100.0 million is spent on Safe and Drug-Free Schools and Communities State Grants, $90.0 million is spent on Drug-Free Communities through Office of National Drug Control Policy and $130.0 million is spent on National Anti-Drug Youth Media Campaign again through the Office of National Drug Control Policy.

Healing America's Users

The second item involves intervening and healing America's drug users with a budget of $3 billion or 29% (Fig. 14) in federal funds to drug abuse intervention and treatment efforts in the fiscal year 2008 representing an increase of nearly $100 million over fiscal year 2007 level. The majority of the budget of 82% ($2,498.4 million) goes to HHS which supports the majority of Federal Government's efforts to help drug users in need. Others include the Justice Department with $136.7 million or 5%, Veterans Administration $392 million or 13%, and others 15.7 million or 1%.

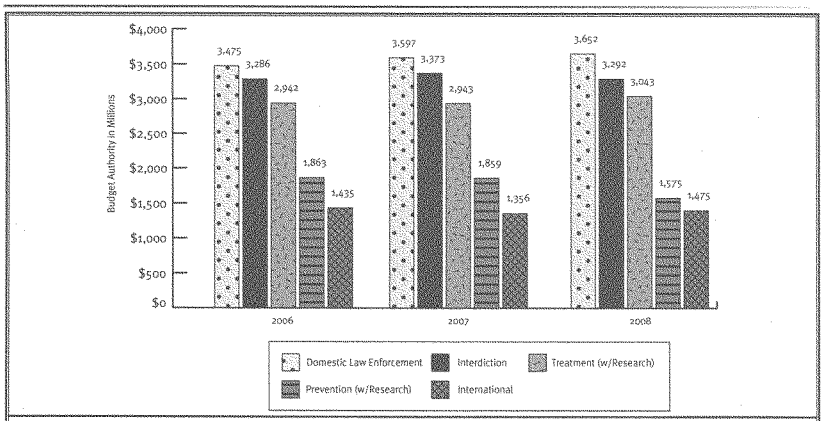


Fig. 12. *Drug resources by function.*

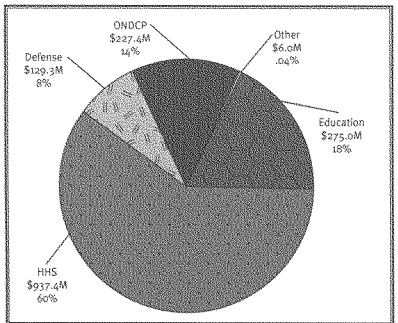


Fig. 13. *Stopping use before it starts ($1.6 billion).*

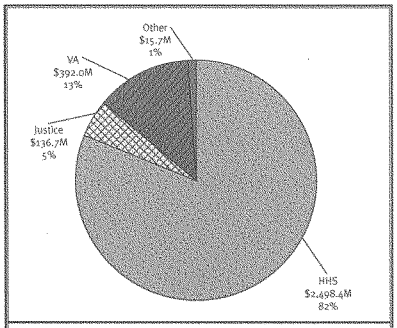


Fig. 14. *Healing America's Users ($3.0 billion).*

Disrupting the Market

The third activity of the National Drug Control Policy is composed of $8.3 billion or 63% of the National Drug Control Policy federal spending with 42% of this allocated to the Department of Homeland Security, 10% to Defense, 1% to Treasury, 13% to State, 32% to Justice and 3% to the ONDCP (Fig. 15).

Distribution of Funds

The total budget is approximately $13 billion, of which the Department of Defense receives approximately $936.8 million, the Department of Education receives $275 million, the Department of Health and Human Services receives $3,435.7 billion, $3,493.7 to the Department of Homeland Security, $2,797.0 billion to the Department of Justice, $473.4 million to the ONDCP, $1,096.8 billion to the Department of State, $2.7 million to the Department of Transportation, $57.3 million to the Department of Treasury, and $392 million to the Department of Veterans Affairs.

The Department of Defense, with a budget of $936.822, is the lead federal agency in efforts to detect and monitor the aerial and maritime transit of illegal drugs towards the United States. Defense also collects, analyzes, and disseminates intelligence on drug activity; provides training for US and foreign drug law enforcement agencies and foreign military forces with drug enforcement responsibility; and, approves and funds Governor's State Plans for National Guard use, when not in federal service, to support drug interdiction and other counter-narcotics activities, as authorized by state laws.

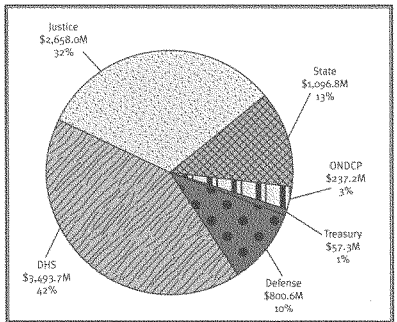


Fig. 15. *Disrupting the market.*

The Department of Education, with a budget of $275 million, administers programs to help ensure that all students can meet challenging standards and improve elementary and secondary education, including: special eduction and early intervention programs for children with disabilities; English language acquisition for limited English proficient and immigrant children; career, technical, and adult education; and higher eduction. Further, the Department of Education also carries out research, data collection, and civil rights enforcement activities.

For the Department of Health and Human Services, a large portion of the funding on federal drug control includes $75 million for Centers for Medicare and

Medicaid Services, $1,000.365 million for the National Institute on Drug Abuse and a large portion to the Substance Abuse And Mental Health Services Administration (SAMHSA) with $2,360.361 million in fiscal year 2008. SAMHSA requested a total of $2,360.4 million for drug control activities, which is a reduction of $82.1 million from 2007 level. The resources of SAMHSA are directed to activities that have demonstrated improved health outcomes and increased capacity and terminations or reduce less effective or redundant activities. SAMHSA has four major drug-related decision units: Substance Abuse Prevention Programs of Regional and National Significance (PRNS), Substance Abuse Treatment PRNS, the Substance Abuse Treatment Prevention and Treatment Block Grant, and Program Management.

The Department of Homeland Security, with various departments including Customs and Border Protection, with a budget of $1,970.345 billion, immigration and customs enforcement with a budget of $450.198 million, and the United States Coast Guard with a budget of $1,073.193.

The Department of Justice includes the Bureau of Prisons with $67.156 million, the Drug Enforcement Administration with a budget of $2,041.818 million and the Interagency Crime and Drug Enforcement with a budget of $509.154 million, and the Office of Justice program $178.869 million.

The Office of National Control Policy with Counterdrug Technology Assessment Center has a budget of $5 million. The High Intensity Drug Trafficking Areas has a budget of $220.0 million and other federal drug control programs have a budget of $224.485 million.

Prevention Of Prescription Drug Abuse

Multiple actions taken to prevent or address theprescription drug abuse epidemic include the activities of Drug Enforcement Agency (DEA), prescription drug monitoring programs, multiple state regulations, education of all concerned, Synthetic Drug Control Strategy, the Food and Drug Administration's ability to classify and approve drugs, various prevention and treatment efforts, and proposed changes to controlled substance formulations.

DEA

In 2005, Congress emphasized its concern regarding the diversion of controlled pharmaceuticals (84). The House report on the Justice Department's fiscal year 2005 appropriations stated . . . "DEA has demonstrated a lack of effort to address this problem." Consequently the DEA increased the amount of resources and manpower dedicated to investigating the diversion of controlled pharmaceuticals (78). However, in a July 2006 Justice Department OIG's report, it was shown that while the DEA has taken important steps to improve its ability to control the diversion of controlled pharmaceuticals, especially pharmaceutical diversion using the internet, several shortcomings in the DEA's diversion control efforts that were identified and reported in 2002 still exist (84).

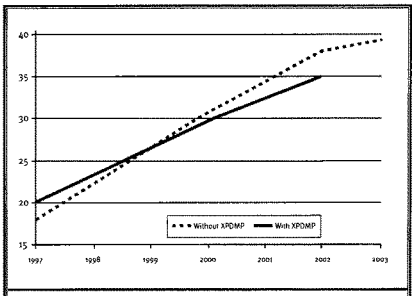


Fig. 16. *Pain reliever admissions in XPDMP states. Source: Ref (86).*

NASPER

The second major weapon against prescription drug abuse is the National All Schedules Prescription Electronic Reporting (NASPER) Act, signed into law on August 11, 2005 (25). It authorized the spending of $60 million from fiscal year 2006 to 2010 to create federal grants at the US Department of Health and Human Services to help establish or improve state-run prescription drug monitoring programs. Unfortunately NASPER has not moved as no funding has been committed either in 2006 or in 2007, in addition, there is no proposed funding in 2008.

DOJ PDMPs

The NASPER has been afflicted by the DEA and Harold Rogers sponsored, state monitoring programs that were initiated by the Department of Justice (DOJ) in 2003 to promote the development of prescription drug monitoring programs (PDMPs) by states. That commitment continues as part of the administration's National Drug Control Strategy for 2008, though incoherent and largely ineffective. PDMPs have the poten-

tial to help cut down on prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient's prescriptions for controlled substances as a goal. However, while these state programs have been useful, predominantly for law enforcement, their numerous deficiencies have not been corrected.

A recent evaluation (85) showed a modest 10% decrease in prescription drug use on a per capita basis (Fig. 16). Historically, 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 and 27 in 2006 (Table 7). With increased funding and resources, these programs have been able to improve the statistics of the DEA, however, have been a major failure in providing assistance to the prevention of drug abuse, educating physicians, or preventing doctor shopping and drug diversion. The fundamental flaw with these programs is that they are created to help law enforcement identify and prevent prescription drug diversion after the fact. The secondary objective of this program, to educate and provide information to physicians, pharmacies and the public has been neglected. Very few programs are proactive to the extent that physicians can access the necessary information to reduce or prevent abuse and diversion. Program design is highly variable across the states. Eighteen of the 27 state programs monitor Schedule IV drugs and 20 of the 27 monitor Schedule III drugs which are the subject of major controlled substance abuse. Of all the available programs, only 3 programs are physician friendly and work proactively.

Synthetic Drug Control Strategy

Among the proposed mechanisms to reduce prescription drug abuse, the Synthetic Drug Control Strategy has taken center stage for the Administration (86). The Administration touts that the Synthetic Drug Control Strategy aims to reduce prescription drug abuse in America by 15% over 3 years from 2005 to 2008. The Synthetic Drug Control Strategy seeks to address each specific method of diversion including doctor shopping or other prescription fraud, shipping illegal prescriptions from online pharmacies, over-prescribing, theft and burglary, selling pills to others, receiving pills at little or no cost from friends or family.

The illicit diversion and theft of pharmaceuticals-currently at very high levels nationally, from legitimate supplies has been curbed somewhat in some areas, such as Kentucky, Michigan, Nevada, and Utah, through education, sustained law enforcement pressure, reduced access in pharmacies and the implementation of prescription monitoring programs in 3 of the 4 states with proactive physician-friendly programs (29).

In addition, part of the Synthetic Drug Control Strategy includes changing controlled substance formulations. The use of newer pharmaceutical technology can help combat the problem of prescription drug abuse by using chemical advances to develop a tamper resistant capsule that provides long-acting effective pain relief when used properly, while also resisting degradations under conditions of abuse (87). Two new pain medications or formulations were developed; however, the issues related to the usefulness of new formulations is the cost of development and the ability to purchase these drugs in the market and coverage by insurers.

NIDA Strategies

National Institute on Drug Abuse (NIDA) (88) has orchestrated a multi-pronged strategy intending to complement and expand the portfolio of basic, preclinical, and clinical research aimed at better understanding prescription drug abuse. Consequently, the NIDA started an initiative on prescription opioid use and abuse in the "treatment of pain," which encourages a multidisciplinary approach using both human and animal studies from across the sciences to examine factors (including pain itself) that predispose or protect again opioid abuse and addiction. Particularly important, NIDA believes, is to assess how genetic influence affects the vulnerability of an individual exposed to pain medication to become addicted. In fact, the NIDA has conducted a seminar on prescription drug abuse, inviting predominantly supporters of opioids, without a balanced presentation, and the next day, released a program on addiction management rather than control of psychotherapeutic substance abuse.

The National Institute on Drug Abuse (26) published a study revealing a new cellular adaptation which contributes to opioid tolerance, another study testing URB597 which relieves pain in rats without cannabinoid-associated side effects, and the use of antidepressants in managing pain. While these are noble investigations and scientific advances that may help some day, in today's environment it will take years to achieve any benefit from this research.

Thus, this entire strategy has been suboptimal for the past 3 years at an expense of $38.77 billion for

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Table 7. The Bureau of Justice Assistance Prescription Drug Monitoring programs at a glance

State	Agency Housing the PDMP	Schedules of Drugs Monitored	Federal Award Amounts		
			FY03	FY04	FY05
Alabama	Department of Public Health	II, III, IV, V	$300,000	$350,000	$350,000
Arizona	Board of Pharmacy	**			$50,000
California	Department of Justice, Bureau of Narcotic Enforcement	II,III	$297,745		$350,000
Colorado	Department of Regulatory Agencies	II, III, IV, V		$50,000	
Connecticut	Department of Consumer Protection	**		$50,000	
Florida	Florida Office of Drug Control	**	$300,000		
Hawaii	Hawaii Department of Public Safety	II, III, IV, V		$349,350	$349,954
Idaho	Board of Pharmacy	II, III, IV	$97,320		
Illinois	Department of Health and Human Services	II			$349,994
Indiana	Indiana Professional Licensing Agency	II, III, IV, V		$281,876	$216,796
Iowa	Department of Public Health	**		$350,000	$292,963
Kansas	Board of Pharmacy	**		$50,000	
Kentucky	Cabinet for Health & Family Services, Office of the Inspector General	II, III, IV, V		$350,000	$350,000
Louisiana	Board of Pharmacy	**			$50,000
Maine	Office of Substance Abuse	II, III, IV	$300,000	$109,650	$339,164
Massachusetts	Massachusetts Department of Public Health	II		$350,000	$350,000
Michigan	Bureau of Health Professions	II, III, IV, V			$350,000
Mississippi	Board of Pharmacy	II, III, IV, V		$349,915	$350,000
Missouri	Department of Health and Senior Services	**			$350,000
Nevada	Board of Pharmacy	II, III, IV	$149,474	$344,581	$340,298
New Hampshire	Department of Justice	**			$49,836
New Jersey	Department of Law and Public Safety	**		$350,000	
New Mexico	Board of Pharmacy	II, III, IV	$245,650		
New York	New York Bureau of Narcotic Enforcement	II, III, IV, V	$300,000	$350,000	$350,000
North Carolina	Department of Health and Human Services	II, III, IV, V		$50,000	
Ohio	Board of Pharmacy	II, III, IV, V			$350,000
Oklahoma	Bureau of Narcotics and Dangerous Drugs	II		$350,000	$350,000
Oregon	Board of Pharmacy	**		$350,000	
Pennsylvania	Office of Attorney General	II		$350,000	
Rhode Island	Board of Pharmacy	II, III			
South Carolina	Department of Health and Environmental Control	**		$350,000	
Tennessee	Board of Pharmacy	II, III, IV, V		$50,000	$350,000
Texas	Department of Public Safety	II			
Utah	Department of Commerce, Division of Occupational & Provisional Licensing	II, III, IV, V			
Vermont	Department of Health	**			$350,000
Virginia	Board of Pharmacy	II		$82,300	$350,000
Washington	Disciplinary Board	Determined by disciplinary authority		$50,000	
West Virginia	Board of Pharmacy	II, III, IV		$350,000	$124,459
Wyoming	Board of Pharmacy	II, III, IV	$214,529		

***These states do not currently have legislation or regulation to establish a PDMP in place.*
Source: Ref (86)

2005-2006 and 2007 with a proposed expenditure of 12.961 billion for 2008. The failure of this strategy is illustrated by the staggering statistics of drug abuse, misuse, illicit drug use, emergency department visits, and deaths in face of escalating costs.

Education

Education is lacking at all levels primarily for physicians, pharmacists, and the public at large (5,89) and compounded by misinformation. Of 979 physicians surveyed regarding the diversion and abuse of controlled prescription drugs showed the following (5):

Physicians

- Physicians perceive the 3 main mechanisms of diversion to be:
  - Doctor shopping (when patients obtain controlled drugs from multiple doctors) (96%)
  - Patient deception or manipulation of doctors (88%)
  - Forged or altered prescriptions (69%).
- 59% believe that patients account for the bulk of the diversion problem.
- 47% said that patients often try to pressure them into prescribing a controlled drug.
- Only 19% of surveyed physicians received any medical school training in identifying prescription drug diversion.
- Only 40% of surveyed physicians received any training in medical school in identifying prescription drug abuse and addiction.
- 43% of physicians do not ask about prescription drug abuse when taking a patient's health history.
- One-third of physicians do not regularly call or obtain records from the patient's previous (or other treating) physician before prescribing controlled drugs on a long-term basis. HIPAA regulations have made this step much more difficult.
- 74% have refrained from prescribing controlled drugs during the past 12 months because of concern that a patient might become addicted to them.

In a recent study (89) based on questionnaire responses from 248 primary care physicians, published results showed that the most common concerns about prescribing opioids for chronic pain were prescription drug abuse and addiction. Other concerns included: adverse effects, tolerance, interaction with other medications, not knowing enough about which narcotic to prescribe, not knowing enough about dosage requirements, and having partners who prefer not to use opioids for treating chronic pain. The majority of the physicians were comfortable in prescribing narcotics to someone with terminal cancer but less confident in prescribing for patients with back pain. They were even less comfortable with prescribing narcotics to patients with a past history of drug or alcohol abuse. The survey also noted that only a small percentage of physicians are conducting urine toxicology screens on their patients either before or during opioid therapy, and that this was dependent on whether or not they had a system to track patients on opioids.

In two prospective evaluations of 500 patients in each study (34,43) with enhanced monitoring, it was shown that overall prescription controlled drug abuse reduced from 18% to 9%; whereas illicit drug use reduced from 22% to 16%. Significant decreases were observed in Medicaid patients.

Van Rooyan (90) described physician education as follows:

- The majority of physicians do not know that the long-term safety and effectiveness of opioids for management of non-malignant pain have *not* been substantiated.
- The majority of physicians do not know that patients seeking pain relief for chronic, non-malignant pain often have underlying psycho-social problems and need psychological or rehabilitation services or would respond well to other non-drug interventions.
- In busy medical practices, particularly primary care and family practice office settings, often, pain therapy is based not on science, but on intuition or hearsay, and ends up aggravating rather than ameliorating prescription pain medication abuse and addiction.
- Expansion of opioid therapy for patients who might benefit more from non-drug interventions or alternate drugs, without consideration of the accompanying risks of opioids, is based on pharmaceutical promotion.

Pharmacists fear of being labeled opiophobic by opioid and advocacy lobby.

The CASA survey (5) of 1,303 pharmacists regarding diversion and abuse of controlled prescription drugs showed the following:

- When a patient presents a prescription for a controlled drug:
  - 78% of pharmacists become "somewhat or very" concerned about diversion or abuse when a patient asks for a controlled drug by its brand name;
  - 27% "somewhat or very often" think it is for purposes of diversion or abuse.

- 52% believe that patients account for the bulk of the diversion problem.
- Only about half of the pharmacists surveyed received any training in identifying prescription drug diversion (48%) or abuse or addiction (50%) since pharmacy school.
- 61% do not regularly ask if the patient is taking any other controlled drugs when dispensing a controlled medication; 25.8% rarely or never do so.
- 29% have experienced a theft or robbery of controlled drugs at their pharmacy within the last 5 years; 20.9% do not stock certain controlled drugs in order to prevent diversion.
- 25% do not regularly validate the prescribing physician's DEA number when dispensing controlled drugs; 1 in 10 (10.5%) rarely or never do so.
- 83% have refused to dispense a controlled drug in the past year because of suspicions of diversion or abuse.

Pharmacists may be involved in prescription drug diversion, first by selling the controlled substances and then, using their database of physicians and patients to write and forge prescriptions to cover their illegal sale.

Patients

Patients also have many concerns about the lack of eduction. The problem list is long and extensive. A non-inclusive list is a follows:

- Undertreatment of pain.
- All patients are under suspicion.
- The interest in receiving opioids for chronic pain, fueled by advertising by pharmaceutical companies.
- Unproven, misunderstood regulations of JCAHO and other organizations mandating monitoring and appropriate treatment of pain.
- Media coverage of undertreatment of pain.
- Numerous organizations providing advocacy guidelines and standards.
- Patient advocacy groups advising them to demand more opioids.
- Very little or no effort on educating the public about non-opioid management.
- Access to Internet and a daily bombardment of the easy availability of drugs.
- Patient beliefs that they have the right to total pain relief.
- The lack of interest on behalf of the patients to understand deleterious effects of opioids and benefits of non-opioid techniques.

Solutions to Drug Abuse Epidemic

A revised national drug control strategy with a 3-pronged approach is essential in combating the epidemic of prescription drug abuse with immediate implementation of NASPER with enhancements; widespread educational programs for physicians, pharmacists, and the general public emphasizing the deleterious effects of controlled substance use and abuse; and implementation of Synthetic Drug Control Strategy along with multiple other programs.

NASPER

The National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005 is a law that provides for the establishment of a controlled substance monitoring program in each state, with communication between state programs (25). The concept for the NASPER was provided by the American Society of Interventional Pain Physicians (ASIPP) whose members and leadership saw such a need for the information exchange program. NASPER was formulator with 3 important goals including:

1) Physicians' and pharmacists' access to monitoring programs
2) Monitoring of Schedule II to IV drugs
3) Information sharing across state lines

Consequently, the purpose of NASPER is to: 1) foster the establishment of state-administered controlled substance monitoring systems in order to ensure that healthcare providers have timely access to accurate prescription history information for use in the early identification of patients at risk of addiction or diversion in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and (2) Establish, based on the experience of existing state-controlled substance monitoring programs, a set of best practices to guide the establishment of new state programs and the improvement of existing programs. NASPER is modeled after a highly successful states monitoring program in Kentucky (Kentucky All Schedules Prescription Electronic Reporting Action - KASPER). In fact, the US Government Accountability Office (GAO) conducted a study on state monitoring programs of prescription drugs (91). They concluded that state monitoring programs provide a useful tool to reduce diversion while most state programs have their major goal to assist law enforcement in identifying and preventing prescription drug diversion. State programs may include educational objectives to pro-

vide information to physicians, pharmacies, and the public. The programs are highly variable not only with monitoring of scheduled substances but with regulations and finally access to providers which is only available in 4 states – Utah, Nevada, Kentucky and Idaho. Thus, only a few programs operate proactively, while most operate reactively. A few states routinely analyze prescription data collected by PDMPs to identify individuals, physicians, or pharmacies that have unusual use, prescribing, or dispensing patterns that may suggest potential drug diversion, abuse, or doctor shopping. However, only three states provide this information proactively to physicians.

The GAO report (91) cited many advantages, as well as disadvantages of these programs. States with PDMPs experience 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. However, while the presence of a PDMP may help one state reduce its illegal drug diversion, diversion activities may actually increase in contiguous states without PDMPs. All 3 of the states providing access to physicians – Kentucky, Nevada, and Utah – help reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increasing number of PDMPs reports are being used by physicians to check the prescription drug utilization history of current and prospective patients to determine whether it is necessary to prescribe certain drugs that are subject to abuse. As expected, most of the reports were requested by prescribers with 87%, followed by law enforcement 6%, pharmacists 4%, life insurer boards 2%, by subpoena, ARNPs, and court orders with 1% or less each (Fig. 17).

In fact, prospective evaluations (34,43) in interventional pain management settings have shown a significant reduction in drug abuse and illicit drug use in chronic pain patients when appropriately monitored and educated (Table 8). The reductions were seen across all patient groups, specifically Medicaid patients.

Further, an evaluation of prescription drug monitoring programs performed on September 1, 2006 (86) showed that PDMPs reduce the per capita supply of prescription pain relievers and stimulants and in so doing reduce the probability of abuse of these drugs. Evidence also suggested that states which are proactive in the approach to regulation are more effective in reducing the per capita supply of prescription pain relievers and stimulants than states which are reactive in their approach to regulation.

The illicit diversion and theft of pharmaceuticals-currently at very high levels nationally, from legitimate supplies have been curbed somewhat in some areas, such as Kentucky, Michigan, Nevada, and Utah, through education, sustained law enforcement pressure, reduced access in pharmacies, and the implementation of prescription monitoring programs, in 3 of the 4 states with proactive physician friendly programs (29).

In conclusion, prescription monitoring programs are effective specifically when they are proactive. Thus, a national program with communication among the states that is also proactive assisting physicians to prevent abuse of drugs in conjunction with education

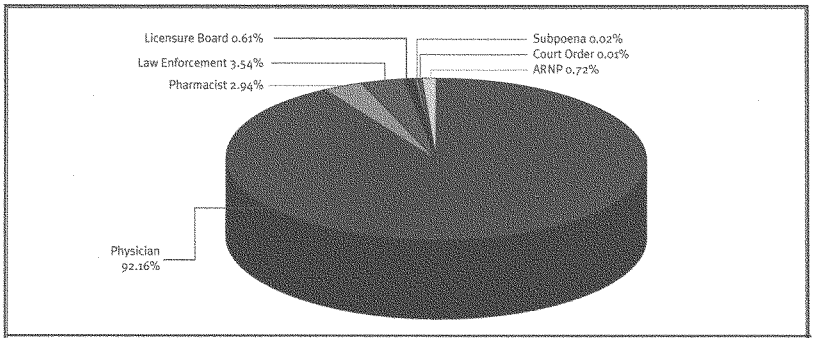

Fig. 17. *KASPER report requests 2005.*

Table 8. *Comparative evaluation of illicit drug use*

	Third party		Medicare w/wo third party		Medicare & Medicaid		Medicaid		Total	
	Present study (192)	Previous study (100)	Present study (154)	Previous study (100)	Present study (85)	Previous study (100)	Present study (69)	Previous study (100)	Present study (500)	Previous study (400)
Marijuana	14%* (26)	11% (11)	5% (7)	8% (8)	12%* (10)	20% (20)	16%*# (11)	34% (34)	11% # (54)	18% (73)
95% CI	9% - 12%	5% - 17%	2% - 9%	3% - 11%	5% - 21%	12% - 28%	8% - 27%	25% - 43%	8% - 14%	14% - 22%
Cocaine	6%* (11)	7% (7)	1% (2)	4% (4)	8%* (7)	6% (6)	6% (4)	8% (8)	5% (24)	6% (25)
95% CI	2% - 10%	2% - 12%	0% - 5%	0% - 8%	3% - 16%	1% - 11%	1% -15%	3% - 13%	3% - 7%	4% - 9%
Methamphetamine/ Amphetamines	4% (8)	3% (3)	1% (1)	2% (2)	1% (1)	4% (4)	1% (2)	3% (3)	2% (11)	3% (12)
95% CI	1% - 8%	0% - 6%	0% - 4%	0% - 5%	0% - 6%	0% - 8%	0% - 8%	0% - 6%	1% -4%	1% - 5%
Total Abuse	20%* (38)	17% (17)	6% (9)	10% (10)	21%* (18)	24% (24)	22%*# (15)	39% (39)	16% # (80)	22% (90)
95% CI	14% - 26%	10% - 24%	2% - 11%	4% - 6%	13% - 31%	16% - 32%	12% - 33%	29% - 49%	13% - 20%	18% - 27%

( ) Number of patients
* Indicates significant difference with Medicare with or without third party insurance
# Indicates significant difference with previous study (within the same insurance group)
Reproduced with permission from: Manchikanti et al (34, 43).

will probably reduce per capita prescription controlled substance use and abuse by 20%.

Enhanced NASPER should also include prescription controlled drug committees at State Health and Human Services Departments, Boards of Medical Licensures, and local Drug Enforcement Agencies. Further, each committees should be represented by at least one or more of interventional pain physicians well versed with opioid abuse.

Thus, funding and implementation of NASPER is a fundamental requirement for controlling the prescription drug abuse epidemic.

Education

Education is required at all levels including physicians, pharmacists, and public. Education is important to understand the functions and the role of the DEA, the functions and role of monitoring programs, the appropriate prescription of opioids, deleterious effects of opioid use and abuse, and the management of chronic pain with non-opioid techniques.

Physicians

Surveys have shown that less than 40% of physicians have received any training in medical school in identifying prescription drug abuse or drug diversion. The ONDCP as planned should organize several events to facilitate the dissemination of pain and addiction information to the general medical community (85). Representatives of the medical and pharmaceutical communities should be called together to develop concerted and effective strategy of change to address this public health problem. This should encourage medical professionals, pharmacists, and pharmaceutical companies to take a leading role in educating physicians and patients as to the importance of retaining control of prescription medications with abuse liability. The educational efforts should reach not only the people who are preaching to the community, resulting in increases in drug abuse, but also to all the physicians in every corner of the United States, specifically persons with balanced approach.

Consequently, controlled substance education must be mandated in medical schools, residency training programs, and supported by continuing education each year, variable from 20 hours in the first year and 10 hours in subsequent years. The training must be accredited and approved and may be monitored mainly by the DEA or state boards of medical licensures. Finally, a separate residency program is needed and must

be instituted in the near future in interventional pain management, which will not only train the physicians about comprehensive programs and other modalities of treatments than narcotics, but also will provide appropriate safety training and guidelines. In addition, an ABMS-approved specialty board certification for interventional pain management will facilitate long-term solutions to the problems of escalating use of controlled substance use and abuse.

Pharmacists

Controlled substance education must be mandated in pharmacy schools and training programs, which also should be supported by continuing education each year, variable from 20 hours in the first year and 10 hours in subsequent years. The training must be accredited and approved and may be monitored mainly by the DEA or State Boards of Pharmacy.

Education for pharmacists is also extremely crucial. Based on the CASA survey (5), only 50% of pharmacists receive any training in identifying prescription drug diversion, abuse, or addiction.

Public

The most important aspect of the training is for the public. The public must be educated on non-opiate techniques of chronic pain management. In addition, the public should be educated about the overall ineffectiveness of opioid use, prevalence of misuse and adverse effects, even if used properly. Further, public education should include youth and family education, prevention strategies specific for people with access to controlled prescription drugs with media campaigns, community coalitions, drug-free America, prescription drug tracking, prevention and intervention by biometric identification at various levels, students and employees, etc.; screening, brief intervention, referral and treatment.

Synthetic Drug Control Strategy and Coordination

Finally, the third prong relates to synthetic drug control strategy and coordination of efforts by agencies. There are more than 10 federal agencies and approximately 5 to 6 agencies in each state, followed by local agencies attempting to curb the drug epidemic. Each organization functions in its own way coupling or tripling the efforts and sometimes interfering with each other.

In summary, Congress and the Administration must proceed in a direction which is not only effective but well coordinated without hindering access. These efforts include the understanding of the monitoring programs, education, a proactive DEA, elimination of Internet pharmacies, development of abuse resistant prescriptions, monitoring of methadone clinics, improved labeling, and evidence-based prescribing guidelines. The major efforts should be directed to uncontrolled methadone clinics, limiting them to treat and manage only heroin addicts, with an emphasis on prevention addiction by substituting high dose methadone for low dose hydrocodone with the addition of reporting requirements. The next step is addiction management and availability of these treatment modalities on an outpatient basis to as many patients as possible such as wide spread training for buprenorphine administration.

The federal government must take a lead in preventing this epidemic by useful and effective programs rather than ineffective and incoordinated programs.

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References

1. Califano JA. Califano calls for fundamental shift in attitudes and policies about substance abuse and addiction. The National Center on Addiction and Substance Abuse at Columbia University (CASA), May 7, 2007.
2. Califano JA. *High Society: How Substance Abuse Ravages American and What to Do About It*. Perseus Publishing, New York, 2007.
3. Kuehn BM. Opioid prescriptions soar: increase in legitimate use as well as abuse. *JAMA* 2007; 297:249-251.
4. Manchikanti L. Prescription drug abuse: What is being done to address this new drug epidemic? Testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. *Pain Physician* 2006; 9:287-321.
5. Bollinger LC, Bush C, Califano JA, Chenault KI, Curtis JL, Dimon J, Dolan PR, Ganzi VF, Fisher M, Kelmenson LA, Keough DR, Kessler DA, Malloy EA, Pacheco MT, Plumeri II JJ, Redstone SE, Rosenwald Jr EJ, Schulhof MP, Sullivan LW, Sweeney JJ, Wiener MA. Under the counter. The diversion and abuse of controlled prescription drugs in the U.S. The National Center on Addiction and Substance Abuse at Columbia University (CASA), July 2005.
6. Substance Abuse and Mental Health Services Administration. (2006). Results from the 2005 National Survey on Drug Use and Health: National Findings. (Office of Applied Studies, NSDUH Series H-30, DHHS Publication No. SMA 06-4194). Rockville, MD. www.oas.samhsa.gov/nsduh/2k5nsduh/2k5Results.pdf
7. Substance Abuse and Mental Health Services Administration. (2005). *Over-*

view of Findings from the 2004 National Survey on Drug Use and Health (Office of Applied Studies, NSDUH Series H-27, DHHS Publication No. SMA 05-4061). Rockville, MD. oas.samhsa.gov/NSDUH/2k4NSDUH/2k4Overview/2k4Overview.pdf

8. Substance Abuse and Mental Health Services Administration. (2004). *Overview of Findings from the 2003 National Survey on Drug Use and Health* (Office of Applied Studies, NSDUH Series H-24, DHHS Publication No. SMA 04-3963). Rockville, MD. oas.samhsa.gov/NHSDA/2k3NSDUH/2k3OverviewW.pdf
9. Substance Abuse and Mental Health Services Administration. (2003). *Overview of Findings from the 2002 National Survey on Drug Use and Health* (Office of Applied Studies, NSDUH Series H-21, DHHS Publication No. SMA 03-3774). Rockville, MD. oas.samhsa.gov/NHSDA/2k2NSDUH/2k2SoFOverviewW.pdf
10. Substance Abuse and Mental Health Services Administration. (2002). *Results from the 2001 National Household Survey on Drug Abuse: Volume I. Summary of National Findings* (Office of Applied Studies, NHSDA Series H-17, DHHS Publication No. SMA 02-3758). Rockville, MD. oas.samhsa.gov/nhsda/2k1nhsda/PDF/cover.pdf
11. Drug Abuse Warning Network, 2005: National Estimates of Drug-Related Emergency Department Visits. DAWN Series D-29, DHHS Publication No. (SMA) 07-4256, Rockville, MD, March 2007. https://dawninfo.samhsa.gov/pubs/edpubs/default.asp
12. Drug Abuse Warning Network, 2004: National Estimates of Drug-Related Emergency Department Visits DAWN Series D-28, DHHS Publication No. (SMA) 06-4143, Rockville, MD, April 2006. https://dawninfo.samhsa.gov/pubs/edpubs/default.asp
13. Drug Abuse Warning Network, 2003: Interim National Estimates of Drug-related Emergency Department Visits DAWN Series D-26, DHHS Publication No. (SMA) 04-3972, Rockville, MD, December 2004. https://dawninfo.samhsa.gov/pubs/edpubs/default.asp
14. US Department of Health and Human Services. Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA). Drug Abuse Warning Network. *The DAWN Report. Narcotic analgesics, 2002 update.* September 2004.
15. US Department of Health and Human Services. Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA). Drug Abuse Warning Network. *The DAWN Report. Benzodiazepines in drug abuse-related emergency department visits: 1995-2002.* April 2004.
16. Paulozzi LJ, Budnitz DS, Yongli X. Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Saf* 2006; 15:618-627.
17. Paulozzi L. *Unintentional poisoning deaths – United States, 1999-2004.* Centers for Disease Control and Prevention. *MMWR Morb Mortal Wkly Rep* 2007; 56:93-96 (www.cdc.gov/mmwr/preview/mmwrhtml/mm5605a1.htm).
18. U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies. Methadone-Associated Mortality: Report of a National Assessment. dpt.samhsa.gov/reports/index.htm.
19. Fingerhut LA. Increases in methadone-related deaths: 1999--2004. Health E-Stats. Hyattsville, MD: National Center for Health Statistics; 2006. www.cdc.gov/nchs/products/pubs/pubd/hestats/methadone1999-04/methadone1999-04.htm.
20. Centers for Disease Control and Prevention (CDC). Unintentional and undetermined poisoning deaths ---11 states, 1990—2001. *MMWR Morb Mortal Wkly Rep* 2004; 53:233-238.
21. Office of National Drug Control Policy. The President's National Drug Control Strategy. February 2006. www.whitehousedrugpolicy.gov/publications/policy/ndcs06/ndcs06.pdf
22. Office of National Drug Control Policy. White House Releases National Plan to Combat Drug Use in America. February 9, 2007. www.whitehousedrugpolicy.gov/NEWS/press07/020907.html
23. Office of National Drug Control Policy. FY 2008 drug control budget. February 2007. www.whitehousedrugpolicy.gov/publications/pdf/bdgt_hghlght_07.pdf
24. Manchikanti L, Brown KR, Singh V. National All Schedules Prescription Electronic Reporting Act NASPER: Balancing substance abuse and medical necessity in interventional pain management. *Pain Physician* 2002; 5:294-319.
25. Manchikanti L, Whitfield E, Pallone F. Evolution of the National All Schedules Prescription Electronic Reporting Act (NASPER): A public law for balancing treatment of pain and drug abuse and diversion. *Pain Physician* 2005; 8:335-347.
26. National Institute on Drug Abuse. Pain, opioids and addiction. *NewsScan NIDA Addiction Research News.* March 5, 2007.
27. The National Center on Addiction and Substance Abuse. "You've got drugs!" Prescription drug pushers on the internet. 2006 Update. A CASA* White Paper. June 2006. www.casacolumbia.org/pdshopprov/files/you_ve_got_drugs.pdf
28. White House Office of National Drug Control Policy – April Recess Kit. *Prescription Drugs: An Emerging Threat.* www.whitehousedrugpolicy.gov.
29. National Drug Intelligence Center U.S. Department of Justice. National Drug Threat Assessment 2007. Product No. 2006-Q0317-003. October 2006.
30. Trescot AM, Boswell MV, Atluri SL, Hansen HC, Deer TR, Abdi S, Jasper JF, Singh V, Jordan AE, Johnson BW, Cicala RS, Dunbar EE, Helm II S, Varley KG, Suchdev PK, Swicegood JR, Calodney AK, Ogoke BA, Minore WS, Manchikanti L. Opioid guidelines in the management of chronic non-cancer pain. *Pain Physician* 2006; 9:1-40.
31. Manchikanti L, Damron KS, McManus CD, Barnhill RC. Patterns of illicit drug use and opioid abuse in patients with chronic pain at initial evaluation: A prospective, observational study. *Pain Physician* 2004; 7:431-437.
32. Fishbain DA, Rosomoff HL, Rosomoff RS. Drug abuse, dependence, and addiction in chronic pain patients. *Clin J Pain* 1992; 8:77-85.
33. Manchikanti L, Pampati V, Damron KS, Beyer CD, Barnhill RC, Fellows B. Prevalence of prescription drug abuse and dependency in patients with chronic pain in western Kentucky. *J KY Med Assoc* 2003; 101:511-517.
34. Manchikanti L, Damron KS, Pampati V, McManus CD. Prevalence of illicit drug use among individuals with chronic pain in the Commonwealth of Kentucky: An evaluation of patterns and trends. *J Ky Med Assoc* 2005; 103:55-62.
35. Manchikanti L, Damron KS, Beyer CD, Pampati V. A comparative evaluation of illicit drug use in patients with or without controlled substance abuse in interventional pain management. *Pain Physician* 2003; 6:281-285.
36. Manchikanti L, Pampati V, Damron KS,

Beyer CD, Barnhill RC. Prevalence of illicit drug use in patients without controlled substance abuse in interventional pain management. *Pain Physician* 2003; 6:173-178.

37. Manchikanti L, Manchukonda R, Pampati V, Damron KS, Brandon DE, Cash KA, McManus CD. Does random urine drug testing reduce illicit drug use in chronic pain patients receiving opioids? *Pain Physician* 2006; 9:123-129.
38. Vaglienti RM, Huber SJ, Noel KR, Johnstone RE. Misuse of prescribed controlled substances defined by urinalysis. *W V Med J* 2003; 99:67-70.
39. Katz NP, Sherburne S, Beach M, Rose RJ, Vielguth J, Bradley J, Fanciullo GJ. Behavioral monitoring and urine toxicology testing in patients receiving long-term opioid therapy. *Anesth Analg* 2003; 97:1097-1102.
40. Passik SD, Kirsh KL, McDonald MV, Ahn S, Russak SM, Martin L, Rosenfeld B, Breitbart WS, Portenoy RK. A pilot survey of aberrant drug-taking attitudes and behaviors in samples of cancer and AIDS patients. *J Pain Symptom Manage* 2000; 19:274-286.
41. Michna E, Jamison RN, Pham LD, Ross EL, Nedeljkovic SS, Narang S, Palombi D, Wasan AD. Urine toxicology screening among chronic pain patients on opioid therapy: Frequency and predictability of abnormal findings. *Clin J Pain* 2007; 23:173-179.
42. Manchikanti L, Damron KS, Pampati V, MCManus CD, Weaver SE. Prospective evaluation of patients with increasing opiate needs: Prescription opiate abuse and illicit drug use. *Pain Physician* 2004; 7:339-344.
43. Manchikanti L, Cash KA, Damron KS, Manchukonda R, Pampati V, McManus CD. Controlled substance abuse and illicit drug use in chronic pain patients: An evaluation of multiple variables. *Pain Physician* 2006; 9:215-226.
44. Manchikanti L, Giordano J, Fellows B, Manchukonda R, Pampati V. Psychological factors as predictors of opioid abuse and illicit drug use in chronic pain patients. *J Opioid Manage* 2007; 3: 89-100.
45. Ives TJ, Chelminski PR, Hammett-Stabler CA, Malone RM, Perhac JS, Potisek NM, Shilliday BB, DeWalt DA, Pignone MP. Predictors of opioid misuse in patients with chronic pain: a prospective cohort study. BMC Health Serv Res 2006: 6:46.
46. Manchikanti L, Manchukonda R, Pampati V, Damron KS. Evaluation of abuse of prescription and illicit drugs in chronic pain patients receiving short-acting (hydrocodone) or long-acting (methadone) opioids. *Pain Physician* 2005; 8:257-261.
47. Manchikanti L, Pampati V, Damron KS, McManus CD. Evaluation of variables in illicit drug use: Does a controlled substance abuse screening tool identify illicit drug use? *Pain Physician* 2004; 7:71-75.
48. Manchikanti L, Manchukonda R, Damron KS, Brandon D, McManus CD, Cash KA. Does adherence monitoring reduce controlled substance abuse in chronic pain patients? *Pain Physician* 2006; 9:57-60.
49. Martell BA, O'Connor PG, Kerns RD, Beck WC, Morales KH, Kosten TR, Fiellen DA. Systematic review: Opioid treatment for chronic back pain: Prevalence, efficacy, and association with addiction. *Ann Intern Med* 2007; 146:116-127.
50. Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (April 6, 2007). *The NSDUH Report: Patterns and Trends in Nonmedical Prescription Pain Reliever Use: 2002 to 2005*. Rockville, MD.
51. Office of National Drug Control Policy Executive Office of the President. Teens and prescription drugs. An analysis of recent trends on the emerging drug threat. February 2007. www.theantidrug.com/pdfs/TEENS_AND_PRESCRIPTION_DRUGS.pdf
52. Monitoring the Future (MTF), National Institute on Drug Abuse (NIDA). 2006. URL: www.monitoringthefuture.org/pubs/monographs/overview2006.pdf
53. Partnership for a Drug-Free American, The Partnership Attitude Tracking Study (PATS): Teens in grades 7 through 12, 2005. May 16, 2006. URL: *www.drugfree.org/Files/Full_Teen_Report*
54. Boyd CJ, McCabe SE, Cranford JA, Young A. Adolescents' motivations to abuse prescription medications. *Pediatrics* 2006; 118:2472-2480.
55. Friedman RA. The changing face of teenage drug abuse – the trend toward prescription drugs. *N Engl J Med* 2006; 354:1448-1450.
56. Gureje O, Von Korff M, Simon GE, Gater R. Persistent pain and well-being: A World Health Organization study in primary care. *JAMA* 1998; 280:147-151.
57. Federation of State Medical Boards of the United States, Inc. Model Policy for the Use of Controlled Substances for the Treatment of Pain. May 2004.
58. Bennett DS, Simon S, Brennan M, Shoemaker SA. Prevalence and characteristics of breakthrough pain in patients receiving opioids for chronic back pain in pain specialty clinics. *J Opioid Manage* 2007; 3:101-106.
59. Davstad I, Stenbacka M, Leifman A, Beck O, Korkmaz S, Romelsjo A. Patterns of illicit drug use and retention in a methadone program: a longitudinal study. *J Opioid Manag* 2007; 3:27-34.
60. Havens JR, Oser CB, Leukefeld CG. Increasing prevalence of prescription opiate misuse over time among rural probationers. *J Opioid Manage* 2007; 3:107-112.
61. Chou R, Clark E, Helfand M. Comparative efficacy and safety of long-acting oral opioids for chronic non-cancer pain: A systematic review. *J Pain Symptom Manage* 2003; 26:1026-1048.
62. Kalso E, Edwards JE, Moore RA, McQuay HJ. Opioids in chronic non-cancer pain: Systematic review of efficacy and safety. *Pain* 2004; 112:372-380.
63. Ballantyne JC, Mao J. Opioid therapy for chronic pain. *N Engl J Med* 2003; 349:1943-1953.
64. Bloodworth D. Issues in opioid management. *Am J Phys Med Rehabil* 2005; 84: S42-S55.
65. Furlan AD, Sandoval JA, Mailis-Gagnon A, Tunks E. Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects. *Can Med Assoc J* 2006; 174:1589-1594.
66. Ballantyne JC. Opioid analgesia: Perspectives on right use and utility. *Pain Physician* 2007; 3:479-492.
67. Eriksen J, Sjogren P, Bruera E, Ekholm O, Rasmussen NK. Critical issues on opioids in chronic non-cancer pain. An epidemiological study. *Pain* 2006; 125:172-179.
68. www.deadiversion.usdoj.gov/arcos
69. CDC. Web-based Injury Statistics Query and Reporting System (WISQARS) [Online]. Available at www.cdc.gov/ncipc/wisqars.
70. Kraman P. Drug abuse in America – prescription drug diversion. The Council of State Governments. April 2004. www.csg.org.
71. Alford R. Arrests of Elderly Rising in Prescription Drug Sales. The Associated Press, December 13, 2005.
72. US General Accounting Office. *Internet Pharmacies: Adding Disclosure Would Aid State and Federal Oversight*, GAO Publication No. GAO-01-69, October 2000, 3.
73. Cole N. "Rx Roulette on the Internet." Wall Street Journal, June 17, 2004, p

A18.

74. Caywood T. "Online Drug Buying Can Turn Into a Nasty Habit; Deals are Illegal, Dangerous," *The Boston Herald*, 14 December 2003, sec. news.
75. Drug Enforcement Administration and the National Alliance for Model State Drug Laws, *A Closer Look at State Prescription Monitoring Programs* (www.deadiversion.usdoj.gov/pubs/program/prescription-monitor/summary.htm
76. ComScore study www.comscore.com/press/release.asp?press=571.
77. Kentucky All Schedule Prescription Electronic Reporting (KASPER). A Comprehensive Report on Kentucky's Prescription Monitoring Program Prepared by the Cabinet for Health and Family Services Office of the Inspector General, Version 1 – 3/29/2006. chfs.ky.gov/NR/rdonlyres/2D46AB2E-FAE8-43DC-9CE6-6BB4B419918F/0/AComprehensiveSummaryofKASPERDraft.pdf
78. Testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, U.S. Department Of Justice, Before the Subcommittee On Criminal Justice, Drug Policy and Human Resources, July 26, 2006
79. Warner EA, Friedmann PD. Laboratory testing for drug abuse. *Arch Pediatr Adolesc Med* 2006; 160:854.
80. Lubell J. VA doctors to report controlled substances. Program targets drugs with high potential for abuse, e.g., Oxycontin, Percocet. *Mod Healthc* 2006; 36:32.
81. Havens JR, Talbert JC, Walker R, Leedham C, Leukefeld CG. Trends in controlled-release oxycodone (OxyContin) prescribing among Medicaid recipients in Kentucky, 1998-2002. *J Rural Health* 2006; 22:276-278.
82. Forman RF, Woody GE, McLellan T, Lynch KG. The availability of web sites offering to sell opioid medications without prescriptions. *Am J Psychiatry* 2006; 163:1233-1238.
83. Rivera JM, Locketz AJ, Fritz KD, Horlocker TT, Lewallen DG, Prasad A, Bresnahan JF, Kinney MO. "Broken heart syndrome" after separation (from OxyContin). *Mayo Clin Proc* 2006; 81:825-828.
84. US Department of Justice Office of the Inspector General Evaluation and Inspections Division. Follow Up Review of the Drug Enforcement Administration's Efforts To Control The Diversion Of Controlled Pharmaceuticals. July 2006.
85. Simeone R, Holland L. An evaluation of prescription drug monitoring programs. September 1, 2006. www.ojp.usdoj.gov/BJA/pdf/PDMPExecSumm.pdf
86. Testimony of Bertha K. Madras, MD, Deputy Director, Demand Reduction Office Of National Drug Control Policy Before The Subcommittee on Criminal Justice, Drug Policy and Human Resources, July 26, 2006.
87. Testimony of Stephen E. Johnson, Executive Director, Commercial Planning Pain Therapeutics, Inc. Before The Subcommittee on Criminal Justice, Drug Policy And Human Resources, July 26, 2006.
88. Testimony of Nora D. Volkow, M.D., Director, National Institute On Drug Abuse, National Institutes Of Health, U.S. Department Of Health And Human Services, Before The Subcommittee On Criminal Justice, Drug Policy, And Human Resources Committee, July 26, 2006.
89. Bhamb B, Brown D, Hariharan J, Anderson J, Balousek S, Fleming MF. Survey of select practice behaviors by primary care physicians on the use of opioids for chronic pain. *Curr Med Res Opin* 2006; 22:1859-1865.
90. Testimony of Barbara Van Rooyan Before The Subcommittee On Criminal Justice, Drug Policy And Human Resources, July 26, 2006.
91. GAO Report. GAO-02-634 Prescription drugs. State monitoring programs provide useful tool to reduce diversion. May 2002.

Mr. STUPAK. Thank you, and I will note you had presented longer testimony, and some of it was a paper done by Dr. Laxmaiah Manchikanti.

Dr. TRESCOT. Manchikanti, yes, sir. And that is available in your packets. That has been published and available on the Web as well.

Mr. STUPAK. Right, and then that will be included in the record. But I know with the great frustration that our witnesses on the previous panel from CDC and SAMHSA, officials did not stay to listen to your testimony. I wish they would have, and I would like to send them a copy of your testimony and a copy of the pill mill tape that you did, you shot last week, you said.

Dr. TRESCOT. Yes, sir.

Mr. STUPAK. And so, could you send the committee a copy of that tape? We would really like to see it.

Dr. TRESCOT. I can actually provide—CBS Evening News did one actually of Texas, which I was asked to comment on, on air. The surveillance that I described is on a case that is currently ongoing, and certainly as soon as that case has adjudicated I am sure that we would be glad to provide that. Unfortunately, because that case is——

Mr. STUPAK. Ongoing.

Dr. TRESCOT. That organization is actually currently being investigated. I am not at liberty to release that information.

Mr. STUPAK. When it is, and when you can, if you would, please provide the committee.

Dr. TRESCOT. I will do the best of my ability.

Mr. STUPAK. It is a great learning tool. Now, one of the things that, and having practiced medicine I am sure you are well aware of it, we have seen, and it seems like I always hear stories every week, that all they did for a senior citizen was change their medication when they went to the hospital, or the medication being received from their family physician and what they received in the hospital was counteractive to the illness or the disease they are trying to prevent. Would NASPER help change that or get better outcomes here? It seems like we are prescribing, multiple doctors prescribe multiple medications, which does not really help out the patient at times.

Dr. TRESCOT. That is absolutely a huge problem. Many patients now are treated at the hospital by a hospitalist and now their family doctor, and there is often a delay in getting the information from the hospital back to the primary care physician, and unfortunately patients in general don't often recognize that the name of one medicine might be the same kind of medicine as another. And a good example of that would be the difference between Vicodin and Lortab——

Mr. STUPAK. Sure.

Dr. TRESCOT. Both of which are hydrocodones, both of which have very different names, and I in my own practice have had patients who have been on both medicines and had no clue they were exactly the same. That obviously raises the risk of overdose because they are taking two doses of the same medicine. NASPER would allow us to be able to access that information from all their locations, from all the prescribers, and to be able to sit down with

the patient and, medicine by medicine by medicine, be able to look at the potential drug interactions.

Mr. STUPAK. Well, let me ask this question. The NASPER Program, there are requirements for receiving grant funds that a State has agreements with bordering States to share information in order to stop the doctor shopping between the States, and you mentioned Florida being an hour away from Georgia. Do you see the effects of Georgia dumping there, or patients going over to Florida from Georgia and vice versa?

Dr. TRESCOT. There is actually a pill mill in my own community, and you can drive by that office and see the huge number of Georgia license plates in the parking lot.

Mr. STUPAK. I think Mr. Burgess might have mentioned it. You have mentioned it. It seems like we are aware of where these pill mills are, but who would have the responsibility for controlling or shutting them down?

Dr. TRESCOT. That is why I volunteered to be the expert witness in this ongoing case, but this particular pill mill has been in existence since April. They have a physician who had never written—sorry—controlled substances before who in September, from April until September, had written at least 8,800 different prescriptions for opioid narcotics, out of this one location.

Mr. STUPAK. So in order to write prescriptions you have to be licensed, so you have a State licensing agency, you have a law enforcement issue, and you have a public health issue, which NASPER takes those components in consideration, but, with all due respect to the Rogers Program, that is more oriented towards law enforcement. Has that been your experience?

Dr. TRESCOT. Absolutely, and the problem comes in, is that there is no way for me as a provider, you come into my office complaining of low back pain. I have no test for pain, I have no ways of telling by looking at you whether you are really hurting or not. So I have two options. One is to consider you a potential drug abuser and refuse you the pain medicines you might need. The other is to be an enabler, to allow you to be able to scam me, just as you have scammed other doctors in the community, by writing a medicine because I believe you. So it immediately sets up an adversarial relationship. We feel that NASPER, because it was written to be HIPAA compliant, requires a written consent from you to allow me to access that data bank. Now obviously if you don't give that consent, I don't write the pain medicine.

Mr. STUPAK. Correct.

Dr. TRESCOT. So it is a quid pro quo. But in any case it allows me to access the data bank to be able to see that you have not gotten medicines from any other prescribers, to be able to identify if you are potentially in trouble, and intervene before your life is destroyed, and to then be able to establish a caring, open relationship with you, to be able to give you the treatment that you deserve.

Mr. STUPAK. Two quick questions, if I may. Do you believe HHS is the appropriate agency to run NASPER?

Dr. TRESCOT. I absolutely do. HHS is by definition involved with healthcare. It allows a physician intervention at an early point, and since the physician, as I said, is the end of the pen, the physician is writing the prescription that is therefore getting abused. So it al-

lows it to be done at a physician level. DOJ focuses on criminal activity, and I will be honest, for instance, in the Panhandle of Florida there have been some very egregious DOJ activities against physicians, to the point that I have physicians telling me that they feel that there are being attacked by, and the quote is "jack-booted thugs". That has created an amazing chilling effect, so that patients come to me from the panhandle telling me that they do not have the ability to get prescription medications in the panhandle, and they have to come to Gainesville.

Mr. STUPAK. Quickly, any other States have a program real similar to NASPER? We have heard all kinds of figures——

Dr. TRESCOT. Yes. There are four.

Mr. STUPAK. Four?

Dr. TRESCOT. We have got Kentucky, Utah, Idaho, and Nevada. Those are the only that allow physicians to have access to that information. Every other one denies physicians that ability.

Mr. STUPAK. Thank you. I am well over my time, but I want to give you and Mr. Whitfield— questions please? Thank you again.

Mr. WHITFIELD. Dr. Trescot, we appreciate your being here very much and thank you for the great job you are doing with the Association, and thank you for providing us with this magazine. And now that we understand opiate pharmacology we can have a better conversation with Dr. Burgess over there. But I am not going to ask you any questions, and here is why. Your testimony is the kind of testimony that we really needed when we were passing this legislation, and we had great testimony, and your testimony reaffirms the necessity for this program. But unfortunately our problem right now is getting the appropriations for it. So thank you very much for being here and for your continued effort in this regard.

Mr. STUPAK. Thanks, Mr. Whitfield. I know you have been a champion on this legislation, along with myself and others, and we appreciate it, and we are going to get some money to get this thing going. Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. Thank you, Dr. Trescot, for being here and sharing this information with us. You referenced the Texas physician. Was that the same series of articles that I referenced in my opening statement?

Dr. TRESCOT. It is actually a different one.

Mr. BURGESS. Wow.

Dr. TRESCOT. This was on the CBS Evening News, was a physician's assistant, actually, who would see the patients with no—they had sent in undercover reporters with video, and it is all videotaped and was presented, where he would come in, what medicines do you want? There was no attempt at a physical exam, no attempt at trying to obtain a history. The reporters were asked at the window if they had records. They said, no. They said, fine. That will be $150 or $200 or $80, whichever one it was at that particular time. They came into the room. They had a blood pressure or weight taken, and then the physician's assistant, describing himself as a doctor, came in and said, what do you need? They asked for the medicines they wanted. The prescription was faxed over to the pharmacy, and actually they got medicines that they didn't even ask for, and with four reporters that went in, they got over 700 tablets in four days of addictive substances.

Mr. BURGESS. Are you familiar with the case that I referenced, Dr. Maynard in south Dallas?

Dr. TRESCOT. Yes, sir, and it is very similar to the ones that we are looking at in Florida and disgustingly similar unfortunately.

Mr. BURGESS. And even with all of the documentary evidence that they brought up, this individual was given probation, and I guess he lost his license. I don't really know about that, but it seems like it was pretty difficult to build the case and get—realistically, he was charged with, I think, 11 counts of murder and gets probation. That is kind of phenomenal.

Dr. TRESCOT. And yet in the panhandle a doctor who was a Board-Certified pain management physician, fellowship trained, seeing 10 patients a day, not 100, had, I believe, two patients who died. He was convicted and given 20 years in prison.

Mr. BURGESS. And that is actually what I was going to ask you about, because that occurred, I think, before I took office here. As a physician you worry about how to strike that right balance. You obviously don't want to bring the wrath of the DOJ down on your neck, but at the same time you are in the treatment room with a patient who is suffering, and your charge is to serve the suffering, so it sets up a conflict that almost cannot be resolved.

Dr. TRESCOT. Except through NASPER, and that is what we think is, with NASPER it allows us to be able to understand immediately whether or not that patient is drug seeking, whether or not that patient is at risk for getting into trouble, and whether or not it is a patient who is actually legitimate.

Mr. BURGESS. Now who would have access to the data in NASPER?

Dr. TRESCOT. NASPER was written so that physicians who are treating the patient, the pharmacists who are dispensing the medications, and law enforcement, only with the equivalent of a search warrant, would have access to that information. And so it is protected information, only released to those people who have a reason to need it.

Mr. BURGESS. What occurs in the instance where the prescribing physician is the non-treating physician but covering for someone? I mean, that is the situation where a drug-seeking behavior—I mean, that would happen almost every weekend I was on call. Someone randomly picks your name out of the phone book, say, I am your partner's patient, would you refill whatever? Either you get tricked or you don't, but how do you get permission from that patient to access their database?

Dr. TRESCOT. And that is a very good question because that is actually, in my practice we had the policy that, for no reason, under any circumstances, were medications called in over the weekend without the ability to review the chart, even though it might have been one of my partners' prescriptions. And when the patients came in, they actually signed a sheet saying that they realized that, and if they had a problem and needed more medicines they were required to go to the emergency room, putting an additional burden on our already overburdened emergency rooms. What we visualize is that you could do the blanket consent that, so those physicians who have a reason to have access, whether—it is an agreement. If you have somebody who is covering you on call, you

have an agreement with them for the exchange of that information, and that consent would theoretically pass over.

Mr. BURGESS. Now, are you familiar with the Genetic Information Non-Discrimination Act that we just passed?

Dr. TRESCOT. No, I am not. I was very intrigued when you said that, and I wasn't familiar with it.

Mr. BURGESS. I guess arguably someone could say that the vulnerability to addictive behavior is an inherited trait, ergo it is a genetic condition, and we did put some pretty significant parameters around the sharing of data. I do wonder if we have encroached upon the turf of NAFTA with—oh, NAFTA—NASPER with this. On the border State issue, Texas is a border State with another country. What do we do in that situation? The trans-border migration in Texas is, of course, the stuff of legend on Lou Dobbs every evening. It seems to me that this trafficking is probably just as rampant as it is across the Georgia-Florida border, if not more.

Dr. TRESCOT. We can't control the flow of bodies much less small pieces of paper that are prescriptions or bottles of medication. Ideally, you would end up with, I would think, a situation where you could have an agreement with Mexico, but that is outside my purview.

Mr. BURGESS. But many of these substances are not controlled substances in Mexico, so Texas and California, New Mexico, and Arizona would have a unique problem in that there may be the flow of contraband essentially across their borders. Well, like Mr. Whitfield, I appreciate so much the compilation of data. I think it is going to be helpful going forward. I actually wish we had had this when we had the GINA discussion, but that is an issue for another day. Mr. Chairman, I do hope we take on the Oxycontin issue, because I think that is something that this committee should look into, and I know there have been a lot of requests in that, and I think it is something we should take up. And I will yield back.

Mr. STUPAK. Thank the gentleman. Doctor, thanks. Unfortunately we have to run to votes right now, but thanks for being here. Thanks for sitting through the last panel, too. You did do that, and we appreciate that.

Dr. TRESCOT. It was my pleasure, and thank you very much for the invitation.

Mr. STUPAK. Thank you, and we will keep on this. We do have our meeting tomorrow at 3:30 with Mr. Nussle, the Director of the Office of Management and Budget, and maybe we can get this funded in the President's request next year.

Dr. TRESCOT. Well, the help of both of you has been greatly appreciated.

Mr. STUPAK. Thanks. That concludes our questioning. I want to thank our witnesses for coming today and for their testimony. I ask for unanimous consent that the hearing record will remain open for 30 days for additional questions for the record. Without objection, the record will remain open. I ask unanimous consent that the contents of our document binder be entered in the record. Without objection, the documents will be entered in the record. That concludes our hearing. With no objection, this meeting of the subcommittee is adjourned. Thank you again.

[Whereupon, at 11:45 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

CBS NEWS

BACK PRINT

June 1, 2007

What's A Pill Mill?

They give good doctors a bad name and they put people's lives at risk. Pill mills are places where bad doctors hand out prescription drugs like candy. In the clip to the left, you'll see more of what leading pain specialist Dr. Andrea Trescot has to say.

Here's a breakdown of what we learned:

WHAT IS A "PILL MILL?"

"Pill mill' is a term used primarily by local and state investigators to describe a doctor, clinic or pharmacy that is prescribing or dispensing powerful narcotics inappropriately or for non-medical reasons.

HOW DOES IT WORK?

"Pill mill" clinics come in 'all shapes and sizes' but investigators say more and more are being disguised as independent pain-management centers. They tend to open and shut down quickly in order to evade law enforcement. Although the problem is nationwide with recent arrests in New York, Ohio, and Chicago, Drug Enforcement Administration officials believe the highest concentration of pill mills are in Florida and Texas.

SIGNS:

- Accept cash only
- No physical exam is given
- No medical records or x-rays are needed
- You get to pick your own medicine, no questions asked
- You are directed to "their" pharmacy
- They treat pain with pills only
- You get a set number of pills and they tell you a specific date to come back for more
- They have security guards
- There may be huge crowds of people waiting to see the doctor

FEDERAL LAW:

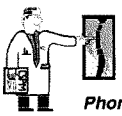
It is against federal law for a doctor to prescribe pain medication without a legitimate medical purpose or "outside the usual course of medical practice." If a prescription is deemed as not "valid," a doctor could be charged with "drug trafficking." This is a felony with the possibility of up to life in prison. It is also illegal to practice or prescribe medicine without a license.

ABUSE FACTS:

A February 2007 report by the CDC shows accidental drug overdoses totaled nearly 20,000 in 2004. That number increased about 80 percent from 1999, mostly due to prescription drug abuse.

The nationwide surge in deaths now places prescription drug overdoses as the second leading cause of accidental death behind traffic crashes and painkillers as the top narcotic contributing to death.

A recent National Drug Assessment study shows that prescription narcotics are the second most abused drug (behind marijuana), surpassing cocaine, heroin, meth and crack.



The Center for Spine & PAIN Medicine
Spine Medicine, Disability, Injury, and Pain Management
Charles M. Grudem, MD, FNASS* CIME**
2100 SE 17th Street, Suite # 801 Ocala, Florida 34471
Phone: (352) 629-7011 *Fax: (352) 629-7924* *E-Mail: spinemd801@cox.net*

October 23, 2007

Andrea Trescot, MD
President, American Society of Interventional Pain Physicians
Medical Director, Professor, and Head
Pain Fellowship Training Program,
University of Florida
Gainesville, Florida

c/o e-mail: AMT57@aol.com

Dear Dr. Trescot;

The following is my statement and Sworn Affidavit about the National All Schedule Prescriptions Electronic Reporting Act, known also as NASPER, and its attempted implementation here in Florida. In lieu of my late patient's wife appearing in person, I have summarized the facts of the case as In know and believe them to be, based on my own medical records and her statements to me, which were obtained in a setting that was credible and consistent with the other facts. Please feel free to use this letter and incorporated affidavit for your appearance before Congressional hearings on the NASPER legislation and its funding reconsideration / needs.

AFFIDAVIT

The following is a Statement of facts and Information known to the undersigned physician, and presented here for the purposes of testimony before the United States Congress and/or its Committees. The Statement is presented as sworn under oath and under penalties of perjury.

1. The National All Schedule Prescription Electronic Reporting Act, also known as NASPER, was signed into law by President Bush on August 11, 2005 after unanimous approval by both houses of the U.S. Congress and original support by the American Society of Interventional Pain Physicians, also known as ASIPP. This undersigned Affiant Physician, hereinafter referred to in the first person, is very familiar with the NASPER legislation, and is a member of ASIPP and its Florida Chapter (FLSIPP) and that Chapter's Board of Directors.
2. The undersigned Affiant Physician represented all FL pain medicine physicians at the Florida Medical Association Board of Governors meeting in April of 2007, upon request of the Boards of Directors of the two groups, FLSIPP and the Florida Academy of Pain Medicine (FAPM). From that time until the present, I have been very actively aware of and engaged in the political process of supporting NASPER implementation in Florida.

3. I am also a practicing Pain Medicine Physician with over thirty years of overall medical practice experience and I was certified as a sub-specialist in Pain Medicine by the American Board of Medical Specialties preferred examination in 2003. My current medical practice has a focus on long term pain management, especially for spine injury patients and it began here in Florida over seven years ago. I have attended several other certification programs in pain medication management and have even authored a standard medical textbook chapter on Acute Low Back Pain (C. V. available on request).
4. In my practice of Pain Medicine and Spine Medicine, I have many cases daily where I do prescribe pain medicines that are "scheduled" on the "Controlled Substances" lists for both federal (DEA) and state government purposes. These are part of overall treatment of the patients who receive such prescriptions. I also have a very strong awareness and professional experience with addiction illness and medical-legal matters dealing with prescription medicines, pain management, addiction, and diversion control.
5. During the Florida 2007 legislative session I monitored the movement of the Florida version of NASPER as it made its way through both the State House of Representatives and the State Senate. This included the attachment of several amendments. I also sent letters and emails to most of the legislators on the various committees that were scheduled to review the bills before they were to come up for a floor vote. My legislator contacts were paralleled by dozens of other Pain Medicine physicians, in this regard.
6. The FOUR BILLS that dealt with the NASPER legislation efforts in Florida were all voted for unanimously by all committee members until the end of the legislative session. The key part of the HOUSE version of NASPER (HB 893) "died in Committee" in the "Policy and Budget Council" on May 4, 2007, the last day of the regular session. The Cost estimate for the embellished version of the NASPER legislation was estimated by staff as $4,818,803 for the first year, $3,251,597 for year two, and $3,726,645 for year three.
7. The Senate Version of the Key part of FLASPER (Florida NASPER) was Senate Bill 518 and it was unanimously supported just like the House bill 893 until the last two days of the session after it was handled in the Government operations Committee and after being pulled from the Health and Human Services Appropriations Committee. On the floor of the Senate, the most critical part of NASPER, that created the Controlled Substance Monitoring system, was effectively removed and all the embellishments were passed without the NASPER-type provisions. The APPORTIONMENT was $100,000.
8. The difference between the estimated costs of the FULL NASPER type legislation with embellishments and that which was substituted from the floor with the embellishments only is $4,718,803. The fact that the Policy and Budget council (in the House) and the Government Operations and Apportionments Committees leads to the very obvious conclusion that BUDGET CONSTRAINTS caused the Florida Legislative Leaders to hold this CRITICALLY IMPORTANT legislation from reaching a floor vote, where it would have easily passed, given the track record noted above in the committee voting.
9. It is equally OBVIOUS that IF the NASPER legislation had been fully funded by Congress, then a more limited NASPER type Florida Law (FLASPER) would have passed the Florida Legislature in 2007. A similar situation existed in 2006, I believe.
10. In my work as a treating pain physician, I had the opportunity to treat a Mr. Brian LoGreco for the past several years. He was known to me to have a problem with addiction in the past, but my consultants had assured me that this was quiescent the last two time he had seen them for assessment. He had a step son with an addiction history, according to his wife Jacque LoGreco, who visited me on September 6, 2007. Ms. LoGreco advised me that her husband and her son had both had exacerbations of their addiction illnesses in the past few and gone "doctor shopping" to acquire inappropriate numbers of scheduled pain medicines from several doctors. Mr. LoGreco apparently died of overdose on September 1, 2007 and her son died of an overdose a week earlier.

11. After review of the facts of this case and the laws in place and the legislation we have tried to have here in Florida, it is clear to me that IF the NASPER LEGISLATION had been passed last year (with appropriate funding), at least my patient, Mr. LoGreco, and possibly his son as well, would be alive today. We, at this clinic would have used the NASPER legislation to detect the inappropriate prescription filling patterns and intervened in time to save my patient's life. He died, in essence, because of both his illness and the failure of our legislature to pass the NASPER legislation previously.
12. The above statements and conclusions are made to a reasonable degree of medical certainty based on the facts as I know them to be on this 23rd day of October, 2007.

Sworn and Affirmed,

Charles M. Grudem, MD, FNASS
Pain and Spine Medicine Physician
Medical Director,
The Center for Spine & PAIN Medicine
Ocala, Florida 34471

Florida House of Representatives

Gayle B. Harrell
State Representative, 81st District

8000 South US Highway 1, Suite #201
Port St. Lucie, Florida 34952
Office: (772) 873-6500
Fax: (772) 873-6502

Room 210, House Office Bldg.
402 South Monroe Street
Tallahassee, Florida 32399
(850) 488-8749

Re: Funding for NASPAR

To Whom It May Concern:

Diversion of prescription drugs for illegal purposes has become a major problem in Florida – one that clearly threatens the health and well being of our citizens. More people die from prescription drug abuse in Florida than from the abuse of cocaine and heroine combined.

In an attempt to address this epidemic, the Legislature in Florida has debated the establishment of an electronic prescription drug registry for the past six years. As the sponsor of this legislation for the past five years, I have encountered great difficulty in passing a drug registry program for a variety of reasons, not the least of which is funding for such a system.

The National All Schedules Prescription Electronic Act (NASPER) could provide a major weapon against prescription drug abuse. It has great potential to limit prescription drug abuse not only within states, but across state lines. Although the bill was signed into law, it has yet to be funded.

The lack of funding for NASPAR directly impacts the ability of states to address this problem. Had there been federal funding for such an electronic drug registry in Florida, one of the major hurdles that we have had to address would have been overcome. Hence, I would urge the US Congress to allocate funds for this program.

Sincerely,

Gayle Harrell

Gayle Harrell,
Rep. District 81

Ex. #	Description	Date
1	Subcommittee on Oversight and Investigations Witness List	10/24/07
2	O&I Hearing Memo; subject: "NASPER: Why Has the National All Schedules Prescription Electronic Reporting Act Not Been Implemented?""	10/23/07
3	H.R.1132, "National All Schedules Prescription Electronic Reporting Act of 2005."	01/04/05
4	U.S. House Report 109-191, "National All Schedules Prescription Electronic Reporting Act of 2005" (to accompany H.R.1132).	07/27/05
5	Committee on Energy and Commerce Hearing, "Review of the Department of Health and Human Services Fiscal Year 2008 Budget," Serial No. 110-2. (pp. cover and 46-47).	02/06/07
6	Letter from Reps. Barton, Dingell, et al. to the Office of Management and Budget Director, Joshua B. Bolton.	01/10/06
7	Letter from Chairman Barton to Committee on Rules Chairman, David Dreier.	06/26/06
8	Letter from Reps. Dingell, Barton, et al to Committee on Appropriations Chairman, David Obey, and Ranking Member Jerry Lewis.	03/29/07
9	Letter from OI Subcommittee Chairman, Bart Stupak and Ranking Member Ed Whitfield to the Office of Management and Budget Director, Jim Nussle	10/15/07
10	The Boston Globe news article by Scott Allen, re: "Massachusetts Tracks Children on Psychiatric Drugs- Prescriptions Eyed After Overdose."	10/07/07

Exhibit 3

H. R. 1132

One Hundred Ninth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the fourth day of January, two thousand and five

An Act

To provide for the establishment of a controlled substance monitoring program in each State.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National All Schedules Prescription Electronic Reporting Act of 2005".

SEC. 2. PURPOSE.

It is the purpose of this Act to—

(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.

SEC. 3. CONTROLLED SUBSTANCE MONITORING PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding after section 399N the following:

"SEC. 399O. CONTROLLED SUBSTANCE MONITORING PROGRAM.

"(a) GRANTS.—

"(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

"(A) to establish and implement a State controlled substance monitoring program; or

"(B) to make improvements to an existing State controlled substance monitoring program.

"(2) DETERMINATION OF AMOUNT.—

"(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

"(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

"(3) TERM OF GRANTS.—Grants awarded under this section shall be obligated in the year in which funds are allotted.

"(b) DEVELOPMENT OF MINIMUM REQUIREMENTS.—Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

"(c) APPLICATION APPROVAL PROCESS.—

"(1) IN GENERAL.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

"(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

"(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

"(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

"(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

"(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

"(v) criteria for availability of information and limitation on access to program personnel;

"(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

"(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

"(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

"(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

"(x) assurances of compliance with all other requirements of this section; or

"(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

"(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

"(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

"(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

"(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

"(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

"(3) INTEROPERABILITY.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

"(4) APPROVAL.—If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

"(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

"(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

"(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

"(2) The State may exclude from the reporting requirement of this subsection—

"(A) the direct administration of a controlled substance to the body of an ultimate user;

"(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

"(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

"(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

"(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

"(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

"(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

"(D) Identification of the drug by a national drug code number.

"(E) Quantity dispensed.

"(F) Number of refills ordered.

"(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

"(H) Date of the dispensing.

"(I) Date of origin of the prescription.

"(J) Such other information as may be required by State law to be reported under this subsection.

"(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

"(e) DATABASE.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

"(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

"(2) The database must be searchable by any field or combination of fields.

"(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

"(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

"(f) USE AND DISCLOSURE OF INFORMATION.—

"(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

"(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

"(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

"(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

"(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

"(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

"(i) the State has an application approved under this section; and

"(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

"(2) DRUG DIVERSION.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

"(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

"(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

"(g) LIMITATIONS.—In implementing or improving a controlled substance monitoring program under this section, a State—

"(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

"(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

"(h) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

"(i) RULES OF CONSTRUCTION.—

"(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

"(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

"(3) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

"(4) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

"(5) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

"(j) STUDIES AND REPORTS.—

"(1) IMPLEMENTATION REPORT.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

"(i) patient access to treatment, including therapy for pain or controlled substance abuse;

"(ii) pediatric patient access to treatment; or

"(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

"(B) ADDITIONAL CATEGORIES OF EXCLUSION.—If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

"(2) PROGRESS REPORT.—Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

"(A) complete a study that—

"(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

"(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

"(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

"(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

"(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

"(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

"(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

"(B) submit a report to the Congress on the results of the study.

"(k) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements

under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

"(l) ADVISORY COUNCIL.—

"(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

"(2) LIMITATION.—A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

"(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

"(m) DEFINITIONS.—For purposes of this section:

"(1) The term 'bona fide patient' means an individual who is a patient of the practitioner involved.

"(2) The term 'controlled substance' means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

"(3) The term 'dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

"(4) The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

"(5) The term 'interoperability' with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

"(6) The term 'nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

"(7) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

"(8) The term 'State' means each of the 50 States and the District of Columbia.

"(9) The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

"(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

"(1) $15,000,000 for each of fiscal years 2006 and 2007; and

"(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010.".

Speaker of the House of Representatives.

Vice President of the United States and
President of the Senate.

Exhibit 4

109TH CONGRESS, 1st Session } HOUSE OF REPRESENTATIVES { REPORT 109–191

NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING ACT OF 2005

JULY 27, 2005.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and Commerce, submitted the following

REPORT

[To accompany H.R. 1132]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1132) to provide for the establishment of a controlled substance monitoring program in each State, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "National All Schedules Prescription Electronic Reporting Act of 2005".

SEC. 2. PURPOSE.

It is the purpose of this Act to—

(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.

SEC. 3. CONTROLLED SUBSTANCE MONITORING PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding after section 399N the following:

"SEC. 399O. CONTROLLED SUBSTANCE MONITORING PROGRAM.

"(a) GRANTS.—

"(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

"(A) to establish and implement a State controlled substance monitoring program; or

"(B) to make improvements to an existing State controlled substance monitoring program.

"(2) DETERMINATION OF AMOUNT.—

"(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

"(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

"(3) TERM OF GRANTS.—Grants awarded under this section shall be obligated in the year in which funds are allotted.

"(b) DEVELOPMENT OF MINIMUM REQUIREMENTS.—Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

"(c) APPLICATION APPROVAL PROCESS.—

"(1) IN GENERAL.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

"(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

"(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

"(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

"(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

"(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

"(v) criteria for availability of information and limitation on access to program personnel;

"(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

"(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

"(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

"(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

"(x) assurances of compliance with all other requirements of this section; or

"(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

"(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

"(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

"(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

"(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

"(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

"(3) INTEROPERABILITY.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

"(4) APPROVAL.—If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

"(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

"(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

"(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

"(2) The State may exclude from the reporting requirement of this subsection—

"(A) the direct administration of a controlled substance to the body of an ultimate user;

"(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

"(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

"(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

"(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

"(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

"(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

"(D) Identification of the drug by a national drug code number.

"(E) Quantity dispensed.

"(F) Number of refills ordered.

"(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

"(H) Date of the dispensing.

"(I) Date of origin of the prescription.

"(J) Such other information as may be required by State law to be reported under this subsection.

"(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

"(e) DATABASE.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

"(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

"(2) The database must be searchable by any field or combination of fields.

"(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

"(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

"(f) USE AND DISCLOSURE OF INFORMATION.—

"(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

"(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

"(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

"(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

"(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

"(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

"(i) the State has an application approved under this section; and

"(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

"(2) DRUG DIVERSION.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

"(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

"(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

"(g) LIMITATIONS.—In implementing or improving a controlled substance monitoring program under this section, a State—

"(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

"(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

"(h) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

"(i) RULES OF CONSTRUCTION.—

"(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

"(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

"(3) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

"(4) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

"(5) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

"(j) STUDIES AND REPORTS.—

"(1) IMPLEMENTATION REPORT.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

"(i) patient access to treatment, including therapy for pain or controlled substance abuse;

"(ii) pediatric patient access to treatment; or

"(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

"(B) ADDITIONAL CATEGORIES OF EXCLUSION.—If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

"(2) PROGRESS REPORT.—Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

"(A) complete a study that—

"(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

"(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use,

abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

"(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

"(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

"(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

"(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

"(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

"(B) submit a report to the Congress on the results of the study.

"(k) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

"(l) ADVISORY COUNCIL.—

"(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

"(2) LIMITATION.—A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

"(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

"(m) DEFINITIONS.—For purposes of this section:

"(1) The term 'bona fide patient' means an individual who is a patient of the practitioner involved.

"(2) The term 'controlled substance' means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

"(3) The term 'dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

"(4) The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

"(5) The term 'interoperability' with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

"(6) The term 'nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

"(7) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to,

administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

"(8) The term 'State' means each of the 50 States and the District of Columbia.

"(9) The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

"(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

"(1) $15,000,000 for each of fiscal years 2006 and 2007; and

"(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010.".

PURPOSE AND SUMMARY

The purpose of H.R. 1132 is to address the issue of illegal diversion and misuse of prescription drugs. This legislation would provide grants to states, through the Department of Health and Human Services, to establish and operate prescription drug monitoring programs (PDMP). Each state operating an authorized monitoring program would be required to cover Schedule II, III, and IV drugs.

H.R. 1132 will provide the resources to states to implement and operate an individual program that best address the needs of the particular state. The bill will also facilitate the interoperability of state systems so drug diversion and abuse that crosses states lines can also be detected.

BACKGROUND AND NEED FOR LEGISLATION

The diversion and abuse of legally manufactured prescription drugs continues to be a pressing national issue. According to the Office of National Drug Control Policy (ONDCP), in 2002 6.2 million Americans abused prescription drugs. Since this Committee passed similar legislation last year, the National Center on Addiction and Substance Abuse at Columbia University released a report indicating the growing nature of this problem. According to this report, the number of Americans who admit abusing prescription drugs nearly doubled to more than 15 million from 1992 to 2003, while the number of teens abusing prescription drugs has tripled in that time.

More than 20 states currently operate some form of a prescription drug monitoring program. Each state program is unique, with states varying the state agency that operates the program, the controlled substances that are covered, and how patient information is collected and monitored. Most prescription drug monitoring programs function as electronic monitoring systems through which pharmacies transmit prescription data for covered controlled substances to a designated state agency. In addition to providing information about existing prescriptions for a patient to a health care provider, these programs also provide information to drug enforcement agencies to identify illegal activities.

Proponents of state prescription drug monitoring programs have highlighted the success of several states in reducing the availability of abused drugs and improving states' ability to investigate and prosecute illegal prescription drug diversion. They claim that the physicians' increased access to drug history information has helped to serve as an initial deterrent for doctor shopping. They also argue that the presence of a prescription drug monitoring pro-

gram may also affect the type of drugs that are being diverted. The Government Accountability Office reports that the existence of a prescription drug monitoring program within one state appears to have increased drug diversion activities in contiguous states without prescription drug monitoring programs.

HEARINGS

The Committee on Energy and Commerce has not held hearings on this legislation.

COMMITTEE CONSIDERATION

On Wednesday, June 22, 2005, the Subcommittee on Health met in open markup session and approved H.R. 1132 for full Committee consideration, amended, by a voice vote, a quorum being present. On Wednesday, July 20, 2005, the full Committee met in open markup session and ordered H.R. 1132 favorably reported to the House, amended by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following is the recorded vote taken on H.R. 1132. A motion by Mr. Barton to order H.R. 1132 reported to the House, amended, was agreed to by a voice vote.

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COMMITTEE ON ENERGY AND COMMERCE – 109TH CONGRESS
ROLL CALL VOTE # 38

Bill: H.R. 1132, National All Schedules Prescription Electronic Reporting Act of 2005.

AMENDMENT: An amendment to the Whitfield amendment in the nature of a substitute by Mr. Markey, No. 1a, to require a patient to be notified if information relating to the patient in a database maintained under subsection (e) is lost, stolen, or used for an unauthorized purpose.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 15 yeas to 32 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns				Mr. Towns			
Mr. Gillmor		X		Mr. Pallone		X	
Mr. Deal		X		Mr. Brown		X	
Mr. Whitfield		X		Mr. Gordon			
Mr. Norwood		X		Mr. Rush		X	
Ms. Cubin		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Stupak			
Ms. Wilson		X		Mr. Engel	X		
Mr. Shadegg		X		Mr. Wynn			
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland		X	
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. Allen		X	
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis	X		
Mr. Terry		X		Mr. Gonzalez		X	
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter	X			Mr. Ross		X	
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy	X						
Mr. Burgess		X					
Ms. Blackburn		X					

7/20/2005

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of H.R. 1132 is to provide incentives to states so each will operate a drug monitoring program and that these programs can communicate between programs to address the public health problem of prescription drug abuse.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1132, the National All Schedules Prescription Electronic Reporting Act of 2005, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 26, 2005.

Hon. JOE BARTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1132, the National All Schedules Prescription Electronic Reporting Act of 2005.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

ROBERT A. SUNSHINE
(For Douglas Holtz-Eakin, Director).

Enclosure.

H.R. 1132—National All Schedules Prescription Electronic Reporting Act of 2005

H.R. 1132 would authorize the Secretary of Health and Human Services to make grants to states to establish electronic database systems for monitoring the dispensing of controlled substances. The database would be used to identify, and report to appropriate authorities, the potential unlawful diversion or misuse of controlled

substances. The bill also would require the Secretary to conduct several studies related to monitoring programs for controlled substances.

The bill would authorize the appropriation of $15 million in each of fiscal years 2006 and 2007, and $10 million a year for fiscal years 2008 through 2010. Assuming appropriation of those amounts, and based on spending patterns for similar programs, CBO estimates that implementing H.R. 1132 would cost $52 million over the 2006–2010 period. Enacting H.R. 1132 would have no effect on direct spending or revenues.

H.R. 1132 contains no intergovernmental or private-sector mandates as defined by the Unfunded Mandates Reform Act. The bill would benefit state, local, and tribal governments; any costs they incur would result from complying with conditions of receiving federal assistance.

On June 6, 2005, CBO transmitted a cost estimate for S. 518, the National All Schedules Prescription electronic Reporting Act of 2005, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on May 25, 2005. The authorizations of appropriations in that bill are equal to those in H.R. 1132; the programs established under both bills are almost identical. Neither bill would impose any mandates on state, local, or tribal governments or on the private sector.

The CBO staff contact for this estimate is Julia Christensen. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short Title

Section 1 designates the title of the bill, the "National All Schedules Prescription Electronic Reporting Act of 2005."

Section 2. Purpose

Section 2 states that the purpose of the legislation is to foster the establishment of state administered prescription drug monitoring systems in order to ensure that health care providers have access to accurate, timely prescription history information. This information may be used as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical intervention and avert the tragic personal, family, and community consequences of untreated addiction. This legislation will also establish, based on the experiences of existing state controlled substance monitoring programs, a set of best practices to guide the establishment of new state programs and the improvement of existing programs.

Section 3. Controlled Substance Monitoring Program

Section 3 amends Part P of Title III of the Public Service Act by adding new section 399O, Controlled Substance Monitoring Program. Under this program, the Secretary of Health and Human Services would award grants to states to establish and operate controlled substance monitoring programs. Each state with an approved application will be guaranteed a minimum amount of 1% of the amount appropriated for that fiscal year. The remainder of funds allocated to each state will be based on a ratio of the number of pharmacies within a state to the number of all pharmacies in states that have monitoring programs approved under this section. The Committee recommends that, in determining the number of pharmacies in each state, the Secretary consult with the National Association of Boards of Pharmacy. The Secretary may adjust each state's allocation based on cost estimates provided by the state.

Prior to awarding any grant, and not later than six months after the date funds are first appropriated for this program, the Secretary shall develop minimum requirements for states to use in their applications. It is the intent of the Committee that the agency consult widely with interested parties in preparing its proposed minimum requirements. The Committee believes interested parties should include other federal government agencies and departments with interests or expertise on the issue of drug abuse and drug diversion. Then, after opportunity for public comment on those requirements, the Secretary shall identify the minimum requirements for the criteria to be used by the states in their grant applications. These requirements apply to states whether applying for an initial grant or support of an existing system.

To receive a grant under this section, a state must submit an application in a time, manner, and form that the Secretary may require. States planning to establish a drug monitoring program must include a cost estimate, and proposed criteria for information security, criteria for meeting uniform electronic formatting, criteria for the availability of information and limitation on access to program personnel, criteria for the use and disclosure of information, and criteria for access to the database and procedures to ensure the information in the database is accurate. The Committee recognizes that persons should be able to have accurate information in the database, and to be able to have any inaccurate information removed or corrected. In existing programs, the physician is normally the responsible party to seek the correction on behalf of the af-

fected individual. It is the intent of the Committee that states would address the issue of how incorrect information would be corrected as part of their responsibility to ensure that the information in the database is accurate.

A state must also include in its application a listing of penalties for misuse of information in their application, and disclose information regarding its state law, policies, and procedures, if any, regarding the purging of information from the database. A state will also have to demonstrate in its application that it has enacted legislation or regulations to permit the implementation of a controlled substance monitoring program. States requesting funds for improving existing systems must include all information required of states applying for a grant to establish a new program. In addition, a state requesting a grant for an existing program must describe its plan to enable the state program to achieve interoperability with border states drug monitoring programs.

In implementing a program under this section, a state shall require all dispensers to report each dispensing in the state not later than one week after the dispensing. For the purposes of this section, controlled substance means any schedule II, III, IV drug or any other drug identified by the state to be subject to the monitoring program. The state may exclude from this reporting requirement the direct administration of a controlled substance to an ultimate user. It is the Committee's intention not to require the reporting of a dispensing when the drug is directly applied. Because the possibility for diversion is small, to require this reporting would present a significant burden on the monitoring programs without an equivalent benefit.

The state may also exclude reporting for the dispensing of a controlled substance in an amount adequate to treat the ultimate user for 48 hours or less. The Secretary may also identify other exclusions from reporting requirements.

The information that must be reported by the dispenser includes: (1) the Drug Enforcement Administration Number of the dispenser; (2) the Drug Enforcement Administration Registration Number and name of the practitioner who prescribed the drug; the name, address, and telephone number of the ultimate user or research subject; (3) identification of the drug by a national drug code number; (4) the quantity dispensed; (5) number of refills ordered or as a first time request; (6) whether the drug was dispensed as a refill; (7) the date of dispensing; (8) the date of origin of the prescription; and, (9) such other information as may be required by state law to be reported under this subsection.

The state shall require manufacturers to report information in accordance with the electronic format specified by the Secretary. The Committee notes that states currently operating a prescription drug monitoring program use the May 1995 version of the Telecommunications Format for Controlled Substances of the American Society for Automation in Pharmacy.

In implementing a controlled substance monitoring program, a state shall establish and maintain an electronic database that is searchable by any field or combination of fields. The state shall take appropriate safeguards to ensure the accuracy and completeness of the database and shall take appropriate measures to protect the integrity of, and access, to the database.

A state may provide the information from the database upon request from a practitioner, or agent thereof, which certifies that the information is to be used to treat a patient. The state may also provide the information to local, state, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authorities that certify that the information is for an individual investigation. It is the Committee's intention that the term program authority should be interpreted to include State Medicaid authorities, or other state or Federal authorities responsible for investigating health care fraud and abuse.

In addition, the state may provide information to any agent of the Department of Health and Human Services, a State Medicaid program, a state health department, or the Drug Enforcement Administration, who certifies that the requested information is for research purposes. When providing information for research purposes, it shall not provide any individually identifiable information. Under this section, the state shall share information with another state with an approved application if the information is for the purpose of implementing the state's controlled substance monitoring program. This includes the dispensing of a controlled substance to an ultimate user or research subject who resides in the other state or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is in the other state.

In consultation with practitioners, dispensers, and other relevant stakeholders, a state receiving a grant under this program shall establish a program to notify practitioners and dispensers of information that will help identify and prevent unlawful drug diversion. A state may also notify the appropriate authorities responsible for drug diversion investigations if the information indicates an unlawful diversion or misuse of a controlled substance. It is the Committee's intention that such determinations of unlawful diversion should be based on a decision made by the monitoring authority itself, and that the monitoring authority have discretion to make any such decision.

This section should not be construed to restrict the ability of any authority to perform functions otherwise authorized by law. This section should also not be construed to preempt any other state law. In addition, nothing in this section shall be construed to supercede any Federal privacy right or confidentiality requirement. The Committee specifically notes that this section should not be read to supercede the confidentiality requirements set forth in 42 CFR part 2 and part 2A. Furthermore, nothing in this section shall be construed to create a Federal private right of action.

Not later than 180 days after enactment the Secretary, based on a review of existing state controlled substance monitoring programs, shall determine whether the implementation of existing state monitoring programs has had a substantial negative impact on patient access to treatment, pediatric access to treatment, or patient enrollment in research or clinical trials. If the Secretary determines that a substantial negative impact has been demonstrated with regard to one or more of these categories, the Secretary shall identify additional appropriate categories of exclusion from reporting.

Not later than three years after the date on which funds are first appropriated, the Secretary shall conduct a study on the progress

of states in establishing and implementing controlled substance monitoring programs. The study shall provide an analysis of the extent to which drug-monitoring programs have reduced inappropriate use, abuse, and diversion of controlled substances. The study shall also examine the feasibility of implementing a real time electronic monitoring program and the progress of States in achieving interoperability. In addition, the study shall examine the privacy protections in place by states with drug monitoring programs and evaluate the penalties that states have enacted for the unauthorized use and disclosure of information. The Secretary shall submit a report to Congress on the results of this study.

The Secretary, in awarding any competitive grant that is related to drug abuse, shall give preference to those states that have established an approved drug monitoring program or have made a good faith effort to meet the requirements of the program. This provision shall take effect three years after the date funds are first appropriated for this program. The Secretary will have discretion to determine which competitive grants should be subject to the preference requirement, and such preference shall only apply to grants that are solely awarded to states. The abuse of prescription drugs is escalating, and any attempt to address the issue of drug abuse in this country must also address prescription drug abuse. Preference for drug abuse grants should go to states that have attempted to implement a comprehensive approach to addresses all types of drug abuse. This provision is designed to provide an incentive for states to create these programs. The effectiveness of a state's program is undermined when a person involved in unlawful diversion or abuse can circumvent the system when contiguous states do not have similar programs.

States may establish an advisory council to assist in the establishment and implementation of the monitoring program. In establishing an advisory council, states should consult with state boards of pharmacy, state boards of medicine, and other interested parties. An advisory council can provide needed expertise to a drug monitoring authority, including assisting in developing standards for indicating unlawful diversion or abuse.

To carry out this section, there is to be authorized $15,000,000 in each of Fiscal Years 2006 and 2007. There is to be authorized $10,000,000 in each of Fiscal Years 2008, 2009, 2010.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART P—ADDITIONAL PROGRAMS

* * * * * * *

SEC. 3990. CONTROLLED SUBSTANCE MONITORING PROGRAM.

(a) GRANTS.—

(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

(A) to establish and implement a State controlled substance monitoring program; or

(B) to make improvements to an existing State controlled substance monitoring program.

(2) DETERMINATION OF AMOUNT.—

(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

(3) TERM OF GRANTS.—Grants awarded under this section shall be obligated in the year in which funds are allotted.

(b) DEVELOPMENT OF MINIMUM REQUIREMENTS.—Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

(c) APPLICATION APPROVAL PROCESS.—

(1) IN GENERAL.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

(ii) criteria for security for information handling and for the database maintained by the State under sub-

section (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

(v) criteria for availability of information and limitation on access to program personnel;

(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

(x) assurances of compliance with all other requirements of this section; or

(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

(3) INTEROPERABILITY.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such appli-

cation, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

(4) APPROVAL.—If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

(2) The State may exclude from the reporting requirement of this subsection—

(A) the direct administration of a controlled substance to the body of an ultimate user;

(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

(D) Identification of the drug by a national drug code number.

(E) Quantity dispensed.

(F) Number of refills ordered.

(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(H) Date of the dispensing.

(I) Date of origin of the prescription.

(J) Such other information as may be required by State law to be reported under this subsection.

(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

(e) DATABASE.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

(2) The database must be searchable by any field or combination of fields.

(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

(f) USE AND DISCLOSURE OF INFORMATION.—

(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or

administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

(i) the State has an application approved under this section; and

(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

(2) DRUG DIVERSION.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

(g) LIMITATIONS.—In implementing or improving a controlled substance monitoring program under this section, a State—

(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

(h) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

(i) RULES OF CONSTRUCTION.—

(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

(3) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(4) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

(5) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

(j) STUDIES AND REPORTS.—

(1) IMPLEMENTATION REPORT.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

(i) patient access to treatment, including therapy for pain or controlled substance abuse;

(ii) pediatric patient access to treatment; or

(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

(B) ADDITIONAL CATEGORIES OF EXCLUSION.—If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

(2) PROGRESS REPORT.—Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

(A) complete a study that—

(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

(B) submit a report to the Congress on the results of the study.

(k) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

(l) ADVISORY COUNCIL.—

(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

(2) LIMITATION.—A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

(m) DEFINITIONS.—For purposes of this section:

(1) The term "bona fide patient" means an individual who is a patient of the practitioner involved.

(2) The term "controlled substance" means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

(3) The term "dispense" means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(4) The term "dispenser" means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

(5) The term "interoperability" with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who re-

sides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(6) The term "nonidentifiable information" means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

(7) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(8) The term "State" means each of the 50 States and the District of Columbia.

(9) The term "ultimate user" means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

(1) $15,000,000 for each of fiscal years 2006 and 2007; and

(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010.

* * * * * * *

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Exhibit 5

REVIEW OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' FISCAL YEAR 2008 BUDGET

HEARING

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

FEBRUARY 6, 2007

Serial No. 110–2

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seven Members here who have not had time to question. And I am just wondering, I know you are scheduled to be here until 12:30. Is there any way you could extend that to 1 o'clock so we can give the Members who are remaining the ability to ask their questions?

Secretary LEAVITT. How about 1:10?

Ms. DEGETTE. That would be great. Thank you very much, Mr. Secretary.

Mr. SHIMKUS. Could the chairman yield? Maybe we close the list, how Members come back and forth. So if those Members present——

Ms. DEGETTE. I would add Mrs. Eshoo to that list.

Secretary LEAVITT. I want to make sure Mr. Matheson from Utah gets his question.

Ms. DEGETTE. Absolutely, Mr. Secretary. Now we know where the power lies. Now we recognize Mr. Whitfield for 6 minutes.

Mr. WHITFIELD. Thank you, Madam Chairman, and Mr. Secretary, we are delighted you are with us today and I want to congratulate you on the tremendous job you do at HHS.

In August 2005, the Congress passed and the President signed a law establishing a national prescription drug monitoring program.

Former Secretary Thompson supported the legislation. You supported the legislation. And last year we worked out—and the legislation housed that program at HHS. And we passed that legislation because prior to that without authorization from anyone, some members of the Appropriations Committee established an earmark that provided funding at the Department of Justice, and they—it was a mechanism that really didn't provide incentives and has not been successful in establishing a program at every State.

And last year, we worked out an agreement so that the new program at HHS would receive $5 million and the old program at Justice would receive $5 million until we could get them meshed together at HHS.

And in this budget that you have just submitted, there is no money requested for the NASPAR program and I would like to know why and was that a decision that HHS made or was it a decision that OMB made?

Secretary LEAVITT. Congressman, I know what an irritation this is to you. And I am sorry. It is a program we support. It is a program we would gladly administer. However, it is a decision that was made at OMB to view it more of a law enforcement program. I say that not as a matter of complaint other than just explanation that we are in a place where we don't control that decision. And I am happy to sponsor more conversation between you and those who do.

Mr. WHITFIELD. Well, thank you, Mr. Secretary. Madam Chairman, I would like to say I think it would be appropriate for our committee to get a letter over to OMB on this issue and also to work with the appropriators to see to it that the authorized program at HHS, where it should be, receives proper funding. And I would yield my time to anyone that wants it. But that is—yes, I would yield to Mr. Pallone.

Mr. PALLONE. I just wanted to support your efforts myself and Ed and a number of us on this committee worked very hard to get

the NASPAR program authorized and we do think it is very important. And I don't hear you saying you disagree. So I think we should initiate that letter. I would be glad to cosponsor it with my colleague from Kentucky and try to get some of this funding in during the appropriations process. And I appreciate your bringing it forward because I do think it is crucial.

Mr. WHITFIELD. I yield the time to Dr. Burgess. Did you want time, Dr. Burgess?

I yield back the balance of my time.

Ms. DEGETTE. Thank you. I now yield to Ms. Solis for 5 minutes.

Ms. SOLIS. Thank you, Madam Chair, and thank you, Mr. Secretary, for staying to hear our questions. I have several. And the first one I would like to start out with is December 15, 2006, a Congressional Hispanic Caucus Task Force on Health sent you a letter. And we have yet to get a response back. And it is regarding your interpretation of documentations that are now going to be required for newborns.

And I wanted to ask you if we could get a response or if we can expect one and how soon? And also if you could please explain how that policy is somehow going to help us achieve eliminating health care disparities with respect to underrepresented communities.

Secretary LEAVITT. Congresswoman, I will confess to you that we worked awfully hard so I wouldn't have to answer the question, why haven't you answered my letter? Most of our letters are current and I will follow up to find out why yours isn't.

Ms. SOLIS. And I would like to submit the letter we sent for the record if I could request unanimous consent, Madam Chair.

Secretary LEAVITT. When was this letter?

Mr. STUPAK. It was December 15.

Secretary LEAVITT. It may be that we count that as a current letter and we are working on it.

Ms. SOLIS. And so when can I expect a response? Soon. OK. Can you explain to me a little bit about that regulation and how you see that fostering identifying these underrepresented groups?

Secretary LEAVITT. You will get a better response in the letter because I am not certain I am in a position to enlighten you very much on it.

Ms. SOLIS. OK. One of the questions I had—and you didn't go from your text that you submitted—but I wanted to ask you about your Adolescent Health Promotion Initiative, $17 million. Does that include extending the Abstinence Only Program?

Secretary LEAVITT. That is a separate proposition.

Ms. SOLIS. One of the concerns I have and something that the Hispanic community and the caucus is very concerned about is the increase, actually the upsurge or upping of teenage pregnancies amongst the Latino population. It is well above, I would say, in some cases 20 percent. In fact the statistics prove that 51 percent of Latino teens get pregnant at least once before the age of 20 and for African American it is 57 percent become pregnant at the age of 20. So obviously the abstinence program is not working well. And one of the concerns we have is that information be provided in a culturally competent, linguistically competent manner. And I have yet to see any evidence that is happening in all the years of funding for these programs.

Exhibit 6

Congress of the United States
Washington, DC 20515

January 10, 2006

The Honorable Joshua B. Bolton
Director
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503-0009

Dear Director Bolton:

We are writing to request that you include $15 million in the Administration's FY 07 Budget for the National All Schedules Prescription Electronic Reporting Act (NASPER), P.L. 109-60.

On August 11, 2005 President Bush signed NASPER into law, making it the only statutorily authorized program to assist states combat prescription drug abuse of controlled substances through prescription drug monitoring programs (PDMPs). NASPER, administered by the Department of Health and Human Services (HHS), provides grants to states to establish and improve PDMPs. The law authorizes $15 million in FY 07 and $10 million each year through FY 10. We urge you to include the entire authorized amount of $15 million in the budget to demonstrate the President's commitment to this program which will assist us secure this funding during the Congressional appropriations process.

In FY 02, the federal government began providing grants to states for the establishment and improvement of PDMPs through the Department of Justice (DOJ) which to date has totaled $36.5 million. While this program has helped combat prescription drug abuse, we believe, as the President does, that battling this problem is first and foremost a public health issue and therefore more appropriately handled by HHS. In addition, addressing a problem this complex should be done through an authorized program such as NASPER which was fully vetted by Congress. DOJ has acknowledged that NASPER is now law and has pledged to work with HHS to ensure what we hope will be a smooth transition from one agency to another.

Because of the strict timetable set forth in NASPER, it is vital funding be included in the FY 07 budget to ensure HHS is able to promulgate regulations and seek public input, thereby allowing the agency to award grants the same year. Given the existence of NASPER, it is inappropriate to fund the current DOJ program which was never authorized. Doing so will not only create confusion among states applying for funding, but to both DOJ and HHS as they try to administer similar programs.

We appreciate your assistance in this matter and we look forward to working with you to ensure NASPER is fully funded in FY 07.

Sincerely,

Joe Barton
Member of Congress

John Dingell
Member of Congress

Ed Whitfield
Member of Congress

Frank Pallone
Member of Congress

Charlie Norwood
Member of Congress

Ted Strickland
Member of Congress

Nathan Deal
Member of Congress

Sherrod Brown
Member of Congress

Ralph Hall
Member of Congress

Bart Stupak
Member of Congress

Michael Bilirakis
Member of Congress

Eliot Engel
Member of Congress

Fred Upton
Member of Congress

Charles Gonzalez
Member of Congress

John Shimkus
Member of Congress

Tammy Baldwin
Member of Congress

Charles "Chip" Pickering
Member of Congress

Mary Bono
Member of Congress

Anne Northup
Member of Congress

Mike Ferguson
Member of Congress

Mike Rogers
Member of Congress

Chris Shays
Member of Congress

Exhibit 7

ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

June 26, 2006

The Honorable David Dreier
Chairman
Committee on Rules
U.S. House of Representatives
H-312, The Capitol
Washington, DC 20515

Dear Chairman Dreier:

I am writing to request that the Rules Committee not protect certain legislative language set forth in the H.R. 5672, making appropriations for Science, the Departments of State, Justice, and Commerce, and related agencies for the fiscal year ending September 30, 2007, from points of order on the House floor. The Committee Print filed on June 22, 2006 contained a provision that constitutes an expenditure not authorized by law, and thus should remain subject to a point of order pursuant to clause 2 of Rule XXI of the Rules of the House.

Specifically, the provision set forth on page 24, lines 17-18 contained in H.R. 5672, should remain subject to a point of order because the pertinent drug monitoring program was never authorized. Accordingly, I request that the Rules Committee not protect this provision from a point of order under clause 2 of Rule XXI on the House floor. My staff conferred with the Office of the Parliamentarian about the primary jurisdiction of the Committee on Energy and Commerce over the provision.

Thank you for your attention to this matter.

Sincerely,

Joe Barton
Chairman

JB/res

cc: The Honorable J. Dennis Hastert
The Honorable John D. Dingell
The Honorable Jerry Lewis
The Honorable David R. Obey
The Honorable Louise Slaughter

Exhibit 8

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

March 29, 2007

The Honorable David Obey
Chairman
U.S. House Committee on Appropriations
H-218, the Capitol
Washington, D.C. 20515

The Honorable Jerry Lewis
Ranking Member
U.S. House Committee on Appropriations
H-323, the Capitol
Washington, D.C. 20515

Dear Chairman Obey and Ranking Member Lewis:

As members of the Committee on Energy and Commerce, we are writing to request that you include $10 million in the FY 08 Labor, Health and Human Services, and Education (Labor/HHS) Appropriations Bill for the National All Schedules Prescription Electronic Reporting Act (NASPER), P.L. 109-60.

On August 11, 2005 President Bush signed NASPER into law, making it the only statutorily authorized program to assist states in combating prescription drug abuse of controlled substances through prescription drug monitoring programs (PDMPs). NASPER, which was authorized by our Committee and is administered by the Department of Health and Human Services (HHS), provides grants to states to establish and improve PDMPs. The law authorizes $10 million in FY 08 and $10 million each year through FY 10.

In FY 02, the federal government began providing grants to states for the establishment and improvement of PDMPs through the Department of Justice (DOJ), which to date has totaled $36.5 million. While this program has helped combat prescription drug abuse, we believe that battling this problem is first and foremost a public health issue and therefore more appropriately handled by HHS. In addition, addressing a problem this complex should be done through an authorized program such as NASPER, which was fully vetted by Congress. The DOJ program was created by an earmark and was never vetted by the House or Senate Judiciary Committees.

We also remain deeply concerned over the apparent acquiescence of the Office of Management and Budget to disregard federal law by including the DOJ program in the administration's FY 07 and FY 08 budget. Indeed, our Committee asserted the right to guard our jurisdiction last year when we made a point of order in the FY 07 Science, State, Justice Appropriations bill against the DOJ program.

Because of the strict timetable set forth in NASPER, it is vital funding be included in FY 08 to ensure HHS is able to promulgate regulations and seek public input, thereby allowing the agency to award grants this year. Given the existence of NASPER, it is inappropriate to fund the DOJ program. The continued funding for the unauthorized DOJ program is creating confusion among states who are seeking to establish and enhance PDMPs by following the guidelines set forth in statute. It also sets a bad precedent by sanctioning the creation and continued operation of federal programs through the appropriations process. We therefore urge you to include $10 million in the FY 08 Labor/HHS Appropriations bill for NASPER.

Thank you for considering our views and we look forward to your response.

Sincerely,

John D. Dingell
Chairman

Joe Barton
Ranking Member

Frank Pallone
Member

Ed Whitfield
Member

Bart Stupak
Member

Nathan Deal
Member

Anna G. Eshoo
Member

Fred Upton
Member

Eliot L. Engel
Member

Mary Bono
Member

Exhibit 9

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

October 15, 2007

The Honorable Jim Nussle
Director
Office of Management and Budget
Executive Office of the President
725 17th Street, N.W.
Washington, D.C. 20503-0009

Dear Director Nussle:

On August 11, 2005, President Bush signed into law the National All Schedules Prescription Electronic Reporting Act (NASPER), (Public Law 109–60). The passage of NASPER in the 109th Congress was the result of extensive hearings and bipartisan and bicameral agreement on the most effective Federal approach to combating the growing problem of prescription drug abuse. NASPER authorizes the Department of Health and Human Services (HHS) to provide grants to States to establish and improve prescription drug monitoring programs (PDMPs). The law authorizes $15 million in fiscal year (FY) 2007 and $10 million each year through FY2010.

The statutory scheme established by NASPER strikes an appropriate balance between the public interest in ensuring patient access to necessary and legitimate medical treatment, while at the same time, detecting and preventing the diversion of controlled substances. The NASPER program, administered by HHS, provides an important complement to the President's Health Information Technology Plan, for which HHS is the lead Executive Branch agency, and draws on the medical privacy and health technology expertise at HHS. It is noteworthy that a significant majority of the States that already have established PDMPs have elected to administer those programs through their State health departments, rather than their law enforcement agencies. We believe that this trend reflects the growing recognition that prescription drug abuse is a critical public health issue that must be addressed "on the front end," by healthcare providers prescribing and dispensing controlled substances, as well as a law enforcement problem that must be addressed with optimal tools. In recognition of these dual public policy challenges, the NASPER program ensures that law enforcement officials have consistent and uniform access to dispensing data for purposes of drug diversion investigations, while healthcare practitioners have ready access to patient prescription histories so that they can best address the patient's legitimate medical needs.

In passing NASPER two years ago, Congress intended to enable healthcare practitioners and law enforcement officials to detect and thwart "doctor shopping" by addicts crossing State lines by ensuring that State PDMPs could share prescription data based on uniform data collection and privacy protections. For that reason, NASPER requires that grantee States adopt health information interoperability standards, including health vocabulary and messaging standards, and be capable of achieving interoperability with at least one other State. We are concerned that all but two States that currently operate PDMPs still cannot exchange data with each other, and have little incentive to do so. In addition, a number of the States operating PDMPs do not track all scheduled drugs, do not consistently make prescription data available to both law enforcement and healthcare providers, and otherwise fail to achieve the minimum standards that NASPER imposes.

In the 109th Congress, the Committee wrote on January 13, 2006, to request that the Office of Management and Budget (OMB) ensure that funding for NASPER was included in the President's 2007 budget, as NASPER is the only Federal program statutorily authorized to assist State PDMPs. Because of the timetable in the statute, it was and is critical that funding be made available so that HHS can promulgate regulations, seek public input, and begin the grant process immediately. Notwithstanding, the Administration included funding not only in its FY2007 budget, but also in the FY2008 budget for an unauthorized grant program administered by the Department of Justice, and failed to include funds for the program in the bill signed into law by the President.

The Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce will hold a hearing on October 24, 2007, entitled "NASPER: Why Has the National All Schedules Prescription Electronic Reporting Act Not Been Implemented?" It is important to the Committee that OMB participate in the hearing and testify on the status and funding of the NASPER program. Concurrently with this letter, you will receive an invitation to appear at the hearing. We look forward to your appearance, and would appreciate your providing the Committee staff with a briefing in advance of the hearing.

Sincerely,

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Exhibit 10

boston.com

THIS STORY HAS BEEN FORMATTED FOR EASY PRINTING

Mass. tracks children on psychiatric drugs

The Boston Globe

Prescriptions eyed after overdose

By Scott Allen, Globe Staff | October 7, 2007

Following the death of a 4-year-old Hull girl from an overdose of psychiatric drugs last December, state officials have set up a unique early-warning system to spot preschoolers who may be getting excessive medication for mental illness. In just the first three months, the system has flagged the cases of at least 35 children for further investigation, and the number is sure to rise.

The state Medicaid program is analyzing records of 82,900 children under age 5, looking for those taking at least three psychiatric drugs or a single prescription of a powerful antipsychotic drug. Mental health professionals will review the care of these children and, if necessary, contact the prescribing doctor for an explanation, say officials of the state insurance program for lower-income families, known as MassHealth.

Although cases like the overdose of Rebecca Riley are rare, the prescription of psychiatric drugs to young children is not. Doctors last year prescribed Clonidine - a drug sometimes used to treat hyperactivity that was found in lethal quantities in the Hull girl's bloodstream - to 955 children under age 7 in MassHealth. Doctors also prescribed antipsychotic drugs, which raise the risk of diabetes and obesity, to 536 children under age 7, according to MassHealth records. MassHealth could not say how many of these cases involve children under age 5 and might be subject to review.

Some psychiatrists have been concerned for years about the rise of psychiatric drug treatment of young children, largely because few preschoolers are old enough to show clear signs of mental illness and there are almost no studies on how the chemicals affect their developing brains. But until Riley's death from three drugs she was taking to treat bipolar disorder and hyperactivity, the state provided little oversight of doctors' prescribing practices.

Riley's death "was a wake up call," said Dr. John Straus, vice president for medical affairs at the Massachusetts Behavioral Health Partnership, one of the organizations that manage mental health care for children in MassHealth. He said MassHealth managers want to make sure that doctors have good reason for prescribing psychiatric drugs to such young patients and that they are not relying solely on the parents or guardians for information about each child's condition. Riley's parents have been charged with deliberately giving her a fatal overdose.

"If the behavior is extreme enough to require this level of medication, we ought to make sure that the behavior exists," said Straus, by checking with day-care providers and other independent observers.

The oversight system is too new to say how many cases will merit contacting the prescribing doctor, officials said, but the largest provider of mental health services for MassHealth - Massachusetts Behavioral Health - identified 35 preschoolers in the first three months of the system who were taking three psychiatric medications or one antipsychotic drug. Four other managed-care organizations have also begun reviewing children's MassHealth prescription records, but their findings have not been released.

Nonetheless, Straus said he hopes that fewer than 100 children under age 5 enrolled in MassHealth will trigger the early-warning system in the course of a year.

Deputy Mental Health Commissioner Robert J. Keane, who led the effort to create the tracking system, stressed that it isn't meant to punish doctors or second-guess their judgment. He noted that some children, such as those who are extremely self-destructive, may need multiple medications. However, he said MassHealth's outreach could help some doctors make more informed decisions when they prescribe drugs for very young children.

"Clinical decision making often happens in isolation. It's a problem in healthcare," said Keane, suggesting that some doctors may not realize they are overprescribing psychiatric drugs to preschoolers.

Until the 1990s, children under age 5 were rarely treated with psychiatric drugs for mental illness, in part because the conditions are hard to diagnose in children too young to discuss their feelings or control their impulses. But by 2000, Dr. Joseph T. Coyle of McLean Hospital in Belmont was warning of a "growing crisis in mental health services to children" amid reports that the number of preschoolers taking drugs for attention deficit/hyperactivity disorder had doubled in four years. Writing about a major study of preschool psychiatric drug prescriptions in the Journal of the American Medical Association, Coyle argued that disturbed children were getting drugs as a "quick fix" instead of more time-consuming therapy and other family services.

Riley's death focused attention on the growing use of drugs among preschoolers for another condition, bipolar disorder, which is characterized by wide mood swings and was once thought to begin in late adolescence. Her doctor, Kayoko Kifuji, diagnosed the girl with the condition when she was 2 1/2 years old. Kifuji has voluntarily given up her license to practice medicine while regulators investigate her treatment of Riley, and the girl's mother, Carolyn Riley, said on "60 Minutes" last Sunday that she no longer believes her daughter was bipolar. The parents blame Kifuji for their daughter's death, though she denies wrongdoing.

Despite unease over the amount of psychiatric drugs being prescribed to preschoolers, few states have tried to rein in prescriptions beyond drug educational programs for doctors or other forms of doctor assistance, such as Massachusetts' popular network of psychiatrists who are available for instant phone consultations concerning young patients.

However, one state's experience is instructive: Texas officials adopted an early-warning system last year for mental health care of children in state foster care, and they saw an immediate drop in prescriptions of psychiatric drugs for children under 18 once they started contacting doctors who prescribe large amounts of psychiatric medication. Since 2004, the percentage of foster children receiving at least one psychiatric drug prescription has fallen from 29.9 to 24.4 today.

"Just the fact that doctors are being asked to get involved in this discussion, they are going to be a little more reflective about what they are doing," explained Ted Hughes, spokesman for the Texas Health and Human Services Commission. He added that foster children tend to have a higher rate of medication than others because they often face complex emotional problems.

MassHealth officials said it's unclear whether Massachusetts needs to reduce the rate of drug prescriptions to young children: their records show that the number of young children receiving antipsychotic drugs began declining in 2005.

Keane said that most psychiatric drug prescriptions for preschoolers are written by child psychiatrists rather than pediatricians or family doctors, meaning that trained specialists are making the drug decisions. Riley's doctor was a child psychiatrist at a Boston teaching hospital, Tufts-New England Medical Center.

Under the early-warning system, managed care organizations are reviewing prescription records for all children under age 5 who are receiving mental health treatment paid for by MassHealth. They are expected to keep a closer eye on those who are taking drugs and to conduct a case review of children receiving an unusual quantity or an antipsychotic.

The reviewers will be looking to make sure that the high rate of prescriptions is not an error caused by more than one doctor writing them, and checking to make sure the drugs don't have dangerous side effects when taken together, Straus said. They will also look at the child's history for signs of abuse, evidence of emotional problems, and other issues aside from mental illness that could explain behavior problems. The point is to make sure doctors try other forms of treatment or social services before turning to drugs, Straus said.

Straus said he is encouraged by results of the early-warning system. He said the behavioral health partnership has only contacted a handful of doctors so far to discuss prescriptions for at-risk children, but they had reasonable explanations for the children's treatment plans. "They were being thoughtful about it," he said.

Keane said the new system is an experiment since apparently no other state has done something quite like it

before. But, if the tracking system works, he said, it could be expanded to many of the 300,000 Massachusetts children under age 5 who are not in the MassHealth program.

"This is really the start of this process," he said.

Scott Allen can be reached at allen@globe.com. ■