S. HRG. 110–750

GENERATION RX: THE ABUSE OF PRESCRIPTION AND OVER-THE-COUNTER DRUGS

HEARING

BEFORE THE

SUBCOMMITTEE ON THE CONSTITUTION

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

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GENERATION RX: THE ABUSE OF PRESCRIPTION AND OVER-THE-COUNTER DRUGS

WEDNESDAY, MARCH 12, 2008

U.S. SENATE,
SUBCOMMITTEE ON CRIME AND DRUGS,
COMMITTEE ON THE JUDICIARY,
Washington, DC

The Committee met, pursuant to notice, at 2:10 p.m., in room SD–106, Dirksen Senate Office Building, Hon. Joseph R. Biden, Chairman of the Subcommittee, presiding.

Present: Senator Grassley.

OPENING STATEMENT OF HON. JOSEPH R. BIDEN, A U.S. SENATOR FROM THE STATE OF DELAWARE

Chairman BIDEN. The hearing will come to order.

I have an opening statement. My colleague and co-chair here can only stay about a half an hour because he has a whole lot of folks he has to be meeting with shortly, so I am going to put my opening statement in the record in order to save some time.

Just let me say, though, that I really appreciate all the witnesses being here today. This is the Judiciary Subcommittee on Crime and Drugs, and the Senate Drug Caucus. We hopefully are going to be able to shed some much-needed light on what seems to be a trend that has crept into households and communities across the country, and that is abuse of prescription drugs and some over-the-counter drugs.

But with that, as I said, I will put my opening statement in the record and I will yield to my colleague, if he has any opening statement to make.

[The prepared statement of Senator Biden appears as a submission for the record.]

STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM THE STATE OF IOWA

Senator GRASSLEY. Yes. I have got a long one, so I should put it in the record, too. But I would like to summarize a little bit. Over here on the right is one of our witnesses, Derek Clark, from Clinton, Iowa.

Chairman BIDEN. I know Clinton. I know Clinton.

Senator GRASSLEY. Yes. You have been in every county in Iowa.

Chairman BIDEN. That is true. It did not do a hell of a lot of good, but I was there.

[Laughter.]

A lot of nice people you have out there.

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Senator GRASSLEY. Now, our witness has served as executive director of the Clinton Substance Abuse Council for the last 10 years. As executive director, Mr. Clark works with a wide variety of community members to develop solutions to substance abuse problems in and around Clinton, Iowa. So, we thank you for being here.

In just a way of summarizing, because it is a long statement I am going to put in the record, we do have some recent statistics of a downturn in the use of illegal drugs. But for the purposes of this hearing, we are finding that there is not this downturn, in fact, a quick awakening that needs to be done about the use and abuse of prescription drugs and over-the-counter drugs.

So to bring attention to this and to bring attention to a piece of legislation that you and I have put in on DXM that we sponsored last year, it is very important to have this hearing. But I think one of the most important things that can come out of this hearing is to alert parents who are very concerned about their young people's use of illegal drugs, that right there in the medicine cabinet could be a source of abuse and a major problem, and things that are harmful to health that we hope this hearing will bring attention to.

Thank you.

[The prepared statement of Senator Grassley appears as a submission for the record.]

Chairman BIDEN. Thank you very much. As I said, we have a very distinguished panel, our first panel. It has not been, as they say, a long time between drinks before we had—Doctor, it's a delight to have you back. Thank you for being here. Is Paulozzi the correct pronunciation?

Dr. PAULOZZI. Paulozzi.

Chairman BIDEN. Paulozzi. I beg your pardon. Dr. Paulozzi is here as well. He is a medical epidemiologist in the Division of Unintentional Injury Prevention at the National Center for Injury Prevention and in control of the CDC. He has been working in public health since 1983 and he's worked 8 years in the State health departments as an epidemiologist, focusing on injuries and chronic diseases. He returned to the CDC in 1993, and joined its Injury Center in 2000. He currently spends most of his time on unintentional poisoning, particularly that involving prescription drugs, as I understand it.

Doctor, I am going to submit again for the record your background. It's impressive. Again, thank you for coming back. I appreciate it very, very much. It's an honor to have you here.

With that, why don't I begin by yielding the floor and going to you, Doctor, first, if you will.

STATEMENT OF NORA VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. VOLKOW. Yes. Good afternoon. The privilege is mine to be here.

In 2006, it is estimated that 7 million individuals abused prescription medications for non-medical use in the United States. Seven million. Last year, actually, the number of new initiates for the abuse of prescription pain relievers was greater than the number of new initiates for marijuana. As you mentioned, this is in the

context of decreases in illicit substance abuse that has occurred in the United States over the past 5 years.

What are the five prescription medications that are abused? There are three types: stimulant medications such as Ritalin, and Concerta, and Adderall that are used for the treatment of attention deficit disorder; pain analgesics that contain opiates that are used for the treatment of severe to moderate pain, like Oxycontin and Hydrocodone; and sedative hypnotics, which are medications such as benzodiazepine, Xanax, Valium, that are used for the treatment of sleep disorders and anxiety disorders.

Why are these drugs or medications specifically abused? They are abused because they increase in the brain the concentration of a chemical, dopamine, in reward centers, and these are exactly the mechanisms by which drugs of abuse produce their rewarding effects and lead to addiction.

There are two factors that determine whether a drug will be rewarding vis-a-vis just being therapeutic. One of them is the doses used. When it is abused, it actually requires much higher doses than when it is used therapeutically, and much more frequently. The other one is the route of administration. When it is abused, it is usually snorted or injected, and that is because this leads to faster concentrations in the brain, and the faster the drug gets into the brain, the greater its rewarding effects.

Now, what are the medical complications? Just as for illicit substances, just as for them, drug addiction. Now, in addition to that there are a series of medical complications that are specific for each class of drugs. The most problematic vis-a-vis the morbidity and mortality relates to opiate analgesics, such as Oxycontin and Hydrocodone because opiates decrease, depress the respiratory centers in the brain and can therefore lead to stopped breathing and death.

The same is true for sedative hypnotics such as benzodiazepines, except that the therapeutic window between the dose that you give for medical purposes and that that will kill you is not as close and dangerous as it is for opiates.

In the case of stimulants, the risks actually involve seizures, they involve hyperthermia, and they involve cardiac arrhythmias and myocardial infarctions and stroke that can also kill you. These drugs can also produce changes in alertness and motor coordination that contribute to accidents. The risk of complications is significantly increased when these medications are consumed with other medications, with alcohol, or with illicit substances.

Everyone is at risk for abusing or becoming dependent on prescription medications. It does not matter your gender, it does not matter your age, it does not matter your socioeconomic classes. Particularly problematic, though, are adolescents, because in adolescents the brain is still developing and these medications may actually interfere with this developmental process.

A question we ask—is: why are we seeing these dramatic increases now? There are multiple factors, but one of the most important has to do with significant dramatic increases in prescriptions for these medications, which lead of course to drug availability. How big are these increases? Looking at the numbers, they speak for themselves: sevenfold increases in the number of prescriptions

over the past 16 years for stimulants. Seven-fold. They have gone from 4.5 million to 33 million. Opiate analgesics, fourfold increases, from more than 40 million to almost 180 million prescriptions per year. Think about it: 180 million prescriptions for opiate analgesics per year in the United States.

There are other factors that are likely to contribute, as society is increasingly willing to accept medications for the treatment of almost any condition: pervasive advertisement, and very important, the sense that because these medications are prescribed by physicians, they are much safer than that of illicit substances, which of course is an incorrect statement.

Now, what is it that science is doing and what is it that NIDA is supporting? We are aware that there are two trajectories, one that is initiating the abuse with a legitimate prescription that, in individuals that are vulnerable, can lead to abuse. The other one that is initiating as drug experimentation. Both of them can lead to drug addiction.

So we are developing research that entails both an understanding about the genetic factors that lead to this vulnerability, the neurobiological consequences, how do these drugs affect the brain and the body, and epidemiological factors, the pattern of their abuse. We are also helping to support the development of medications that can serve as powerful analgesics or as stimulant medications that do not have abuse liability, as well as new delivery systems that minimize the risk of addiction and dependence.

We are also very aware that these medications, when used properly, can be life-saving. The importance of educating the community, both the medical and the lay public, as well as developing standards and evaluating so that we can maximize the therapeutic benefits of these medications and minimize their abuse is critical.

The problem of prescription drug abuse is an urgent one that requires urgent action. I applaud you for your interest in this subject, and I would be happy to answer any questions you may have.

Chairman BIDEN. Thank you.

Doctor?

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

Dr. PAULOZZI. Good afternoon, Chairman Biden and Senator Grassley. My name is Dr. Leonard Paulozzi and I'm a medical epidemiologist with the CDC, which is part of HHS. Thanks for the opportunity to appear before you on behalf of CDC to discuss our Agency's research and prevention activities addressing drug overdose deaths. Thanks also for your continued support of CDC as we work toward becoming the healthiest Nation.

I will be talking about unintentional overdose deaths today. Drug suicides are not included in the data I'm going to show you. The information I share with you will be based primarily on death certificates. I have a set of slides, and I will walk you through them. They are numbered in the bottom right-hand corner.

Slide two. This slide shows the trend in the drug overdose deaths, or mortality, in the United States from 1970 through 2005. As you can see from this, there has been a steady increase in the drug overdose mortality rate. There were increases for epidemics of heroin in the mid-1970s and the crack cocaine problems in the late 1980s and early 1990s. Currently, we are in the midst of what we are calling a prescription drug overdose epidemic. Rates now are twice the rates obtained during the crack cocaine era, and four to five times the rates in the mid-1970s.

Chairman BIDEN. And we are talking, Doctor, about overdose deaths?

Dr. PAULOZZI. We are talking about drug overdose deaths, exactly.

Chairman BIDEN. And the chart shows, in the upper righthand corner, from 2002 to 2004, prescription drug. That is cumulative, right? In other words, are we talking about the same chart?

Dr. PAULOZZI. Yes, we are. Yes.

Chairman BIDEN. OK. The prescription drugs. These aren't totally a consequence of prescription drugs.

Dr. PAULOZZI. No.

Chairman BIDEN. This is when prescription drugs became more of a problem.

Dr. PAULOZZI. Right. They are accounting for the increases I will show you in just a moment.

Chairman BIDEN. Got you. Thank you.

Dr. PAULOZZI. The rate in 2005, which is the last bar in the figure, translates into 22,400 deaths in the United States. To put this into context, there were 17,000 homicides that year. Drug overdose deaths are second only to motor vehicle crashes.

Chairman BIDEN. Excuse me again, Doctor.

Dr. PAULOZZI. Sure.

Chairman BIDEN. This is not prescribed. This is a combination. We're both asking each other the same question.

Senator GRASSLEY. About the 22,000 deaths.

Chairman BIDEN. Twenty-two thousand deaths.

Dr. PAULOZZI. Yes.

Chairman BIDEN. They are overdose deaths. But are they overdose deaths that include people who were prescribed the medicine and abused it as well as people who were not prescribed the "legal" drug, but acquired it and used it, correct?

Dr. PAULOZZI. Yes. Just to be clear, this is total drug overdose deaths, drugs of all types, whether prescribed or not.

Chairman BIDEN. Got you.

Dr. PAULOZZI. And in subsequent slides, I will break it down for you—

Chairman BIDEN. OK. Thank you.

Dr. PAULOZZI.—as to what proportions were accounted for by prescriptions.

Chairman BIDEN. That's good.

Dr. PAULOZZI. So drug overdose deaths are second only to motor vehicles as a cause of unintentional injury death. Recently, for the 45- to 54-year-old age group in the United States, they became the leading cause of unintentional injury death, passing motor vehicle

crashes for the first time in as long as we have been tracking these statistics.

So how do we know that this is prescription drugs? Slide three. This shows you the trend in drug overdose rates from 1999 through 2005. We have broken down the earlier figure we were just talking about into the three major components. The red line is "Deaths Due to Narcotics", which includes the narcotic painkillers, cocaine, and heroin. The yellow line is called "Other, Specified and Other Drugs", and then the white line is "Sedatives and Psychotherapeutic".

You might think from looking at this that the increase in recent years has been because of narcotics, which we think of as cocaine and heroin. But in fact that is not the case. If you go to the next slide, number 4, this slide also looks at 1999 through 2004 data. It comes from a study we published in 2006, where we drilled down a little bit further into this narcotics category and were able to break it down into three main constituents. Those are prescription opioids, which is the line in red, cocaine and heroin.

What this slide shows, is that the increase from 1999 is being driven by prescription opioids, which is the prescription painkillers. That includes Oxycontin, Vicodin, it also includes methadone, which is increasingly being used as a narcotic painkiller. Most of the increases, only some of it is due to cocaine, and very little is due to heroin-related deaths.

For the most recent year of data we broke it down even more finely, and this is slide five. This shows you the specific drugs that are involved, the first listed drug codes among the drug overdose deaths in the latest year we have available, 2005. The red bars represent the prescription painkillers. They accounted for 38 percent of these drug overdose deaths.

As you can see, a substantial fraction had methadone listed as the first listed painkiller. The white bar is psychotherapeutic drugs, like Valium and antidepressants. Together, they account for 45 percent of these drug deaths. Street drugs—cocaine, heroin, methamphetamines—accounted for 39 percent. The other specified drugs are mostly prescription drugs as well. So you can see that we have moved from an era of illicit drugs to an era where prescription drugs dominate the picture, and they are accounting for the increases you see in the first figure.

With this shift in the type of drugs, we are also seeing a shift in the demographics, the people who are dying. It is still men who primarily die of drug overdose deaths, as it always has been, but now it is people in their 40s and early 50s who have the highest rates of drug overdose death in the United States. Rates in whites recently passed drug overdose rates in African Americans. It is no longer an urban phenomenon, which is what we tend to associate with drug overdose deaths.

If you look at a map of the United States, which is the sixth slide, you can see that the States with the highest rates, shown in the darkest color, are some of our more rural States. West Virginia, for example, has the highest rate. The State of Maine has a high rate. So the problem has shifted from an urban to a rural focus.

Slide seven. What's causing these deaths? These are not the accidental poisoning deaths of children and these are not elderly people

mistakenly taking too much medication. These deaths are related to the increasing use of certain prescription drugs, particularly the painkillers, by people in the middle years of life. In most of these deaths, there is evidence that they were related to the misuse or abuse of prescription drugs.

Slide eight shows the same trend. It marks on that a red line showing sales of painkillers, indicating since painkiller sales seem to be tracking with—we expect an increase in 2006 in the mortality rates. Indeed, data from the Drug Abuse Warning Network's Emergency Department Surveillance System shows an increase in the number of emergency department visits associated with opioid painkillers in all the years since 2005 through 2007.

Slide nine. What can we do about this? We need to get the most out of State prescription drug monitoring programs to identify doctors and patients who are abusing the system. We need to modify patients' behavior with insurance mechanisms. Hospitals might require screening for substance abuse in their emergency departments before opioids are prescribed. Primary care doctors need practice guidelines for when to prescribe and when to take people off the drugs. The drug manufacturers can make the prescription drugs more tamper-resistant so people do not crush them, dissolve them, and inject them.

Prescription overdoses are a serious public health problem, and the CDC will continue to respond with surveillance and epidemiologic studies and evaluation of interventions.

I would like to thank you for the opportunity to talk about this problem, and I appreciate your continued support of the CDC Injury Center. I would be happy to answer any questions.

[The prepared statement of Dr. Paulozzi appears as a submission for the record.]

Chairman BIDEN. Thank you. You both represent two of the greatest assets this country has, NIH and CDC.

I have a lot of questions, which is very convenient that I am the only one here, so I get to ask them.

[Laughter.]

My staff is going to be upset because I am not using their questions.

Folks, let me ask, the NIH is looking at—Doctor, you indicated, looking at genetic factors. Going to be looking at, or have begun. I was not quite sure I understood your statement. Talk to me a little bit about that. Tell me what you are doing different at NIH recently relative to looking at genetic factors relating to drug abuse.

Dr. VOLKOW. For many years now, at NIDA we have been studying the genetic factors that makes individuals more vulnerable to experimenting with drugs, and when they experiment with drugs, as we know, not everybody becomes addicted. So what are the genetic factors that lead to people becoming addicted and those that do not? We know that approximately 50 percent of drug vulnerability to the risk of addiction is genetically determined.

What we are doing now vis-a-vis this new problem of addiction to prescription medications, it becomes increasingly urgent to try to understand what those vulnerabilities may be, because, for example, for me as a physician, having a patient that may require a strong medication against pain, it will be incredibly important to

know their risk. Why? Because if they do have the genetics and vulnerability for addiction, the way that I will prescribe may be affected by it. Thus, from the medical perspective that becomes a very urgent need.

Genetics is also important because, as you identify what genes are involved in vulnerability, what we are finding, for example, is we are uncovering genes that we have never paid attention to, so new molecules that can now be looked into as potential treatments, or even prevention strategies for addiction. That is why this area of research is so important.

Chairman BIDEN. One of the areas that I have had the greatest interest in for over 30 years, is this area, all the way back to dealing with trying to find—I introduced years and years ago legislation calling for the expenditure of a billion dollars a year, and then I went to a billion dollar program to find antigens or antagonists for certain drugs.

The drug companies do not want to become the drug company. Drug companies do not want to do this investigation. I understand why. Even if they find "a cure" for cocaine addiction, folks who are addicted ain't looking to buy it, don't have the money to buy it. The universe is not that big, they're not going to make that much on it. So we came up with the Orphan Drug Act a long time ago to try to promote that.

One of the things I find startling is the number of doctors who do not ask before they prescribe painkillers, even whether or not someone is a recovering alcoholic or a recovering drug abuser, someone in recovery. Well, they are always in recovery. But let me ask you a crazy question. Do they teach that in medical school? I mean, I am not being a wise guy, now. I am being deadly earnest. I am not being a wise guy and I'm not out looking to pick on the medical profession, or anyone else.

But it astounds me, the number of times—having an uncle who is an alcoholic, and a brother who is a recovering alcoholic, the number of times that, you know, they have other physical ailments. In other words, in one case, broken bones. The prescription is just automatic. No one asked any questions. Is that part of the protocol that more doctors are learning about or is that even worth the effort?

Dr. VOLKOW. The answer is, of course it's worth the effort. I am very sensitive to that same issue, and I'm sensitive because I've encountered multiple cases where patients have relapsed, that had a problem with drug abuse, because they were given a pain opiate and the doctor never asked the question.

I also smile because it has been also very frustrating for me to be aware that in the medical system there is very little education regarding substance abuse. As a result of that, medical students are not taught how to screen and evaluate it. That is a lost opportunity, because by doing an intervention at that point where patients go to seek help, you can have a much greater impact.

With respect to opiate medications, while we do not have the genetics about what makes you vulnerable, we know that individuals that have a past history of drug abuse or dependence in themselves or their family members are likely to be at greater risk. I just add that that's not just for illicit substances, it is alcohol, it is nicotine.

If you have a past history of nicotine dependence, you are very likely to have a higher risk of becoming dependent. Physicians are not asking.

So we put an initiative—that was what I was mentioning, the issue of education, to really develop educational guidelines for medical students and specialties to be able to recognize and do interventions in the case of substance abuse.

Chairman BIDEN. Doctor, do you have any response?

Dr. PAULOZZI. Yes. I think that most physicians today have gotten some training. But for most, it's focused on the illicit drugs. The widespread use of powerful narcotic painkillers is a relatively recent phenomenon in the United States. It is really just since 1990 and 1992 that these drugs have come into favor.

Chairman BIDEN. Why?

Dr. PAULOZZI. Well, there was around the time a sense that pain is being under treated in the United States, that people who suffer from serious diseases like cancer were not being given narcotics for fear of addiction. A lot of that was definitely the case. There were some studies that suggested the risk was low for use of opioids. The drugs are safe and effective, when used as directed. But the key is in that phrase "as directed".

What's happened, is physicians today do not have a great deal of experience, and certainly not training in medical school, for the management of long-term opioid therapy. There are guidelines out there, but we don't think they're being routinely followed.

Chairman BIDEN. What I find kind of astounding, is I can understand the increase because some of these drugs are relatively new to the market in the last decade, decade and a half. As you said, used as prescribed, they're of great benefit to people. But I didn't realize that there were, respectively, seven and four times—in the case of opiates, it as seven times. Is that correct?

Dr. VOLKOW. Four times.

Chairman BIDEN. Four times. In the case of stimulants?

Dr. VOLKOW. Seven times.

Chairman BIDEN. Seven times the number of prescriptions written. Now, I mean, that surely does not correspond to population increases. I should not say "surely". It doesn't appear to me to relate to that many new and more effective, efficacious stimulants and/or opiates that are prescribable now. So has there been any study done to suggest that?

We're going to hear from a witness on a second panel who's done a lot of good work in the prevention area, and indicated that abuse of prescription drugs tends to be for reasons—as I remember reading the testimony last night on my way home on the train—that had to do with pressure from grades, classes, studying for a test, coming down after a stressful day as opposed to what I would have thought back in the old days when I was doing most of this work, was just to literally feel the effect, the "abuse" factor just because it felt good, dopamine was produced in the case of opiates.

So are there any studies out there indicating why this incredibly exponential increase in the number of prescriptions written?

Dr. VOLKOW. Well, certainly, epidemiologists have to look at this to understand why there are increases. You are pointing out, there are multiple factors. That's going to be dependent also on the age

of individuals. Among college students, for example, there have been studies that actually determine exactly that, that the reason why they are abusing—and this relates to stimulant medications—is in order to improve their cognitive performance.

Just today I got an e-mail from a professor at Stony Brook that said he was approached by a student because he was concerned that his fellow students were taking stimulants for study, and he resented it because they could study more, so he wanted my advice. So these have been documented as one of the reasons we see an increase in the use of stimulant medications in college years.

With respect to pain medications—that is why I repeated it, 180 million prescriptions per year in the United States. How many individuals do we have in the United States? There are 3 million people that suffer from severe pain, and still it's 180 million. I think it reflects a greater propensity to give opiate medications by the medical community.

Again, I do respect the tremendous value of opiate medications, but I do believe at the same time, while we are under-medicating patients that need it, we are also over-medicating individuals that we should not. For many years, we still believed in the medical community that if you have pain and you get an opiate medication, you are not going to become addicted, that pain protects you. The epidemiological data show that that's not the case. Approximately 5 to 7 percent of those individuals will become dependent. So there is, again, the lack of proper understanding about the effects of these medications that has led, I think, to increasing the risk of seeing these diversions of painkillers.

Chairman BIDEN. I am going to repeat something you said, because I hear it all the time in the community. Not all the time. I hear it in the community. Consuming an opiate to deal with pain, if you're really in pain, you are not going to become addicted. The pain somehow is the thing that keeps you from being addicted to the very thing you're taking in order to reduce the pain. That is not physiologically correct, is it?

Dr. VOLKOW. Well, what the epidemiological data are showing, is it is not. It's protective. It's definitely not a complete protection, because we are seeing people that have pain are becoming dependent through their opiate medication. Now we're actually studying in animal models the extent to which we can prevent the dependence, or in certain instances accelerate the dependence, by pain. So it depends how severe the pain is, how you properly are scheduling the doses. So certainly the answer to, is pain protective so you don't have to worry, the answer is no. Even with pain, you can become dependent to opiates.

Chairman BIDEN. Now, methadone. We've gone through cycles over the last 75 years dealing with how we view methadone. Back in the late 1980s and early 1990s there was sort of a renaissance of the notion that in order to treat heroin—or not treat it, but as a substitute, basically—became, once again, viewed as a more appropriate avenue. Methadone clinics were kind of shut down, then they were opened up and increased.

What is the reason for the methadone? Are there more methadone clinics? Are these people who are, in your chart, overdosing, including the 16 or whatever percent of those who OD'd were be-

cause of methadone, are they people who are in methadone clinics who are trying to beat heroin and then abusing the methadone, or is this a prescription written for other reasons than dealing with heroin addiction?

Dr. PAULOZZI. Well, I am glad you asked the question, because we do think this is methadone written for pain rather than methadone dispensed by narcotics treatment programs.

Chairman BIDEN. Right.

Dr. PAULOZZI. This is methadone in pill form. The clinics use methadone in liquid and wafer form. Various reasons tell us that this is probably a painkiller problem. Studies that have looked at the data from medical examiners have found that only a small fraction of the people dying with methadone in their system were ever enrolled in methadone treatment programs in their States.

Chairman BIDEN. That's an important thing to know, because urban legend spreads pretty rapidly. So if you give me that last statistic, of the people—

Dr. PAULOZZI. Of the people who die and go to the medical examiner and they find methadone in their bodies—

Chairman BIDEN. Right.

Dr. PAULOZZI.—a small percentage—some studies, fewer than 10 percent—have ever been enrolled in a narcotics treatment program.

Chairman BIDEN. Got you. OK.

Now, the other statistic—and every cycle I get back into it. There is always something that surprises me. What surprises me, and I'm going to be revealing my ignorance here, is the age of those abusing prescription drugs. I would bet you that the vast majority of my colleagues, and maybe the public if they were aware this hearing was being held, would assume—we're going to hear witnesses on this issue—that we're talking about teenagers, and sometimes preteens and teenagers, students for whom, as you pointed out, there's more—it's only exceeded by marijuana in the last year, 2007. Is that right?

Dr. VOLKOW. 2006.

Chairman BIDEN. 2006. As sort of the gateway drug, the first time using or abusing a substance. It is, first marijuana is Number one, and prescription drugs are number two. Is that correct?

Dr. VOLKOW. Well, last year, prescriptions outdid marijuana.

Chairman BIDEN. OK.

Dr. VOLKOW. prescription pain relievers outdid marijuana.

Chairman BIDEN. All right. Thank you.

Now, again, when we use those kinds of statistics, which are accurate, it leads people to again focus on young people. But one of you gave a statistic that is either the bulk of the overdose deaths, that people between the ages of 25 and 40, is that what you said?

Dr. PAULOZZI. Well, no. I think I said that the highest drug overdose mortality rates are with people are in their 40s.

Chairman BIDEN. Yes.

Dr. PAULOZZI. The rates basically rise up to 45 and then come back down again. It is really the baby boomer generation in their 40s and early 50s that have the highest death rates. That doesn't necessarily mean that the abuse rates follow that same pattern.

Chairman BIDEN. That's what I wanted to clarify.

Dr. PAULOZZI. Yes. For some reason, the deaths are more concentrated in the middle age group. Maybe they use different drugs, maybe they inject them more, maybe they use heavier doses. But I think surveys from SAMHSA have indicated that people in their 20s may be more likely to report having used a drug recreationally in the previous month.

Chairman BIDEN. Got you.

Now, the other issue was, we talked about at the last hearing we had, Doctor, was the means of ingesting this to abuse it. It's not just merely the abuse, it's the manner in which you abuse. So snorting or injecting an opiate, a prescription drug that's an opiate is, in fact, a quicker way to get a bigger bang out of whatever you're seeking.

Now, both of you said that that there are—are there any discussions, are there any actions being taken on making these drugs more tamper-resistant? What are some of those methods? Are there any manufacturers who are spending any time on this, as you know?

Dr. VOLKOW. Multiple pharmaceutical companies are spending time on this. This is a key component. For many, many years, pharmaceutical companies have been working on developing both analgesics that do not produce independence. Working with changing the delivery system has already happened. Many medications, for example, in terms of stimulants, are already delivered through mechanisms that lead to slower uptake into the brain, for example, Concerta, with longer-lasting effects. Oxycontin actually started as a medication that, in principle, should lead to slower, more stable, uptake in the brain.

The problem with it is, you can extract the substance and then inject it. So what the companies are now working with, are new polymers where you can actually mix the drug with them, and even if you crush it, you cannot inject it. So that's the issue of tampering.

Chairman BIDEN. Good.

Dr. VOLKOW. The other approach that, for example, we've been working with for the development of medications against heroin and for the treatment of addiction to pain analgesics, is to mix these medications with an antagonist. When you take it orally, the antagonist will not be absorbed. But when you take the same medication and inject it, the antagonist will interfere with its effects. So, these are two mechanisms.

Chairman BIDEN. Is that occurring now? I mean, are pharmaceutical companies doing that now?

Dr. VOLKOW. Correct. Absolutely. Absolutely. It's a major area of research, both on opiate medications and stimulants.

Chairman BIDEN. Got you.

Now, one of the statistics that gets people's attention, because when we use percentages, which we have a tendency to do, there's been an X percent increase, so on, and so forth. It doesn't calculate. But I found the comparison that you used, Doctor, saying that those dying from overdose of prescribed and controlled substances exceeded the number of, or was second only to, last year, motor vehicle deaths and this year exceeded motor vehicle deaths?

Dr. PAULOZZI. No, no. I'm sorry. What I said was that unintentional drug poisonings are second to motor vehicle deaths. They are still second to motor vehicle crashes.

Chairman BIDEN. There are roughly 22?

Dr. PAULOZZI. There are roughly 22,400. Motor vehicles are roughly 43,000 per year. I made the comparison to homicide, which has 17,000 deaths per year. I mentioned that in the 45 to 54 age group. Just in that age group, there are now more overdose deaths than there are motor vehicle crashes.

Chairman BIDEN. OK. That's what you said. It was only in that age group.

Dr. PAULOZZI. In that age group.

Chairman BIDEN. OK.

Going back to what I was sort of stumbling around trying to get at, is is there an explanation of why younger people using these drugs have a lower mortality rate from overdose than older people? Not older, but people in their 40s, for example.

Dr. PAULOZZI. Well, it's conjecture, really. It may have something to do with the differences in the types of drugs they use. They may be less likely to tamper with the drugs and inject them. It may have something to do with the pattern and chronicity of their use. It could be that people dying in their 40s are people who are long-term drug users who use much larger amounts of drugs.

Chairman BIDEN. OK.

And is it true—and I'd ask either one of you, if you know—that there is the perception—are there any data that demonstrate this? The perception, particularly among young people, that the abuse of a prescription drug is less dangerous than the abuse of a controlled substance, Schedule I or II substance?

Dr. VOLKOW. Yes, indeed. There have been epidemiological papers that actually have documented specifically what you are saying, that indeed, young people overall have a sense that these are safer drugs, because after all they are being prescribed by physicians.

Dr. PAULOZZI. And the potency has been established. It's not like they're dealing with an unknown, in a sense.

Chairman BIDEN. Yes.

Dr. PAULOZZI. There's no risk of HIV from these drugs. It's because most of the exposure is oral with the prescription opioids. It may be a variety of reasons.

Chairman BIDEN. Now, the recent monitoring figures in the survey, the Monitoring the Future Survey, showed that 7 of the top 11 drugs most commonly abused by high school seniors are prescription drugs or over-the-counter drugs, not illegal street drugs. Now, this figure strikes me as being different than it was a couple of decades ago. Have trends always shown that medicine abuse is such a large proportion of the problem among teenagers? Did we just start asking that question or is this a genuinely new phenomenon?

Dr. VOLKOW. Well, we have been asking the question in Monitoring the Future about certain prescription medications now for many years. Dextromethorphan is a new addition, because we started to see increasing numbers of emergency room admissions mentioning dextromethorphan. So based on data from both the Na-

tional Survey on Drug Use and Health and the Monitoring the Future Survey, there were indications of increased prescription medication abuse, particularly opiates, among youth and young adults beginning in the mid-1990s.

Some of the medications are new. In the past, for example, Monitoring the Future did not differentiate among the opiate medications like Hydrocodone or Oxycontin. However, since 2002, we have asked about these medications separately and have seen steady but alarmingly high levels of abuse among high school seniors: about 5% abusing Oxycontin and about 10% abusing Vicodin in the past year. Among the stimulant medications, we now also differentiate methylphenidate. For the past few years, abuse of stimulants and tranquilizers has been more or less stable. However, we did see the increases in the abuse of sedatives up until this past year, which was the first to show a decline.

The sustained high levels of Vicodin and Oxycontin abuse among adolescents took us by surprise because we did not have a sense about how use of opiates affects adolescents, because most of the heroin abusers were in their 20s. So all of us in the medical community were faced with very young people abusing opiate medications, with which we had no experience.

Chairman BIDEN. I see. There does seem, just from a layperson's eyes, a correlation between the number of prescriptions written and the increase in these studies. I mean, if you have a seven-times increase in opiate prescriptions that are written since the mid-1990s to today and you see this kind of increase, there is some correlation, I guess. I mean, is it that they're just more available in your parents' medicine cabinet?

Dr. VOLKOW. It's both. There are two factors that determine the extent to which you will have abuse of a substance. Number one, availability, so by increasing this massive number of prescriptions. It's fourfold in opiates, sevenfold in stimulants. So you increase prescriptions, you increase production. So in parallel, there is an increase in production, so there's more drug available.

The second one, which is very important—almost as important—is the sense that you have another using the drug. So if you believe that others are using, whether it's true or not, they're much more likely to actually experiment with that drug and use it than you have the sense that it's not. So in stimulant medications, they are so widely prescribed among teenagers or children, that kids feel that it's actually a safe thing to do.

They get it from their friends, actually very frequently. So both of those two are contributing. The excess availability, the fact that there's much more medication available, and the other one, the perception that people are taking it and nothing bad is happening to them.

Chairman BIDEN. Now, the last question I have is, tell me if there is a correlation between the abuse of stimulants, for example, and moving on to controlled substances. In other words, one of the things I remember is that you find real serious drug abusers deciding they need just a higher and higher high, so they keep figuring out ways to concoct what they're ingesting in order to get a bigger hit from what they're doing.

Is that part of the pattern? A kid abuses a drug that his friend is taking for attention deficit syndrome that has been prescribed by his doctor. Does that kid end up staying in that realm, or is there a likelihood that they move into other drugs, street drugs? I mean, is there any correlation between prescription drug abuse and what people refer to as street drugs?

Dr. VOLKOW. We know that, for the opiate analgesics, there is clear-cut evidence that initiation with an opiate analgesic, in many instances, can precede the initiation of heroin. The individual becomes dependent to it and then they shift to heroin, which is less expensive.

In the case of stimulant medications, a kid abusing it, not using it for prescription reasons, passing to other drugs, illicit drugs, there, I do not know that we have sufficient data yet to actually determine that answer.

Chairman BIDEN. Do you have any view on that, Doctor?

Dr. PAULOZZI. I would agree. I don't think we have the data.

Chairman BIDEN. Now, what's the difference in the treatment regime, if there is any, for addiction to pain relief medicine like Vicodin compared to illegal drugs like heroin?

Dr. VOLKOW. Well, there is a significant difference. Usually what happens, it is usually reflected in two aspects of them. A heroin abuser usually has histories, much longer histories, of abuse and, per potency of the drug, has been exposed for many more years to a much more potent drug. They usually have initiated the abuse of the substance much younger than for prescription medications.

As a result of that, that increases their risk and they need much higher doses, for example, of methadone to be able to control withdrawal. When you have someone that is initiated in opiate analgesics, they tend to have shorter periods of time. Many of them may have been taking drugs that are much less potent, like Hydrocodone, so you can manage them with much lower doses of methadone, or even better with buperenorphine. In general, their outcomes are much better.

The issue that is problematic, is if you have a patient that has genuine pain that requires an opiate medication and it is at the same time addictive, that is the challenge because you need to treat the pain, while at the same time monitoring that addictive component of that individual. That's where the issue becomes much harder to deal with.

If chronic pain is not an issue, then your outcomes are much, much better with someone that is addicted to opiate analgesics for these demographic characteristics.

Chairman BIDEN. I am trying to see. I do not want to keep you too long here.

Is there a different profile—and you may not know this. I mean, there may not be any studies done on this—of the kid whose introduction to abuse is through prescription drugs and the profile of a kid whose introduction of drugs is through the street with cocaine or methamphetamine or speed? Are there different characteristics or are they not able to be differentiated?

Dr. VOLKOW. Well, there is not sufficient data to tell you categorically, but I can tell you what data has emerged from it. The differences tend to actually relate more to environmental factors

than anything else. So if you come from, for example, a rural area where methamphetamine—like in Hawaii—is widely available, the likelihood that you actually may even initiate with methamphetamine is much higher than if you come from New York, where it has actually been shown by these geographical areas, also the likelihood of initiating prescription medication is much lower. But on the other hand, if you are in New York in a neighborhood where there is a lot of cocaine, you may initiate that way, or marijuana.

Again, people don't necessarily consider it, and yet it is very important, that in most instances the first drug of abuse—in most instances—is either nicotine or alcohol, and from there you can go into marijuana or you can go into prescription medications. Which one you choose may be more of a function of access to that medication than itself the properties of the drug or the unique characteristic of the person.

Now, having said that, there's another thing that we need to consider that we also recognize. I told you, people who are in pain are basically prescribed medications, but the other side is people that may have an underlying psychiatric disorder that is not recognized and are at greater risk of ending up using these medications as a mechanism of medicating themselves.

So kids that may have depression, that may have attention deficit disorder may be at higher risk because they do not feel comfortable. They take a drug by experimenting and they feel better, and then they learn that, and without really being conscious about it they start to take it because they improve, temporarily, their performance. Long term, it actually makes it worse, but short term, they may feel better. So that is the other aspect, that a kid having a psychiatric disorder that is not properly diagnosed may be at greater risk of abusing stimulants because he actually may feel better with them.

Chairman BIDEN. Not directly related, there is a recent piece I read about the number of Americans who have been diagnosed with depression. The essence of the article was, it's a staggering larger number. If I can make an analogy. When I started doing a lot of research about violence against women and statistics started coming out from the FBI crime statistics between the late 1970s and early 1980s, it rose precipitously, the statistics-reported crimes.

After literally over a thousand hours of hearings we had over that whole period, it turned out that some portion of it was the feeling of women being more liberated to report. It sounds like an oxymoron, liberated to report abuse. But who were more inclined to report abuse than their mothers would have reported that abuse, or their counterparts 15 years earlier would have.

Is it that people are a hell of a lot more depressed in America or is that it is sort of the diagnosis of choice these days when people used to deal with problems better? Talk to me about that a little bit, about depression and the correlation.

Dr. VOLKOW. Yes. You are picking up on something else that alerted us in the psychiatric community. Now I'm speaking as a psychiatrist, because there is a National Institute of Mental Health on this issue. There's been significant increases in the diagnosis of

depression, and also particularly in young children. The numbers are really staggering and it doesn't seem to be abating.

Is it because we really are seeing an increase in depression or is it because we are recognizing it more, as you say? It's likely that both cases would be the case. It's evident that more symptomatic cases are being diagnosed that in the past would not have met criteria for diagnosis and treatment, and that's where that same issue happens for the case of personality disorders—not just depression, but personality disorders or autistic type syndrome disorders, not autism.

So it is possible that we are diagnosing many more and we're diagnosing people that, per se, don't meet the criteria of depression itself. However, when you see numbers like that, it's your responsibility to try to understand if indeed there is an increase of the disease itself.

Based on the data, I do not think that we can say that there is such an increase, however, we cannot rule it out. It's not just for depression. If you look at the statistics in psychiatry, there's a significant increase in cases of attention deficit/hyperactivity disorder; obviously the case of autism has attracted a lot of attention.

Chairman BIDEN. Well, thank you very much. As you can tell, I could keep asking you questions all day because this fascinates me, and I think it's a big, big deal. But I've trespassed on your time too much already. Do either of you have any closing comment you'd like to make to the committee as to what you think we should be doing most?

Dr. PAULOZZI. Well, I appreciate the opportunity to speak here. I think a lot more work needs to be done to investigate the risk factors for these deaths, to look into the wide variation geographically across the country, both in the overdose death rates and in the rates of prescribing from one State to another as to the reasons for that. We'll continue to do our work in surveillance and etiologic studies and try to evaluate the impact of some interventions at CDC.

Dr. VOLKOW. My perspective is, my ending remark is that this is an urgent problem that needs urgent action. It was very categorical, the way that I feel. We're already seeing significant increases in mortality associated from prescription medication. I think that slide number two that Dr. Paulozzi showed speaks for itself.

The other thing is, we are seeing an increasing number of people requesting treatment for drug dependence, both for opiate analgesics and stimulants. They are just going way, way up. At the same time, we are increasing the number of people being prescribed these medications. We need to be aware of what has happened in the past. We had an epidemic of stimulant abuse in the United States in the 1960s which was very much tied to the increasing prescriptions at that time for medications to lose weight.

We need to learn from those past experiences, because if we do not control these we will have a serious problem of dependence, not just in terms of abuse and addiction, not just in opiates, but also for stimulant medications. This, it has been shown, can have very adverse consequences. So I applaud you for your leadership, because this is an area that in my view has not received the level of attention that it deserves.

Chairman BIDEN. Quite frankly, the reason it got my attention, is it seems to me that I've been doing this long enough to notice and to observe that there are sort of early warning signs that a new epidemic is on its way. I remember, years ago, writing a report saying Ice is on its way, that methamphetamine is going to be a giant problem, and no one wanted to pay attention. It was coming out of Hawaii at the time. It was like, OK, well, we've got an isolated problem. I don't mean that like I was some kind of oracle. I don't mean that. A lot of experts like you had come before my committee and talked about it.

One of the things that I am least informed about is what is reasonable to expect of the medical profession, because again they are overburdened in a whole lot of ways. I mean, what is reasonable to expect of the medical profession in terms of the regimes for prescribing, essentially the sieve they should put their patients through before they decide to prescribe, and what to prescribe. I mean, it's a pretty extensive problem.

So for me, one of the things we're going to be pursuing, I will pursue privately as well with the medical profession, the AMA, and others, is what do they think about this? I mean, what are they thinking about? What are they recommending? What are the medical schools talking about? What are young doctors being trained to do? How high up on the agenda is this?

The whole issue of drug abuse has so many complicated ramifications for society, economically, politically, criminally, and physically. I mean, I've always thought—and I'm no expert on this—that the medical profession has almost, in a sense, understandably basically said this is not on my watch, this is not really our responsibility, it's the policymakers'. But it seems to me, we need to look to them for some guidance.

Well, I thank you both very, very much for being here. I do appreciate your time. As I warned the Doctor last time around, we'll call on you again. We're like poor relatives. When you say you'll show up, we invite you. So, I appreciate the help very, very much. Thank you.

Dr. VOLKOW. Thanks to you.

Dr. PAULOZZI. Thank you.

Chairman BIDEN. Thank you, Doctors.

Our second panel is Steven J. Pasierb, from The Partnership for a Drug-Free America. It's a nonprofit organization, uniting communications professionals, renowned scientists, and parents. Steve joined The Partnership in 1993 and became president in 2001.

Derek Clark has been the executive director for the Clinton Substance Abuse Council in Clinton, Iowa, a town I've learned to love.

Misty Fetko—I hope I'm pronouncing correctly—is a registered nurse and the parent of Carl Hennon, who died tragically in 2002 due to an overdose of a combination of over-the-counter and prescription pain relievers. Since then, she's dedicated much of her life to raising awareness about the risks associated with medicine abuse.

I say to you, Ms. Fetko, I admire you doing this. As someone who lost a child in a different circumstance, I never had the nerve to face up to it. I just didn't want to deal with it. The fact that you are, in a sense, it's a bitter irony. Every time you testify, you're

brought back and that takes a lot of courage. I want to personally thank you for being willing to do it.

Why don't you, if you would, deliver your opening statements in the order in which you were called, and then I'll have some questions. Thank you.

STATEMENT OF STEVE PASIERB, PRESIDENT AND CEO, THE PARTNERSHIP FOR A DRUG-FREE AMERICA, NEW YORK, NEW YORK

Mr. PASIERB. Thank you very much, Chairman Biden. And thank you for calling this hearing. As you've said throughout this, you've been on this issue for a long time. Those of us in this field appreciate everything you've done, most recently with the dextromethorphan legislation. We were proud to support that.

I'm going to submit to you, obviously it's been established here today that the abuse of prescription and over-the-counter medications, legal substances, of benefit if used appropriately, is the single most troubling phenomenon on today's drug abuse landscape. The Partnership has devoted a good measure of our research over the last 4 years, our focus, and our voice to this issue, yet clearly much more has to be done.

The 2007 Partnership Attitude Tracking Study looked at over 6,500 teenagers in grades 7 through 12. And what that showed, is we have 19 percent, or 1 in 5 teens, who are actually reporting that they've tried a prescription drug without having a prescription, so they've engaged in this behavior. One in 10 report that they've used over-the-counter cough medicine to get high. As we've established, only alcohol, cigarettes, and marijuana are abused by teenagers at higher rates than prescription drugs, while cocaine, Ecstacy, and methamphetamine are each roughly half as prevalent as prescription drug abuse in these young people's lives.

Now while it is true that the prevalence of medicine abuse has not increased in the last 3 years, it is troubling to realize that teen use of virtually all other substances of abuse—alcohol, tobacco, marijuana, even methamphetamine—has declined over that same period of time, and in fact many of these have been in decline steadily over the last decade.

What has this trend really shown us about what we need to do as a Nation? We think there are a few areas we need to focus and we need to pay attention to. First, these substances are readily available to our teenagers across this country. They're getting it in their home medicine cabinets and the medicine cabinets of friends for free. Our data is very much in line with the national findings from the survey on drug use and health, which shows over 75 percent of teenaged prescription drug abusers say they got those drugs from immediate friends or family.

Second, teens' perception of the risks of abuse is very low. Our past research shows that less than half of teens see great risk in experimenting with prescription pain relievers such as Vicodin and Oxycontin. Even more alarming on top of that, over one-quarter of the teens believe prescription pain relievers are not addictive.

University of Michigan's Monitoring the Future survey, going back over 30 years, has helped us establish that we need that perception of risk associated with any substance of abuse. When

they're there and social disapproval is there, those correlate significantly with actual teen substance abuse rates.

So, low perception of risk, low disapproval, coupled with the easy availability that we've been talking about, is a recipe for ongoing problems.

Research conducted by The Partnership in 2007, with support from Abbott Pharmaceuticals, gave us really a new light. It cast a light on the motivations of teens around prescription drug abuse. Traditionally, as you said earlier, we think about this as "to party, to escape, to get a buzz, get high", but our 2007 research with Abbott, like the research done among college students by Carol Boyd and Sean McCabe, suggests a much wider range of motivations for young people's abuse of prescription drugs beyond getting high, including an emerging set of what we call "life management" or "regulation" objectives.

Teens appear to be abusing these drugs in a very utilitarian way, using stimulants to help them cram for a test or lose weight, pain relievers to escape some of the pressure they feel to perform academically or to perform socially, and tranquilizers to wind down at the end of a stressful day.

Once these substances have integrated themselves into teens' regular lives and really have been abused as study aides, as management of life, as relaxation, it's going to become increasingly more difficult to persuade teenagers that these very same drugs are unnecessary and unsafe when they're taken without a prescription.

Fourth, are parents, who typically are our biggest ally on these issues when we deal with them. They're always right at our side. What we find in the research, is parents are generally ill-equipped to deal with teens' abuse of prescription drugs. Parents find it hard to understand the scale and the purposefulness of which today's teens are abusing medications, because this is not something that went on when they themselves were teenagers. It is not clear to them that they may be one of the prime sources of supply to their teenagers out of their very own medicine cabinet.

Further, many parents themselves—we saw this in the Abbott study—are engaging in a similar behavior. In our study with Abbott, 28 percent of parents said they had used a prescription drug without having a prescription for it, and 8 percent of parents said they had given their teenaged child a prescription drug that was not prescribed for that teen.

In our studies, parents tend to underestimate the damage and danger of abusing medicines, some actually expressing relief and saw less social stigma to hear that kids might be abusing "safe prescription drugs" versus "dangerous illegal street drugs."

Finally, the reason I don't think we're seeing declines in this behavior in the face of all the other declines, is simply our efforts as a United States up to now have not been enough. There simply hasn't been enough public attention, there hasn't been enough resources devoted to this issue like there has been in recent years on other emerging drug threats. Luckily, that's now beginning to turn.

ONDCP's National Youth Anti-Drug Media Campaign should be applauded. They just invested $14 million, which will then be doubled by their media match to target parents around the prescrip-

tion drug abuse issue, provide them with information on how to safeguard their homes, and how to keep their kids away from it.

In some quarters of the pharmaceutical and over-the-counter drug industries, there's been real concern, there's been action, and there's been active support for prevention and education efforts, from associations like PHRMA, the Pharmaceutical Research and Manufacturers, from the Consumer Health Care Products Association, as well as select companies that have really stepped forward and should be commended for taking what is largely a proactive approach.

As you heard, our Federal agencies, with NIDA at the lead and the fore, have done a superb job and have been at the forefront of helping us understand this problem. But reducing the actual abuse of these products, getting ahead of this and getting it turned in the right direction is going to take a heck of a lot more across all of our society.

We had the tragic death of Heath Ledger, and that really cast a sudden spotlight on this, much like Len Bias's death did in 1987, which helped America understand cocaine was not a drug without harm and without destruction. We've got to build on this small bit of understanding we have right now and accelerate that, and devote all the necessary resources, education, prevention, addiction treatment that it is going to take to drive down the intentional abuse of these products.

So, sir, I thank you for calling this hearing. Mr. Grassley, for all he does on a day in, day out basis, and we will stay with you on this throughout.

Chairman BIDEN. Thank you.

Mr. Clark.

[The prepared statement of Mr. Pasierb appears as a submission for the record.]

STATEMENT OF DEREK CLARK, DIRECTOR, CLINTON SUBSTANCE ABUSE COUNCIL, CLINTON, IOWA

Mr. CLARK. Chairman Biden, thank you for giving me the opportunity to testify.

Chairman BIDEN. One important question, first. How much snow is on the ground?

Mr. CLARK. It's getting better.

Chairman BIDEN. OK. Good.

Mr. CLARK. It's all melting right now. It's a big mess.

Well, thank you for letting me testify on behalf of the Clinton Substance Abuse Council. I'm going to represent the community and the coalition aspect for this issue.

First, last week a Clinton woman—let's call her Jane—was charged with six counts, felony counts, of fraudulently obtaining prescription drugs. Jane was being treated by several doctors over the past 3 years. She was receiving prescriptions for Hydrocodone and fentanyl—these are powerful drugs—from one doctor, while receiving methadone prescriptions from another doctor, and neither doctor knew this woman was seeing the other doctor.

One of the fastest-growing threats to youth today is the abuse of prescription and over-the-counter drugs. This is true at the national level, as well as the local level. As a result of the needs as-

sessment that we conduct for our drug-free communities as a grantee, we know that 15 percent of the Clinton Community School District 11th graders report having used prescription drug medication not prescribed to them at least once in the last 30 days. That's compared to 7 percent of all Iowa 11th grade students.

Eleven percent of Clinton Community School District 11th grade students report having used over-the-counter medications different from the directions at least once in the past 30 days, and this is compared to 7 percent of Iowa 11th grade students.

While prescription over-the-counter drug abuse is clearly a problem, because the Clinton Substance Abuse Council is a Drug-Free Communities grantee, we have the necessary infrastructure in place to effectively deal with this issue and involve all sectors of the community. This includes law enforcement, schools, parents, youth, and the business and faith communities.

The Clinton Substance Abuse Council uses the strategic prevention framework when conducting their community planning and decisionmaking process. This is a five-step process: the first one is needs assessment; the second one is capacity building; third is planning; fourth is implementation; and last, evaluation. This framework ensures the focus of CSAC is always current with the local trends and we are being as effective as possible with the resources available to us.

We involve the community in the strategic plan by holding monthly meetings to discuss local substance abuse problems, emerging drug use trends, designing solutions to address these problems, and developing outcomes from programs and projects. When needed, task forces and ad hoc workgroups are formed to allow individuals to focus on each issue, whether it is addressing a specific problem or implementing a project or program.

In addition to the regular meetings, the Clinton Substance Abuse Council also conducts focus groups with local law enforcement, substance abuse treatment providers, mental health providers, human service professionals, and community members. When individuals are not available, we also do key informant surveys to ensure that we are getting the widest amount of information from people and ensuring that people have their voice heard.

CSAC's prescription drug abuse strategic plan works to develop social marketing campaigns to change the perception of risks associated with prescription drug abuse, implement environmental strategies to reduce access to prescription drugs—environmental strategies are focused on changing the aspects of the environment that contribute to the use of drugs—educate the community and target segments on the dangers and problems; facilitate participation in the online prescription drug tracking system that is currently being developed by the State of Iowa, and with these actions we hope to increase the perception of harm related to prescription drug abuse, reduce the number of people reporting illegal use of prescription drugs, reduce the number of people arrested for prescription drug abuse, and medical facilities will participate in Iowa's online prescription drug trafficking system.

Before I leave, let me just leave you with this. A local high school student—let's call him Billy—was caught by his mother stealing her heart medication. Billy was crushing this medication and snort-

ing it in the hopes of getting high. He didn't. Billy's mother became suspicious when she noticed her medication was disappearing, and confronted him. He admitted his actions. The good news is that Billy is currently receiving counseling.

Thanks for this opportunity to testify.

Chairman BIDEN. Thank you.

[The prepared statement of Mr. Clark appears as a submission for the record.]

Chairman BIDEN. Ms. Fetko.

STATEMENT OF MISTY FETKO, R.N., PARENT OF CARL HENNON, NEW ALBANY, OHIO

Ms. FETKO. Thank you. My name is Misty Fetko and I'm a registered nurse who works in a very busy emergency department in central Ohio. But most importantly, I'm a mother of two wonderful boys. I am here today to tell you the story of my oldest son, Carl. Carl was my beautiful boy, eyes like large dark chocolates, an infectious smile, and an insatiable curiosity.

I spent years protecting him from harm, but 4 years ago harm found a way to sneak in and steal the life of this gifted young man. It was the morning of July 16th of 2003. Carl had just graduated from high school and was getting ready to leave for Memphis College of Art in 2 days. The college had courted him after he had won an award for artwork he created his junior year of high school.

The night before, Carl and I had sat in his room and talked with each other about his day at work and the pending trip to Memphis. At the end of the conversation, he smiled and hugged me. He said, "Good night, Mom. Love you." The next morning I decided to walk the dog before waking Carl. By walking next to his car, I noticed an empty bottle of Robitussin in his back seat. Instantly, I knew something was wrong. I had been very vigilant for signs of drug abuse in the past and hadn't seen many, but the previous summer I'd found two empty bottles of Robitussin in our basement after a sleep-over he had had with friends. I knew something was up.

I rushed to his bedroom door, only to find it locked. After finding my way in, I discovered Carl laying peacefully in bed, motionless, with legs crossed, but he wasn't responding to my screams and he wasn't breathing. I quickly transformed from mother to nurse and began CPR, desperately trying to breathe life back into my son.

I could not believe what I had feared most in life had happened, but I still did not know what had caused my nightmare.

We are a very close family and I'm a very involved mother. Carl had always assured me that he wasn't using drugs or alcohol, and I, the ever-watchful mom, believed him as there wasn't any evidence to prove differently.

During Carl's junior year of high school, though, I found the first evidence of marijuana in his room. After all the talks and reassurances between us, what had changed? I intervened and didn't see anything else suspicious until that summer when I found those two empty bottles of Robitussin in our basement. I was determined to keep drugs out of our house. But cough medicine?

I went to search for answers on the Internet and found nothing, and then confronted my son. Carl explained that he and his friends had heard you could get high off of cough medicine and had tried

it, but nothing happened. I was reassured once again that he wasn't using hard drugs and not to worry. Finding no further evidence, I believed him.

During his senior year, we had some incidents with his interest that he had developed with marijuana, but I thought we were doing what we needed to to address this problem. So why, on that dreadful July morning, did I discover that my son had passed away during the night? Over the next several months after his death, I frantically searched for answers. What signs did I miss? During my search, I found two more empty bottles of Robitussin, but it wasn't until after talking to his friends and finding journal entries on his computer that I discovered that Carl had been abusing cough medicine intermittently over the past two and a half years.

He documented his abuse in his computer journal. Through the Internet and through his friends, he had researched and educated himself on how to use these products to get high. He wrote about, and enjoyed, the hallucinations achieved upon intentionally overdosing on cough and cold products. He described the pull that he felt toward the disassociative effects of abusing cough medicine and seemed to crave these effects.

According to his journal, he had gradually increased the amount of cough medicine he was abusing from 4 ounces to 12 ounces. As his abuse increased, many things in his life were changing; graduation, college, his parents' divorce, and increasing pressures in life. I wouldn't find out until the morning of his death what he and many others knew about his abuse of cough medicine.

The danger that I so desperately had tried to keep out of our house had found a way to sneak in, though the signs at the time did not indicate what I knew as signs of drug abuse, as there were no needles, there were no powders, there were no smells, or large amounts of money being spent, none of the typical signs that I associated with drug abuse.

Carl's autopsy report revealed that he had died from a lethal mix of drugs: fentanyl, a strong prescription narcotic, cannabinoids found in marijuana, and dextromethorphan, or DXM, which is the active ingredient in cough medicine, were found in his system. To this day, I don't know where he obtained the fentanyl patch. There were no journal entries that talked about his use of painkillers. I don't know if this was his first time or why he made the wrong choice to abuse prescriptions and over-the-counter drugs. I only know parts of his story by the words he left behind in his journal. His words are now silent.

Abuse of over-the-counter and prescription drugs is a very large and very concerning problem. We are seeing more teens in our emergency departments who are overdosing on these drugs. It is becoming more of a norm for us to see than an exception. A couple of weeks ago, a young man was brought into our emergency department who was at the home of a friend. They had found him unresponsive and barely breathing. The paramedics rushed him to the hospital. He had been chewing on a fentanyl patch. Several unopened patches were found in his pants pockets.

Just a couple days ago, a young lady was brought in from high school, where she had taken 30 Coricidin cough and cold tablets that morning at school just to get high. She spent the next several

days in our intensive care unit. These are just a couple of stories of the stories I see daily in our emergency department.

I want to thank you for inviting me to share Carl's story. If loving Carl were enough, he would have lived forever. It is now with this love that I tell his story so others are aware of the grave dangers of this type of drug abuse.

Thank you very much.

[The prepared statement of Ms. Fetko appears as a submission for the record.]

Chairman BIDEN. Thank you.

Let me start with you, Ms. Fetko. In your attempt to sift through the pattern your son got into, did his friends or anything reveal how the progression took place from cough medicine to fentanyl? I mean, was it sort of part of the culture among his friends?

Ms. FETKO. What I was able to discover, through the journal entries and through talking to some of the young men that were his friends, it seemed like the cough medicine was what they first became attracted to. It sounds like the first experience with it after they had heard about it and read about it on the Internet, they had actually gone to a local grocery store and stole a four-ounce bottle to try it, is what his journal entry talks about.

Really, the journal entries really focused on his use of the cough medicine and the hallucinations that he was achieving from overdosing on it. It seems like the group of friends had discovered this and developed an interest in it, but there wasn't any talk about any other drugs at the time, except for the marijuana that I had found.

Chairman BIDEN. Gentlemen, is Ms. Fetko's story remarkably different from what you have become aware of and associated with in your work in Clinton and all the work done by the drug council?

Mr. PASIERB. Unfortunately, we get far too many parents that contact us through our web site or call the Partnership and tell very similar stories, or not of kids who have died, but kids who are in the hospital or kids who are now profoundly addicted and in treatment centers. If you just took those alone, those would be warning signs that something is going on, let alone the research that we have.

Chairman BIDEN. Mr. Clark.

Mr. CLARK. We haven't had any fatalities yet. But the way that the numbers are going and what we're learning now, it may be only a matter of time. So, we're very concerned.

Chairman BIDEN. The focus of The Partnership for a Drug-Free America on this issue is to focus on—you do multiple things, but focus on educating parents. Is that right?

Mr. PASIERB. Primarily we're going after mom and dad, because what we find in the research—or whoever that adult is in a kid's life—is they're actually behind the kids. We get about 60 percent of kids who understand this issue that know that it goes on, have heard it's happening, whereas, when we look at very similar studies around mom or dad or grandma and grandpa, whoever that caring adult is, they don't understand this. As I said in my testimony, we have the most drug-experienced generation of parents in history, is one way to look at it. This behavior did not go on when they

were in high school in the 1980s or the early 1990s, it was cocaine or things like that.

So what we see, is parents saying, yes, I'm having these conversations with my kid. They tend to overestimate those. But when you dig deeper, you find that prescription drug abuse/over-the-counter medicines don't enter into most of those conversations. So mom and dad are well behind their kids. Kids know this is going on. They're finding it on the Internet. They're seeing it in chat rooms. They're Googling "cheap way to get high" and getting 10,000 web sites that offer to sell them something. So for teenagers, this is pretty omnipresent in their lives.

As we've seen in our research, they're getting very tactical in how they use them. The kids that we saw in some of our qualitative studies would tell you they are not a drug abuser, they are not a drug user, they simply get other people's Ritalins because it helps them get better grades, and isn't that what they're supposed to be doing? So they're looking at this in a very, very different way.

So, those kids need to be met by a mom and dad who understand this in some way, shape, or form, so we really believe that we have got to make some headway with parents and get them engaged in this, help them understand they've got to safeguard their medication, they've got to educate themselves, and then they've got to get out with their kids and deliver a very strong message that this is not a safer way to get high.

Chairman BIDEN. Mr. Clark.

Mr. CLARK. Yes. Actually, I sit on the Board of Directors for The Partnership for Drug-Free Iowa, so we work closely with the material that they do, because we don't want to create material that is already out there when we can be better using our time. So, like I talked about that we do social marketing campaigns, what we try to do is work with the youth or with the targeted area we want to address. Let's say we're working with the youth on this one. We're going to pull in a group of youth to help create a marketing campaign, a social marketing campaign, which is pretty much the same principles as a marketing campaign, a general one selling a product. We're selling a product, change of social norms, you know the risk of use.

So we're pulling these youth in to create a campaign to target their friends, their peers. And not only are we changing and educating those youth working on the campaign, but then they're going to go out and they're going to deal with their friends, their social network and change the norms, perception of risk related to prescription drug and over-the-counter drug abuse.

Then not only are we working with youth, their peers, but we're also working towards community-level change by creating this campaign that is then working with the community trying to market these youth on changing their social norms, their perception of risk.

Chairman BIDEN. What do these kids talk about? Look, this is, in my view, incredibly complicated, but not complicated. I mean, there is always a social structure that revolves around the social setting in which these kids act, whether it's their attitude toward sex, their attitude toward drug abuse, or their attitude toward studying.

Is there a difference between the kids who are using street drugs and—there are still a lot of street drugs out there. It's down, but there's still an unacceptably large number of kids in high school who are using cocaine. There are still a large number of kids who are abusing speed, methamphetamine, et cetera.

Are they a different, in a sense, clique of kids? I mean, do you find that kids who abuse prescription drugs or over-the-counter medicines, do they think themselves different than the kid, the four kids who are getting stoned in the back of the school, or getting high on speed, you know, or showing up at parties where it's open and notorious use of these drugs? I mean, what's the mind-set of the kids in the street or the kids in the classroom?

Mr. PASIERB. All these kids share that common, it's not going to be me, I can handle this, I can do this. I can go out and I can try it. When you get back to the research that's been done, perception of risk, social disapproval, whatever you want to call it, one way that we're beginning to think about this is it isn't that they're gateway drugs as much as there are gateway attitudes. Young people come into society and they say, look, I get great grades, I want better grades, I can use prescription drugs. Or I have nothing to attach to in society, so I'm going to try meth because it'll make me feel perked up.

It's these attitudes they bring which are interrelated and complicated, and we've only really begun to understand what causes them to make that decision the first time when somebody comes in and says, here, try this with us, do this. What they bring to them, the perception of risk, the social disapproval, the feelings that they can get away with it, their own personal feelings of—

Chairman BIDEN. Talk to me about the social disapproval piece of it?

Mr. PASIERB. Pardon me?

Chairman BIDEN. Talk to me about the social disapproval piece. I remember back in the 1980s, and actually in the 1970s and 1980s you could show up certain places. If someone in a high-end neighborhood, young professionals were having lunch on Monday in the early 1980s and said, I did a line of coke at so and so's place, they'd say, OK, all right, I don't do that, but what's the big deal? Whereas, no one is going to sit down and say that today.

Mr. PASIERB. Exactly.

Chairman BIDEN. So that is what I'm trying to get at. What are the kind of conversations? Like, your son's friends are not likely to say, you know, I tell you what, man, I've got some of the purest stuff I ever had before, man, heroin. This stuff I got was really pure. They're not going to sit around your basement and talk about that, probably, those kids.

But would they sit around and say, man, I've figured out how to mix this stuff, or I've figured out how to extract this stuff? I mean, is there a social acceptance that is broader in this area than there is, and how much of the moral disapprobation of society, their peers, their teachers, their parents, is real? I can remember the lovely, brilliant woman sitting behind you who used to work for me and do all this. I remember her producing the study for me early on, where we started off in hearings a decade ago saying, this ain't your mother's marijuana. The marijuana that my generation used

in the 1960s ain't nothing like the marijuana that's available today. And yet, parents back then, the parents of the kids who were teenagers in the 1980s, said, well, thank God they're only using marijuana. Thank God that's all it is, because, man, they could really be doing something bad.

Our parents say the same thing now. When you confront a parent—not confront. A parent finds out his kid is abusing cough medicine, is the response, well, thank God it's cough medicine and not whatever? I mean, talk to me about—don't talk to me like a manager, talk to me like somebody when you deal in the neighborhood, when people come in to talk to you. What do they say to you? How do they view it? Do they view it with alarm or do they view it as—in a sense, Misty, you said—excuse me for using your first name. You said, well, you know, it was cough medicine, at least it wasn't—or at least you implied, it wasn't something really bad.

Ms. FETKO. Exactly.

Chairman BIDEN. What was your attitude?

Ms. FETKO. Exactly. At first, I thought maybe it was possible that there was still alcohol in cough medicines, which I thought had been removed. Then when I went to the Internet and I didn't find anything, I mean, I was, I was relieved. I was relieved there weren't syringes. I was relieved there wasn't powder. And, you know, here I work in a busy emergency department. I should have had my finger on the pulse of the changing environment, and we hadn't even been seeing it or hearing it there. So I did, I felt a sigh of relief. But I think the boys also saw it—and these were very intelligent, gifted young men.

I think the fact that they didn't have to have a drug dealer to get it, it wasn't shady, they weren't uncomfortable about doing it. Carl wrote about the first time that he had the nerve to walk in and purchase it at the drug store. I mean, I don't think they associate the same feelings that they do with the illegal street drugs.

Mr. CLARK. Another problem is, it's readily available. Say a high school student can go to high school and they could get some Ritalin from their buddy at school because they may have it because it's prescribed and no one is going to say anything. So another issue to consider is, the schools are also having to address this problem. How exactly do they want to handle prescription drugs? Do they want, all drugs have to be checked in to the school nurse?

Then that brings up another issue. What if the student runs out of medication, they don't bring it in? There's a lot of things that right now are being discussed and trying to figure out because this is such a relatively new problem, and it has a lot of different dynamics to it because these are prescribed. The youth or the user does need this medication, but then if the schools don't regulate it, these students have the medication at school and they may be distributing them, selling them, or just sharing.

Chairman BIDEN. I thought it was pretty instructive, the comment made by NIH. They got a call from a professor saying, it reminded me of the hearings I held on steroids. The hearings I held on steroids were, athletes like me resented the hell out of the fact that somebody, with one-tenth the work, was getting twice the muscle mass and maybe would take my job on the team. I found

it interesting, the comment made, one student complaining to a professor that he was at an intellectual disadvantage in class, and his grades, because of the use of—I don't know which drug she said. Whatever.

Mr. PASIERB. We're hearing those exact same things, both from college kids and high school kids, from a very competitive nature. I'm here to compete, I'm here to get better grades, a better job, and I resent those people who may be using it, therefore I feel drawn to it. We're stunned when we pull parents together and they begin with this disbelief. We're here to talk about prescription drug abuse. Oh, you mean if the label says take two you take two, not three? No, about taking six and chasing them down with alcohol. No, that doesn't go on, is the reaction. No, that doesn't happen. They begin to try to disabuse us that such a thing would happen in society.

So you go from this disbelief to almost a relief. Well, it's prescription drugs. They're safer. They're made in sterile labs, the doctor prescribes those. That's much better than cocaine or heroin. Then you begin, as Dr. Volkow did, to help us understand: an opioid is an opioid is an opioid, and they're shocked and then they want to leave. Then they want to go home and take an inventory of their medicine cabinet and talk to their kid right away. We need to kind of take that "in" of 15 parents in a focus group and get it out to 15 million parents, and 150 million, to help them understand that they're in a unique position on this. They can control supply, unlike any aspect of the drug issue, control it in their own home and open up their radar to it, and they can control demand by engaging their kid and helping them understand, this is not only safer, it is extraordinarily dangerous. This is Russian roulette on a scale we haven't seen before.

Chairman BIDEN. The last question I have. I realize I'm just asking you from your experience base, which is extensive, from the early 1990s on. Actually, any one of you can respond. First of all, I doubt if there's any data to sustain the question I'm about to ask—the answer, I'm implying. But if, in fact, figuratively speaking, the medicine cabinet is closed, there is no access at the drug store over the counter, is the same kid who would be inclined to go that route just going to turn around and go to the street?

The kid who wants to abuse Oxycontin, the kid who wants to abuse cough medicine, the kid who wants to abuse whatever the over-the-counter prescription drug is, is it just that it's easier to get there and that kid—I'm going to say something really ridiculous-sounding: abuse of prescription drug is up among teenagers, other drugs are down. Is it because that if you didn't have this abuse, would those other drugs of choice, street choice, would they be back up where they are? Do you understand the point I'm trying to make?

Mr. PASIERB. Yes. Yes. We're not seeing this as a replacement, I'm doing this instead of that. None of the data are showing this. We're seeing that for some kids it's a bridge between the casual alcohol and marijuana user, to then adding these on and then moving on to other drugs. So if from a bridging standpoint on that ladder of drug use, this behavior appears to be there.

But your earlier question, we believe right now all the studies we're doing is showing only about 1 percent of kids are getting these drugs from the Internet. I would wager that if we truly did lock down the medicine cabinets and we really did limit that supply, these kids would migrate to the Internet because supply is there, at least on some of the lesser opioid products.

We don't know if a kid who becomes a dedicated user, who exhausts mom, grandma, dad, and all those other and friends, whether or not he or she, four or five steps down, doesn't turn to the Internet. I believe, as long as there is a demand, supply finds a way and we've got to go after that demand, otherwise these kids, as motivated and as intelligent as they are, will find ways.

Chairman BIDEN. I appreciate that.

Does anyone have a closing comment you'd like to make? With your permission, I have several questions on behalf of several of my colleagues, and myself as well—I'm not going to burden you with a whole lot of questions—in writing that I'd like to be able to submit to you, if that's OK.

[The questions appear as a submission for the record.]

Chairman BIDEN. Did anyone have any closing comment?

Mr. PASIERB. I just want to thank you for forcing this on the national agenda, because it needs to get high up on the agenda. Methamphetamine is a huge problem in parts of our country, other drugs are huge problems. This seems to be a universal issue from Maine to Florida, Hawaii, and every point in between, and we've really got to help the country understand that this falls into that classic, this is a preventable behavior, and where kids end up in trouble, this is a treatable addiction, but we've got to get this out there.

Chairman BIDEN. Well, I thank you all. I particularly thank you, Mrs. Fetko. Like I said, I just think it takes a special kind of person to be able to, in effect—I watched you as you read your statement. It's always present.

Ms. FETKO. Thank you.

Chairman BIDEN. So I thank you for your courage and thank you for your willingness to share with us.

I know you know, Steve, we'll be back to you for additional help here.

Mr. PASIERB. Yes.

Chairman BIDEN. This is the beginning of this process, not the end of it. I thank you for making the trip in.

As Senator Grassley says, his office is yours for as long as you are here, and maybe I could talk to you about how to vote, OK?

[Laughter.]

Thank you all very, very much.

[The prepared statement of Senator Leahy appears as a submission for the record.]

[Whereupon, at 3:51 p.m. the Subcommittee was adjourned.]

[Questions and answers and submission for the record follows.]

QUESTIONS AND ANSWERS

Clinton Substance Abuse Council

215 6th Ave. So., Suite 21, Clinton, Iowa 52732 (563)241-4371

November 20, 2008

Senator Joseph H. Biden, Jr.
Chairman of the Judiciary Subcommittee on Crime and Drugs
305 Hart Senate Office Building
Washington, DC 20510

RE: Generation RX: The Abuse of Prescription and Over-the-Counter Drugs

Dear Senator Biden,

Thank you for the opportunity to testify in front of you and the Senate Judiciary Subcommittee on Crime and Drugs, it was a great honor. Also, congratulations on your new position, Vice President.

Attached are the answers to your questions.

1. **Dr. Volkow described two factors that contribute to the likelihood a person will try a drug: availability and local perceptions.**

How can a local community work to change the perception that prescription and over-the-counter medications are safer to abuse than street drugs?

We know that Clinton, Iowa is no different than the rest of the country in this growing problem of prescription and over the counter drug misuse and abuse. With that said there are several things that the Clinton Substance Abuse Council (CSAC) is doing to address this problem. They include: 1) improving Clinton, Iowa's data collection system on Rx & OTC drug misuse and abuse 2) developing social marketing campaigns targeted at the general public 3) educating doctors, nurses, pharmacists, and other medical professionals of this problem 4) hosting town halls and community forums to educate the public.

CSAC is working to improve the data collection process to accurately collect data on prescription drug misuse and abuse within Clinton, Iowa; but this also needs to happen in Iowa and the U.S. We will use this data to target our marketing/education campaigns but also to assess the impact that we are having on the problem and how best to improve our efforts. Because this is a new and emerging problem, extensive data has not been collected on this problem in the past.

CSAC is developing a social marketing campaign to change the social norms, perception of harm, and availability of over-the-counter and prescription drugs. To help increase community awareness about these issues we have partnered with local television, radio,

"The Clinton Substance Abuse Council, through collaboration, works to develop solutions to community problems that are related to substance abuse issues through the process of facilitation, cooperation, and communication."

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and newspapers to educate the public about the prevalence of RX & OTC drug use in the community, and to bring it out into the open. In the past year, we have had approximately 653,000 impressions (Clinton Herald, local newspaper, equals 28,149 impressions; Paula Sands Live, local daytime talk show, equals 100,000 impressions; etc.).

We also had a town hall meeting with Senator Grassley, General Dean (Chairman and CEO of CADCA) and other community members to draw awareness to this problem and begin the discussion in our community on how we are going to address it. There were over 50 people that attended this Town Hall Meeting. The press coverage from these event raised awareness in the community. A summary of the meeting has been attached.

The Iowa Governor's Office of Drug Control Policy provides free brochures about "How to talk to youth about Prescription Drug Abuse" and "Talking about Senior Drug Misuse" and we have handed these out in the community and worked with parents about how to talk to their children about these issues. All the pharmacies in the community helped us to promote the Clean Out Your Medicine Cabinet event as well as hand out the above brochures.

We are currently in the process of working with the local school district, including the SAAD group, and local physicians on better ways to work with families to help reduce the idea the RX & OTC are safer than street drugs.

2. **Are the national trends that we talked about at the hearing consistent with what you have seen on the ground in Clinton, Iowa.**

As we stated previously, Clinton, Iowa is in the process of improving the way that we collect data on Rx and OTC drug problem. In response to the question, YES, we know that Clinton, Iowa's numbers are similar to those on a national level. We know that 15% of Clinton 11th graders have used prescription drugs not prescribed to them in the last 30 days, and 15 % of Clinton 11th graders have used over-the-counter drugs in a way other than listed on the directions.

This data comes from the Iowa Youth Survey, and was most recently done in 2005. We anticipate that the IYS this year would show even higher usage rates, which would put Clinton right in line with the rest of the nation.

3. **What steps have you taken in Clinton to educate parents about the risk of medicine abuse? What efforts have you made to work with your local medical community and pharmacies? Which of these has your experience demonstrated are effective? Which has your experience demonstrated are not effective?**

CSAC has developed a strategic plan, with the input of the community, to address this problem and has formed a coalition, Community Action Against Drugs, to specifically address this problem. One of the things that the coalition developed, planned, and facilitated was the "Clean Out Your Medicine Cabinet" program. There were 3 main elements to this program: "Monitor, Secure, and Dispose."

"The Clinton Substance Abuse Council, through collaboration, works to develop solutions to community problems that are related to substance abuse issues through the process of facilitation, cooperation, and communication."

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- The "Monitor" component is designed to motivate/educate the general public to learn what medications they were taking, learn about these medications, why they were taking these medications, in other words "Monitor" their drug use.
- The "Secure" component is designed to raise awareness that Rx and OTC medications may be stolen or misappropriated and how they can monitor these medications in their house and how they can secure them so that they are not stolen or misappropriated. These tips included: Secure medications in a safe place in their home, away from visitors, youth, or other people that may intentionally abuse drugs; keep track of the amount of pills/liquid in the bottle.
- The "Dispose" component provided an opportunity for the general public to drop their Rx and OTC drugs, that were expired or no longer using off, to be disposed of properly. By reducing the number of drugs in people's home CSAC will reduce the access to prescription and over the counter drugs. Law enforcement was present to ensure that medications were not stolen and disposed of properly.

This coalition is a truly collaborative group supported by law enforcement, hospitals, doctors, pharmacists, parents, schools, media, etc. and they all helped make "Clean Out Your Medicine Cabinet" a success. At the conclusion of the "Clean Out Your Medicine Cabinet' event, the sites collected over 330 pounds of medication from over 200 cars. Because this was such a success, plans are being made to continue this event.

To help increase community awareness about this issue we partnered with local television, radio, and newspapers to talk about the prevalence of RX & OTC drug use in the community, and to bring it out into the open. The press coverage from these event raised awareness in the community.

CSAC has been working on this problem for the past 18 months and are still growing and learning more about the problem. We are in the process of working with the local school district, including the SAAD group, and local physicians on better ways to work with families to help reduce the idea the RX & OTC are safer than street drugs. We have also been keeping an eye on the Prescription Drug Monitoring Program that Iowa will be implemented in April 2009 and will work with the State to educate the community about it. At this time, we have not done anything that we would consider to be ineffective.

CSAC is funded in part by the Drug Free Communities Support Program grant and has been able to accomplish most of what was outlined above through this program.

Sincerely,

Derek Clark, Executive Director
Clinton Substance Abuse Council

"The Clinton Substance Abuse Council, through collaboration, works to develop solutions to community problems that are related to substance abuse issues through the process of facilitation, cooperation, and communication."

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Questions for the Record – Misty Fetko
Generation Rx: The Abuse of Prescription and Over-the-Counter Drugs
U.S. Senate Judiciary Committee
March 12, 2008

Questions from Senator Charles E. Grassley

Advocates like you play a major role in raising awareness about prescription medicine abuse. You mentioned at the hearing that you didn't know what signs to look for when your son was at risk.

a. *What signs can parents watch out for, in terms of behavior changes and tangible evidence of abuse?*

There are different physical signs for each class of medications. If a teen is abusing pain relievers, he or she will exhibit constricted pupils, nausea and vomiting, and respiratory depression. Stimulant abuse is characterized by anxiety, delusions, flushed skin, and heart palpitations. The abuse of depressants results in slurred speech, dizziness, and respiratory depression. Finally, if the teen is abusing cough syrup or DXM, they will appear high or drunk without the odor of alcohol or marijuana, confusion, slurred speech, hallucinations, itch or "robo itch," and/or a robotic gait or "robo walking" to complete loss of muscle control.

Look for empty prescription or cough medicine bottles or blister packs of cough and cold products in backpacks, cars, garbage, or dresser drawers. Be aware if there is any medicine missing from your medicine cabinet.

b. *You discussed the sense of relief you felt as a parent when you learned your son wasn't trying harder drugs. What can we do to inform parents of the urgency of the problem? What should parents know?*

Like most parents, I underestimated the dangers of this behavior. Parents need to know that prescription and over-the-counter medications can be just as dangerous as illicit drugs when taken in excessive quantities and abused. The opportunities are numerous for this type of abuse and no socioeconomic level is exempt.

We must inform parents, through school programs; medical community, through continuing education and journals; and the community, through outreach and websites. They need to be informed that teens are abusing over the counter and prescription drugs so that awareness is increased at home, school, hospital, the grocery store, and pharmacy.

Teaching through pharmacist and healthcare professionals when family members are prescribed medications that teens are abusing that they need to be monitored, accounted for, and disposed of properly. Many people are being cared for at home

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and many of these people are prescribed medications that are being abused; potent, time released narcotics. These medications are prescribed in large quantities and there is access in the homes. These medications need to be monitored and should be locked up and accounted for just like they are in the hospital.

In addition to talking to their kids, parents need to do three things to help keep their adolescent safe:

- Monitor – Parents should keep track of the number of pills in a bottle so that they will notice if some are missing. They should also alert others to do the same so that their teen does not have access to these substances at a friend or family member's house.
- Secure – parents should **lock** up these substances just like they lock the liquor cabinet.
- Dispose – when they are done with a prescription, parents should dispose of it properly to get leftover medication out of the house.

Questions from Senator Joseph R. Biden, Jr.

1. *Do you believe that if you were provided with and had more access to education about the dangers associated with medicine abuse that you might have been able to better spot warning signs in Carl's case?*

   If I had known more about medicine abuse, I may have been able to spot the signs that my son was abusing these substances. I didn't think that my child had any possible access to dangerous narcotics or that cough syrup when taken in large quantities would produce hallucinations. After finding the 2 empty bottles after a sleepover, I googled Robitussin, but found no information so when I didn't find any information to alert me, I had a feeling of relief when I went to confront Carl. There was no information in the media or my professional environment in the Emergency Room to alert me to the changing drug landscape. There was a lot of information on Meth and Ecstasy, so I thought that I was still chasing just these street drugs. I just didn't know how dangerous abusing over the counter and prescription drugs was. I'll never know if that would have been enough to make a difference. My goal is to help other parents know the signs so that they have a chance to intervene as soon as possible and not have to experience the pain I have felt.

2. *In your testimony you indicated that Carl always assured you that he wasn't using drugs or alcohol. Do you believe that Carl – like so many teens across the country – simply didn't recognize the danger of abusing prescription or over-the-counter medicines?*

   Carl was a very intelligent young man. I believe from the bottom of my heart that Carl -- and many adolescents just like him – viewed prescription and over-the-

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counter medications as safe and legal. I don't think that teens put these substances in the same category as illicit drugs, even though they should.

3. *What advice would you give to parents who may believe that prescription or over-the-counter medicines are far less dangerous than illegal street drugs? What advice would you give to parents regarding addressing the dangers of prescription or over-the-counter medicines with their children?*

   I'm here to tell parents that prescription and over-the-counter medicine abuse is serious and they should not trivialize it. Parents need to be aware of the drugs, over the counter and prescription that are available in their homes. They should also make sure other family members and friends do the same. Parents need to educate themselves. The dug landscape is vey different from our teenage days. Communicate to their kids their standards about drug abuse and include over the counter and prescription abuse. Monitor their child's internet use and website visited. Parents must safeguard these medications and make sure their kids are aware of the substantial risks of abusing these substances to get high.

4. *What do you see as the components to reversing the rise in prescription and over-the-counter drug abuse?*

   Ease of access- over the counter and prescription medications are in our medicine cabinets or on the store shelves. Many long term care patients are being cared for at home without a good system to secure, account for, or dispose of these medications.

   Access to information on the internet about how to abuse these medications have weighed the information about the dangers of this type of abuse. This information is spread quickly and across continents.

   So, public **education is key**. As we learn more about new drug trends and their dangers we need to communicate this information to the public; that is why I continue to speak out on this topic. The more parents know that prescription and over-the-counter substances can be deadly when abused by adolescents looking to get high, the more empowered parents will be to educate their kids and lock away potential hazards. And the more that teens hear Carl's story, the more they will come to realize that medicine abuse is serious and can have deadly consequences.

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Responses to Questions for the Record
Stephen J. Pasierb
President and CEO, Partnership for a Drug-Free America

Joint Hearing of the Subcommittee on Crime and Drugs and
the Senate Caucus on International Narcotics Control

Generation Rx: The Abuse of Prescription and Over-the-Counter Drugs
Wednesday March 12, 2008

Question from Senator Joseph R. Biden, Jr.

(1) Do you think pharmaceutical companies and other drug manufacturers have a role to play in addressing these issues? If so, what steps do you think they can take to reduce non-medical use of prescription and over-the-counter drugs?

Pharmaceutical companies and drug manufacturers certainly do have a role to play in preventing the consumer behavior of misusing and abusing prescription and over-the-counter medicines and many of them have already been great partners in our efforts. We commend the companies that have been working proactively to address this problem.

Abbott Labs has funded innovative research so we can learn more about teens' motivations for abusing these substances and are now funding a campaign helping us to educate parents – including a terrific resource on the web at drugfree.org/NotInMyHouse. Endo Pharmaceuticals and Cephalon have supported some of our on-line and off-line resources to provide parents with an in-depth understanding of the risks of medicine abuse and the steps they can take to prevent it. The Consumer Healthcare Products Association has been a steadfast partner over the past decade helping on a number of fronts including supporting multi-pronged research leading to a public information campaign with the American Academy of Pediatrics and helping us develop a first-of-its-kind website with teen-relevant information about the risks of abuse of dextromethorphan, the active ingredient in many cough medicines

The Partnership is also working with partners such as Wyeth Consumer Healthcare and King Pharmaceuticals to reach parents with prevention programs such as our "Time to Talk" parents movement helping parents to communicate with their children about the risks of abusing alcohol and drugs, including prescription and over the counter medications.

In partnership with PhRMA and others, we implemented research with healthcare providers and are currently exploring the development of useful tools which would help them more effectively identify and assess prescription drug abuse in their patient populations. Takeda Pharmaceuticals underwrote the development of a brochure for parents about preventing prescription and over-the-counter drug abuse and distributed it to 100,000 doctors. Reckitt Benckiser has distributed that brochure to pharmacists nationwide through *Pharmacy Today* magazine and retail drug stores. A number of

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other companies have also provided general operating support to the Partnership to help us with all of these endeavors.

(2) What do you think the medical community can do to help reverse the prescription and over-the-counter drug abuse trends?

The medical community has a vital role to play preventing this behavior. Prescription and over-the-counter medications -- legal substances of tremendous benefit if used appropriately -- can be just as dangerous as "street" drugs when abused. When a health professional prescribes medication, he or she should advise the patient to be aware of the abuse potential of the medication, let them know how to properly dispose of any extra medication, and the need to talk to teens and young adults in their lives to make sure that they know that taking prescription medications without a doctor's prescription is dangerous and illegal. We are currently exploring ways to help educate health professionals about the problem as well as help them to identify and assess prescription drug abuse in their patients. Wee see provider education as a vital component in effectively dealing with this issue and one that must be emphasized in the coming years.

(3) Surveys show that medicine cabinets are a major source of the prescription and over-the-counter drugs that are abused by teens. Do you anticipate that this trend will continue? What steps should we be taking to reduce teens' ability to obtain and misuse prescription and over-the-counter drugs? Are there other potential sources, like the internet, that are of particular concern to you? If so, what can we do to prevent teens from turning to these other sources?

According to Partnership research, 75 percent of prescription drug abusers say that they got medication from family or friends. The family medicine cabinet is the leading source of supply and the reason we continually implore the public to monitor their medications, secure them, educate their children about the risks of abuse, and properly dispose of any leftover pills.

Just because teens are not currently using the Internet as a major source of supply does not mean that they never will. The Partnership was pleased that the online pharmacy legislation was signed into law earlier this year. We continue to be concerned about the Internet as a source of information helping teens develop a sophisticated understanding of how to abuse prescription medication.

(4) Can abuse of powerful prescription drugs lead to abusing other illegal street drugs? Does your data show that those who abuse prescription drugs are more or less likely to abuse illegal drugs?

We are continuing to conduct research on this topic. We have learned that prescription drug abuse is not a replacement behavior for the progress made over the past decade in reducing overall teen use of illicit street drugs, rather it is a additive to other substances some teens are already abusing. It also appears that prescription drug abuse is a "bridge" between entry-level teen behaviors – such as binge drinking and smoking marijuana – to

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the use of harder drugs such as Ecstasy or cocaine that might not have otherwise occurred. There is also mounting anecdotal evidence about people who abuse opiate medications graduating to heroin use and people abusing prescription stimulants going on to use cocaine.

(5) Do you have any concern that proactively reaching out to kids and informing them about the dangers of prescription and over-the-counter drug abuse will plant the seed that such drugs can be used for non-medical purposes for kids who otherwise would never have abused these drugs?

No. Abuse of prescription and over-the-counter drugs is already incredibly high and most teens and young adults not only are aware of the behavior but also know someone who has abused these medications. We refer to this as an "entrenched" behavior among American teens. According to Partnership research, roughly one in five teens report have tried a prescription drug without a doctors' prescription at least once in their lives. One in ten report having used over-the-counter cough medicine to get high. Only alcohol, cigarettes, and marijuana are abused by teenagers at higher rates than prescription drugs. Cocaine and Ecstasy are each roughly half as prevalent as prescription drug abuse. The prevalence of teen abuse of methamphetamine is just over one third that of prescription drugs.

(6) Please describe for me what exactly the National Youth Anti-Drug Media Campaign has been and will be doing to address the rise in prescription and over-the-counter drug abuse. Do you have an effective means of measuring the Campaign's success?

The National Youth Anti-Drug Media Campaign (NYADMC) is mounting a major effort, targeting parents and providing them with information on how to safeguard their home supplies of prescription drugs and prevent their teenage children from abusing them. Nationwide television and print advertising are being supplemented with solid web-based information and point-of-sale educational brochures stapled to pain reliever prescriptions in three major drug chains during the months of February and March. Nearly one fourth of the Campaign's media budget this year is being spent in support of this initiative, and – as is the case with all NYADMC advertising-- leveraged via a dollar-for-dollar match by the media.

The research on the effectiveness of the recent flight of ads addressing prescription drug abuse has been quite positive. The in-market tracking study conducted among 400 parents and 400 youths per month showed strong awareness among parents of the NYADMC prescription drug advertising following the launch of the Campaign, as well as significant increases in parents' perceptions of the prevalence of teen abuse of prescription drugs and parents' stated likelihood that they will undertake preventive measures at home: setting clear rules, monitoring prescription drug quantities and safeguarding prescription drugs.

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Question from Senator Charles E. Grassley

(1) Changing Parents' Perceptions: You told us that you learned from your research that parents remain largely ignorant of the danger of prescription drug abuse because this type of drug abuse didn't exist when they were young.

(a) What advice do you have to educate parents on the dangers?
(b) What can be done on a national level and what can be done on a local level?

This dangerous consumer behavior, a mindful and purposeful abuse of prescription medicines, did not exist when this generation of parents were teenagers themselves. Therefore, today's parents have no real frame of reference for the behavior and tend to see prescription drug abuse as somehow a safer alternative to the use of illicit street drugs. The Partnership believes that there needs to be a sustained multi-pronged approach to educate parents about the extent, facts and dangers of teen prescription drug abuse. We are reaching out to parents in a wide variety of ways, including: through the National Youth Anti-Drug Media Campaign's impactful prescription drug abuse themed ads; our own hard-hitting national advertisements about the health risks and harms of abusing these products; extensive public relations efforts to get local and national media to report frequently about the problem; mobilizing our community partners across the nation to take on the Rx issue as part of their work with the public; urging Members of Congress to speak out and educate their constituents; working to get our information distributed through partner organizations including the National Association of School Nurses, the National PTA, American Pharmacists Association, American Medical Association Alliance, the YMCA and the Boys and Girls Clubs; and making all of our materials immediately accessible to the public on line through innovative uses of the Internet.

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Centers for Disease Control and Prevention
Dr. Len Paulozzi
Questions for the Record, March 12, 2008

Questions from Senator Charles E Grassley (R-IA)

(1) Public and Medical Care Provider:

It is important for the public to understand the dangers of inappropriately using medicine, which can help treat or heal one person, but harm another. Doctors are on the front lines of this fight against prescription drug addiction. At the hearing, you testified that medical schools are not doing enough to educate doctors about prescription drug abuse and how to screen for abusers.

a. **Do you have any recommendations or guidelines for Congress to ensure that doctors, especially those in the emergency rooms, screen patients for substance abuse problems?**

CDC estimates that approximately 40% of prescription narcotic painkillers implicated in drug overdose deaths are prescribed in hospital emergency departments in the United States. Screening and brief intervention for substance abuse, including abuse of prescription drugs, should be standard practice in all emergency departments, inpatient units, ambulatory care clinics, especially in situations where caring for the patient requires prescribing abusable drugs. Hospitals are most likely to adopt this practice if it becomes a standard of good care required by the Joint Commission on Accreditation of Healthcare Organizations.

b. **Do you think the public is getting the message about the harms of prescription and over-the-counter drug abuse? If not, how can we do a better job?**

Currently, there is no evidence that improving the public's knowledge about the harms of prescription and over-the-counter drug abuse is an effective strategy at preventing or reducing the harms associated with drug poisonings. Public awareness campaigns aren't always effective and hence, the problem is not likely to be solved by public or provider health messages. Instead, regulatory or policy interventions, such as placing more restrictions on the use of habit-forming drugs by physicians, may be a better prevention method at this time.

c. **What role do you think Congress should play in the problem of prescription and over-the-counter drug abuse?**

Drug overdoses are the second leading cause of unintentional injury death in the United States, exceeded only by motor vehicle fatalities. CDC

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remains committed to responding to prescription drug overdoses through continued surveillance, epidemiologic research, and evaluation of potential interventions. For example, there is a need for a review of the effectiveness of prescription monitoring programs and a review of the risk management programs for risky drugs. Additionally, there is a need for better surveillance of the prescribing of prescription narcotics at the state level.

Questions from Senator Joseph Biden, Jr. (D-DE)

Question: The CDC found that overall mortality rates for poisoning deaths increased 79.5% in the six years between 1999 and 2005, and the CDC suggests that nearly all poisoning deaths are attributable to prescription and illegal drug overdose.

Can you give us a sense of how that breaks down – how many of these deaths result from prescription overdoses, how many from illegal drug overdoses, or a combination of the two?

Each drug overdose death may have several drugs other than prescription drugs contributing to a death and captured on the death certificate. For deaths with multiple drugs listed as a cause of death, one method to determine the contribution of different drug types is to count the first drugs listed on death certificates. For example, in 2005 the first-listed drug was a prescription drug in 50% of deaths, an illicit or street drug like cocaine in 39% of deaths, and an unspecified narcotic in 11% of deaths. The category "unspecified narcotics" may also include prescription or illicit narcotics, so the actual number of deaths due to prescription drugs may constitute more than half of the total deaths.

Deaths with prescription drugs listed first on the death certificate in 2005 break down as follows: 38% prescription narcotic painkillers (such as Vicodin and methadone) and 12% other prescription or over-the-counter drugs. Among the illicit drugs, 25% are cocaine, 8% heroin, and 6% other illicit drugs. The other 11% are unspecified, as mentioned above, but may likely include prescription drugs.

Question: In your view, how can we reverse the trends associated with the alarming rate of prescription drug abuse?

In my professional opinion, the current trend of prescription drug abuse can be reversed in a variety of ways. Some suggestions include:

1. Reducing marketing of scheduled drugs by drug company representatives. Physicians already know the drugs are available, and marketing may not accurately represent the risks of use of these drugs by patients.

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2. Prescription drug monitoring programs must actively share their information on patients and physicians who are abusing the system with local law enforcement. Law enforcement must make prescription drug diversion a high priority.
3. Medicare and Medicaid formularies should carefully review all the evidence about overdose risk before putting drugs like methadone on their preferred drug lists. Methadone is very inexpensive, but it is abuseable and dangerous in unskilled hands. It is probably now associated with more overdose deaths than any other prescription drug. Less risky alternative long-acting opioids are available.
4. Medical societies and hospitals must put all available pressure on providers to follow existing chronic pain treatment guidelines. Guidelines for use of opioids in acute pain need to be developed for use in emergency departments.

Question: According to your data, unintentional poisoning mortality rates for opioids or pain relief medicines are highest among middle-aged persons – 35 to 54 years in age. Yet, the prevalence of non-medical use of these same drugs is highest for younger age groups – around 20 years old.

If young people abuse these drugs more frequently, can you explain why the mortality rate is higher among the older population group?

Currently, there is no scientific explanation for why the mortality rate is higher among the middle-aged population than among young people. However, my speculation is that people in their 20s may be more likely to use drugs in groups and therefore have someone around to help them when they overdose. Young people may use drugs on weekends while older adults use them daily. Younger people may use smaller amounts each time. They may simply be more likely to admit to nonmedical drug use when questioned in SAMHSA's surveys. Finally, mortality data is a couple of years older than SAMHSA data, so it is possible that recently increased usage rates in the young have not yet been detected in available mortality data.

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SUBMISSIONS FOR THE RECORD

"Generation Rx: The Abuse of Prescription and Over-the-Counter Drugs"
Statement of Senator Joseph R. Biden, Jr.
Joint Hearing in the Senate Judiciary Subcommittee on Crime & Drugs and Caucus on International Narcotics Control
March 12, 2008

Good afternoon. Today, this joint hearing in the Judiciary Subcommittee on Crime and Drugs and Senate Caucus on International Narcotics Control will examine and hopefully shed much needed light on an alarming trend that has crept into households and communities across America—the abuse of prescription and some over-the-counter drugs.

For more than three decades, I've been fighting the scourge of illegal drugs like methamphetamine and ecstasy, but I'm here today to tell you that it's not just the illegal street drugs that we parents and policymakers have to worry about. Prescription drugs can also be dangerously addictive and lethal.

One need look no further than the recent death of actor Heath Ledger, who died from an overdose of a lethal combination of prescription drugs. Less visibly, but no less tragically, prescription drug abuse impacts the lives of ordinary, hardworking families like that of Misty Fetko, who is here to tell the story of her son Carl's fatal overdose.

The nonmedical use of prescription drugs that caused these tragic deaths reflects a disturbing national trend: seven of the top eleven drugs most commonly abused by high school seniors are prescription or over-the-counter drugs. Vicodin and Amphetamines now rank up there with marijuana as the top three most commonly abused drugs among 12th graders. And, in 2006 more people started abusing prescription pain relievers than any other drug.

Finally, as you will hear from the Centers from Disease Control and Prevention, poisonings caused largely by prescription drug abuse are the second leading cause of death from unintentional injuries, second only to motor vehicle accidents.

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In my home state of Delaware, the trends are just as apparent: in 2006, 20% of Delaware 11th graders reported that at some point in their life they had abused prescription drugs and 17% had abused an over-the-counter medicine. But this is clearly a national problem that is going to require a coordinated, national solution.

A key component to reversing these trends is raising public awareness so that parents, teachers, and communities recognize the real dangers associated with medicine abuse and take appropriate measures, like safeguarding medicines and talking to kids about the dangers of abuse. Parents need to recognize that if they see a prescription drug or cough syrup bottle next to their child's bedside or in their car, it might be cause for real concern.

Parents must consciously safeguard their prescriptions drugs. 60% of teens reported that prescription drugs are easy to get from parents' medicine cabinets, turning unassuming parents into their own children's drug dealers.

We've also got to fundamentally change the attitude of teens when it comes to abusing medicines. Teens have a misperception that because these drugs are easily accessible and legal when properly prescribed and monitored, they are always safe—in any dose. Nothing could be further from the truth. Abuse of prescription painkillers, for example, can lead to dependency, overdose, and even death. Abusing cough and cold medicine to get high off of its Dextromethorphan ingredient, or "DXM", which about 6% of 12th graders reported doing last year, can cause disorientation, motor impairment, blurred vision, nausea, rapid or irregular heartbeat, high blood pressure, loss of consciousness, and death. Educating parents and teens about these facts is critical.

As is true with illegal street drugs, the abuse of powerful prescription drugs carries with it the potential for a serious addiction. Treatment programs must be available,

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affordable, and open to addicts with a prescription drug abuse problem. The most recent estimates show that of about 24 million Americans who needed treatment for an illegal drug or alcohol problem, only 10%—or 2.5 million—actually received treatment. This under-treatment epidemic is simply unacceptable and we've got to do a lot more to encourage all addicts into treatment.

I've been in this business a long time. What I've learned is that any balanced approach to fighting a drug scourge includes prevention, treatment, and enforcement components. The DEA must be given the tools it needs to shut down rogue, Internet pharmacies that are dispensing these powerful drugs without requiring that a doctor even see the patient—and I support Senators Feinstein and Sessions in this effort. And, while we've got to make sure doctors are able to prescribe these narcotics to those with legitimate needs, at the same time we have to do more to crack down on doctors who rubber stamp prescriptions for those who simply seek to abuse these drugs.

Moreover, Congress should pass my Dextromethorphan Abuse Reduction Act to restrict who can purchase pure, unfinished DXM and require that purchasers of DXM-containing products be at least 18 years of age. My bill, supported by my friend Senator Grassley, among others, would also robustly fund prevention and education campaigns around the country.

Since the issue came to my attention some time ago, I have worked to get the word out to parents and communities that medicine abuse is a real problem. Understanding that this is a serious concern is one of the keys to solving the problem.

Take my word for it: trends matter. We've got to get a handle on these abuse rates before they get worse. This hearing is a start, but we've got a lot of work to do and I would like to thank all the witnesses for coming to help jumpstart this campaign.

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Generation Rx: The Rising Abuse of Prescription and Over-the-Counter Drugs
International Narcotics Control Caucus

Written Testimony of Derek Clark
Executive Director
Clinton Substance Abuse Council
Clinton, Iowa

Recently, there was a local high school student that was caught by his mother stealing her heart medication. This boy was crushing the medication and snorting it in the hopes of getting high, he didn't. This mother became suspicious when she noticed her medication was disappearing and confronted her son, he admitted his actions. The boy is currently receiving treatment. Unfortunately, this is a growing trend with an uncommon ending.

Clinton, Iowa, the State of Iowa, and the country face an array of drugs of abuse; many have plagued us for decades. One of the fastest growing threats to youth today is the abuse of prescription and over-the-counter drugs. 15% of CCSD 11th grade students report having used prescription medications not prescribed to them at least once in the last 30 days compared to 7% of all Iowa 11th grade students. 11% of CCSD 11th grade students report having used over the counter medications different from the directions at least once in the last 30 days compared to 7% of all Iowa 11th grade students. There are several reasons for this new phenomenon.

- The perception that these drugs are not harmful or dangerous.
- They have easy access to the drugs; they are stealing them, buying them, or getting a prescription for themselves or a family member.
- Individuals are "doctor shopping" or "pharmacy shopping" to obtain large amounts of medications.
- User generated video websites show youth how to get high and with what over-the-counter drugs to use.

Prescription Drug and Over the Counter Drug Abuse Data

Prescription drug and over-the-counter drug abuse is a relatively new problem and there is not a lot of historical data. The Iowa Youth Survey only began asking students about their prescription drug and over-the-counter drug abuse/misuse since 2005 and they only have 2 questions included, see below. Law enforcement only recently began tracking this data and treatment is still trying to find a universal way of reporting this data.

The **Iowa Youth Survey** is prepared by the Iowa Department of Human Rights, Division of Criminal & Juvenile Justice Planning and Statistical Analysis Center. The State of Iowa conducts this survey every 3 years and surveys 6th, 8th, and 11th graders. The survey includes questions about the students' behaviors and attitudes/beliefs, as well as perceptions of their peer, family, school and neighborhood/community environments.

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Youth Prescription Drug Abuse

15% of CCSD 11th grade students report having used prescription medications not prescribed to them at least once in the last 30 days compared to 7% of all Iowa 11th grade students (IYS 2005).

Students reporting using prescription medications not prescribed to them at least once in the past 30 days.			
	6th Grade	8th Grade	11th Grade
Clinton Community School District (Clinton, Iowa)	3%	6%	15%
Clinton County, Iowa	2%	4%	9%
State of Iowa	2%	3%	7%

The above data was collected by the Iowa Youth Survey, 2005.

Youth Over-the-Counter Medication Abuse

11% of CCSD 11th grade students report having used over the counter medications different from the directions at least once in the last 30 days compared to 7% of all Iowa 11th grade students (IYS 2005).

Students reporting using over-the-counter medications different from the directions at least once in the past 30 days.			
	6th Grade	8th Grade	11th Grade
Clinton Community School District (Clinton, Iowa)	2%	4%	11%
Clinton County, Iowa	2%	2%	7%
State of Iowa	1%	3%	7%

The above data was collected by the Iowa Youth Survey, 2005.

Calls involving Abuse/Misuse of Substances of Abuse (excluding suicide attempts)

The data shows a notable increase over the years in abuse/misuse of prescription (i.e. hydrocodone) and over-the-counter medications (specifically the dextromethorphan-containing products such as Coricidin and cough syrups). However, health care providers/hospitals are not mandated to call the poison center in cases of poisoning/overdose so there is probably hundreds of cases out there that are not reported.

Substance	2002	2003	2004	2005	2006	2007
Benzodiazepines (ie. Valium®, Xanax®)	48	68	74	87	102	123
Oxycodone (ie. Oxycontin®, Percocet®, Percodan®)	12	11	12	15	23	35
Hydrocodone with APAP (ie. Vicodin®, Lortab®, Lorcet®)	19	25	41	43	33	74
Coricidin HBP® & cough syrups (containing dextromethorpham or DM)	28	55	67	57	91	113
SSRI's (ie. Paxil®, Zoloft®, Prozac®)	38	35	47	35	35	42

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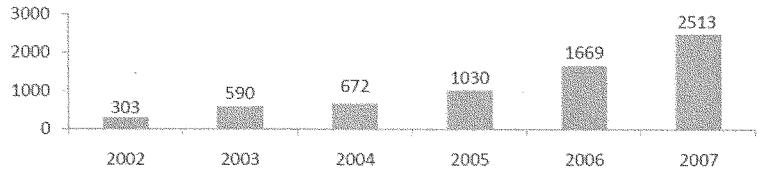
Methylphenidate (ie. Ritalin®)	8	10	13	17	14	9
Propoxyphene (Darvocet®, Darvon®)	13	11	13	10	9	11
Morphine	3	4	9	3	5	10
Methadone	3	3	7	10	7	13
Tramadol (Ultram®)	0	3	10	11	10	22
Other Narcotic (ie. Dilaudid®, hydrocodone other)	4	15	16	14	21	21

The above data was collected by the Iowa Statewide Poison Control Center, 2007.

Public Calls to Identify Unknown Pain Pills

Public calls to the Statewide Poison Control Center to identify unknown pain pills have increased 643% since 2002 in Iowa.

Pain Reliever Drug ID Calls from Iowans (Iowa SPCC-CYs)



Community Strategy

CSAC involved the community in developing the Strategic Plan by holding monthly meetings to discuss local substance abuse problems, emerging drug use trends, solutions designed to address that problem, and outcomes from programs and projects. When needed task forces and ad hoc workgroups were formed to allow individuals to focus on that issue, whether it is addressing a specific problem or implementing a project or program. In addition to the regular meetings, CSAC also conducted focus groups with local law enforcement, substance abuse treatment providers, mental health professionals, human service professionals, and community members. When individuals were not available to meet they completed a key informant survey to ensure the widest amount of people had their voice included in CSAC's Strategic Plan.

Through this process, the top three most widely used drugs in Clinton are alcohol, tobacco, and marijuana but the trend data shows that usage rates are going down. However, Clinton has a growing problem with prescription drug abuse.

CSAC's Strategic Plan would address Clinton's prescription drug abuse problem by:

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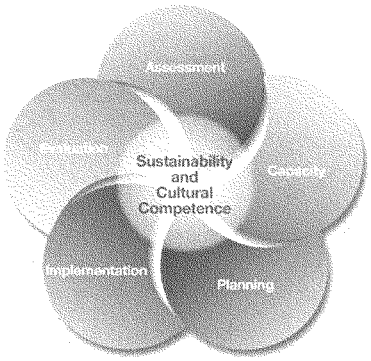
- Developing social marketing campaigns to change the perception of risk associated with prescription drug abuse
- Implementing environmental strategies to reduce access to prescription drugs
- Educating the community and targeted segments on the dangers and problems
- Facilitating participation in the online prescription drug tracking system being developed by the State of Iowa.

CSAC uses the Strategic Prevention Framework when conducting their community planning and decision making process. This 5 step process 1) needs assessment 2) capacity building 3) planning 4) implementation 5) evaluation, ensures the focus of CSAC is always current with local trends and being as effective as possible with the resources available to them.



Projected Outcomes

Community level change that CSAC expects to see include evidence of increased perception of harm, decreased age of onset of substance abuse, increased parental disapproval of substance use, and decreased youth use rates. CSAC uses environmental strategies, social marketing campaigns, training opportunities for local professionals and the community, and community forums to affect change on prescription drug abuse, underage drinking, marijuana use, and illicit drug use.

CSAC has a Drug Free Communities Support Program grant and will achieve the following outcomes:

- By Sept. 2012, CC youth report a 15% increase in perception of harm for non-medical use of prescription drugs.
- By Sept. 2012, youth will report a 10% reduction in illegal use of prescription drugs.
- By Sept. 2012, arrest records will show a 15% reduction in prescription drug related arrests.
- By Sept. 2012, 95% of Clinton medical facilities will participate in the prescription drug abuse prevention program.

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Logic Model: Prescription Drug Abuse

Theory of Change: Implementing multiple strategies to address prescription drug abuse will likely delay use and use less.

Problem Statement			Strategies	Activities	Outcomes		
Problem	**But why?**	**But why here?**			**Short Term**	**Intermediate**	**Long-Term[1]**
Increasing number of youth & adults are abusing prescription drugs. 15% of CCSD 11th grade students report having used prescription medications not prescribed to them at least once in the last 30 days. Compared to 7th of all Iowa 11th grade students. IYS, 2005.	Perceived as safe.	Because prescriptions are prescribed by a doctor people believe the side effects are known and safe	Provide Information	Develop and implement social marketing campaign	Research most abused drugs and side effects	Development of campaign Implement campaign.	By Sept. 2012, CC youth report a 15% increase in perception of harm for non-medical use of prescription drugs.
	Doctors hand out prescriptions easily.	Lack of awareness on local doctor shopping problem and practices that reduce/support doctor shopping.	Build Skills Provide Information	Increase awareness of problems among medical professionals	Work with pharmacists to create information for medical professionals (including ER staff)	Create social marketing to educate medical professionals on this issue.	By Sept. 2012, youth will report a 10% reduction in illegal use of prescription drugs.
		No central database or control to ensure no doctor shopping.	Reduce access	Create multiple doctor reporting process.	Work with medical professionals to report if patient is under the care of another physician to report to pharmacist.	Develop a way to track form	By Sept. 2012, arrest records will show a 15% reduction in prescription drug related arrests.
	Easy access	Easy to steal/obtain.	Provide Information	Develop and Implement a social marketing campaign	Research most abused drugs and side effects	Develop campaign to restrict access to prescript. Drugs.	By Sept. 2012, 95% of Clinton medical facilities will participate in the prescription drug abuse prevention program.
		Users order drugs over the Internet.	Provide Information	Research the dangers of getting your prescriptions online.	Develop and Implement a social marketing campaign	Create a social marketing campaign with medical professional and law enforcement.	

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Clinton Substance Abuse Council

CSAC's mission statement is "The Clinton Substance Abuse Council, through collaboration, works to develop solutions to community problems that are related to substance abuse issues through the process of facilitation, cooperation, and communication."

The Clinton Substance Abuse Council (CSAC), founded in 1989, is a community-based coalition focused on substance abuse and related issues. CSAC addresses substance abuse and related issues through community planning and development, program planning and management, and education. Wide cross sections of Clinton County residents are involved in CSAC from the mayor of Clinton to high school students to local business to law enforcement, etc. etc..

For the past 18 years, the CSAC has met monthly to address substance abuse and related issues within our community, addressing all cultural groups in the community. Through our planning, we have identified problems and gaps within the community and found programs and/or solutions to fill these problems/gaps. In addition to the CSAC community meetings and CSAC Board of Directors meetings, CSAC has numerous short-term and long-term task forces and workgroups to focus on specific issues or complete specific duties. In order to ensure each group has a complete picture of the issue, all groups are culturally representative of the community.

The CSAC Board of Directors is made up of 11 community members to supervise all functions and duties of CSAC and staff. Duties include: fiscal oversight and management; ensure that the organization has proper internal controls and policies to safeguard, promote and protect the organization's funds and other assets; assist in the strategic planning process. Members include: executive from Mercy Medical Center; Mayor of Clinton, a pastor from a local church, local businessman, County Attorney, etc.

Clinton, Iowa

The City of Clinton is located on the eastern-most tip of Iowa along the Mississippi River, within Clinton County. Clinton has a population of 27,086 (2005, Census). Clinton's population is composed of: persons under 5 years old 6.6%; Persons under 18 years old 24.6%; persons older than 65 years old is 17%. There are 52.3% females and 47.7% male. Clinton County is a predominantly Caucasian community, 93.8%, with the second largest group being African-American, 3.2%, the third closest is Asian Americans, 0.8%. Clinton is classified by the US Census as an urban cluster.

Clinton County has a higher rate of unemployment (4.0%) compared to the State (3.3%) (February, 2007, IA Workforce Development). Clinton Community School District's free and reduced lunch rate, for grades 1st thru 6th, is 53.52%. And the Clinton Community School District has 44.4% of their students fall in the economically disadvantaged category whereas the

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State rate is 30% (2005, www.schoolmatters.com). Also, Clinton's population has declined by 7.2% since 1990, whereas the state's population has grown by 7.4% since 1990.

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ATTACHMENTS

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Please join the Clinton Substance Abuse Council, for

A Dose of Prevention: Combating Prescription & Over-the Counter Medicine Abuse in Clinton

Thursday, March 27, 2008, 6:30 PM

According to the 2006 National Survey on Drug Use and Health, more teens abuse prescription drugs than any illicit drug except marijuana--more than cocaine, heroin, and methamphetamine combined.

You already know about illegal street drugs like marijuana, meth, and cocaine, but do you know that every day adults and YOUTH abuse prescription and over the counter drugs to get high? This townhall meeting will provide the answers to many questions that you may have about prescription and over the counter drug use. We have a panel of experts here to answer all of your questions.

Guests will include:

Senator Charles Grassley
United States Senator

General Arthur Dean
Chairman & CEO of CADCA

Director Gary Kendell
Director of the Governor's Office of Drug Control Policy

Andrew Fish
Senior VP, Legal & Government Affairs, CHPA

Mike Wolf, Welcome
Clinton County Attorney

Sheriff Rick Lincoln, Moderator
Sheriff of Clinton County

Panel of Local Professionals including:
Clinton Police Department
Darlene Fox, M.S., R.N., School Nurse, Clinton High School
Trisha Atkinson, BA, ACADC Adolescent Treatment Counselor, New Directions
Cindy Ryan, RPh, Pharmacist, Jewell-Osco
Dr. Wade Lenz, Family Practitioner, Medical Associates

CADCA

Town Hall Meeting
Thursday, **March 27, 2008, 6:30 PM**
CCC-Graphic Arts & Technology Center, Room 10
1951 Manufacturing Drive, Clinton, Iowa

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Seats are limited, call 563-241-4371, or email kristin@csaciowa.org to reserve your seat.
This is a free event, and open to the public.

This event is made possible by: Clinton Substance Abuse Council, ASAC/New Directions, Senator Grassley's Office, Community Anti-Drug Coalitions of American (CADCA), and Consumer Healthcare Products Association (CHPA), Iowa ODCP, ONDCP, IDPH, and a DFC grant.

Quad-City Times

Clinton woman faces felony charges in methadone scheme

By Steven Martens | Tuesday, March 04, 2008

CLINTON, Iowa — A Clinton woman has been charged with six felony counts for allegedly scheming to fraudulently obtain prescriptions for methadone.

Lisa A. Fullerton, 39, was arrested last week after an investigation by the Clinton Police Department, according to court records.

A search of her medical history showed that Fullerton had been treated by several doctors between 2004 and 2007 for chronic pain, usually back pain, according to court records.

In November 2005, Fullerton allegedly called Dr. Steven Hanas in DeWitt and told him she had dropped more than

100 methadone tablets in the toilet, but Hanas refused to replace them, according to court records.

In April 2006, Fullerton allegedly told Hanas that she had left her bottle of methadone pills in California after visiting family there. Hanas prescribed her 180 tablets, but Fullerton later admitted to investigators she had not been to California, according to court records.

Investigators also believe Fullerton went to see Dr. Luis Barrios in Clinton in September 2007 while she still was under the care of Hanas, and that she saw Barrios nine times in three months, obtaining prescriptions for pain killers such as hydrocodone and fentanyl while she was still getting methadone prescriptions from Hanas. Neither doctor knew Fullerton was seeing another doctor, according to court records.

Fullerton was charged with six counts of prohibited acts, a Class C felony punishable by a maximum of 10 years in prison. She was being held Monday in the Clinton County Jail on $50,000 bond. A preliminary hearing has been scheduled for March 10.

Steven Martens can be contacted at (563) 659-2595 or smartens@qctimes.com.

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PRESS RELEASE
January 12, 2006

In an attempt to demonstrate and quantify the problem of "doctor shopping" and "pharmacy shopping" in Iowa, the Iowa Board of Pharmacy Examiners has begun an ongoing study into the matter. The Board's initial inquiry began last fall when compliance officers for the Board randomly visited a small number of Iowa pharmacies to review prescription records. The purpose of the survey was to identify "drug-seeking" persons who had utilized 3 or more pharmacies and 3 or more physicians to obtain excessive quantities of narcotics and other addictive controlled substances.

The Board's initial inquiry revealed 85 patients having drug-seeking behavior. Fifty-five percent of the patients were female and forty-five percent were male. The age range was 19 to 63 and with the average age being 40. The patients resided in 32 cities scattered across the state from Sioux City to Fort Madison. The inquiry also revealed 153 other patients who may be drug-seekers. The records of those individuals are continuing to be evaluated by Board staff.

The findings of the Board's initial survey include the following examples:

- A 49 year-old female from Carroll who utilized five pharmacies and multiple prescribers to obtain nearly 1,200 tables of Oxycodone in one month.
- A 34 year-old male from Winterset who utilized three pharmacies and seven prescribers to obtain controlled substances including Hydrocodone.
- A 47 year-old female from West Des Moines who utilized three pharmacies and nine prescribers to obtain controlled substances including Hydrocodone.
- A 40 year-old male from Fort Dodge who utilized 3 pharmacies and four prescribers to obtain controlled substances. This individual allegedly forged prescriptions for Dilaudid.
- A 40 year-old male from Des Moines who utilized nine pharmacies (including pharmacies in Cedar Rapids and Coralville) and twenty prescribers to obtain controlled substances including Oxycodone, Hydrocodone, and Morphine.
- A 47 year-old female from Mason City who utilized three pharmacies and four prescribers to obtain controlled substances including Hydrocodone. This individual had insurance but also paid cash for some of the prescriptions.
- A 34 year-old female from Des Moines who utilized six pharmacies and eight prescribers to obtain controlled substances including Hydrocodone and Oxycodone.
- A 19 year-old female from Des Moines who utilized three pharmacies and twelve prescribers to obtain controlled substances including Hydrocodone and Oxycodone.
- A 40 year-old female from Des Moines who utilized three pharmacies and ten prescribers to obtain controlled substances.

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- A 39 year-old male having multiple Iowa addresses who utilized seven pharmacies and 18 prescribers to obtain controlled substances. This individual had insurance but also paid cash for some of the prescriptions.
- A 42 year-old male from Davenport who utilized six pharmacies and 13 prescribers to obtain controlled substances including excessive amounts of Oxycodone.
- A 22 year-old female from Davenport who utilized six pharmacies and **25** prescribers to obtain controlled substances including Hydrocodone.
- A 27 year-old female from Burlington who utilized five pharmacies and **23** prescribers to obtain controlled substances.
- A 45 year-old female from Iowa City who utilized six pharmacies and eight prescribers to obtain controlled substances including Hydrocodone.
- A 43 year-old female from Fairfield who utilized three pharmacies and nine prescribers to obtain controlled substances including Hydrocodone.
- A 45 year-old male from Fort Madison who utilized seven pharmacies and four prescribers to obtain controlled substances including Hydrocodone.
- A 26 year-old male from Keokuk who utilized ten pharmacies and **41** prescribers to obtain controlled substances including Hydrocodone and Oxycodone.
- A 32 year-old male from Davenport who utilized eight pharmacies and **23** prescribers to obtain controlled substances including Hydrocodone and Oxycodone.
- A 50 year-old female from Davenport who utilized six pharmacies and **28** prescribers to obtain controlled substances. This individual is an Iowa Medicaid patient.
- A 50 year-old female from Dubuque who utilized six pharmacies and ten prescribers to obtain controlled substances. During the month of January 2005, she had 14 prescriptions for Hydrocodone filled at four different Dubuque pharmacies.
- A 36 year-old female from Marion who utilized nine pharmacies and five prescribers to obtain controlled substances including Amphetamines.
- A 42 year-old male from Vinton who utilized **20** pharmacies and **16** prescribers to obtain controlled substances.
- A 63 year-old female from the state of Colorado who utilized **18** Iowa pharmacies to obtain excessive controlled substances. This individual was reported to travel with a prescriber who wrote prescriptions while in the pharmacy with the patient.
- A 40 year-old male from Cedar Rapids who utilized 14 pharmacies and 12 prescribers to obtain controlled substances including Hydrocodone.
- A 26 year-old female from Sioux City who utilized six pharmacies and 16 prescribers to obtain controlled substances including Hydrocodone.
- A 22 year-old female from Kingsley who utilized ten pharmacies and **24** prescribers to obtain controlled substances. This individual obtained a total of ½ gallon of Phenergan & Codeine Liquid in May 2005 by having nine prescriptions written by seven different doctors filled at seven different pharmacies.

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- A 48 year-old male from South Sioux City who utilized eight pharmacies and five prescribers to obtain controlled substances including Hydrocodone. This individual was admitted into drug treatment in July 2005.
- A 31 year-old female from Cedar Rapids who utilized 12 pharmacies and **20** prescribers to obtain controlled substances. A pharmacy "hot-line" alert from a dentist stated that "she likes to call dentists after hours."
- A 29 year-old female from Cedar Rapids who utilized 12 pharmacies and **22** prescribers to obtain controlled substances including Hydrocodone.
- A 39 year-old female having multiple names and multiple Iowa addresses who utilized 18 pharmacies and multiple prescribers to obtain controlled substances including Hydrocodone. This individual was detected by an alert relief pharmacist who was working in various pharmacies in central and eastern Iowa.
- A 49 year-old female from Muscatine who utilized 14 pharmacies and **26** prescribers to obtain controlled substances.
- A 33 year-old male from Council Bluffs who utilized six pharmacies and 16 prescribers to obtain controlled substances including Oxycodone.

Oxycodone is a Schedule-II controlled substance and Hydrocodone is a Schedule-III controlled substance. Both drugs are highly addictive and are two of the top-abused substances in the U.S. The prescribers who were involved in these cases were physicians, dentists, and other practitioners. The pharmacies were all community retail businesses, including many well-known chain pharmacies.

This information was compiled by Board consultant Jacqueline Devine, a former inspector/investigator for the Iowa Board of Pharmacy Examiners.

Patients identified in this study resided in the following Iowa cities/towns:

Burlington
Carroll
Cedar Rapids
Clive
Council Bluffs
Creston
Davenport
Des Moines
Dubuque
Fairfield
Fort Dodge
Fort Madison
Iowa City
Keokuk
Kingsley
Marion
Mason City
Mingo
Mount Vernon
Muscatine
Perry
Robins
Sherrill
Sioux City
South Sioux City
Urbandale
Vinton
Walcott
Waukee
West Des Moines
Wilton
Winterset

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celebrating 125 years

Subcommittee Hearing Statement

Generation Rx: The Abuse of Prescription
and Over-the-Counter Drugs

United States Senate
Committee on the Judiciary
Subcommittee on Crime and Drugs
and The Senate Caucus on International Narcotics Control
Room 226 of the Senate Dirksen Office Building

March 12, 2008

Statement of the Consumer Healthcare Products Association

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to submit this written statement to the U.S. Senate Judiciary Subcommittee on Crime and Drugs and the Senate Caucus on International Narcotics Control. CHPA is the national trade association representing the leading manufacturers of nonprescription, over-the-counter (OTC) medicines.

CHPA and its member companies take seriously our obligation to educate and raise awareness among consumers, parents, community leaders, and policymakers about medicine abuse. CHPA is committed to continuing the fight against medicine abuse, including through partnerships with such key organizations as the Partnership for a Drug-Free America, the Community Anti-Drug Coalitions of America, and D.A.R.E. America. Our programs already have reached 100 million people across the country. In addition, our member companies that make OTC cough medicine are moving ahead to incorporate an informational icon on product packaging that will direct parents to our comprehensive web site, www.StopMedicineAbuse.org.

We also thank Senator Biden for his introduction last year of a resolution that established August 2007 as "National Medicine Abuse Awareness Month." As described further below, CHPA and its partners leveraged this recognition to spread awareness of cough medicine abuse to communities nationwide.

In addition to our long-term commitment to education and awareness, CHPA supports federal legislation that would ensure that raw, unfinished dextromethorphan—the active ingredient in cough medicine—does not fall into the wrong hands, and that minors under the age of 18 are not allowed to purchase cough medicine.

In our efforts to educate parents, we've learned that far too many parents and teens see medicine abuse as less risky behavior than the abuse of illicit drugs. According to research conducted by the Partnership for a Drug-Free America, one in five teenagers has abused prescription medicines, and one in 10 teenagers—or about 2.4 million young people—reports having abused cough medicine to get high. These teens are intentionally taking excessive amounts of OTC cough medicines—sometimes up to 50 times the recommended dose—to get "high" from the active ingredient dextromethorphan (sometimes referred to as "DXM").

First approved by the U.S. Food and Drug Administration in the 1950s, dextromethorphan is a safe and effective ingredient found in well over 100 over-the-counter cough and cold medicines. Dextromethorphan is an effective, non-narcotic cough suppressant that works by raising the coughing threshold in the brain; it has no pain relieving properties and is not addictive. While dextromethorphan is used safely by millions of Americans each year to relieve coughs due to the common cold or flu, parents need to be aware that some teenagers and young adults intentionally abuse OTC medicines containing dextromethorphan to get high.

Federal Legislation

The leading manufacturers of cough medicines support both federal and retailer efforts to implement sales restrictions prohibiting the purchase of products containing

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dextromethorphan by those under the age of 18. We commend Chairman Biden and Senators Grassley, Durbin, and Feinstein for introducing S. 2274, the "Dextromethorphan Abuse Reduction Act of 2007," which would establish this sales restriction.

CHPA also supports federal legislation that would make it illegal for anyone who is not appropriately licensed under federal or state law to possess or distribute raw, unfinished dextromethorphan. Currently, there are no restrictions on the sale of raw, unfinished dextromethorphan. While there are no reports of unfinished dextromethorphan being illegally diverted from the supply chain, there are a few cases in which unfinished dextromethorphan was purchased and purposely distributed as a drug for abuse. Because unfinished dextromethorphan is the form of the ingredient that poses the most risk when abused, and several deaths have been associated with abuse of the raw ingredient, it is critical that Congress make the illicit distribution of unfinished dextromethorphan illegal.

The Dextromethorphan Abuse Reduction Act proposes to classify unfinished dextromethorphan under Section V of the Controlled Substances Act. On October 15, 2007, the U.S. House of Representatives unanimously passed a bill that takes a different approach to controlling distribution of unfinished dextromethorphan, by simply prohibiting the possession or distribution of raw dextromethorphan by anyone who does not have a legitimate need for it. This bill, the "Dextromethorphan Distribution Act of 2007" (H.R. 970), further establishes that illicitly distributed unfinished dextromethorphan is considered adulterated, giving the U.S. Food and Drug Administration authority to seize it wherever it is found. The House also passed similar legislation in 2006.

Senator Murray has introduced a Senate companion to the Dextromethorphan Distribution Act, S. 1378. CHPA thanks Senator Murray for her leadership, and urges Congress to enact restrictions on the sale and distribution of raw, unfinished dextromethorphan this year.

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CHPA Education and Awareness Programs

As the makers of over-the-counter medicines, CHPA member companies take medicine abuse very seriously and are committed to effectively addressing this dangerous problem. While national sales restrictions and preventing raw dextromethorphan from falling into the wrong hands would serve as major steps forward in reducing cough medicine abuse, education remains paramount. We are spearheading several major campaigns to raise awareness of dextromethorphan abuse, all of which can be accessed through our comprehensive web site, www.StopMedicineAbuse.org.

In 2003, CHPA and the Partnership for a Drug-Free America began an ongoing initiative to ensure that adults with influence and oversight over young people are aware that teens may be considering abusing medicines containing dextromethorphan. In May 2006, our two organizations began the Rx and OTC Medicine Abuse Education Campaign. This multi-year communications campaign helps parents and families understand and prevent the abuse of medicines, including cough medicines containing dextromethorphan, by teenagers and young adults.

Specifically, CHPA and the Partnership are:

- Distributing television, radio, and print public service announcements to help raise parental awareness;
- Disseminating an educational brochure for parents, *Preventing Teen Cough Medicine Abuse: A Parent's Guide*, in English and Spanish.
- Operating a parent-oriented web site with information on dextromethorphan abuse, as well as a teen-oriented site—www.dxmstories.com—to provide teens with accurate information; and
- Presenting information to a variety of organizations, including parent groups, educator associations, the poison control center network, health professional organizations, and law enforcement.

CHPA also joined forces with the Community Anti-Drug Coalitions of America (CADCA) to develop a new educational community toolkit to help coalition and prevention

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leaders mobilize their communities and educate key stakeholders about the dangers of OTC cough medicine abuse. CADCA represents over 5,000 community coalitions nationwide. This toolkit, which is available at www.DoseofPrevention.org, was unveiled at CADCA's National Leadership Forum in February 2007.

Dovetailing with the recognition of August 2007 as "National Medicine Abuse Awareness Month," CHPA and CADCA hosted town hall meetings around the country during last year, supported by local CADCA affiliates. CHPA continues to support and participate in such town hall meetings, including an upcoming meeting with Senator Grassley scheduled on March 27th in Clinton, Iowa. Communities interested in hosting their own town hall meetings have access to all materials via www.DoseofPrevention.org.

Because of the importance of the online community in raising awareness about medicine abuse, CHPA launched in May 2007 "Five Moms: Stopping Cough Medicine Abuse," an online grassroots campaign to help parents fight teen medicine abuse. At the heart of the Five Moms Campaign are five exceptional women, from different walks of life and areas of the country, who are all dedicated to spreading the word about the dangers of cough medicine abuse.

This campaign uses the very same tactics as medicine abusers: spreading and promoting information on the Internet. The Five Moms' goal is to get the word out to as many parents as possible that cough medicine abuse is happening in their homes, and that the Internet is a driving force. Through their website www.FiveMoms.com, the Five Moms offer information about cough medicine abuse. These remarkable women have reached 25 million people with this powerful campaign, and continue to reach many more.

To address this form of abuse in the schools, CHPA, the Pharmaceutical Research and Manufacturers of America (PhRMA) and Abbott Laboratories teamed up with D.A.R.E. America to launch a new, specialized curriculum for fifth-, seventh-, and ninth-graders that targets students with strong messages about medicine respect and against the abuse of prescription and over-the-counter drugs. These lessons are designed to be taught after students complete their regular D.A.R.E. curriculum. D.A.R.E. America's Rx and OTC Drug

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Abuse Curriculum was developed with the support and expertise of law enforcement officers, the U.S. Office of National Drug Control Policy, the National Council on Patient Information and Education, the U.S. Drug Enforcement Agency, the U.S. Food and Drug Administration, the National Institute of Drug Abuse, the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAP), and the Partnership for a Drug-Free America.

Conclusion

Thank you again to the members of the Subcommittee and the Caucus for the opportunity to address the important topic of medicine abuse. In addition to maintaining and expanding our innovative programs, CHPA continues to reach out to many organizations, including parent groups, education associations, health professional societies, law enforcement, the retail community, pharmacists, and others to raise awareness of medicine abuse and how to fight it.

CHPA is pleased to see strong leadership in Congress on this issue, and urges the enactment of federal legislation ensuring that raw, unfinished dextromethorphan does not fall into the wrong hands, and that minors under the age of 18 are not allowed to purchase cough medicine.

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Why Untreated Chronic Pain is a Medical Emergency

Alexander DeLuca, Senior Consultant, Pain Relief Network, 2008-02-28

Untreated Chronic Pain is Acute Pain

The physiological changes associated with acute pain, and their intimate neurological relationship with brain centers controlling emotion, and the evolutionary purpose of these normal bodily responses, are classically understood as the "Fight or Flight" reaction, which was elegantly explained by W.B. Cannon in "The Emergency Function of the Adrenal Medulla in Pain and the Major Emotions", published in 1914. [1]

Cannon describes how adrenalin, "Liberated Normally in Fear, Rage, Asphyxia and Pain," a reflex response to pain and major emotion, leads to hyperglycemia necessary "for putting forth supreme muscular efforts," and to vascular changes that shunt blood away from vital organs in the gastrointestinal and urinary system in order that "the 'tripod of life' - the heart, lungs and brain (as well as the skeletal muscles) - are, in times of excitement... abundantly supplied with blood..." Cannon concludes this most basic and well known medical tract with these words:

> These changes in the the body are, each one of them, *directly serviceable in making the organism more efficient in the struggle which fear or rage or pain may involve*; for fear and rage are organic preparations for action, and **pain is the most powerful known stimulus to supreme exertion.**[2] **(bold** emphasis added)

"Fight or Flight", Chronically Thwarted, Leads to Pathophysiological Changes

When these adaptive physiologic responses outlive there usefulness, as when access to effective dosage of analgesic medications is denied, then the fight or flight response becomes pathological, leading to chronic cardiovascular stress, hyperglycemia which both predisposes to and worsens diabetes, splanchnic vasoconstriction leading to impaired digestive function and potentially to catastrophic consequences such as mesenteric insufficiency, etc.

Unrelieved pain can be accurately thought of as the "universal complicator" which worsens all co-existing medical or psychiatric problems through the stress mechanisms reviewed above, and by inducing cognitive and behavioral changes in the sufferer that can interfere with obtaining needed medical care.[3] In a New York Times Magazine article in 2001, Dr. Daniel Carr, director of the New England Medical Center, put it this way:

> "Some of my patients are on the border of human life. Chronic pain is like water damage to a house - if it goes on long enough, the house collapses," [sighs Dr. Carr] "By the time most patients make their way to a pain clinic, it's very late." **What the majority of doctors see in a chronic-pain patient is an overwhelming, off-putting ruin: a ruined body and a ruined life.**[4] **(emphasis** mine)

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1 Cannon, W. B. (1914). The emergency function of the adrenal medulla in pain and the major emotions, Am J Physiol, 33(2), 356-372. (Available: http://ajplegacy.physiology.org/)

2 Cannon (1914). Emergency function of adrenals in pain. page 372.

3 For example, five recent academic review articles about consequences of chronic stress on various organ systems: 1) Mayer, E. A. (2000). The neurobiology of stress and gastrointestinal disease, Gut, 47(6), 861-9; -- 2) Heim, et al. (2000). The potential role of hypocortisolism in the pathophysiology of stress-related bodily disorders, Psychoneuroendocrinology, 25(1), 1-35; -- 3) Pickering, T. G. (2001). Mental stress as a causal factor in the development of hypertension and cardiovascular disease, Current hypertension reports, 3(3), 249-54; -- 4) Loeser & Melzack. (1999). Pain: an overview, Lancet, 353(9164), 1607-9; -- and, 5) Morrison et al. (2003). Relationship between pain and opioid analgesics on the development of delirium following hip fracture, J Gerontol A Biol Sci Med Sci, 58(1), M76-81.

4 Thernstrom, M. (2001). Pain the Disease, New York Times Magazine, 2001-12-16. (Available: http://query.nytimes.com/gst/fullpage.html?res=9C02E4DD163FF935A25751C1A9679C8B63&sec=&spon=&pagewanted=1)

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Specific Consequences of Untreated and Inadequately-treated Pain
Following our discussion in the preceding section, the medical consequences of untreated pain are legion. In addition to the direct morbidity of pain induced physiologic stress, including chronic hypertension, ischemic cardiac disease, renal insufficiency, stroke, and gastrointestinal bleeding, we must also consider the very real risk of suicide, often profound decrements in family and occupational functioning, iatrogenic morbidity consequent to the very common mis-identification of pain patient as drug seeker.

What happens to patients denied needed pharmacological pain relief is well documented. For example, morbidity and mortality resulting from the high incidence of moderate to severe postoperative pain continues to be a major problem despite an array of available advanced analgesic technology.[5] In a study of pain following hip fracture, undertreated pain was demonstrated to significantly increase the risk of delirium:

> Patients who received less than 10 mg of parenteral morphine sulfate equivalents per day were more likely to develop delirium than patients who received more analgesia (RR 5.4, 95% CI 2.4–12.3)... **Avoiding opioids or using very low doses of opioids increased the risk of delirium.** Cognitively intact patients with undertreated pain were nine times more likely to develop delirium than patients whose pain was adequately treated. Undertreated pain and inadequate analgesia appear to be risk factors for delirium in frail older adults.[6] (emphasis added)

Pain Sufferers are a Medically Discriminated Against
One very important reason that untreated pain is a medical emergency, particularly in the United States, has nothing to do with neuropathology or cardiovascular complications or even the current state of the medical art. It is that **chronic pain patients are routinely treated as a special class of patient**, often with severely restricted liberties - prevented from consulting multiple physicians and using multiple pharmacies as they please, for example - that are unquestioned in a free society for every other class of sufferer.

In effect, chronic pain patients are often seen by medical professionals as primarily as prescription or medication problems, rather than as whole individuals who very often present an array of complex comorbid medical, psychological, and social problems, all of which demand expert medical assessment and stabilization in the untreated or undertreated pain patient. This phenomenon is painfully on display in Wichita, Kansas in the early months of 2008, as the entire country watches droves of ordinary Kansans unable to access basic primary care services, basic medical assessment and stabilization; instead these complex general medical patients are 'cared for' as if their primary and only medical problem was taking prescribed analgesic medication. Obviously the major medical problem of these patients is that they have been forcibly cleaved from their physician, and their obvious primary medical need is for medical stabilization, not knee-jerk detoxification. [See Appendices: 1) **The Distortion of Medical Practice** and, 2) **The Ethical Obligation to Relieve Suffering**]

Finally it is well known and documented that special groups of pain sufferers have even higher rates of unrelieved pain. These include the elderly or those with neurological conditions, children, minorities, and

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5 Filos, K. S., & Lehmann, K. A. (1999). Current concepts and practice in postoperative pain management: need for a change?, European surgical research. Europäische chirurgische Forschung. Recherches chirurgicales européennes, 31(2), 97-107.

6 Morrison, R. S., Magaziner, J., Gilbert, M., Koval, K. J., McLaughlin, M. A., Orosz, G., et al. (2003). Relationship between pain and opioid analgesics on the development of delirium following hip fracture, J Gerontol A Biol Sci Med Sci, 58(1), M76-81. Retrieved February 23, 2008, from http://biomed.gerontologyjournals.org/cgi/content/abstract/58/1/M76.

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those with more severe pain, and pain patients accessing emergency room services.[7 8 9]

Chronic Pain is a Legitimate Medical Disease

Chronic pain was established as a legitimate, progressive, neurodegenerative disease state in exhaustive research in the 1990's[10] and reported in very widely read academic review articles in 2000.[11] Chronic pain is probably the most disabling, and most preventable, sequelae to untreated, and inadequately treated, severe pain.

The etiology and pathophysiology of chronic pain are very well understood and have been widely published in the medical literature, and have stood the test of time. This understanding is the literal basis of the current legally relevant "reasonable physician" standard of care.[12] Following a painful trauma or disease, chronicity of pain may develop in the absence of effective relief. A continuous flow of pain signals into the pain mediating pathways of the dorsal horn of the spinal cord alters those pathways through physiological processes known as central sensitization[13], and neuroplasticity.[14 15] **The end result is the disease of chronic pain in which a damaged nervous system becomes the pain source generator separated from whatever the initial pain source was.**

Aggressive treatment of severe pain, capable of protecting these critical spinal pain tracts, is the standard care recommended in order to achieve satisfactory relief and prevention of intractable chronic pain. For example, Pappagallo, in an authoritative monograph of the Rheumatic Disease Clinics of North America thoroughly reviewing the pharmacology of nociception as well as the classes of drugs used for pain control, and concluding:

> [M]edications represent the mainstay therapeutic approach to patients with acute or chronic pain syndromes... aimed at controlling the mechanisms of nociception, [the] complex biochemical activity [occurring] along and within the pain pathways of the peripheral and central nervous system (CNS)... Aggressive treatment of severe pain is recommended in order to achieve satisfactory relief and prevention of intractable chronic pain.[16]

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7 Clay, R.A. (2002). Overcoming Barriers to Pain Relief. Monitor on Psychology, 33(4).

8 Chronic Pain in America: Roadblocks to Relief," a study conducted by Roper Starch Worldwide for American Academy of Pain Medicine, American Pain Society and Janssen Pharmaceutica, 1999

9 Barletta et al. A prospective study of pain control in the emergency department. Am J Ther., 7(4); 2000.

10 For example, here are six references including major articles from prestigious journals and chapters from medical textbook publications: 1) Besson JM. The neurobiology of pain. Lancet 353:1610, 1999 -- 2) Dickerson AH. NMDA receptor antagonists as analgesics. In Progress in Pain Research, vol 1, Fields HL, Liebeskind VC (Eds), IASP Press, Seattle, 1994, pp 173-188 -- 3) Borsook D (Ed). Molecular Neurobiology of Pain. IASP Press, Seattle, 1997 -- 4) Sicuteri F et al (Eds). Pain Versus Man. Raven Press, New York, 1992 -- 5) Urban MO, Gebhart GF. Central mechanisms in pain. Med Clin North Am 83:585, 1999 -- and, 6) Willis W (Ed). Hyperalgesia and Allodynia. Raven Press, New York, 1992.

11 Brookoff, D. wrote two very widely read and hugely important review articles, **Chronic Pain I - A New Disease?** (Available: http://www.doctordeluca.com/Library/Pain/CP1NewDisease2K.htm, and, **Chronic Pain II -The Case for Opiates** (Available: http://www.doctordeluca.com/Library/Pain/CP2CaseForOpiates2K.htm). Hospital Practice; Volume 35; Issues 7 and 9, respectively; 2000.

12 Rich,B.A Medical Custom and Medical Ethics; Cambridge Quarterly of Healthcare Ethics; 14: 27-29; 2005. From p. 39: "When credible evidence has been presented that not just a particular physician, or an isolated, retrograde group of them, but a majority of the profession has failed to adopt practices that would materially reduce patient suffering, **courts may properly conclude, in the tradition of great justices like Holmes and Hand, that a reasonable physician would not practice in this way** and those who do should be called to account for the adverse consequences such practice has on the well-being of patients." (emphasis added)

13 Gudin, J.A. Expanding Our Understanding of Central Sensitization. Medscape Today, Pharmacologic Management of Pain Expert Column; 2004-06-28. (Available: http://www.medscape.com/viewarticle/481798) This is a particularly readable review of the medical literature aimed at an educated, but medically lay, readership.

14 Brookoff D. Chronic Pain: Part 1. A New Disease?; Hospital Practice, 35(7); 2000.

15 Brookoff D. Chronic Pain: Part 2. The Case for Opiates; Hospital Practice, 35(9); 2000.

16 Pappagallo, M. (1999). Aggressive pharmacologic treatment of pain, Rheumatic Disease Clinics of North America, 25(1), 193-213. doi: 10.1016/S0889-857X(05)70060-0.

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More recently, we are seeing ominous scientific evidence in modern imaging studies of a maladaptive and abnormal persistence of brain activity associated with loss of brain mass in the chronic pain, especially in the areas of the brain that process pain and emotions. In a 2006 news article, a researcher into the pathophysiological effects of chronic pain on brain anatomy and cognitive/emotional functioning.

> This constant firing of neurons in these regions of the brain could cause permanent damage, Chialvo said. "We know when neurons fire too much they may change their connections with other neurons or even die because they can't sustain high activity for so long," he explained.[17]

It is well known that chronic pain can result in anxiety, depression and reduced quality of life. Recent evidence indicates that chronic pain is associated with a specific cognitive deficit, which may impact everyday behavior especially in risky, emotionally laden, situations.[18] The areas involved include the prefrontal cortex and the thalamus, the part of the brain especially involved with cognition and emotions, and it is these same areas that were found in 2004 to undergo striking atrophy in chronic back pain patients, compared to normal controls:

> Patients with CBP showed 5-11% less neocortical gray matter volume than control subjects. The magnitude of this decrease is equivalent to the gray matter volume lost in 10-20 years of normal aging. The decreased volume was related to pain duration, indicating a 1.3 cm3 loss of gray matter for every year of chronic pain... Gray matter density was reduced in bilateral dorsolateral prefrontal cortex and right thalamus...[19]

Medical science is not conflicted on this very important point. That chronic pain is a disease whose etiology and basic pathophysiology are quite well understood in the published literature since the 1990's. That medical science has had a firm grip on the pathophysiological mechanisms and consequences of untreated or undertreated pain since the 1914 publication of Dr. Cannon's seminal and classic research. Further, there can be no question but that Dr. Schneider's patients in Kansas 2008, many with multiple chronic medical problems, or any pain patient maintained on opioid analgesic medication with good result, will be at high risk of serious medical harm if withdrawn from these medications in any precipitous manner.

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17 Chronic Pain Can Damage Brain. redOrbit Staff; 2008-02-06. (Available: http://www.doctordeluca.com/forum/viewtopic.php?pid=1640)

18 Apkarian, A. V., Sosa, Y., Krauss, B. R., Thomas, P. S., Fredrickson, B. E., Levy, R. E., et al. (2004). Chronic pain patients are impaired on an emotional decision-making task, **Pain**, 108(1-2), 129-136.

19 Apkarian, A. V., Sosa, Y., Sonty, S., Levy, R. M., Harden, R. N., Parrish, T. B., et al. (2004). Chronic back pain is associated with decreased prefrontal and thalamic gray matter density, **Journal of neuroscience**, 24(46), 10410-5.

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APPENDICES

1) **The Distortion of Medical Practice**
2) **The Ethical Obligation to Relieve Suffering**
3) **A Modern Understanding of Chronic Pain and Opioid Therapy**

Appendix 1 - A Brief Discussion of the Distortion of Medical Practice, the Standard of Care, and Medical Community Norms

In fields of medicine involving controlled substances, especially addiction medicine and pain medicine, the doctor-patient relationship has become grossly distorted.

This distortion is profound and significant. One manifestation is the 'chilling effect' - *the 'chilling effect' is the withdrawal, for fear of litigation or loss of livelihood, by physicians from the appropriate treatment of pain.*[20] It is important to note that much of the public health damage here is caused not by the doctors accused of wrongdoing, rather it is caused by doctors-in-good-standing who, faced with a patient in pain and therefore at risk of triggering an investigation, modify their treatment in an attempt to avoid regulatory attention. The chilling effect on appropriate pain management leads inexorably to the national problems of the undertreatment of pain and the shortage of physicians knowledgeable and experienced in opioid therapy for chronic pain, and willing to provide this legitimate professional service.

This distortion of the doctor-patient relationship is complex and can be gross or subtle. Examples include a blanket refusal to prescribe controlled substances even when clearly indicated, or selecting less effective and more toxic non-controlled medications when a trial of opioid analgesics would be in the best interests of a particular patient. At the very least, some degree of suspicion and mistrust will surely arise in any medical relationship involving controlled substances.

For most common medical conditions (not involving controlled substances) the quality of care most physicians provide is fairly close to the medical standard of care which is what the textbooks say one should do, and which is generally in line with core medical ethical obligations such as holding the interests of the individual patient before you above all other interests, patient confidentiality, etc. For example, the care a person would receive for an acute asthma attack is pretty much the same no matter what ER he walked into, and that care would be pretty much by-the-book. So, in most medical fields we could say: "How most reputable physicians practice approaches the (textbook) standard of care."

This is NOT true in the fields of addiction and pain medicine. For example, modern pain management textbooks universally recommend 'titration to effect' (simplistically: gradually increasing the opioid dose until the pain is relieved or until untreatable side effects prevent further dosage increase) as the procedure by which one properly treats chronic pain with opioid medications. Yet the overwhelmingly physicians in America do not practice titration to effect, or anything even vaguely resembling it, for fear of becoming 'high dose prescriber' targets of federal or state law enforcement.

In pain medicine we have the deeply disturbing situation that what most doctors do (medical community norm) is at odds with the medical standard of care. Literally, in the treatment of chronic pain, an ethical physician attempting to practice in good faith, according to the clinical literature, is an outlier, deviating from how most reputable physicians would practice.[21]

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20 DeLuca, A. War on Drugs, War on Doctors, and the Pain Crisis in America. Addiction Pain and Public Health website; 2004. (Available: http://www.doctordeluca.com/Library/WOD/WOD-PCA-TOC.htm)

21 See also, Vastag B. Mixed message on prescription drug abuse. JAMA; 285(17):2183-2184; 2001. (Available:

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Appendix 2 - The Ethical Obligation of Physicians to Relieve Suffering

It is a foundation of medicine back to ancient times that a primary obligation of a physician is to relieve suffering. A physician also has a fiduciary duty to act in the best interests of the individual patient at all times, and that the interests of the patient are to be held above all others, including those of family or the state.[22] These ethical obligations incumbent on all individual physicians extend to state licensing and regulatory boards which are composed of physicians monitoring and regulating themselves. [23]

Many studies have shown the practice and custom of physicians in managing pain, even in terminal cancer cases, is extremely conservative and below the (textbook) standard of care. [24] [25] In the literature analyzing this discrepancy a number of barriers to effective pain relief have been identified and include:

1. The failure of clinicians to identify pain relief as a priority in patient care;
2. Fear of regulatory scrutiny of prescribing practices for opioid analgesics;
3. The persistence of irrational beliefs and unsubstantiated fears about addiction, tolerance, dependence, and adverse side effects of opioid analgesics. [26]

Regardless of the particular barriers impacting any particular case, in fields of medicine involving the use of controlled substances a rift has developed between the usual custom and practice standard of care (the medical community norm - what most reputable physicians do) and the reasonable physician standard of care (what the textbooks say to do - the medical standard of care), and this raises very serious and difficult dilemma for both individual physicians and medical boards. From an ethical perspective, and on the basis of precedent in criminal law:

> "When credible evidence has been presented that not just a particular physician, or an isolated, retrograde group of them, but a majority of the profession has failed to adopt practices that would materially reduce patient suffering, courts may properly conclude, in the tradition of great justices like Holmes and Hand, that a reasonable physician would not practice in this way and those who do should be called to account for the adverse consequences such practice has on the well-being of patients." [27]

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http://www.doctordeluca.com/Library/WOD/MixedMessagePrescripDrugAbuse01.htm), for a stark example. Brown and colleagues reported, at a NIDA symposium in April 2001, on a survey they developed that measured the prescribing practices for benzodiazepines and opioid analgesics by groups of physicians in response to variations of a single presented case. The physicians' prescribing decisions were then compared with recommendations from a panel of pain management experts. The findings:

> "While the expert panel recommended that virtually all patients with [common idiopathic back pain] who do not respond to other treatments be given an opioid analgesic, only 20% of physicians said they would actually write that prescription..."

22 Rich,B.A An Ethical Analysis of the Barriers to Effective Pain Management; Cambridge Quarterly of Healthcare Ethics; 9: 27-39; 2005; p. 66.

23 Rich. Ethical Analysis; p. 66.

24 SUPPORT Principle Investigators. A Controlled Trial to Improve Care for Seriously Ill Patients.; JAMA; 274: 1591-1598; 1995.

25 Marks,R.M., Sachar,E.J. Undertreatment of medical inpatients with narcotic analgesics; Archives of Internal Medicine; 78:173-181; 1997.

26 Rich. op.cit., p. 54

27 Rich,B.A Medical Custom and Medical Ethics; Cambridge Quarterly of Healthcare Ethics; 14: 27-29; 2005; p. 39

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Appendix 3 - A Modern Understanding of Chronic Pain and Opioid Therapy

Research into pathophysiology and natural history of chronic pain have dramatically altered our understanding of what chronic pain is, what causes it, and the changes in spinal cord and brain structure and function that mediate the disease process of chronic pain, which is generally progressive and neurodegenerative.[28] Simply put, a continuous flow of pain signals into the pain mediating pathways of the dorsal horn of the spinal cord alters those pathways through physiological processes described as central sensitization, and neuroplasticity. [29] [30] [31] The end result is the disease of chronic pain in which a damaged nervous system becomes the pain source generator separated from whatever the initial pain source was.

The end result is the disease of chronic pain in which a damaged nervous system becomes the pain source generator separated from whatever the initial pain source was. This understanding explains many clinical observations in chronic pain patients, such as phantom limb syndrome, that the pain spreads to new areas of the body not involved in the initiating injury, and that it generally worsens if not aggressively treated. The progressive, neurodegenerational nature of chronic pain was recently shown in several imaging studies showing significant losses of neocortical grey matter in the prefrontal lobes and thalamus. [32] [33]

The implications for how acute and early chronic pain should be treated, the medical standard of care, are very serious. The analgesic effects of opioids are primarily mediated in the dorsal horn of spinal cord where they bind with receptors blocking pain transmission and thereby protecting the dorsal horn from being bombarded with pain signals which is believed to be the pathophysiological mechanism underlying the development of chronic pain, as just discussed. NSAIDs, antidepressants, and other commonly used non-opioid analgesics do not have this protective property. Therefore, regarding the standard of care for pain management:

1) Delaying aggressive opioid therapy in favor of trying everything else first is not rational based on a modern, scientific understanding of the pathophysiology of chronic pain, and is therefore not the standard of care. Delaying opioid therapy could result in continuous pain signals overwhelming the dorsal horn, would be expected to promote the development of chronic pain and making the patient's illness progressively more difficult to treat. Opioids in adequate doses can prevent the development of the disease of chronic pain.

2) Opioid titration to analgesic effect represents near ideal treatment for persistent pain, providing both quick relief of acute suffering and possible prevention of neurological damage known to underlie chronic pain.

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28 Argoff C.E. Managing Neuropathic Pain: New Approaches for Today's Clnical Practice; Medscape; 2003. Available; accessed: 2007-07-17.

29 Gudin J. Expanding Our Understanding of Central Sensitization. Medscape Neurology & Neurosurgery; Pharmacologic Management of Pain Expert Column; 2004. (Available at: http://www.medscape.com/viewarticle/481798)

30 Brookoff D. Chronic Pain: Part 1. A New Disease?; *Hospital Practice*. 2000.

31 Brookoff D. Chronic Pain: Part 2. The Case for Opiates; *Hospital Practice*. 2000.

32 Apkarian,A. et al. Chronic Back Pain Is Associated with Decreased Prefrontal and Thalamic Gray Matter Density; The Journal of Neuroscience; 24(46):10410-10415; 2004.

33 Schmidt-Wilcke,T. et al. Affective components and intensity of pain correlate with structural differences in gray matter in chronic back pain patients. Pain; 125(1-2):89-97; 2006.

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Hearing Statement

"Prescription and Over-the-Counter Drug Abuse"

Senator Dianne Feinstein

March 12, 2008

I thank Chairman Biden for holding this hearing, on an issue of growing importance and urgency.

There is no doubt that prescription drug abuse a growing epidemic in this country. I have been concerned about the rise in prescription drug abuse and particularly about the proliferation of narcotics and prescription drugs available over the Internet for a number of years.

According to the DEA, nearly 7 million Americans are abusing prescription drugs today. To put this in perspective, this is more than the number of people who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants -- combined. Opioid pain relievers now cause more drug overdose deaths than cocaine and heroin combined. Twenty-five percent of drug-related emergency department visits are associated with the abuse of prescription drugs.

Prescription drug abuse is also a growing national health crisis. According to the National Center on Addiction and Substance Abuse (CASA), the number of adults who abused prescription drugs rose 81% from 1992 to 2002. The number of 12 to 17 year olds who abused controlled prescription drugs jumped an astounding 212% during the same time frame. Abuse of controlled prescription drugs has grown at twice the rate of marijuana abuse, five times the rate of cocaine abuse, and 60 times the rate of heroin abuse.

The rise of prescription drug abuse among our youth is particularly troubling. In 2003, 2.3 million 12 to 17 year olds – nearly 1 in 10 -- abused at least one prescription drug. And prescription drug abuse can be a gateway to the abuse of other substances. According to CASA, teens who abuse controlled prescription drugs are five times as likely to abuse marijuana, 12 times more likely to abuse heroin, 15 times more likely to abuse Ecstasy, and 21 times likelier to use cocaine as teens who do not abuse prescription drugs.

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Not surprisingly, the staggering increase in prescription drug abuse since 1992 corresponds with the ease of access over the Internet. The DEA has called the Internet the "perfect medium" to sell controlled substances and prescription drugs illegally.

The ease of availability and the amount of drugs sold online is stunning. A typical brick-and-mortar, neighborhood pharmacy sells about 180 prescriptions per day. Only about 11% of these sales involve controlled substances. In comparison, a typical online pharmacy sells around 450 prescriptions per day – 95% of which are controlled substances. The Internet has become an open-air market for the sale of illegal prescription drugs. Rogue internet pharmacies, operating without any oversight, are selling prescription drugs to anyone with an Internet connection and a credit card. And adults and children are suffering and sometimes dying as a result.

It's time for Congress to put a stop to this and pass S. 980, the Ryan Haight Online Pharmacy Consumer Protection Act of 2007. This bill, named after a teenager died after overdosing on drugs he obtained from a rouge pharmacy, would do the following:

- Bar the sale or distribution of all controlled substances over the Internet without a valid prescription;
- Require online pharmacies to display on their website a statement of compliance with U.S. law and DEA regulations – allowing consumers to know which pharmacies are safe, and which are not.
- Clarify that rogue pharmacies who sell drugs over the Internet will face the same penalties as people who illegally sell the same drugs on the street.
- Increase the federal penalties for illegally distributing controlled substances;
- Create a new federal cause of action that would allow a state attorney general to shut down a rogue website selling controlled substances.

This legislation is a critical first step in stemming the tide of online drug trafficking and prescription drug abuse.

I look forward to the testimony of the witnesses today on how we can best address the problem of prescription drug abuse, as well as their thoughts on addressing the scourge of rogue Internet pharmacies.

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Senate Judiciary Hearing
March 12, 2008

Good afternoon.

My name is Misty Fetko and I am a registered nurse who works in a very busy Emergency Room in Central Ohio, but more importantly, I am a mother of two wonderful boys.

I am here today to tell you the story of my oldest son, Carl.

Carl was my beautiful little boy; eyes like large, dark chocolates, an infectious smile, and an insatiable curiosity. I spent years protecting him from harm, but four years ago, harm found a way to sneak in and steal the life of this gifted young man.

It was the morning of July 16, 2003. Carl had just graduated from high school and was getting ready to leave for Memphis College of Art in two days. The college had courted him after he won an award for artwork he created his junior year of high school.

The night before, Carl and I had sat in his room and talked with each other about this day at work and the pending trip to Memphis. At the end of the conversation, he smiled and hugged me, he said, "Goodnight Mom. Love you."

The next morning I decided to walk the dog before waking Carl. While walking next to his car, I noticed an empty bottle of Robitussin in Carl's backseat. Instantly, I knew something was wrong. I had been vigilant for signs of drug abuse in the past and hadn't seen many, but the previous summer I had found two empty bottles of Robitussin in our basement after a sleepover with friends. I knew something was up. I rushed to his bedroom door only to find it locked. After finding my way in, I discovered Carl lying peacefully in bed, motionless with leg crossed, but he wasn't responding to my screams, and he wasn't breathing.

I quickly transformed from mother to nurse and I began CPR, desperately trying to breathe life back into my son. I could not believe that what I had feared most in life had happened, but I still did not know what had caused this nightmare.

We are a very close family. I am a very involved mother. Carl had always assured me that he wasn't using alcohol or drugs. I, the ever watchful mother, believed him, as there wasn't any evidence to prove differently.

During Carl's junior year of high school, I found the first evidence of marijuana in his room. After all the talks and all the reassurances between us, what had changed? I intervened, and didn't see anything else suspicious until that summer when I found the two empty bottles of Robitussin in our basement. I was determined to keep drugs out of our house, but cough medicine? I went to search for answers on the internet, but found

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nothing and then confronted my son. Carl explained that he and his friends had heard you could get high off cough medicine and tried it, but nothing happened. I was reassured, once again, that he wasn't using "hard" drugs and not to worry. Finding no further evidence, I believed him.

During Carl's senior year, I knew the he had developed an interest in marijuana, but I thought we were doing what we needed to address this problem. So why on that dreadful July morning did I discover my son had passed away during the night?

During the next several months after Carl's death, I frantically searched for answers. What signs did I miss?

During my search, I found two more empty bottles of Robitussin. But it wasn't until after talking with his friends and finding journal entries on his computer did I discover that Carl had been abusing cough medicine intermittently over the past 2 ½ years. He documented his abuse on his computer journal. Through the internet and his friends, Carl had researched and educated himself on how to use these products to get high. He wrote about and enjoyed the hallucinations achieved upon intentionally overdosing on cough and cold products. Carl had described the "pull" that he felt towards the disassociative effects of abusing the cough medicine and seemed to crave the effects.

According to the journal, Carl had gradually increased the amount of cough medicine he was abusing from 4 ounces to 12 ounces.

As his abuse increased, many things in his life were changing: graduation, college, his parent's divorce, and increasing pressures in life.

I wouldn't find out until the morning of Carl's death what he and many others knew about his abuse of cough medicine. The danger that I so desperately tried to keep out of our house had found a way to sneak in secretly. The signs at the time did not indicate to me signs of drug abuse: there were no needles, powders, smells, large amounts of money being spent, or other signs that are typically associated with drug abuse.

Carl's autopsy report revealed that he had died from a lethal mix of drugs: Fentanyl, a strong prescription narcotic, Cannaboids found in marijuana, and Dextromethorphan or DXM, the active ingredient in cough medicine where found in his system.

To this day, I don't know where Carl obtained the Fentanyl patch. There were no journal entries which talked about any use of painkillers. Was this his first time? Was he looking for a different high? We will never know why Carl made the wrong choice to abuse prescription and over the counter drugs. We only know parts of his story by the words he left behind in his journal; his words are now silent.

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Abuse of over the counter and prescription drugs is a very large and very concerning problem. We are seeing more teens in our Emergency Department who have overdosed on these drugs. It is becoming more of the norm than the exception. A couple of weeks ago a young man was brought into the Emergency Room who was at a home with his friends. They found him unresponsive and barely breathing. He was rushed to the hospital by medics. He had been chewing on a Fentanyl patch; several unopened patches were found in his pants pockets. A couple of days ago a young girl was brought in from school where she had taken 30 Coricidin tablets that morning just trying to get high. She spent the next several days in our intensive care unit.

Thank you for inviting me so that I could share Carl's story. If loving Carl were enough, Carl would have lived forever. It is now with this love that I tell his story so that others are aware of the grave dangers of this type of drug abuse.

Thank you.

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Chuck Grassley

Generation Rx: The Rising Abuse of Prescription and Over-the-Counter Drugs

WEDNESDAY, MARCH 12, 2008

U.S. SENATE, JOINT CRIME & DRUG SUBCOMMITTEE AND DRUG CAUCUS HEARING
Washington, D.C.
Room 226 Dirksen Senate Office Building

OPENING STATEMENT OF SENATOR CHARLES E. GRASSLEY

SENATOR GRASSLEY STATEMENT AT THE JOINT HEARING ON PRESCRIPTION DRUG ABUSE

Chairman Biden, thank you for calling this hearing today on prescription and over-the counter drug abuse. This dangerous trend is on the rise across the country, especially among

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our youth. I hope today's hearing will help shed light on the problem and spark solutions.

It's been widely reported that youth drug use has declined in the last six years. While the efforts of law enforcement and drug treatment professionals should be praised, this should not lull us into believing that the drug problem is over. That is far from true. Drug abuse is like a virus that constantly mutates into new strains.

One new strain is the increase in illegal use and abuse of prescription drugs. While it's true that some statistics show a decline in overall drug use, prescription drug abuse has remained steady and risen in some places. According to the 2007 Monitoring the Future Study, issued by the University of Michigan, over 15% of all 12th graders abuse prescription

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drugs. OxyContin, Ritalin, and Vicodin are the most commonly abused prescription drugs.

We see this trend happening in my own state of Iowa. For example, the 2005 Iowa Youth Survey reported that 15% of eleventh-grade students in Clinton, Iowa, had abused prescription drugs in the past month, while across Iowa, 7% of eleventh-graders abused prescription drugs in the past month.

This trend is alarming for a number of reasons. First, these drugs are powerful and require the supervision of a doctor for proper use. Drugs such as Oxycontin and Vicodin are narcotic pain medications that come in many different dosage forms which may not be recognizable to the average teenager. Because different dosages often look the same, there is a heightened risk for an overdose.

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Second, it's difficult for children to understand when the use of a good medicine becomes dangerous. Kids and parents alike underestimate the danger of the inappropriate use of prescription drugs, perceiving them to be less dangerous than other drugs because those medications happen to be doctor-prescribed. According to the annual survey of the Partnership for a Drug-Free America, four out of ten teens think that prescription drugs are much safer to abuse than street drugs. More than one in four parents share that same belief. Yet we well know that abuse of over-the-counter and prescription drugs can inflict just as much harm on a person as illegal drugs.

Third, access to prescription drugs is readily available in medicine cabinets in many homes. According to the National Survey of

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Drug Use and Health, 70% of teens who reported using prescription drugs said they received their drugs from a friend or relative.

Prescription drug abuse can cause just as much damage as illegal drug abuse. Abuse of prescription medication can produce dangerous addictions, put a strain on families and medical communities, and increase crime rates. Further, parents may have a difficult time identifying prescription drug abuse because of the range of behavioral changes that may vary depending on the type of prescription drug abused.

The most tragic part of this new trend is the senseless loss of life. The Centers for Disease Control reports unintentional poisoning deaths from prescription drugs rose 84% from 1999 to 2004.

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I'm also concerned about the increase in poisoning cases related to abuse of the over-the-counter drug, dextromethorphan, or DXM. DXM is a cough suppressant found in most cold medicines, which can cause hallucinations and lead to death in large doses. Since DXM is available for purchase in any drug store, children can easily obtain this addictive and potentially deadly substance. Data from the Archives of Pediatric and Adolescent Medicine shows that abuse of DXM has jumped seven-fold between 1999 and 2004.

Senator Biden and I introduced the DXM Abuse Reduction Act last year to regulate the sale of bulk DXM, as well as over-the-counter medicines containing DXM. Our bill restricts the sale of DXM products and penalizes vendors who knowingly or intentionally sell

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DXM to persons under 18. Finally, the bill allows the Drug Enforcement Administration (DEA) to regulate DXM and the dangerous loophole of internet sales.

I believe that the DEA is in the best position to regulate DXM as a controlled substance. The DEA has the expertise and enforcement capability to do the job. Some have suggested that perhaps the Food and Drug Administration (FDA) would be a better regulator of over-the-counter drugs. However, I've spent the last four years conducting extensive oversight of the FDA and found that this agency has extensive shortcomings. So, I have reservations about giving the FDA additional responsibilities based on the problems I've seen the FDA experience with its current caseload.

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Given the tremendous dangers of prescription drug abuse, it's imperative that we are vigilant and keep one step ahead of the new trends in drug abuse. At the same time, we must remain cognizant that traditional illegal drug abuse is still a problem and drug cartels continue to plague our country.

So, I look forward to working with Senator Biden on these important drug issues, from prescription and over-the-counter drug abuse to money laundering and international drug trafficking. I'd also like to thank our hearing witnesses who will tell us about the prescription and over-the-counter drug problems facing our communities. In particular, I'd like to thank a fellow Iowan, Mr. Derek Clark, from Clinton, Iowa, for testifying today. Mr. Clark has served as the executive director of the Clinton Substance Abuse Council

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for the last 10 years. As executive director, Mr. Clark works with a wide variety of community members to develop solutions to substance abuse problems in Clinton, Iowa. Mr. Clark, thank you for being here today to share your experiences with us. Unfortunately, Mr. Chairman, I'll have to leave the hearing a little early because of other previously scheduled appointments, but I'll be sure to review the hearing record.

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Statement of Senator Patrick Leahy
Chairman, Senate Judiciary Committee
Hearing on "Generation Rx:
The Abuse of Prescription and Over-the-Counter Drugs"
March 12, 2008

This afternoon, we pick up where we left off last year with our second hearing in this Congress on the growing problem of prescription drug abuse. Last May, the full Judiciary Committee held a hearing on rogue online pharmacies that illegally traffic highly addictive painkillers and other controlled substances. Today, the Crime and Drugs Subcommittee examines a troubling and related trend in drug use – the rising abuse of beneficial prescription and over-the-counter drugs by American youth. I thank Senator Biden for holding today's hearing.

In many ways, prescription and over-the-counter medicines have made our lives better. Faced with countless illnesses and conditions each year, Americans of all ages count on these drugs to improve their health. When used properly, these medicines can improve extend, and even save lives. When abused, these drugs can cause harm, illness, addiction, and, as we will hear this morning, tragically, even death.

Earlier this week, 41 million Americans learned that dangerous pharmaceuticals – including prescription and over-the-counter drugs – may be present in their drinking water. I think all of us understand that even small concentrations of medicines, when not being used for their legitimate purpose, may pose serious hazards to our health.

I remain concerned about the dangers posed by the abuse of medicines in the growing number of circumstances where the proper constraints that doctors and pharmacists usually provide are absent. Too often nowadays these drugs are only a click away on the Internet or are readily available in the medicine cabinet. It should therefore come as no surprise that the abuse of these otherwise beneficial medicines has spiraled out of control. According to the 2006 National Survey on Drug Use and Health, almost six million people currently misuse prescription drugs. That is far too many.

Even more disturbing, an alarming number of teenagers and young adults are abusing prescription drugs and over-the-counter medicines. Among young people, prescription drugs have become the second most abused illegal drug, behind only marijuana. That means more teenagers abuse prescription drugs than abuse cocaine, hallucinogens, inhalants, and heroin combined. Similarly, over three million teenagers report misusing over-the-counter drugs for a non-medical purpose, which means one in every ten teenagers has used cough medicine to get "high." That is unacceptable.

If we want to reduce the high rates of medicine abuse, we must work to educate teenagers and parents about the realities and dangers of this serious problem. Too many Americans mistakenly believe that abusing addictive narcotics is a safe way to get "high." The truth is, when intentionally abused for a non-medical purpose, medicines found in the home are just as dangerous and addictive as drugs found in the streets. We need better drug education programs to make sure this public hears this message loud and clear.

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The recent death of Heath Ledger serves as a harrowing reminder of the ultimate danger presented by prescription medicine abuse. His death should serve as a wake-up call alerting all Americans to the reality that prescription medicine drugs are not inherently safe. I hope that parents and children will draw lessons from his tragic death, and the deaths of many others. That knowledge will improve drug prevention, correct misinformation, and save lives.

I thank the witnesses for appearing here today, and I look forward to their testimony.

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Statement of:

The National Association of
Chain Drug Stores

On:

"Generation Rx: The Abuse of Prescription
and Over-the-Counter Drugs"

Submitted To:

United States Senate
Committee on the Judiciary
Subcommittee on Crime and Drugs
Senate Caucus on International Narcotics
Control

Wednesday, March 12, 2008

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Introduction
The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit a statement for the record about the abuse of prescription and over-the-counter drugs.

NACDS represents the nation's leading retail chain pharmacies and suppliers, helping our members better meet the changing needs of their patients and customers. NACDS members operate more than 35,000 pharmacies, which employ 108,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of over $700 billion. Other members include almost 1,000 suppliers of products and services to the chain drug industry.

According to the White House's *National Drug Control Strategy, 2008 Annual Report.* prescription drug abuse remains a problem in the United States. A number of factors have contributed to this problem, including the mistaken belief that prescription drugs are safer than illicit drugs, prescription drugs are easy to obtain from friends and family, and people are not aware of the potential consequences of using prescription drugs non-medically. Our membership is deeply concerned about the problems of drug abuse, and we have proactively worked to develop solutions to drug abuse problems in our country. Our members have voluntarily taken steps to restrict access to methamphetamine precursors, such as pseudoephedrine and ephedrine, have placed age restrictions on dextromethorphan and dihydroepiandrosterone products, support federal and state efforts to prevent prescription drug abuse, such as education, outreach, legislation, and public advisories, and support federal and state efforts to shut down illegal Internet sites that illegally provide medications to consumers.

NACDS has collaborated with the White House Office of National Drug Control Policy (ONDCP) to lend our voice in ONDCP's communications, such as open letters printed as advertisements in media publications and direct outreach to NACDS members. Another example of our work in this area is an NACDS Foundation grant last year to the Boys & Girls Clubs of Greater Washington to support a program to raise awareness among at-risk teens about the dangers of abusing prescription and over-the-counter drugs. This project has the potential to be replicated in other communities. Our goal is to work as part of the solution to the problem of drug abuse, and recognize that we all must remain agile and fleet footed to confront these problems.

Illegal Internet Sites Remain a Problem
Shutting down a major source of abused medications, illegal rogue Internet sites, remains a challenge. These rogue Internet sites, both domestic and foreign, are engaged in a pattern of illegal activity regarding the prescribing and dispensing of medications. These Internet sites are not pharmacies. They are not licensed by any state or other jurisdiction, and are shipping unapproved, counterfeit, mislabeled or adulterated products within or into the United States. Medications sold through these so-called "pharmacies" are often available to consumers without any legitimate relationship with a physician and without a valid prescription.

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NACDS and our members are greatly concerned about the patient safety implications of medications sold through these rogue sites. We appreciate the opportunity to work with Congress to eliminate these illegal Internet suppliers from the market, and protect patient health. We believe that the most effective way to guard against these rogue Internet sites is to enact narrowly-tailored solutions that focus resources on shutting down these illegal suppliers, rather than developing broad policies that sweep up legitimate, state-licensed pharmacies into a federal regulatory scheme that could potentially limit consumer access to state-licensed pharmacies through the Internet.

Internet Access to Pharmacy Provides Convenience for Patients
In this age of immediate information and consumer convenience, most retail businesses have Internet sites available to consumers. Retail pharmacies often maintain Internet sites that provide consumers with convenient access to their products and services. The vast majority of legitimate pharmacy-based Internet sites are operated by traditional state-licensed, "brick and mortar" pharmacies that maintain websites for the convenience of their patients. These sites allow patients to order prescription refills and non-prescription items. Some Internet sites of state-licensed pharmacies allow the ordering of new prescriptions, but this involves a pharmacist contacting the patient's physician, where a legitimate medical relationship with the consumer has already been established. Legitimate retail pharmacy Internet sites are not affiliated with, and do not provide, a prescriber for the patient.

Legitimate Pharmacies are Highly Regulated
State boards of pharmacy have effectively regulated the practice of pharmacy for over 100 years. Pharmacies must be licensed in the state(s) where they are located, and pharmacists must also be licensed in the state where they practice. In addition, many states also require licenses for out-of-state pharmacies that mail pharmaceuticals into the state to residents – in other words, many states require non-resident pharmacy licenses. To secure and maintain these state licenses, all legitimate pharmacies must comply with voluminous regulations, which are continuously updated. Illegal "pharmacies" are those without state licenses. It is critical that Congress pass federal legislation that distinguishes between traditional brick-and-mortar pharmacies with Internet connections that are already licensed by state boards of pharmacy and Internet drug sellers who lack state licensure and whose primary means of access by consumers is via the Internet.

We believe it is important to base federal legislation on several important criteria:

- **Entities Subject to Legislation:** The entities that any Internet pharmacy legislation regulates must be carefully defined. The broader the definition, the more likely that it will include traditional brick-and-mortar pharmacies with Internet sites and therefore fail to target rogue Internet drug sellers.

- **Internet Disclosure Requirements:** Some congressional proposals would require Internet pharmacies to disclose certain information, similar to the information that traditional pharmacies post in their stores about licenses, pharmacists, and certain other information as required by state boards of pharmacy. The goal of any Internet pharmacy legislation would be to provide

consumers with sufficient information to make informed decisions about whether they want to obtain prescription medications from an Internet site. NACDS believes that such information can be helpful to consumers in assessing the quality of the Internet site. However, such disclosure requirements could be interpreted to require every community pharmacy that has an Internet site to post on the site information relating to the names and licensure status of its pharmacists for each pharmacy that it operates. Duplicative and burdensome "posting" requirements should not be imposed on legitimate retail pharmacies simply because they operate an Internet site.

- **Certification of Internet Pharmacies:** Many legitimate pharmacies have invested substantial resources in obtaining certification of their Internet site under the National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) certification program. NABP is a professional association that represents the state boards of pharmacy in all U.S. jurisdictions. In response to public concerns regarding the safety of pharmacy practices on the Internet, NABP developed the VIPPS program in 1999. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

Dextromethorphan (DXM) Issues

NACDS and our members are acutely aware of the potential for abuse by teens of products containing dextromethorphan ("DXM"). At the same time, DXM is a highly-effective nonprescription cough suppressant with very few side effects and a decades-long track record of safety when taken correctly. We are committed to the health care of our patients and consumers. Accordingly, we believe it is important to maintain reasonable access to necessary medications, while preventing the devastation and tragedy caused by drug abuse. NACDS commends Chairman Biden for his leadership in striking this balance by sponsoring S. 2274, the "Dextromethorphan Abuse Reduction Act of 2007." We have already conveyed our support for this legislation

As awareness of DXM abuse by teens has increased, many NACDS members have instituted voluntary sales restrictions to only those over 18 years of age. Additionally, we support efforts to educate parents about teenage prescription and nonprescription drug abuse so they can safeguard these products in their homes.

Similar to the problem of readily available medications via rogue Internet sites, teens unfortunately are able to purchase bulk DXM powder via the Internet. Bulk DXM powder is only useful to manufacturers of cough and cold products and to pharmacies for drug compounding purposes. It can be harmful for teens that are seeking to abuse it, and should be banned for sale to consumers. Consequently, we support the provision of Chairman Biden's sponsored legislation, S. 2274, affecting bulk DXM and thank the Chairman for including this provision. We similarly support S. 1378 and its House companion, H.R. 970.

All of these bills would allow sales of bulk DXM powder only to drug manufacturers and licensed pharmacies for their use, and not for resale. We urge Congress to pass this legislation as soon as possible.

Related Issue: DHEA
Because of concerns that teens are abusing dihydroepiandrosterone (DHEA), we support federal legislation that would prohibit sales of DHEA to anyone under 18 years of age. Many of our members have already voluntarily adopted this restriction.

State Initiatives to Address Prescription Drug Abuse
Numerous states utilize prescription monitoring programs as a tool to curb diversion and abuse of controlled substance prescription drugs. Prescription monitoring programs provide one option to identify and prevent drug abuse and diversion at the prescriber, pharmacy and patient levels. The programs collect prescription data from pharmacies either in paper or electronic format on an ongoing basis. Data is reviewed and analyzed for educational, public health and investigative purposes. The effectiveness of these programs has been recognized by Congress both by passing the National All Schedules Prescription Electronic Reporting Act of 2005 ("NASPER"), and by continuing to appropriate funding for the Harold Rogers Prescription Drug Monitoring Program, which was enacted in 2002. The goals of these programs are to provide grant money to states to encourage states to establish controlled substance prescription monitoring programs, or to "upgrade" existing controlled substance prescription monitoring programs.

Over two-thirds of all states have adopted prescription monitoring programs and many of these are expanding their programs to include additional schedules of drugs and/or moving to an electronic format. NACDS and our members support state and federal laws and regulations that are designed to address drug diversion and abuse, such as prescription monitoring programs. We only ask that prescription monitoring programs and other tools designed to benefit law enforcement and regulatory agencies not be administratively burdensome or disruptive to providing patient care and the legitimate practices of pharmacy and medicine.

Methamphetamine Precursors
Methamphetamine abuse remains a significant drug abuse problem in many regions in the U.S. Even before the introduction of state and federal legislation, the majority of the chain and community pharmacies took voluntary, proactive steps to reduce the theft and illegitimate use of methamphetamine precursors, that is, products containing pseudoephedrine and ephedrine. Our industry took these steps because we understood the importance of addressing the methamphetamine problem, despite the potential that instituting barriers to consumer access to these products may have led to consumer complaints and reduction in sales. NACDS member companies:

- Placed these products behind pharmacy and/or sales counters voluntarily, or had otherwise limited access to these products in their stores,
- Initiated voluntary sales limits of these products,
- Participated in voluntary education and theft-deterrent programs such as Meth Watch,

- Voluntarily eliminated consumer self-access to pseudoephedrine products in their stores in geographic areas where methamphetamine abuse has been a problem,
- Participated in youth anti-methamphetamine education efforts,
- Educated their employees about methamphetamine abuse to raise awareness and prevent questionable sales of these products, and
- Worked with law enforcement by reporting suspicious activity in their stores.

Moreover, our members have worked closely with the Drug Enforcement Administration (DEA) and state and local law enforcement officials since 1995 to stem the tide of methamphetamine production in communities across the country.

The Combat Methamphetamine Epidemic Act "Combat Meth Act" created a national standard for retailers to follow for limiting access to methamphetamine precursors. NACDS worked closely with Members of this Committee to help craft the Combat Meth Act and we appreciate your willingness to continue this working relationship.

To make the Combat Meth Act even more effective, Senator Feinstein has sponsored S. 2071, the "Combat Methamphetamine Enhancement Act of 2007." We support this legislation that would require mail-order facilities that sell pseudoephedrine and ephedrine to self-certify with DEA, would require DEA to publish a list on its website of self-certified retailers and facilities, would require distributors of pseudoephedrine and ephedrine to sell only to self-certified entities, and would impose a penalty of up to $10,000 for failing to self-certify. This legislation will ensure that mail order facilities comply with the same requirements as traditional retailers, and would ensure that wholesale distributors sell pseudoephedrine and ephedrine only to legitimate entities.

To address concerns about the electronic recordkeeping of retail sales of pseudoephedrine and ephedrine products, Senators Grassley and Durbin have sponsored S. 1276, the "Methamphetamine Production Prevention Act of 2007." This legislation would amend the Combat Meth Act to improve the feasibility of retailers' using an electronic logbook to record these sales. Also, the bills would establish a grant program that would authorize grants to state and local governments to plan, develop, implement, or enhance electronic logbook systems. Although we support provisions to improve the feasibility of using electronic logbook systems, we have concerns about the grant provisions in the bill. Specifically:

- The legislation refers to logbooks that have a "block sale" function. Although a logbook with a "block sale" function gives a retailer real-time information about whether a purchaser has reached their legal limit for purchasing pseudoephedrine and ephedrine products, it also essentially requires a retail clerk to become the enforcer of the law. It would place the clerk at risk for physical violence by dangerous methamphetamine cooks and addicts for refusing to conduct a sale.
- We have concerns about the cost of these programs to retailers. We would like to see programs similar to Kentucky, in which the state is wholly responsible for the costs of establishing and maintaining the electronic logbook.
- We are concerned about the lack of standards for electronic logbooks. Before a state or local government could implement an electronic logbook requirement, there would have to be standards in place, otherwise chain retailers that operate in

various jurisdictions would be required to comply with different requirements for each town, city, county, or state in which they operate.

We believe that the Combat Meth Act is helping significantly to reduce domestic methamphetamine production, that is, the numerous "mom-and-pop" methamphetamine labs that had become the scourge of rural America. Across the U.S., the DEA recorded 17,170 meth lab incidents in 2004. By 2006, this number had dropped 57% to 7,347. For these reasons, we ask Congress to amend the Combat Meth Act so that its provisions affecting the retail sale of methamphetamine precursors preempt state laws and local ordinances. Almost every state has laws that are different from the Combat Meth Act, as well as scores of localities. This patchwork of requirements causes difficulties for chain retailers that operate in numerous states and localities. Since a highly effective federal law has passed, we urge Congress to make that law uniform nationwide.

Now that the domestic methamphetamine production problem is being addressed, we support Congressional efforts to focus more keenly on eradicating methamphetamine addiction and importation. With the recent, steep decline in domestic methamphetamine production and availability, foreign methamphetamine sources are filling the void.

Electronic Prescribing of Controlled Substances
A paperless prescribing system is preferable to today's paper world because it adds new dimensions of safety and efficiency to current practice. Errors can occur at many points in the paper-based medication prescribing and delivery system; many of these potential points of error are due to failures in process and communication. These include:

- Miscommunication due to illegible handwriting
- Unclear abbreviations and dose designations
- Unclear telephone or verbal orders
- Ambiguous orders and fax-related problems
- Complex benefits plans
- Complex prescription regimens and dosages
- Wide range of drug choices for treating a medical problem

In 2006, the Institute of Medicine (IOM) recommended that all prescriptions be written and received electronically by the year 2010. Electronic prescribing could be used for controlled substances, but is not allowed at the present time under regulations promulgated by the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ). Although the proportion of prescriptions for controlled substances is modest--the DEA has estimated that such prescriptions account for up to a fifth of total prescription volume-- the ability to prescribe them electronically will accelerate electronic prescribing adoption. That is because a large number of physicians and other clinicians are waiting to purchase a system that will prescribe the complete range of drugs their patients need.

Electronic prescribing is far safer and more secure than today's paper world, in which prescription pads are stolen, home computers easily can print out counterfeit prescriptions, signatures can be easily forged, and drug quantities can be altered manually by patients before prescriptions are delivered to the pharmacy.

The electronic prescribing industry works diligently to ensure the privacy and safety of patient data, and the secure transmission of that data among the various points in the electronic prescribing chain. The industry is constantly making changes to ensure that the infrastructure complies with the state of the art, as well as all federal and state standards, laws and regulations.

Federal and State officials are struggling to keep pace with identifying and prosecuting the diversion of controlled substances. This is further slowed and complicated in today's paper world by the time-consuming and expensive process required for law enforcement staff to painstakingly sift through thousands of paper prescriptions in disparate locations, many months after the fact.

Electronic prescribing offers a potential solution today to these challenges by helping identify drug abuse and diversion of controlled substances, as well as being a tool for assisting law enforcement create documentation for prosecution of drug diversion. When the paper prescription (printed or written) is removed from the patient's hands, a key capability to deter patient abuse is established. Electronic prescribing addresses loss of forensic evidence. With appropriate authentication and security/audit controls, proof of prescribing should be maintained. Electronic prescribing offers real-time controlled substance reporting and monitoring capabilities that allow the DEA, as well as state and local law enforcement agencies, the ability to identify potential abuse immediately rather than days or weeks after dispensing.

Electronic prescribing also could help to quickly identify patients who doctor shop and garner multiple prescriptions for controlled substances. Electronic prescribing creates an immediate electronic audit trail that is documented and time-stamped through each point in the process, from the physicians' office to the pharmacy. These electronic audit trails show who touched the prescription and when. If the prescription is created and sent electronically, these built-in audit trails could be used to identify drug shopping, even if the patient pays cash. These records, when subpoenaed, could assist law enforcement in prosecuting diversion control cases, much as is done in today's reactive process.

It should be noted that there is no silver bullet and that electronic prescribing cannot address every instance of drug diversion. However, electronic prescribing will help eliminate illicit prescribers and facilitate the identification of illicit prescribers and prescription channels, which will help mitigate the problem over time. We urge Congress to work with DOJ and DEA to issue regulations as soon as possible to allow for workable requirements for the electronic prescribing of controlled substances.

Conclusion

Again, we thank Chairman Biden, and members of the Subcommittee and Caucus on International Narcotics Control, to provide this statement on the abuse of prescription and over-the-counter drugs. As health care providers of these critical and highly beneficial products, we are deeply concerned about the problem of consumers' using these products in potentially harmful ways. Our members have taken voluntary, proactive steps to prevent the abuse of these products, such as restricting access to methamphetamine

precursors, implementing age restrictions on DXM and DHEA products, and working with states to implement prescription monitoring programs. Moreover, we look forward to working with Congress to craft legislation that will shut down rogue Internet operators while still allowing legitimate pharmacies to function. These rogue sites are a major source of abused prescription drugs in the U.S. We urge Congress to work with DOJ and DEA to allow for the electronic prescribing of controlled substances. Finally, we will continue to support efforts to educate the public about the dangers of using prescription and nonprescription drugs for non-medical purposes.

Testimony of Charles Parsons
Executive Director, D.A.R.E. America

"Generation Rx: The Abuse of Prescription and Over-the-Counter Drugs"

U.S. Senate Drugs Caucus
Dirksen Senate Office Building Room 226
Wednesday, March 12, 2008

Chairman Biden and Ranking Member Grassley, and members of the Caucus, thank you for the opportunity to testify on this very important topic. My name is Charles Parsons and, as the Executive Director of D.A.R.E. America, I have the honor of representing the thousands of police officers who deliver the Drug Abuse Resistance Education (D.A.R.E.) curriculum.

D.A.R.E serves on the front lines of America's drug prevention efforts. Each day, our officers work with children in classrooms across the Nation, teaching the DARE curriculum, and listening to the challenges and peer pressure that kids face when confronted with drugs. In this role, we have often served as an early warning system about the evolving trends in youth drug use.

In recent years, we have watched as prescription drugs made their way out of the medicine cabinets and into the hallways of our school. Despite shrinking attention and budgets, it is a problem that we felt that D.A.R.E. had to address. As a result, we have developed the supplemental D.A.R.E. OTC/Rx Abuse lessons which we hope to disseminate to our elementary, middle and High school program across the country. By bringing together the efforts of law enforcement, teachers, parents and community leaders, we intend to bring to light the dangers of misusing pharmaceuticals by America's youth.

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DARE Background

Drug Abuse Resistance Education (D.A.R.E.) has been in existence for over 25 years. D.A.R.E. started in 1983 as a partnership between the Los Angeles Police Department and the Los Angeles Unified School District. The mission of D.A.R.E. is to provide students with the knowledge and skills needed to lead lives free from drug abuse and involvement in violence. Without any marketing effort the well developed state-of-the-science D.A.R.E. curricula and its companion "gold standard" delivery system has grown to become this nation's preeminent substance abuse and violence prevention education program.

The D.A.R.E. curriculum is designed to be taught by police officers whose training and experience give them the background needed to respond to young students questions about drugs and crime. Prior to entering the D.A.R.E. program, officers undergo 80 hours of special training in areas such as child development, classroom management, teaching techniques, and communication skills. 40 hours of additional training are provided to D.A.R.E. instructors to prepare them to teach the high school curriculum.

Today, D.A.R.E. provides K-12th grades school-based programs and a D.A.R.E. Community Education Program. More than 14,000 D.A.R.E. instructors presently deliver the D.A.R.E. curricula in 10,000 communities across the country. D.A.R.E. programs are delivered in 75% of the school systems in America, reaching millions of students and families each year. D.A.R.E. programs also are provided in over 47 foreign countries.

In 2003, D.A.R.E. America adopted new science-based curricula for both the elementary and middle school programs and next year we will implement a new high school curriculum. Using the most current research available, all new curricula and supplemental lessons were developed through the participation of expert panels of researchers, educators and law enforcement officials.

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The supplemental lessons are intended for delivery following presentation of the base D.A.R.E. curriculum lessons and are designed to be compatible with and enhance those lessons. To date D.A.R.E. America has implemented supplemental lessons on Bullying, Gangs, Role Modeling, Methamphetamine and Internet Safety. It is through supplemental lessons that D.A.R.E. is working to address the prescription drug problem.

Drug Prevention: An Evolving Challenge

From 1996 to the present, substance abuse prevention education efforts have evidenced positive outcomes as drug abuse among youths has shown a steady decline. Since 2001, a 19% decline in illicit drug use by 8th, 10th and 12th grade students has been documented. D.A.R.E. has been cited as having contributed to this accomplishment.

During the same period of time, however, a substantial increase in the abuse of over the counter (OTC) and prescription (Rx) drugs by our nation's youth has been evidenced.

The trend of increasing abuse of OTC and Rx medicines has been the subject of research and intensive media reporting. It has been reported that:

- In the United States alone, the abuse of painkillers, stimulants, tranquilizers and other prescription medications has gone beyond "practically all illicit drugs with the exception of cannabis."
- The California Poison Control System, the number of DXM overdoses reported in patients ages 9 to 17 has increased more than ten-fold – from 23 cases in 1999 to 375 cases in 2004.
- Today's teens are more likely to abuse OTC and Rx medications than illegal drugs.
- One in ten (10% or 2, 400,000) teens report abusing cough medicines to get high.
- Abuse of OTC and Rx medicines are occurring at a level higher than that of illicit substances.
- More than half of teens do not believe there is a high risk associated with using cough medication to get high.

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The specific topic of OTC/Rx drug abuse has been discussed during recent meetings of the D.A.R.E. America Scientific, Education and Law Enforcement Executive Advisory Boards. These advisory boards have advocated D.A.R.E. America taking prompt, appropriate and positive action to address the subject of OTC/Rx medicine abuse.

D.A.R.E and Prescription Drug Abuse Education

A number of organizations and individuals have expended significant resources in an attempt to develop programs and materials in hopes of positively impacting the growing trend of OTC and Rx medicine abuse. The difficulty is not in producing the material, but accomplishing effective dissemination. D.A.R.E. has a well-developed and acknowledged delivery system; the issue at hand is developing or adapting existing materials to marry to the D.A.R.E. delivery system.

D.A.R.E. America has accepted the responsibility of creating D.A.R.E. supplemental lessons addressing OTC/Rx drug abuse. Representatives of the following organizations have engaged in meetings with D.A.R.E. America staff to provide insight, direction and resources to assist D.A.R.E. America in realizing success in this endeavor.

- White House Office of National Drug Control Strategy
- Drug Enforcement Administration
- Food and Drug Administration
- National Institute on Drug Abuse
- Center for Substance Abuse Prevention
- Association for Supervision and Curriculum Development
- Partnership for a Drug Free America
- Abbott Laboratories
- Consumer Healthcare Products Association
- Pharmaceutical Research and Manufactures of America

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Supplemental D.A.R.E. OTC/Rx Abuse lessons will be prepared for implementation in elementary, middle school/junior high and high school environments. Also, a D.A.R.E. OTC/Rx Abuse Community Education Program will be created.

The objective of the lessons will be to emphasize the benefits OTC and Rx medications offer and to impart knowledge allowing participants to develop skills and abilities to prevent bad behaviors that contribute to abuse of OTC/Rx drugs.

Conclusion

Implementing special curricula like the *"Helping Communities Respond to Rx and OTC Abuse"* will not be possible without on-going funding. Costs such as officer training and classroom materials continue long after the curriculum is developed. It is an investment well worth taking to support the hard work and commitment that our police, schools, parents and children have taken in DARE. The potential loss of DARE would leave a void in drug education that we cannot allow our communities to face.

I want to personally thank Senators Biden and Grassley for holding this hearing and I would be happy to answer any questions you may have either in person or for the hearing record.

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Testimony of Stephen J. Pasierb, President and CEO
Partnership for a Drug-Free America

"Abuse of Prescription and Over the Counter Drugs"

Senate Subcommittee on Crime and Drugs
and the
Senate Caucus on International Narcotics Control

United States Senate, March 12, 2008

Mr. Chairman, Senator Grassley, members of the Subcommittee and the Caucus, thank you for inviting me to testify about the problem of prescription and over-the-counter drug abuse among America's teenagers. I'm Steve Pasierb, President and Chief Executive Officer of the Partnership for a Drug-Free America.

I'd like to begin by thanking you, Mr. Chairman, and you, Senator Grassley, for your steadfast leadership on the substance abuse issue in general, and your concern with the abuse of medicine in particular. Your focus today on the public health threat posed by prescription and over the counter drug abuse is of critical importance and tremendous value to parents, healthcare professionals, the prevention and treatment communities, and ultimately, of course, to our children.

Overview

The abuse of prescription and over the counter medications –legal substances of tremendous benefit if used appropriately—is the single most troubling phenomenon on today's drug landscape.

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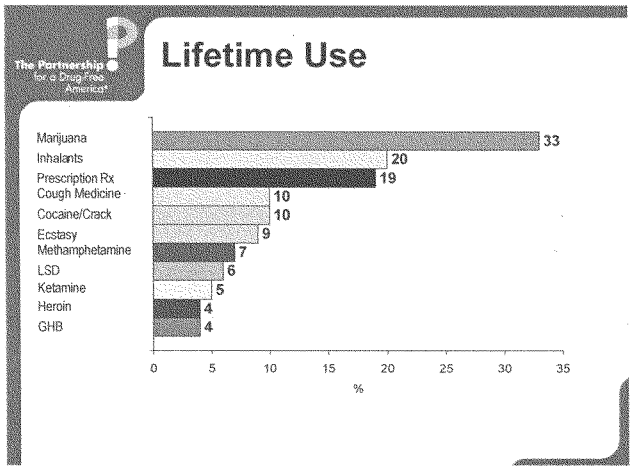
The latest Partnership Annual Tracking Study* of roughly 6500 teens in grades 7 through 12 shows that 19%, or roughly one in five, teens report having tried a prescription drug without having a prescription for it at least once in their lives. About one in ten report having used over-the-counter cough medicine "to get high." Only alcohol, cigarettes, marijuana and inhalants are abused by teenagers at higher rates than prescription drugs. Cocaine and Ecstasy are each roughly half as prevalent as prescription drug abuse. The prevalence of teen abuse of methamphetamine is just over *one third* that of prescription drugs.



Source: Partnership Attitude Tracking Study (PATS), Teens 2007

While it's true that the prevalence of prescription and over the counter drug abuse has not *increased* over the past three years, it's troubling to realize that with just one or two exceptions, teen use of virtually *all other* substances of abuse –alcohol, tobacco, marijuana, methamphetamine and cocaine—has *declined* over the same period, and in fact has been in steady decline over the past decade.

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Reasons Why

Why has this trend proved resistant thus far to the nation's collective efforts at education and prevention? There are several reasons:

1. These substances are **readily available** to teens – in their own medicine cabinets and the medicine cabinets of friends—and very often they're available *for free*. Our data are very much in line with the findings of the National Survey on Drug Use and Health, which shows over 75% of teenage prescription drug abusers saying they got those drugs from friends or family.

I think it's worth noting that less than 1% of teens --in both the National Survey and in our research-- claim to have ordered their drugs over the internet.

It *is* true that many teens are searching the web for *information* about how how to abuse prescription and over the counter medications, on web sites such as www.erowid.com. The Partnership, working with the Consumer Healthcare Products Association (CHPA), has developed an "intercept strategy" for such web searches, so that a teenager typing "dxm abuse", for instance, into his / her search engine, will find among the top entries www.dxmstories.com – which is a Partnership developed site with teen-relevant information about the *risks* of abuse of dextromethorphan, the active ingredient in many cough medicines.

2. Teens' **perception of the risks of abuse** is relatively low. Our Partnership research shows that less than half of teens see "great risk" in trying prescription pain relievers such as Vicodin or Oxycontin that a doctor did not prescribe for them. Over one quarter of teens believe prescription pain relievers are not addictive. The University of Michigan's "Monitoring the Future" survey data going back over thirty years demonstrates that teens' perception of the risk associated with any substance of abuse, along with perceptions of "social disapproval", correlates significantly with actual teen abuse of that substance. So low perception of risk, coupled with easy availability, is a recipe for ongoing problems.

3. Research conducted by the Partnership in 2007, with support from Abbott Pharmaceutical, cast new light on the **motivations of teens** to abuse prescription drugs. We have traditionally thought of teens abusing illegal drugs and alcohol either to "party", or to "self-medicate" for some serious problem or disorder: adolescent depression, for example. But our 2007

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research, like the research done among college students by Carol Boyd and Sean McCabe at the University of Michigan, suggests a wider range of motivations for young people's abuse of prescription drugs, including an emerging set of "life management" or "regulation" objectives. Teens appear to be abusing these drugs in a utilitarian way, using stimulants to help them cram for a test or lose weight, pain relievers to escape some of the pressure they feel to perform academically and socially, tranquilizers to wind down at the end of a stressful day. Once these substances have been integrated into teens' lives and abused as study or relaxation aids, it may become increasingly difficult to persuade teens that these drugs are unnecessary or unsafe when taken without a prescription.

4. **Parents** – who are usually our most valuable ally in preventing teen drug use – are generally ill equipped to deal with teens' abuse of prescription drug use, a behavior that was probably not on their radar when they were teenagers. They find it hard to understand the scale and purposefulness with which today's teens are abusing medications, and it's not immediately clear to them that the prime source of supply for abusable prescription drugs is likely to be their own medicine cabinet. Further, many parents themselves are misusing, or perhaps abusing, prescription drugs without having a prescription. In our study with Abbott, 28% of parents said they had used a prescription drug without having a prescription for it, and 8% of parents said they had given their teenaged child an Rx drug that was not prescribed for the teen.

5. And **finally,** the reason our efforts have not resulted in declines in teen abuse of prescription or over the counter medications is that **our efforts as a nation –to date at least-- have been inadequate.** There has simply not been the public attention or resources devoted to this issue that we have seen for other emerging drug threats.

There *are* some bright spots.

What Is Being Done

Mr. Chairman, the legislation you sponsored last year preventing abuse of **dextromethorphan, or DXM, powder** is important and very welcome.

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The Partnership for a Drug-Free America has been working since 2003 on this issue, fielding research and developing research-based communications raising awareness among parents of the risks of prescription drug abuse, and what they can do to prevent it.

The Partnership has:

- Fielded **research** in 2004 identifying prescription drug abuse as a teen behavior involving the prescription and over the counter categories, not merely a brand-specific problem;

- Developed **public service announcements** addressing abuse of both prescription drug and over the counter medicines, beginning in 2004;

- Created **online resources** for teens and parents, putting forward the risks of abuse and identifying steps parents can take to safeguard their household medicines (2004 – present);

- Fielded **in-depth research** in 2007, surveying teens and parents on the attitudes and beliefs underlying their behavior related to prescription drug abuse;

- Focused in **press events, town hall meetings and public relations outreach** (covered by major national media) on the emerging threat of prescription drug abuse

And there have been other important steps as well.

The **National Youth Anti-Drug Media Campaign** (NYADMC) is mounting a major effort this year, targeting parents and providing them with information on how to safeguard their home supplies of prescription drugs and prevent their teenage children from abusing them. Television and print advertising are being supplemented with solid web-based information and point-of-sale educational brochures that are being stapled to pain reliever prescriptions in three major drug chains during the months of February and March. Nearly one fourth of the Campaign's media budget this year will be spent in support of this initiative, and –as is the case with all NYADMC advertising-- leveraged via a dollar-for-dollar match by the media.

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The **National Institute on Drug Abuse** and some other federal agencies have been in the vanguard of those taking action.

Private sector rganizations in the **prevention field,** such as the Community Anti-Drug Coalitions of America and DARE, are doing their part.

In some quarters of the pharmaceutical and over the counter industries, there have been concern and support for prevention and education efforts – and those companies and professional associations should be commended for their pro-activity.

We at the Partnership for a Drug-Free America, in addition to our ongoing research with partners such as Abbott Pharmaceutical and the MetLife Foundation, are reaching parents with prevention programs such as our **"Time to Talk"** promotion, encouraging parents to communicate with their children about the risks of abusing alcohol and drugs, including prescription and over the counter. medications.

We have built robust **web-based resources** at www.drugfree.org, providing parents with an in-depth understanding of the risks of medicine abuse and the steps they can take to prevent it.

In partnership with PhRMA and others, we are exploring the development of simple **tools for healthcare professionals**, which would help them more effectively identify and assess prescription drug abuse in their patient populations.

And of course we continue to call on the pro bono resources of America's best communications companies and the media to create and run **public service announcements** helping parents understand the risks that this new, emerging drug threat poses to their teenaged children.

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The Partnership for a Drug-Free America

The Partnership is a non-profit coalition of volunteers from the communications industry. Using a national drug-education advertising campaign and other forms of media communication, the Partnership exists to reduce illicit drug use in America.

The organization began in 1986 with seed money provided by the American Association of Advertising Agencies. The Partnership is strictly non-partisan and accepts no funding from manufacturers of alcohol and/or tobacco products. All actors in the Partnership's ads appear pro bono through the generosity of the Screen Actors Guild and the American Federation of Television and Radio Artists.

National research suggests that the Partnership's national advertising campaign – the largest public service campaign in the history of advertising – has played a contributing role in reducing overall drug use in America. Independent studies and expert interpretation of drug trends support its contributions. *The New York Times* has described the Partnership as "one of the most effective drug-education groups in the United States."

In addition to its work on the national level, the Partnership's State/City Alliance Program supports the organization's mission at the local level. Working with state and city governments and locally-based drug prevention organizations, the Partnership provides the guidance, on-site technical assistance and creative materials necessary to shape anti-substance abuse media campaigns tailored to the needs and activities of any given state or city.

The Partnership also participates in the National Youth Anti-Drug Media Campaign, coordinated by ONDCP. At the core of this multi-faceted initiative is a paid advertising program, featuring messages created by the Partnership.

Today, the Partnership is run by a professional staff of 50. Partnership campaigns have received every major award in the advertising and marketing industries for creative excellence and effectiveness, including the American Marketing Association's highest honor for marketing effectiveness.

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Conclusion

But reducing adolescent abuse of prescription and over the counter drugs will require much more. The tragic death of Heath Ledger cast a sudden spotlight on this issue –much as Len Bias's death in 1986 focused the country's attention on the risks of cocaine abuse, which had been underestimated till that point. We must build on this growing understanding, and devote the necessary resources to prevention, education –and treatment—programs addressing the abuse of these legal, beneficial medications.

On behalf of the Partnership for a Drug-Free America, Mr. Chairman and Senator Grassley, let me thank the Subcommittee and the Caucus again for your concern.

*The Partnership Attitude Tracking Study of teens is conducted annually among approximately 6500 teens in grades 7-12, drawn from a nationally projectable sample of roughly 128 public, private and parochial schools. The questionnaire is self-administered and completed anonymously.

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Testimony
Before the
Subcommittee on Crime & Drugs
Committee on the Judiciary and
the Caucus on International Narcotics Control
United States Senate

Trends in Unintentional Drug Overdose 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

For Release on Delivery
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Good afternoon, Chairman Biden, members of the Subcommittee, and members of the Caucus. 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 drug overdose deaths. Thank you also for your continued support of CDC as we work towards becoming the "Healthiest Nation."

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

Definitions

Drug overdoses basically are the result of taking too much of a drug. I will use the term to apply to both legal and illegal drugs. I will not include intentional or suicidal drug overdoses or alcohol poisoning in this presentation. I will focus almost exclusively on the "unintentional" or "accidental" drug overdoses. In other settings we have used the phrase, "unintentional drug poisonings," but I will refer to them as "overdoses" today.

The death certificates that are the source of the statistics I cite do not tell us whether the person was abusing the drug, taking it medically, or taking it by mistake. Therefore, the

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term "overdose" in this context should not be interpreted to mean that all these deaths necessarily resulted from misuse or abuse of drugs. Some of them did not.

I will concentrate on *fatal* drug overdoses because such events are extensively investigated, coded in a standardized process, and available for analysis in annual mortality files created by CDC's National Center for Health Statistics (NCHS). I will discuss data through 2005, the latest year for which complete mortality statistics are available for the United States.

Historical Trends in Mortality Rates

The mortality rates from unintentional drug overdose (not including alcohol) have risen steadily since the early 1970s, and over the past ten years they have reached historic highs. Rates are currently 4 to 5 times higher than the rates during the "black tar" heroin epidemic in the mid-1970s and more than twice what they were during the peak years of crack cocaine in the early 1990s. The rate shown for 2005 translates into 22,400 unintentional and intentional drug overdose deaths. To put this in context, just over 17,000 homicides occurred in 2005. The number of drug overdose deaths does not yet exceed the number of motor vehicle crash deaths overall, but for the first time more people in the 45-54 age group now die of drug overdoses than from traffic crashes.

Type of Drugs Involved, 1999-2005

We have the best information about the drugs involved for the seven years of the trend beginning with 1999. In 1999, almost all drug overdose deaths fell into one of three

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categories. The most common type was called "narcotics," and it included prescription painkillers, called opioids, in addition to cocaine and heroin. OxyContin® and Vicodin® are examples of opioid painkillers. Methadone is also now widely used as a painkiller in addition to its use for treatment of addiction. The second most common was "other and unspecified drugs." The third most common was a group containing sedatives like Valium® and other psychotherapeutic or psychotropic drugs. All three of these categories increased after 1999.

One might assume that the increase in drug overdose deaths is due to an increased use of street drugs like heroin and cocaine, because we have in the past associated such drugs with overdoses. However, in a paper published in 2006, the CDC drilled down to another level to look at the codes given to the specific drugs recorded on the death certificates through 2004. When these more specific drugs were tabulated, we found that street drugs were not behind the increase. The increase from 1999 to 2004 was driven largely by opioid analgesics, with a smaller contribution from cocaine, and essentially no contribution from heroin. The number of deaths in the narcotics category that involved prescription opioid analgesics increased from 2,900 in 1999 to at least 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 in this category.

[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 in 2006 and recently updated)

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With the latest, 2005 death data, we were able to drill down even further and look at the specific drugs causing the deaths. For deaths with multiple drugs involved, we looked at only the first-listed drug, which is a method to assign responsibility when multiple drugs are involved. This analysis showed that opioid painkillers were still the most commonly found drugs, accounting for 38.2% of the first-listed drugs, with methadone by itself contributing to almost half of these deaths. Benzodiazepine sedatives such as Valium® and antidepressants accounted for 6.5%. Even without including the category of "other specified drugs," which are mostly prescription, the total of prescription opioids, benzodiazepines, and antidepressants (about 45%), exceeds the total of cocaine, heroin, and methamphetamines/amphetamines (about 39%).

Characteristics of Those Dying from Drug Overdoses

The shift in the type of drugs responsible for most overdoses has also changed the demographics of those dying from overdoses. As has historically been the case, men are more likely to be affected than women. However, people in their 40s are more likely than those in their 20s or 30s to die of an overdose. Overdose death rates of whites have passed rates for African Americans in recent years. The highest rates are likely no longer in the inner cities and may well be found in our most rural counties. A map of the United States in 2004 shows an 8-fold variation in overdose death rates among states, with the highest rates concentrating in the more rural Appalachian states, the Southwestern states, and New England.

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Why are Deaths Occurring?

The vast majority of unintentional drug overdose deaths are not the result of toddlers getting into medicines or the elderly mixing up their pills. All available evidence suggests that these deaths are related to the increasing use of prescription drugs, especially opioid painkillers, among people during the working years of life. A CDC study showed a correlation on the state level between usage of opioid painkillers and drug overdose death rates.[2] Perhaps because of differences in marketing or physician prescribing practices, there were wide differences among states in their per capita use of opioid analgesics. For example, people in Maine were using four times more opioid painkillers than people in South Dakota.

Other evidence also suggests that most of these deaths involve the misuse and abuse of prescription drugs. The strongest evidence of this comes from investigations of these deaths by 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, that many have no prescriptions for their drugs, that many mix prescription drugs with illicit drugs, and that some alter the prescription drugs by crushing and snorting them or dissolving and injecting them.

Although this information refers to fatalities, the same kinds of trends and patterns can be seen in rates of hospitalizations for substance abuse, emergency department visits

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

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for overdoses, and self reports of use of drugs in national surveys sponsored by HHS's Substance Abuse and Mental Health Services Administration (SAMHSA).

Projection of Trends Since 2005

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 2005. However, the overall drug overdose mortality trend closely correlated with the rapid rise in sales of opioid analgesics per capita reported by the Drug Enforcement Administration (DEA) from 1997 through 2005, and sales of opioid analgesics rose further in 2006, so we expect to see additional increases in the drug overdose mortality rate during 2006. Moreover, the number of emergency department visits for opioid overdoses increased steadily through 2007 in hospitals that participated in SAMHSA's Drug Abuse Warning Network (DAWN) system. Therefore, it appears that the mortality statistics through 2005 probably underestimate the present magnitude of the problem.

What Can Be Done

Judged by any measure—person years of life lost, health care costs, self reports of drug abuse—the prescription drug problem is a crisis that is steadily worsening. Addressing it requires the fielding and testing of more aggressive measures than have been taken to date.

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It is important that state prescription drug monitoring programs share data with law enforcement officials for the purpose of investigating the unlawful diversion or misuse of certain controlled substances. For example, some state prescription drug monitoring programs are administered by a law enforcement agency in conjunction with a state board of pharmacy.

Washington State and a number of others use information about the drug use of their Medicaid populations to identify high-volume users. After further investigation, they have the option of "locking in" such users to a single provider and a single pharmacy to reduce the likelihood of "doctor shopping," when prescription abusers visit multiple doctors until they get the desired amount of drugs.

Insurers can take steps to modify the behavior of patients who use dangerous amounts of prescription drugs. Hospitals may also want to consider requiring their emergency departments to screen patients for a history of substance abuse before dispensing opioid painkillers. Roughly 40% of opioids are dispensed in emergency departments.

Physicians should observe practice guidelines for use of opioids in chronic, non-cancer pain such as those being piloted by the Washington State Agency Medical Directors' Group.[3] Guidelines should address criteria to be met before initiating opioid treatment; principles for prescribing opioids, such as use of a single prescriber and a single

[3] Available at: http://www.agencymeddirectors.wa.gov

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pharmacy; and when to consult a pain management specialist, e.g., when doses exceed 120 milligrams of morphine per day.

And drug manufacturers should modify opioid painkillers so that they are more difficult to tamper with and/or combine them with agents that block the effect of the opioid if it is dissolved and injected.

CDC Activities

This coming year, CDC will 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 other persons using the same class of drugs. We are looking for 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 (PDMPs) nationwide. The study will compare changes in prescription drug sales and overdose rates in states that start PDMPs with changes in states not initiating such programs. Information obtained on program characteristics associated with effectiveness could be used to enhance the effectiveness of PDMPs nationwide.

In addition, 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. We plan on publishing the lessons learned from that survey this calendar year.

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Conclusion

Prescription drug overdoses are a serious public health problem. CDC continues to respond to this problem through 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 injury prevention activities. I will be happy to answer any questions.

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The Epidemiology of Prescription Drug Overdoses in the United States

Leonard J. Paulozzi, MD, MPH
Medical Epidemiologist

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

CDC

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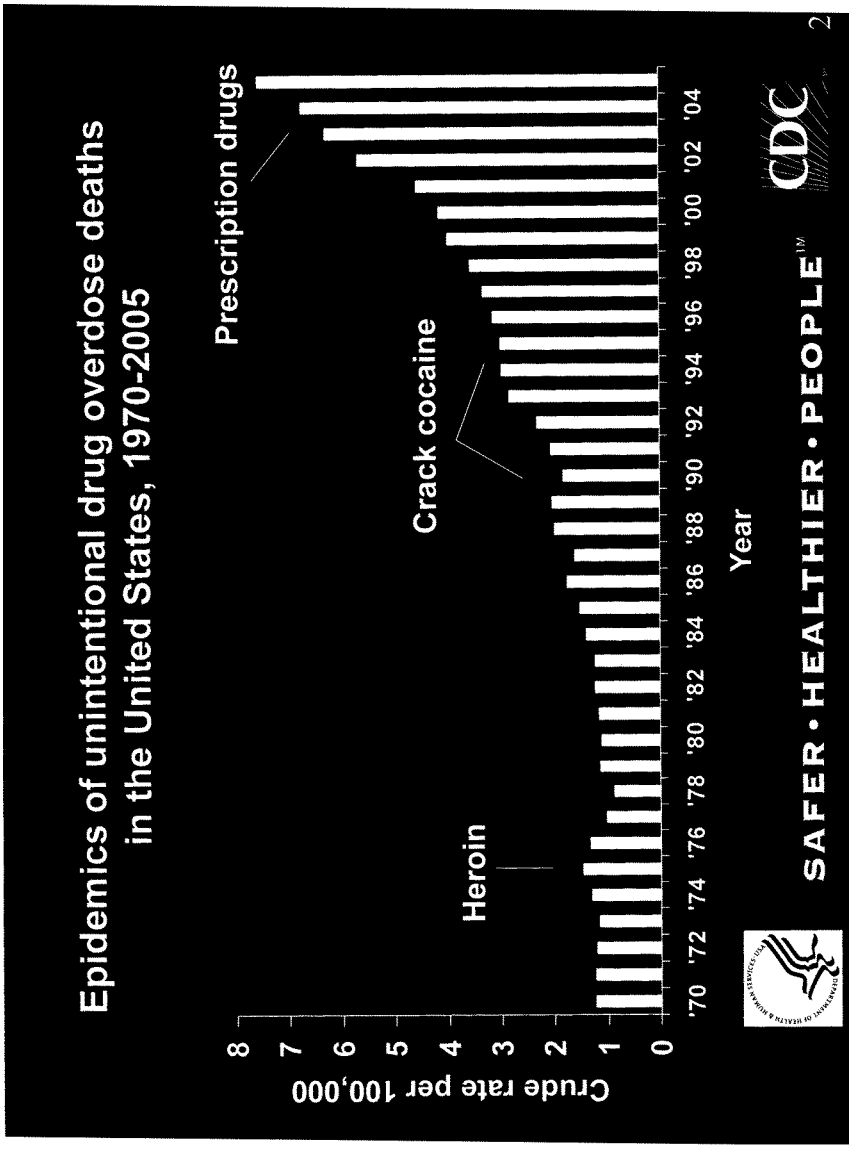
Epidemics of unintentional drug overdose deaths
in the United States, 1970-2005
Prescription drugs
Crack cocaine
Heroin
Crude rate per 100,000
0
1
2
3
4
5
6
7
8
'70 '72 '74 '76 '78 '80 '82 '84 '86 '88 '90 '92 '94 '96 '98 '00 '02 '04
Year
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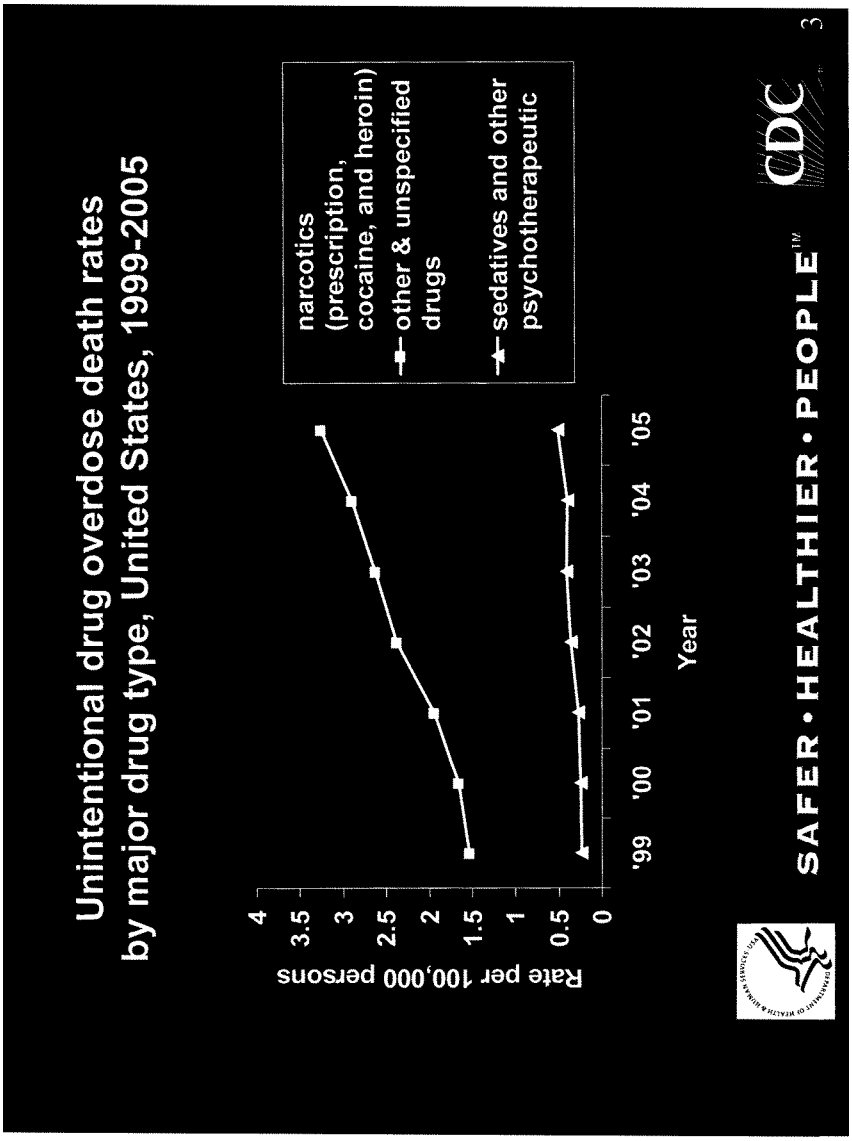
Unintentional drug overdose death rates
by major drug type, United States, 1999-2005
Rate per 100,000 persons
4
3.5
3
2.5
2
1.5
1
0.5
0
'99
'00
'01
'02
'03
'04
'05
Year
narcotics (prescription, cocaine, and heroin)
other & unspecified drugs
sedatives and other psychotherapeutic
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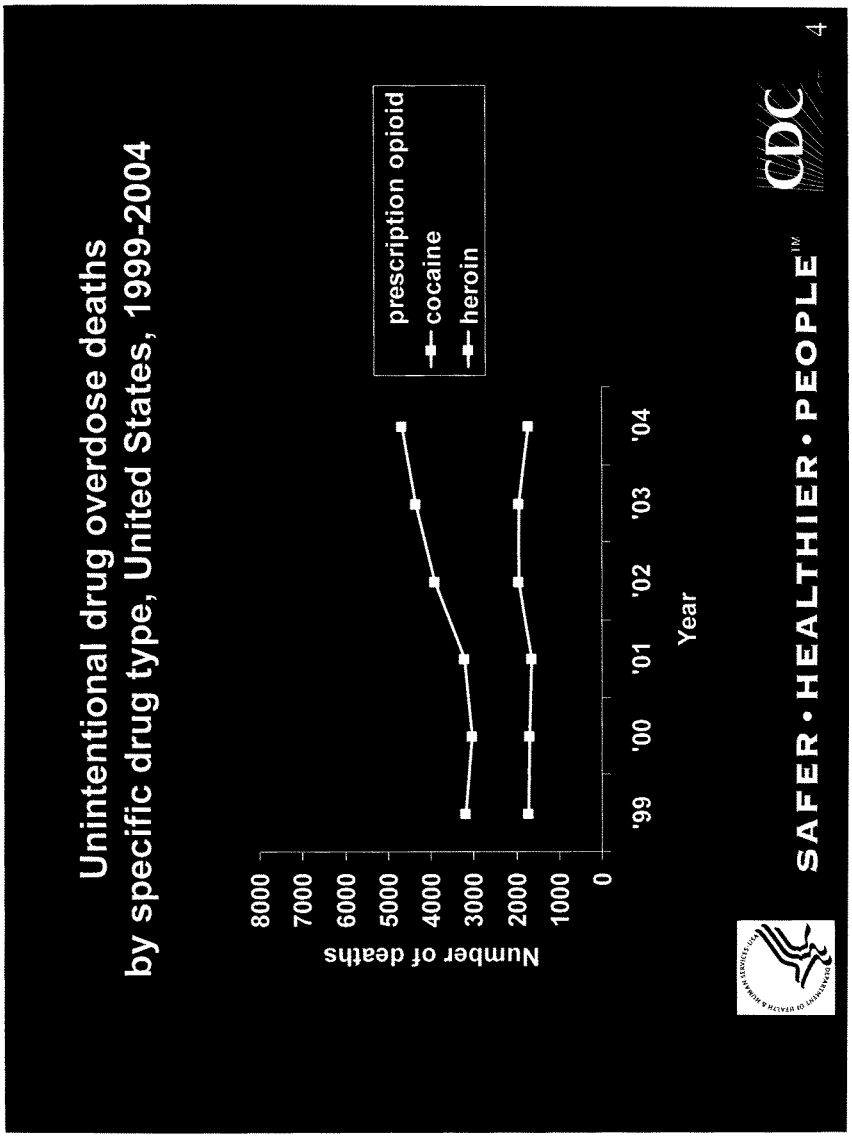
Unintentional drug overdose deaths
by specific drug type, United States, 1999-2004
Number of deaths
8000
7000
6000
5000
4000
3000
2000
1000
0
'99
'00
'01
'02
'03
'04
Year
prescription opioid
cocaine
heroin
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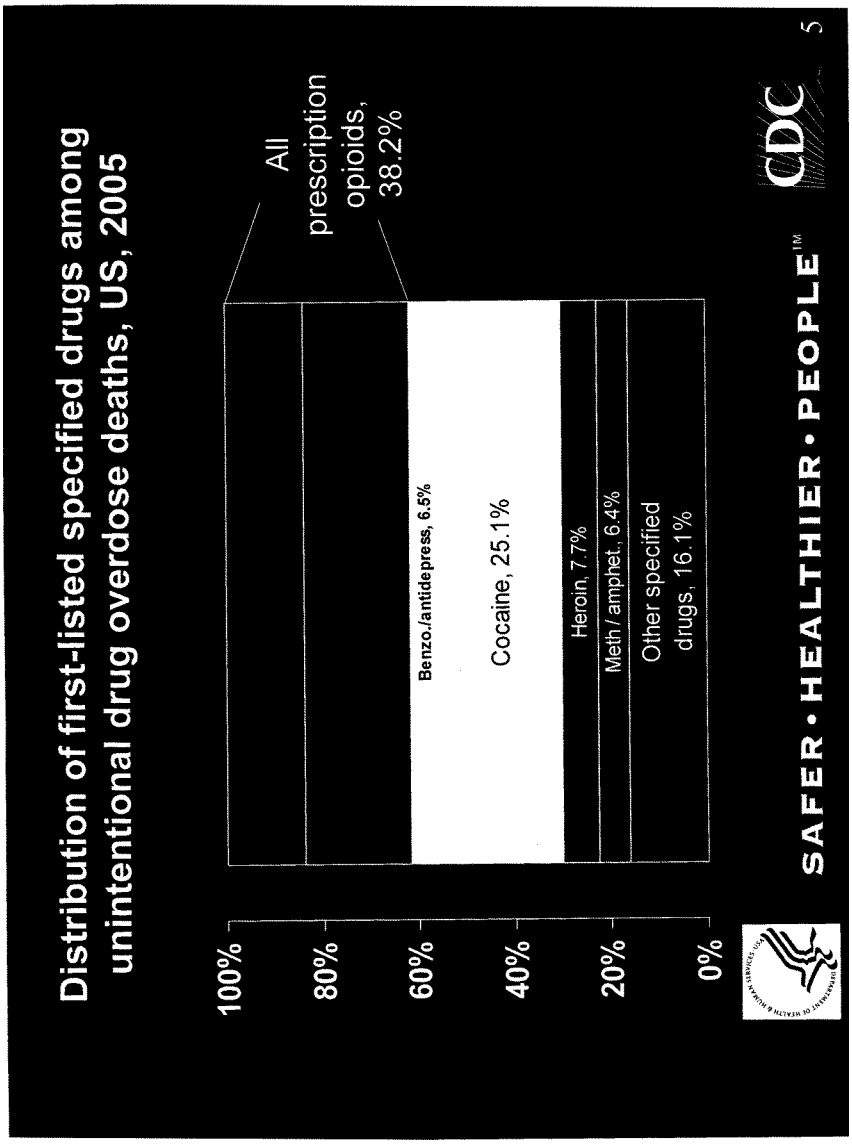
Distribution of first-listed specified drugs among unintentional drug overdose deaths, US, 2005
100%
80%
60%
40%
20%
0%
All prescription opioids, 38.2%
Benzo./antidepress, 6.5%
Cocaine, 25.1%
Heroin, 7.7%
Meth/amphet, 6.4%
Other specified drugs, 16.1%
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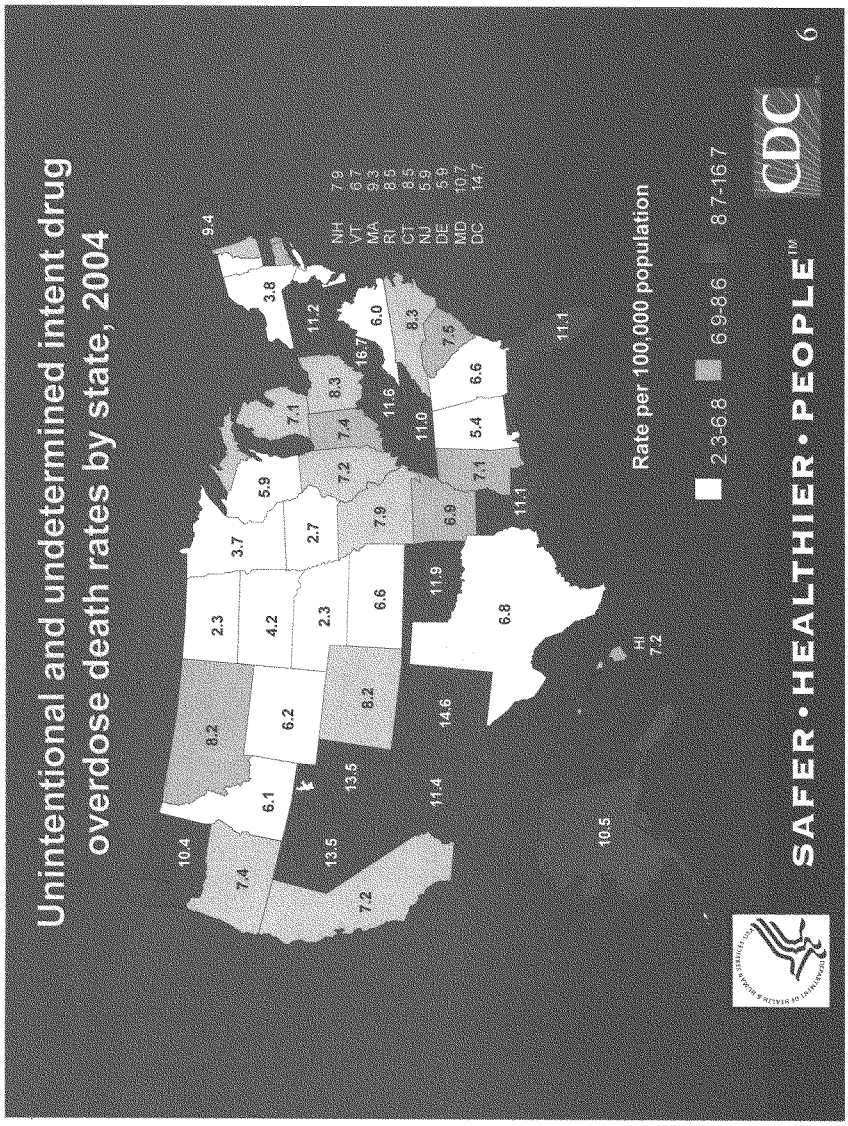
Unintentional and undetermined intent drug
overdose death rates by state, 2004
10.4
7.4
8.2
6.1
7.2
13.5
6.2
13.5
8.2
2.3
4.2
2.3
6.6
11.4
14.6
3.7
2.7
7.9
11.9
5.9
7.2
6.9
6.8
7.1
8.3
7.4
11.1
11.6
16.7
11.0
9.4
3.8
11.2
6.0
8.3
7.5
6.6
5.4
7.1
11.1
10.5
HI
7.2
NH 7.9
VT 6.7
MA 9.3
RI 8.5
CT 8.5
NJ 5.9
DE 5.9
MD 10.7
DC 14.7
Rate per 100,000 population
2.3-6.8
6.9-8.6
8.7-16.7
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What is causing these deaths?

- These are not the accidental poisoning deaths of childhood or elderly people mistakenly taking too much medication.
- Deaths are related to the increasing use of certain prescription drugs by people in the middle years of life.
- Most such deaths are related to the misuse and abuse of prescription drugs.

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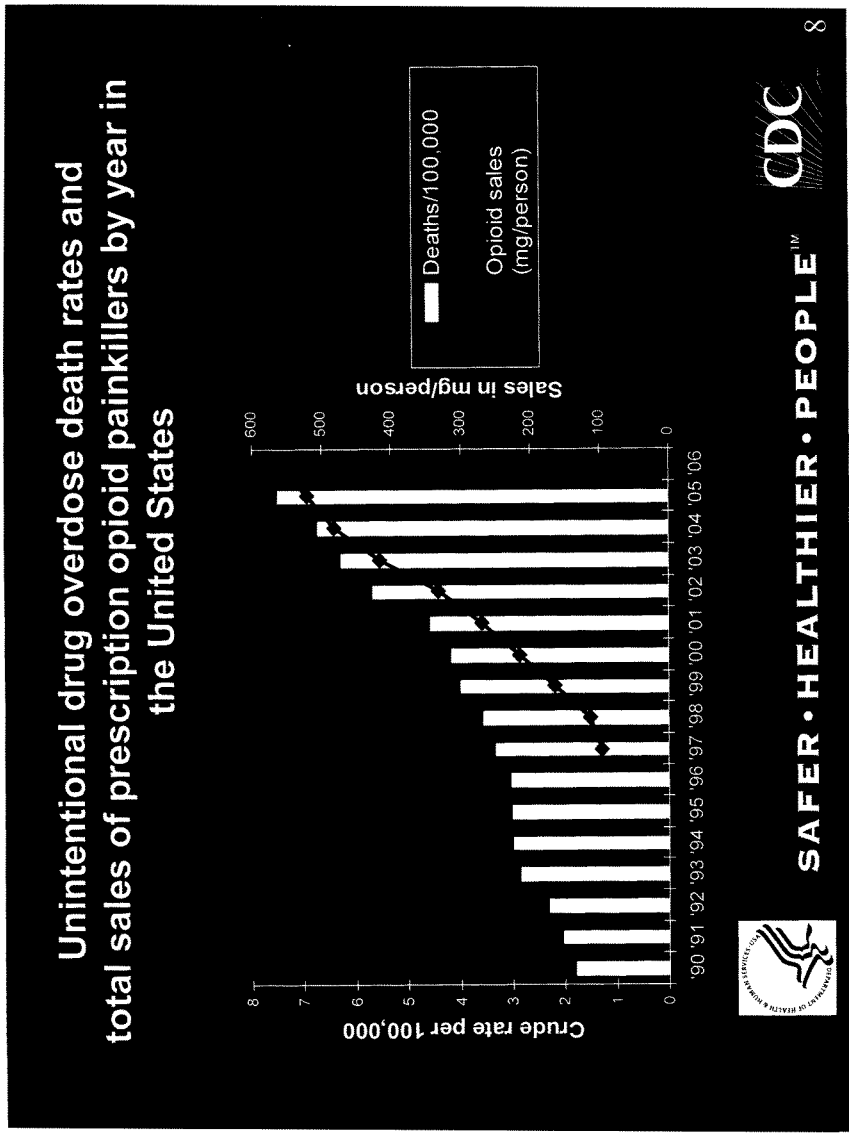
Unintentional drug overdose death rates and total sales of prescription opioid painkillers by year in the United States
Crude rate per 100,000
Sales in mg/person
Deaths/100,000
Opioid sales (mg/person)
'90 '91 '92 '93 '94 '95 '96 '97 '98 '99 '00 '01 '02 '03 '04 '05 '06
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Proposed Prevention Measures

- Get the most out of state prescription drug monitoring programs
- Modify patient behavior with insurance mechanisms
- Screen for drug misuse in EDs
- Provide practice guidelines for primary care
- Make painkillers tamper resistant

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9

Testimony
Before the
Subcommittee on Crime and Drugs
Committee on the Judiciary and
the Caucus on International Narcotics Control
United States Senate

Scientific Research on Prescription Drug Abuse

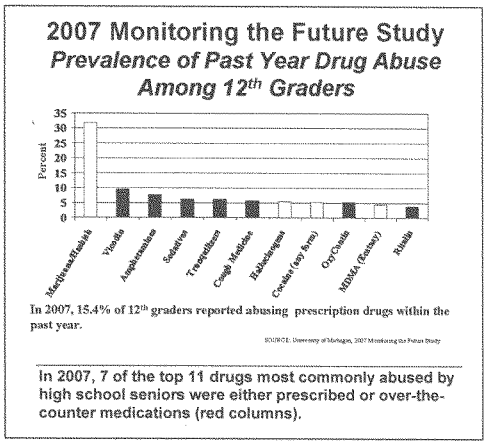
Statement of
Nora D. Volkow, M.D.
Director
National Institute on Drug Abuse
National Institutes of Health
U.S. Department of Health and Human Services

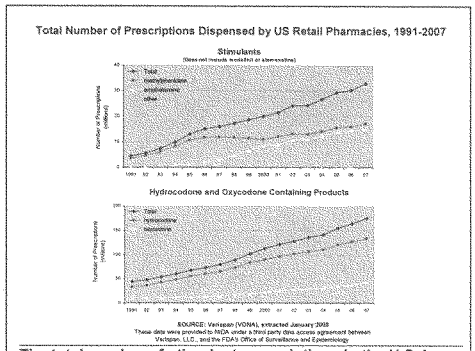
For Release on Delivery
Expected at 2:00 p.m.
Wednesday, March 12, 2008

47336.101

Mr. Chairman, Members of the Subcommittee, and Members of the Caucus:

Thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), to participate in this important hearing and contribute information about the growing problem of prescription drug abuse in this country. This problem is particularly complex because the benefits and the risks of prescription drugs are so closely intertwined. Thus, it is critical that we learn how to strike the right balance between providing maximum relief from suffering and minimizing associated risks and adverse effects. We must be deeply concerned by the fact that, according to the Monitoring the Future (MTF) study supported by NIDA, 7 of the top 11 most commonly abused drugs by high school seniors are either prescribed or purchased over-the-counter (see figure), but this challenge must also recognize the fundamental and unassailable role played by these medications in healing and reducing human suffering when properly used. Therefore, how we address the problem of abuse of drugs that have legitimate medical use must necessarily differ from how we address illicit drug abuse.





Several factors have recently contributed to the severity of prescription drug abuse, including drastic increases in the number of prescriptions written, greater social acceptance of using medications, and aggressive marketing by pharmaceutical companies. These factors together have helped create the broad "environmental availability" of prescription drugs. To illustrate, the total number of stimulant prescriptions in the U.S. has soared from around 5 million in 1991 to nearly 35 million in 2007. Prescriptions for opiates (hydrocodone and oxycodone products) have escalated from around 40 million in 1991 to nearly 180 million in 2007 (see figure), with the U.S. their biggest consumer. The U.S. is

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supplied 99 percent of the world total for hydrocodone (e.g., Vicodin) and 71 percent of oxycodone (e.g., OxyContin).

This greater availability of prescription drugs has been accompanied by increases in their abuse. To clarify our terminology here, when we say "prescription drug abuse" or "nonmedical use," this includes use of approved prescription medications without a prescription, use for purposes other than prescribed, or use simply for the experience or feeling the drug can cause. Unlike illicit drug use, which shows a continuing downward trend, prescription drug abuse, particularly of opioid pain medications, has seen a continual rise through the 1990s and has remained stubbornly steady among persons 12 or older during recent years.[1] Because prescription drugs act directly or indirectly on the same brain systems affected by illicit drugs, their abuse carries substantial abuse and addiction liabilities. They are most dangerous when taken to get high via methods that increase their addictive potential (e.g., crushing the pills, then snorting or injecting their contents, or combining them with alcohol or illicit drugs). Some people also take prescription drugs for their intended purpose, though not as prescribed, thus heightening the risk of dangerous adverse reactions; and still others may become addicted even when they take them as prescribed. Given that more than 30 million people suffer from chronic pain in this country, even if a fraction of this group takes prescription drugs for their pain and becomes addicted, it could affect a large number of people.

I am pleased to have the opportunity today to share with you what we know about this complex multi-faceted problem.

Which medications are being abused, and what do they do to the brain and body?

The psychotropic prescription drugs[2] that present abuse liability (i.e., have potential for abuse relative to their pharmacological and behavioral effects) fall into three broad categories: opioids (analgesics), stimulants, and central nervous system (CNS) depressants (anxiety and sleep medications). How they work is described briefly below:

- Opioids, mostly prescribed to treat moderate to severe pain, include drugs such as OxyContin and Vicodin. Opioids act on the brain and body by attaching to specific cell surface proteins called opioid receptors, which are found in the brain, spinal cord, and gastrointestinal tract. When these drugs attach to certain opioid receptors, they can block the perception of pain. These drugs also can induce euphoria by indirectly boosting dopamine levels in the brain regions that influence our perceptions of pleasure. This feeling is often intensified by abusers who snort or inject the drugs, amplifying their euphorigenic effects and increasing the risk for serious medical consequences, such as respiratory arrest, coma, and addiction. Combining opioids with alcohol can exacerbate these consequences.

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[1] *The NSDUH Report: Patterns and Trends in Nonmedical Prescription Pain Reliever Use: 2002 to 2005*, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, 2007.
[2] For purposes of this testimony, the focus will be only on psychotherapeutic drugs, so even though NIDA's prescription drug portfolio includes work on other prescribed drug categories, such as anabolic steroids, these will be excluded from this discussion.

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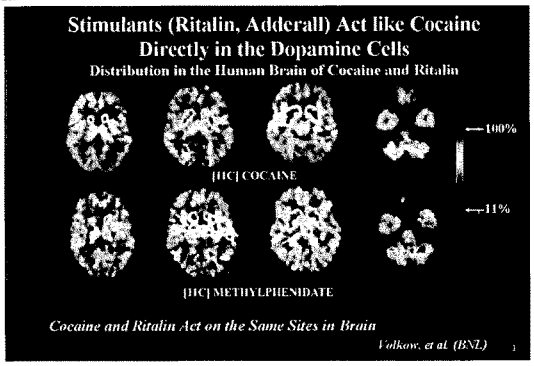
- Stimulants, prescribed to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy, include drugs such as Ritalin, Adderall, and Concerta. These prescription medications stimulate the central nervous system, with effects similar to but more potent than caffeine. When taken orally, as prescribed, these stimulants elicit a gradual and sustained increase in the neurotransmitter (brain chemical) dopamine, which produces the expected therapeutic effects seen in many patients. In people with ADHD, stimulant medications generally have a calming and "focusing" effect, particularly in children. However, because these medications affect the dopamine system in the brain (the reward pathway), they are also similar to drugs of abuse. For example, Ritalin, or methylphenidate, has much in common with cocaine—the two drugs bind to similar sites in the brain and both increase dopamine through the same molecular targets (see figure). When administered intravenously, both drugs cause a rapid and large increase in dopamine, which a person experiences as a rush or high. For those who abuse stimulants, the range of adverse health consequences includes risk of dangerously high body temperature, seizures, and cardiovascular complications.



Ritalin, or methylphenidate, has much in common with cocaine—the two drugs bind to similar sites in the brain and both increase dopamine through the same molecular targets.

- CNS depressants, typically prescribed for the treatment of anxiety, panic, sleep disorders, acute stress reactions, and muscle spasms, includes drugs such as Valium, Librium, and Xanax. Most CNS depressants act on the brain by affecting the neurotransmitter gammaaminobutyric acid (GABA). GABA works by decreasing brain activity. Although the different classes of CNS depressants work in unique ways, it is through their ability to increase GABA activity that they produce a drowsy or calming effect that is beneficial to those suffering from anxiety or sleep disorders. These drugs are also particularly dangerous when mixed with other medications or alcohol; overdose can cause breathing problems and lead to death. Although the newer sleep medications—such as Ambien, Lunesta, and Sonata—appear to have reduced dependence and abuse liabilities, they still react with some of the same receptors in the brain, so they may share some of the risks.

Over the counter medications, such as certain cough suppressants containing dextromethorphan (DXM), are also abused for their psychoactive effects, producing hallucinations and dissociative ("out-of-body") sensations. However, overdose of DXM can also produce confusion, disorientation, motor impairment, blurred vision, nausea, rapid or irregular heartbeat, high blood pressure, and loss of consciousness.

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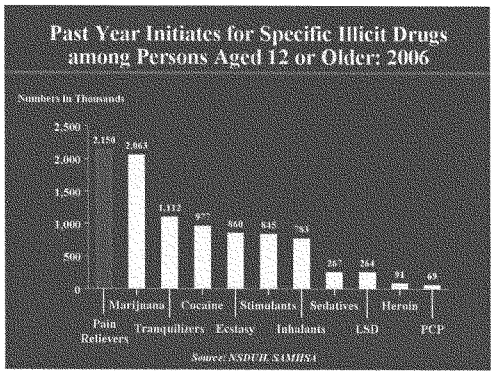
What is the scope of the prescription drug problem in this country?



In 2006, 2.2 million persons aged 12 and over initiated abuse of pain relievers in the past year.

Several indicators show that prescription drug abuse is a significant problem in the United States. According to the National Survey on Drug Use and Health (NSDUH), conducted by HHS's Substance Abuse and Mental Health Services Administration (SAMHSA), in 2006 approximately 7 million persons 12 and older took a psychotherapeutic drug for non-medical purposes in the 30 days before the survey. Most reported abusing opiate pain relievers in particular. In fact, 2.2 million persons aged 12 and over initiated abuse of pain relievers in the past year (see figure). Young adults (ages 18-25) by far showed the greatest use overall and the largest increases in past month, past year, and lifetime use between 2002 and 2006, compared to all other age groups (NSDUH, 2007). Still, even by the time they graduate from high school, roughly a quarter of 12th graders report having abused a prescription drug (MTF, 2007). Other significant indicators of the prescription drug problem include the following:

- In 2006, more than half a million adolescents aged 12-17 used stimulants nonmedically in the past year (NSDUH, 2007).
- Although abuse of sedatives decreased among high school seniors between 2005 and 2007, it is still near peak levels, at over 6 percent among this group (MTF, 2007).
- Nearly 6 percent of 12th graders reported abusing cough medicine to get high in 2007 (MTF, 2007).
- Data on drug-related emergency department visits that involved prescription opioids show a 153 percent increase from 1995–2002, from 42,857 to 108,320 (SAMHSA's Drug Abuse Warning Network, 2004).
- Treatment admissions for opiates other than heroin surged from 16,121 in 1995 to 67,887 in 2005, a 321 percent increase (SAMHSA's Treatment Episode Data Set, 1995–2005).
- Prescribed pain medications are driving the upward trend in drug poisoning mortality. The number of deaths involving prescription opioid analgesics increased 160 percent in just 5 years from 1999 to 2004. By 2004, opioid painkiller abuse deaths outnumbered

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total deaths involving heroin and cocaine (HHS's Centers for Disease Control and Prevention, 2006).

What factors are driving abuse of prescription drugs?

The far-ranging scope of prescription drug abuse in this country stems not only from the greater prescribing of medications, but also from misperceptions of their safety. For example, many students, and even some parents, see nothing wrong in the abuse of stimulants to improve cognitive function and academic performance. In fact, being in college may even be a risk factor for greater use of amphetamines or Ritalin nonmedically, with reports of students taking pills before tests and of those with prescribed medications being approached to divert them to others. Pain relievers show a similar link with regard to access. Evidence suggests that parents sometimes provide their children with prescription medications not prescribed by a physician for the child to relieve their discomfort.[3] According to the 2006 NSDUH, 55.7 percent of those 12 and older who misused pain relievers said they received their medications from a friend or family member, the vast majority of whom had gotten the drugs from just one doctor. Only 3.9 percent cited obtaining these drugs from a drug dealer or stranger, and only 0.1 percent cited an internet purchase. Notably, the leading reason for the abuse is to relieve pain, although other top motives include intent to get high and experimentation.

Similar motivations characterize younger groups, with high school students reporting that they primarily abuse prescription drugs for the medications' intended purpose, albeit without a prescription. Using these medications without a prescription or in ways other than prescribed poses multiple risks, including dangerous interactions with other medications, accidental poisoning, and risk of addiction.

Nonmedical use among children and adolescents is particularly troublesome, given that adolescence is the period of greatest risk not only for drug experimentation but also for developing addiction. At this stage, the brain is still developing and exposure to drugs could interfere with these carefully orchestrated developmental changes. Today we know that the last part of the brain to fully mature is the prefrontal cortex, a region that governs judgment and decision-making functions. This may help explain why teens are prone to risk-taking and to experimentation with alcohol and other drugs.

Research also shows that adolescents who abuse prescription drugs are twice as likely to have engaged in delinquent behavior and nearly three times as likely to have experienced an episode of major depression compared to teens who did not abuse prescription medications over the past year. Finally, several studies link the illicit use of prescription drugs with increased rates of cigarette smoking, heavy drinking, and marijuana and other illicit drug use in adolescents and young adults in the U.S.

Older adults represent another area for particular concern. Although this group currently comprises just 13 percent of the U.S. population, they receive approximately one-third of all

[3] Boyd et al. Medical and nonmedical use of prescription pain medication by youth in a Detroit-area public school district. Drug and Alchol Dependence 81:37-45, 2006.

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medications prescribed in the Nation. In a culture in which medications are considered a "quick fix" for whatever ails you, combined with the greater rates of lifetime drug abuse among the "baby boom" generation as compared to those in the current older generation relative to its size, it is possible that the number of persons aged 50 or older abusing prescription drugs could increase 190 percent over the next two decades, from 911,000 in 2001 to almost 2.7 million in 2020.[4] Because older adults also experience higher rates of other illness as well as normal changes in drug metabolism, it makes sense that even moderate abuse or unintentional misuse of prescription drugs by elderly persons could lead to more severe health consequences. Therefore, physicians need to be aware of the possibility of abuse and to discuss the health implications with their patients.

What is NIDA doing about it?

Recognizing the dangerous trend of prescription drug abuse as well as the need to promote additional research on the subject and to inform the public, physicians, pharmacists, and others, NIDA first launched its prescription drug abuse public health initiative in 2001. Through NIDA's support of surveillance instruments, including our Community Epidemiology Work Group and the Monitoring the Future survey, we continuously monitor trends in all forms of drug abuse, including the abuse of prescribed medications. In addition, NIDA and ONDCP are co-sponsoring an initiative on designing appropriate questions for screening and brief interventions for prescription drug abuse. Identifying trends as soon as they begin to surface in the population helps NIDA continue to lead the effort to surmount increasing abuse through a multi-pronged strategy intended to complement and expand our already robust portfolio of basic, preclinical, and clinical research and educational and outreach initiatives targeting the prescription drug phenomenon.

Targeted research initiatives. Although opioid medications effectively treat pain, their addiction risk presents a dilemma for healthcare providers who seek to relieve suffering while preventing drug abuse and addiction. Little is yet known about the risk for addiction among those being treated for chronic pain, or how basic pain mechanisms interact with prescription opioids to influence addiction potential. Therefore, NIDA recently launched a research 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 against opioid abuse and addiction. Funded grants cover clinical neurobiology, genetics, molecular biology, prevention, treatment, and services research. This type of information will help develop screening and diagnostic tools that physicians can use to assess the potential for prescription drug abuse in their patients. Because opioid medications are prescribed for all ages and populations, NIDA is also encouraging research that assesses the effects of prescription opioid abuse by pregnant women, children, and adolescents, and how it might increase the lifetime risk of substance abuse and addiction.

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[4] Colliver JD, Compton WM, Grroerer JC, Condon, T. Projecting drug use among aging baby boomers in 2020. Ann Epidemiol. 2006 Apr;16(4):257-65.

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Another important initiative pertains to the development of new approaches to treat pain, which reduce the potential for abuse. For example, compounds are being developed that act on a combination of two distinct opioid receptors (mu and delta), preclinical studies showing them to induce strong analgesia without producing tolerance or dependence. Researchers are also getting closer to developing a new generation of non–opioid-based medications for pain that would circumvent the brain reward pathways, thereby greatly reducing abuse potential. Included are compounds that work through a cannabinoid receptor subtype located primarily in the peripheral nervous system. NIDA is also exploring the use of "neurofeedback," where patients learn to regulate neural activity in specific brain regions by getting pictorial representations from the activity in those areas fed back to them in real-time. This technique has shown promising results for altering the perception of pain in healthy adults and chronic pain patients and could even evolve into a powerful psychotherapeutic intervention capable of rescuing the circuits and behaviors impaired by addiction.

NIDA is also leading efforts in the treatment of addiction to prescription pain relievers. Our Clinical Trials Network is sponsoring the first large-scale, multi-site national study on the treatment of addiction to prescription pain medication, testing the effectiveness of buprenorphine/naloxone, a medication used in the treatment of heroin addiction, along with different models of drug counseling.

Education and Outreach. Education is a critical component of any effort to curb the abuse of prescription medications and must target every segment of society. For example, NIDA is advancing addiction awareness, prevention, and treatment in primary care practices, including the diagnosis of prescription drug abuse, having established four Centers of Excellence for Physician Information. Intended to serve as national models, the Centers will target physicians-in-training, including medical students and resident physicians in primary care specialties (e.g., internal medicine, family practice, and pediatrics). In a more general vein, we will also continue our close collaborations with the Office of National Drug Control Policy, SAMHSA, and other Federal agencies, as well as professional associations with a strong interest in preserving public health. NIDA recently sponsored a 2-day meeting in conjunction with the American Medical Association and the NIH Pain Consortium (an NIH initiative established to enhance pain research and promote collaboration among researchers across the many NIH Institutes and Centers that have programs and activities addressing pain), where more than 500 medical professionals, scientific researchers, and interested members of the public had a chance to dialogue about the problems of prescription opioid abuse and to learn about new areas of research.

Prevention strategies. Because prescription drugs are safe and effective when used properly and are broadly marketed to the public, the notion that they are also harmful and addictive when abused can be a difficult one to convey. Thus, we need focused research to discover targeted communication strategies that effectively address this problem. Reaching this goal may be significantly more complex and nuanced than developing and deploying effective programs for the prevention of abuse of illicit drugs, but good prevention messages based on scientific evidence will be difficult to ignore.

Conclusion

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In conclusion, it is hardly surprising that the availability of more, new, better, and safer psychotherapeutics has been followed by a huge upswing in the prevalence of their non-medical use and abuse by varied populations. We should be seriously concerned: for although prescription drugs can be powerful allies, they also pose serious health risks related to their abuse, which can lead to addiction and to death. It will be a question of balance, difficult to achieve, so that people suffering from chronic pain, ADHD, or anxiety can get the relief they need while minimizing the potential for abuse.

Consistent with one of NIDA's most important goals, our response has been framed by our commitment to translate what we know from research to help the public better understand drug abuse and addiction, and to develop more effective strategies for their prevention and treatment.

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

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"Generation Rx: The Abuse of Prescription and Over-the-Counter Drugs" "
Senate Judiciary Committee
Subcommittee on Crime and Drugs
DATE: March 12, 2008
TIME: 02:00 PM
ROOM: Dirksen-226

Senator Joseph R. Biden Jr.

Dear Mr. Chairman,

Thank you for accepting my testimony on the subject before your committee today. As the president of the Pain Relief Network, the nation's leading advocacy organization for the promotion of medical pain management, it is my duty to inform you that our nation's increasing focus on legal medications as a matter of law enforcement concern is costing vulnerable Americans their lives.

Opioid pain medications have been a Godsend to man for over two thousand years. They are as vital to the treatment of pain as insulin is to the treatment of diabetes. But now, in America under the Bush Administration and its "War on Prescription Drug Abuse", American men and women, children, babies, and veterans are unable to access effective dosages of these medications, the only medications that actually provide relief. Under the guise of working to protect the public health, the Federal bureaucracy is criminalizing the medical use of controlled substances, even though the structural premise of the Controlled Substances Act is that medical practice and its employment of opioids in the treatment of pain will be untouched by Federal police interference. So what you have, Mr. Chairman is a press and legislative campaign on the part of the drug war bureaucracy to expand its purview into the area of legal medications, an area where they simply have no legitimate business.

All across the country, medical boards and Federal police are summarily suspending the licenses of doctors who treat pain with Controlled Substances. At the moment, Pain Relief Network is actively involved in a Federal criminal case in Wichita, Kansas, where a pain-treating doctor and his wife have been jailed without bond, have had all their assets seized, and have been smeared in the press. With a win-at-all-costs imperative motivating the prosecutor's behavior, the thousand or so patients of the clinic run by the doctor have been thrown to the curb, forced to fend for themselves in a world polluted by a century-old propaganda campaign that furthers the interests of criminals and law enforcement and no one else. Shut out of emergency rooms, viewed suspiciously by the medical community at large, patients who require Controlled Substances for the management of their illness have become a hunted minority. Spied on by NASPER computers, drug-tested by their doctors and hospital personnel, and referred to as "drug addicts" by anyone seeking to deny them care or reimbursement, patients in pain and others who rely on Controlled Substances have been rendered a suspect class by virtue of our nation's prohibition statutes.

The government officials who will speak at the hearing will talk about compassion and

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the scourge of prescription drug abuse, but what they will be doing is delivering a message of fear and intimidation to the vulnerable patients and their families. And as has been a tried and true method of gaining government power, where limits should be enforced, these government employees will attempt to shift the focus away from the humanitarian and public health disaster resulting from their misbegotten policies, and focus your mind, and the mind of the public, on "stamping out addiction" – as if such a thing were even possible.

Patients in pain and others who rely on Controlled Substances are being destroyed in this country every day, and yet these officials, who purport to care so much about doing the right thing, refuse to acknowledge that this is, in fact, what is going on. When medically ill people arrive at emergency rooms in desperate need of actual medication, they are instead left in withdrawal and referred to addiction treatment facilities. And indeed the terror has spread, for we hear every day that children of patients of the doctors targeted by law enforcement are being refused care by emergency rooms. So the stigma is not confined to the Controlled Substances themselves, but has spread to the human beings and their families who were unlucky enough to have been part of a targeted practice.

While we at Pain Relief Network sympathize with the plight of those who find themselves addicted to prescription medications, we have to bring the larger and far more serious problem to your committee's attention. It is unfortunate that Pain Relief Network was not invited to represent the patients at this hearing, and so the public will instead be treated to a kind of government fear show that seeks merely to distract attention away from the government's astonishingly brutal and thoughtless campaign.

Siobhan Reynolds
President
Founder
Pain Relief Network
Painreliefnetwork.org

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In 2005 Methadone is indicated in over 4700 deaths nationwide and this number is underestimated due to an error in ICD10 coding and non uniform procedures in reporting and determining causes of death. Methadone is killing more people than any other prescription drug, killing 2 people for every 100 exposed. The American Journal of Medicine just released new research stating Methadone kills at therapeutic levels and there is a risk of sudden cardiac death. Please help to stop this epidemic and protect the American public from these dangerous drugs that kill so many. These are not drugs that are being smuggled into this country or manufactured in someones kitchen ...they are controlled drugs put on our streets by physicians and clinics and into the hands of victims by so called legitimate and stable patients.

On June 24th 2006 I lost my fiancé (Ron) to this deadly drug prescribed by a physician with a combination of other medications that acted as additives to the Methadone. Ron was a professional Jai Alai player at Hamilton Downs Jail Alai in Jasper, FL. He had knee surgery and became addicted to the percocet he was prescribed. He checked himself into Greenleaf Center in Valdosta, GA for detoxification. Upon entering the facility he was drug tested and did not come up positive for opiates (he had stopped taking the percocet 4 days before entering the facility). "Dr." Nitin Patel prescribed him 60 mg of Methadone for addiction, valium, Klonopin, and restoril (all CNS depressants). "Dr." Patel is NOT licensed to prescribed Methadone for addiction treatment and neither is Greenleaf Center. On the fourth day in detox he died sometime between 2am and 1pm in the afternoon (he was never checked on in all of those hours). The night before he died he was complaining of migraines and vomiting, apparently the staff thought he was still experiencing withdrawals and was not concerned about these symptoms. The symptoms of methadone toxicity mimic withdrawal symptoms physicians and staff must be very cognizant of the complex properties and metabolization of methadone. There were many errors made in my fiancé's death including the fact that he was given numerous amounts of additive medications such as benzodiazepines. He had only been taking percocet for about 4 months and according to the DSM IV he wouldn't be an appropriate candidate methadone maintenance treatment. I'm not sure if Ron was given methadone for the sole purpose for detoxification from opiates or if it was a combination of pain relief associated with numerous surgeries and opiate addiction. Methadone is difficult to properly dose no matter what reason it's being used for and primarily relies on the patient's indications of how they feel (assumedly they are being monitored). There are ways to make the administration of methadone safer, it's just a matter of putting the focus on this drug and the deadly consequences when administered incorrectly or not monitored. Ron was 32 years old and has 2 children from a previous marriage that now do not have a father.

Methadone is now the #2 Killer Drug in the U.S. This is a legal drug that has been thought to be safe for the past 40 years. Only recently when its use became approved for pain management patients has the cardio toxic risks emerged. Previously methadone has been used exclusively for replacement therapy for heroin patients and death was thought to be an effect of the accumulation of many years of drug abuse. With the surge in pain medication misuse and abuse more patients are being referred to methadone clinics and physicians treating pain who believe the myth that methadone is safer or non addictive because of it's use with weaning addicts from heroin. Methadone is more addictive then

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any other pain medication including heroin and because of it's extremely long half life, cardio toxic risks, numerous fatal drug interactions, dosages based on tolerance, and small margin of error. Up until Nov 2006 the government and pharmaceutical companies have been suppressing the numerous health and fatality risks related to methadone.

there are between 800,000 & 900,000 (some stats give diff numbers) heroin addicts in the U.S and 1,881 people died from heroin in the U.S. in 2004.

there are 200,000 people on methadone for drug treatment and I don't have the number of people on it for pain but even if we double the 200,000 and assume it's 400,000 total people on methadone there were 3,849 deaths in 2004

It looks like the "gold standard" is killing more then the drug its supposed to save people from!!!!

Every day 10.9 people die from Methadone (according to 2004 stats, not including car accident deaths caused by drivers under the influence of Methadone)

We (the families of methadone victims) are requesting new laws surrounding who can prescribe Methadone, clinic rules and regulations as well as stiffer penalties for those caught selling their take home doses. The whole methadone maintenance system needs an overhauling. We cannot continue to allow a legal medication to be killing more people then the illegal drugs. Our government cannot be allowed to use tax dollars to fund their legal drug dealing operations.

We are asking government agencies to enact stricter guidelines in prescribing methadone for any reason. It must be mandatory that all doctors be certified and trained in the pharmacology of methadone; inpatient stays must be required during induction to methadone; all staff be extensively trained in monitoring methadone patients for symptoms of toxicity. Clinic patients should be tested weekly for legal and illegal drugs that are taken with methadone to get " high" or experience "euphoria" such as benzodiazepines, alcohol, cocaine, heroin, marijuana etc... and face severe consequences or mandatory detoxification from the methadone program after 3 dirty urines. Selling of take home doses must result in termination from methadone program permanently throughout the U.S. When presenting inebriated at clinic, clinic should also document such activity as well as prevent client from driving. Take home doses for all patients receiving methadone should be eliminated thus preventing the risk of diversion or precautions such as pill safe should be implemented. http://www.thepillsafe.com/

Current statistics show that nearly 4000 people a year die from methadone. These deaths are mostly happening to pain management and detoxification patients' wit hi n the first 10 days of taking initial dose. Most of these deaths are related to methadone prescribed with other medications that react as additives with the methadone. Diversion of methadone is a serious problem because it lands t hi s most deadly drug on streets. Statistics also state that methadone is contributing to more deaths nationwide then heroin

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and only second to cocaine deaths.

The potential of abuse, diversion, and overdose to new patients being prescribed methadone is overwhelming. The unique properties of methadone, it's long half life, and it's negative interaction with numerous drugs make it an optimal choice as a last result treatment for chronic pain and addiction.

Thank you for taking the time to read this letter.

Sincerely

Melissa Zuppardi
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