S. HRG. 110–472

ROGUE ONLINE PHARMACIES: THE GROWING PROBLEM OF INTERNET DRUG TRAFFICKING

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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CONTENTS

STATEMENTS OF COMMITTEE MEMBERS

	Page
Feinstein, Hon. Dianne, a U.S. Senator from the State of California	15
Leahy, Hon. Patrick J., a U.S. Senator from the State of Vermont	1
prepared statement	161
Sessions, Hon. Jeff, a U.S. Senator from the State of Alabama	3
Specter, Hon. Arlen, a U.S. Senator from the State of Pennsylvania	2

WITNESSES

Califano, Joseph A., Jr., Chairman and President, The National Center on Addiction and Substance Abuse at Columbia University, and former Secretary, Department of Health, Education, and Welfare, New York, New York	7
Haight, Francine H., Founder of RYAN's Cause, Laguna Niguel, California	5
Heymann, Philip B., James Barr Ames Professor of Law, Harvard Law School, and Former Deputy U.S. Attorney General, Cambridge, Massachusetts	10
McLellan, A. Thomas, Chief Executive Officer, Treatment Research Institute, Philadelphia, Pennsylvania, statement	14
Rannazzisi, Joseph T., Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice, Washington, D.C., statement	13

QUESTIONS AND ANSWERS

Responses of Joseph A. Califano to questions submitted by Senators Leahy and Specter	27
Responses of Philip B. Heymann to questions submitted by Senators Leahy and Specter	38
Responses of A. Thomas McLellan to questions submitted by Senators Leahy and Specter	45
Responses of Joseph Rannazzisi to questions submitted by Senators Leahy, Durbin and Specter	51

SUBMISSIONS FOR THE RECORD

American Pharmacists Association, Washington, D.C., statement	85
Califano, Joseph A., Jr., Chairman and President, The National Center on Addiction and Substance Abuse at Columbia University, and former Secretary, Department of Health, Education, and Welfare, New York, New York, statement and attachment	89
Federation of State Medical Boards, James N. Thompson, M.D., President and Chief Executive Office, Dallas, Texas, statement	111
Haight, Francine H., Founder of RYAN's Cause, Laguna Niguel, California, statement	116
Heymann, Philip B., James Barr Ames Professor of Law, Harvard Law School, and former Deputy Attorney General, Cambridge, Massachusetts, statement and attachments	122
Marshall, Jon, Kentucky State Police, National Narcotic Officer's Associations Coalition, Frankfort, Kentucky, statement	163

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00003 Fmt 5904 Sfmt 5904 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

Page

McLellan, A. Thomas, Chief Executive Officer, Treatment Research Institute, Philadelphia, Pennsylvania, statement 169
National Association of Chain Drug Stores, Alexandria, Virginia, statement ... 173
Rannazzisi, Joseph T., Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice, Washington, D.C., statement 178

ROGUE ONLINE PHARMACIES: THE GROWING PROBLEM OF INTERNET DRUG TRAFFICKING

WEDNESDAY, MAY 16, 2007

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 10:07 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Feinstein, Specter, and Sessions.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Good morning. Today the Committee will be holding an important hearing on the growing problem of rogue online pharmacies that illegally traffic in highly addictive painkillers and other controlled substances.

You know, in many ways, the Internet has made our lives better. I have been one of its biggest proponents for those reasons. It removes the historic constraints from geography; it provides access to information and knowledge that might otherwise remain unavailable, especially to people like myself who live in rural areas. Distance learning, access to medical knowledge at the finest hospitals, and increased commercial competition—these are all aspects of the Internet that are important. Vermont businesses sell Vermont products throughout the Nation and around the world through the Internet. At the same time, the Internet has enabled Vermonters, and others, better access to convenient and more affordable medicine, which should be stressed.

But the online sale of pharmaceuticals presents a more complicated and problematic aspect. Rogue online pharmacies increasingly have become a source for the illegal supply of controlled substances. Dangerous and addictive prescription drugs are too often only a click away without the proper constraints of local doctors and pharmacists.

Controlled drugs, such as pain relievers, tranquilizers, stimulants, and sedatives, can be too easily bought illegally over the Internet. Anyone—including children—can readily obtain dangerous controlled substances from online pharmacies. All they need is access to a computer and a credit card. The check and security provided by our local pharmacists in local pharmacies—those who have served Americans for generations and helped us get well and keep us well—is not always replicated online.

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The 2006 National Survey on Drug Use and Health indicates that almost 6 million people currently misuse prescription drugs and, of them, more than two-thirds 4.4 million people—abuse pain relievers such as OxyContin. Some celebrities have been involved in high-profile cases, but I am more concerned about the fact that people in every state and increasingly from every age group and demographics are affected. When abused, these drugs have enormous potential to cause harm and illness and addiction, and as we are going to hear this morning from one of our witnesses, tragically even death.

American teenagers are always particularly vulnerable to Internet drug trafficking. Among young people, prescription drugs have become the second most abused illegal drug. In fact, if you exclude marijuana, more adults and teens report abusing prescription drugs than all the other illicit drugs combined.

Too many American teenagers mistakenly believe that abusing addictive narcotics is a safe way to get "high."

As we learned just last week, some drug companies have themselves contributed to that dangerous impression by giving consumers misleading information about the addictive qualities of these drugs. Purdue Pharmacies, the maker of the powerful painkiller OxyContin, and three of its corporate executives pled guilty to intentionally misleading the public when it promoted OxyContin as less addictive than narcotics. It is a sad day when pharmaceutical companies act like tobacco companies and mislead the public rather than alerting the public to the risks associated with the use of its products.

We have legislation referred to this Committee that would create potent new tools for law enforcement to prosecute those who illegally sell drugs online and allow State authorities to shut down online pharmacies even before they get started. And I will work with the Senators from California and Alabama and others on these matters.

As the longtime Co-Chair of the Congressional Internet Caucus, I will ask the Caucus to consider the issue of the growing danger that online pharmacies pose to youth.

Internet drug trafficking has presented another challenge for law enforcement. If drug dealers came into our neighborhoods selling these kinds of drugs, Americans would be up in arms.

So I thank our distinguished panel of witnesses for appearing today, and I also especially want to thank Senator Specter for his work in connection with this hearing.

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

Senator Specter?

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman, for scheduling this important hearing. The problem of drug addiction has been with our society for decades. I first saw it in an intense fashion when I was district attorney of Philadelphia four decades ago, and the problem has been increasing in seriousness and is a major problem in our society.

With the Internet and technological advances, we now find that drugs are accessible by the rogue pharmacies, and the problem is one of enormous importance. It came into sharp view in Philadelphia in 2006 when there was a DEA bust of a major Internet drug ring run from Philadelphia by two foreign graduate students at Temple University and 25 co-conspirators who were arrested in four different countries.

It is possible to have legitimate purchase of drugs over the Internet, but there were only 12 such DEA registered pharmacies. Most of the other Internet pharmaceutical sales in the United States are legally suspect. Federal law mandates that there is a prescription before dispensing the drugs, which we all know, but that is avoided. The Center on Addiction and Substance Abuse discovered over 3 years the total number of websites been selling prescription drugs has increased enormously. The regulation of online pharmacies and doctors consists of a very patchwork arrangement so that it is the subject which requires, I do believe, Federal legislation, so I am glad to see such a distinguished panel here today.

We very much appreciate your presence, Mrs. Haight, with the situation that your son, Ryan Thomas Haight, died of an overdose of narcotics he had purchased on the Internet without a prescription.

We have a very distinguished array of experts, and, regrettably, we are not going to have a very extensive array of Senators—not necessarily distinguished even when present, except for Senator Leahy and Senator Sessions. But it is a very, very busy day on Capitol Hill.

I am going to have to excuse myself to return to deliberations which are underway on the immigration issue. We have had more than two dozen meetings of lengthy duration, mostly in excess of 2 hours, where 12 Senators sit still—that is, we sit still; our jaws are not still—as we try to work through an extraordinarily difficult legislative issue.

Then that is compounded by the problem that we are having a series of votes at 10:30, and votes come ahead of everything else. That is our basic paycheck in the United States Senate, what our voting record is. But I have staff here who will be following the proceedings very closely, and I am sorry to miss the testimony, because this is an extraordinarily distinguished panel.

Chairman LEAHY. During this, as the votes start, we will stop and start. Some of you are familiar with that.

Senator Sessions has worked hard on this. Jeff, did you want to say anything?

Senator SESSIONS. If you do not mind, Mr. Chairman.

Chairman LEAHY. Go ahead.

STATEMENT OF HON. JEFF SESSIONS, A U.S. SENATOR FROM THE STATE OF ALABAMA

Senator SESSIONS. I will not be long, because we do have a distinguished panel and we want to hear from them. But I am glad that with your leadership and, really, with Senator Specter last year, we have had a good chance to move this important legislation forward. I am convinced that it is good legislation. As a former Federal prosecutor who prosecuted a great many drug cases, it is

amazing to me that with the regulations we have in so many different areas that even a teenager with very little effort can order drugs, controlled substances, off the Internet. It just undermines this entire system that we have.

I remember after I ceased being United States Attorney representing an individual who was a young person that had a knee injury, started taking pain pills. He was going all over town. There was nothing he would not do. He was president of his class. But he just had to have these drugs. The addiction is very powerful. Some people think it is because it is a prescription drug, the addiction is not as powerful or cocaine or some of the other drugs. It is a powerful addiction, and people do things that destroy them, and they cannot seem to stop. And being able to obtain large amounts of drugs off the Internet allows that addiction to continue and delays the intervention that can be life saving.

The bill that Senator Feinstein and I have introduced—and I certainly appreciate her leadership. She understands this issue very well. She has had a personal experience with people who have tragic losses as a result of prescription drug abuse through the Internet, and it is a pleasure to work with her.

I was interested to note and am pleased to note that in the Washington Times today, there is an op-ed by John Horton, a former Assistant Deputy Director of the White House Drug Policy Office, and Kristi Remington, a former Deputy Assistant Attorney General in the Justice Department, which endorses the legislation Senator Feinstein and I have offered. And they note in their article that, "The Online Pharmacy Protection Act, which will be considered today by the Judiciary Committee, brings the law regulating the sale of controlled substances into the Internet age and is a vitally important tool in our Nation's anti-drug efforts. It should be sent to the full Senate for passage." They note that, "Ms. Feinstein and Senator Sessions have ensured the bill takes into account legitimate issues concerning telemedicine and the practice of covering practitioners, but in each case, a physician who is familiar with the patient, can determine whether medication is truly necessary or if the person is possibly acquiring the prescription drug because of an addiction."

So thank you, Mr. Chairman, and I would offer this article for the record.

Chairman LEAHY. Thank you. It will be included in the record.

Would you please stand, all of you, and raise your right hand? Do you solemnly swear that the testimony you will give in this matter will be the truth, the whole truth, and nothing but the truth, so help you God?

Ms. HAIGHT. I do.

Mr. RANNAZZISI. I do.

Mr. CALIFANO. I do.

Mr. HEYMANN. I do.

Mr. MCLELLAN. I do.

Chairman LEAHY. We will begin with Ms. Francine Haight. I have already chatted with her briefly and, again, I commend you for your courage in being here.

She is the founder of RYAN's Cause, Reaching Youths Abusing Narcotics. It is a nonprofit organization dedicated to educating par-

ents, families, and communities on issues concerning the Internet and drug abuse. Ms. Haight founded RYAN's Cause after her 18-year-old son, Ryan Thomas Haight, tragically died from an overdose of prescription drugs which he had purchased through the Internet.

Ms. Haight has told her story around the country to help educate and bring public awareness to the danger of sales of drugs on the Internet. Her son's story was mentioned in the recently aired HBO series "Addiction." In June of last year, Ms. Haight was a sponsor to the first national candlelight vigil out at DEA headquarters in Arlington, Virginia, for those that died from the drugs.

Ms. Haight, I know this is not an easy time for you, but I just want you to know how much we appreciate the fact you have come here from California to speak, and please go ahead.

STATEMENT OF FRANCINE H. HAIGHT, FOUNDER OF RYAN'S CAUSE, LAGUNA NIGUEL, CALIFORNIA

Ms. HAIGHT. Good morning. My name is Francine Haight, and thank you for inviting me to testify at this hearing about a very important topic that tugs at my heartstrings every day. Many of the speakers here today will give you statistics and numbers, but I am here to put a face to those numbers. And I am very sad that today that face is my son, Ryan Thomas Haight. Unfortunately, he was a victim of illegal sales of pharmaceuticals through the Internet.

Ryan was born on December 28, 1982, and died on February 12, 2001, from an overdose of prescription drugs he had purchased on the Internet. He was only 17 when he purchased these drugs, and he was only 18 when he died.

He was an incredible boy. From the time he was little, I always believed that he would make a difference in this world. He was intelligent and excelled in school, was an A student and maintained a 4.0 or above during his years in high school. He looked forward to going to college.

He was athletic, loved the thrill of competition, played Open Junior Tennis tournaments, and went on to play varsity tennis for Grossmont High School in La Mesa, California. He loved to ski, snow ski, water ski, kneeboard, and he attempted all sports with great enthusiasm.

But Ryan also loved using the computer. He was thrilled to find out that he could chat online, that he could receive and send e-mails, and that he learn and talk about educational and current events. He learned to surf the Internet. It was a perfect place for him to use for his papers in school or to seek information he was curious about. He used the computer to play games, and he enjoyed trading baseball cards on eBay. But on February 12, 2001, that all stopped.

On February 12, 2001, I found Ryan in his bed, lifeless. I tried to resuscitate him, but could not bring him back. Ryan had died. And I was in shock. Just the night before, we had dinner together after he came home from working at a nearby retail store. That night I had kissed him and said good night, and he said, "I love you, Mom." Those were the last words I would hear from him. Ryan died from an overdose of the prescription drug Vicodin. He

also had a small amount of Valium and morphine. And I thought, How? How did he get these drugs? After one of his friends told me that he got them on the Internet, we gave our computer to the DEA to investigate. And through their investigation, they found how Ryan had ordered the drugs.

Ryan had made up a story. He had said he was 21. He said he had been in a car accident and had back pain, and he made up a doctor's name, Dr. Thomas, which happened to be his middle name. Dr. Robert Ogle, whom Ryan never saw and was never examined by, prescribed them, and an Internet pharmacy, Clayton Fuchs of Mainstreet Pharmacy, delivered them to our home. I was in shock. I thought, How could this be possible? I am a registered nurse; Ryan's father is a physician. We know that all controlled substances have to be accounted for. We count each and every drug that we give when we administer it to a patient. They are under lock and key. How could he get these off the Internet so easily? At a time when we were worried about our children being exposed to pornography and predators, marijuana and alcohol, we did not know that drug dealers were in our own family room.

After a long investigation and trial, Dr. Robert Ogle and Clayton Fuchs, who together made millions by their drug dealings, were prosecuted by the United States Attorney in Dallas and are now in Federal prison. I attended the sentencing of Clayton Fuchs, and although it does give me some peace that justice was served, it does not bring Ryan back. I am still shocked at the ease and availability of buying controlled substances on the Internet. I receive e-mails every day from 13-year-old children to adults that they are just overwhelmed by the problems that they see happening from drugs being sold.

Over the last few months, Ryan's story has been told in a documentary called "Online Nightmares," and it was produced by E Entertainment. It has aired about 15 times, and since then the mail that I get is just overwhelming in my mailbox. This is an ongoing problem.

After Ryan died, it took me almost 3 years to get enough strength to do what I am doing, and I started RYAN's Cause—Reaching Youths Abusing Narcotics. And I have done a lot of news and gone out, and I just hope that it will raise awareness of this growing problem among our teens in hopes to prevent other families from suffering such a devastating loss.

I am here today because I want to help fight this war against drugs and too many people are dying.

Congress needs to attempt to counter the growing trend of prescription drug abuse by passing a bill, the Ryan Haight Internet Pharmacy Consumer Protection Act or perhaps by adding Ryan's bill as a noncontroversial amendment to the prescription drug user fee which governs FDA issues and prescription drug review and addresses the safety issue incumbent in drug sales.

I am a parent that belongs to a club that I never wanted to join. I am an ordinary person who could be your neighbor, your coworker, or member of your house of worship. But drugs took my son from me, and some days the grief is still unbearable. Drug abuse is an equal opportunity killer. It is not confined to one kind of neighborhood, one socioeconomic group, or one kind of child.

Ryan was the boy next door. We need to do everything we can to protect our children. Tighter regulations on the sale of controlled substances on the Internet will not totally solve the drug problem, but I guarantee you it will help and it is a good place to start.

Thank you for allowing me to speak and for listening to this very important issue. Ryan continues to make a difference. I just did not know he would be so far away.

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

Chairman LEAHY. Thank you very much, Ms. Haight. We were talking about your testimony last night at home. My wife is a registered nurse, and she is struck by what you said about having to account for all narcotics, and she remembers how careful those are checked and double-checked. You are absolutely right.

Joseph Califano is the Founding Chairman and President of the National Center on Addiction and Substance Abuse, CASA. It is an independent, nonprofit think tank affiliated with Columbia University. He is an adjunct professor of public health at Columbia University's Medical School and School of Public Health and a member of the Institute of Medicine of the National Academy of Sciences. He has extensive experience in Government. He joined the Kennedy administration in 1961, served as general counsel of the Army and Special Assistant to the Secretary and Deputy Secretary of Defense. From 1965 to 1969, he served as Special Assistant for Domestic Affairs to President Lyndon Johnson. From 1977 to 1979, he was Secretary of Health, Education, and Welfare in the Carter administration. He is a graduate of Holy Cross and Harvard University Law School.

Mr. Califano, thank you for being here. Please go ahead.

STATEMENT OF JOSEPH A. CALIFANO, JR., CHAIRMAN AND PRESIDENT, THE NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA UNIVERSITY, AND FORMER SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, NEW YORK, NEW YORK

Mr. CALIFANO. Thank you, Mr. Chairman, for the invitation to testify today. The National Center on Addiction and Substance Abuse at Columbia University has studied the Nation's problem of controlled prescription drug abuse and has documented for 4 consecutive years the Internet availability of these drugs.

In 2005, CASA released its landmark report, "Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S." This report revealed that our Nation is in the throes of a growing epidemic of controlled prescription drug abuse involving opioids like OxyContin and Vicodin, depressants like Valium and Xanax, and stimulants like Ritalin and Adderall.

From 1992 to 2002, prescriptions written for such controlled drugs increased more than 150 percent, 12 times the rate of increase in our population and almost 3 times the rate of increase in prescriptions written for all other drugs.

Mirroring this increase in prescriptions has been an increase in the abuse of these drugs. From 1992 to 2003, the overall number of Americans abusing controlled prescription drugs rose 94 percent, 7 times faster than the increase in the U.S. population. The num-

ber of 12- to 17-year-olds who abused controlled prescription drugs jumped 212 percent, more than triple.

In 2003, the number of Americans who abused controlled prescription drugs exceeded as you said, Mr. Chairman, the combined number abusing cocaine and all other illegal drugs except marijuana, and they are on course to exceed abuse of marijuana on the track they are on. Abuse of controlled prescription drugs has grown at a rate twice that of marijuana abuse, 5 times that of cocaine abuse, 60 times that of heroin abuse.

Particularly troubling are the implications for our children. From 1992 to 2002, new abuse of prescription opioids among 12- to 17-year-olds was up an astounding 542 percent, more than 4 times the rate of increase among adults. In 2003, nearly 1 in 10 12- to 17-year-olds abused at least one controlled prescription drug; for 83 percent of them, that drug was an opioid. Teens who abuse controlled prescription drugs are twice as likely to use alcohol, 5 times likelier to use marijuana, 12 times likelier to use heroin, 15 times likelier to use Ecstasy, and 21 times likelier to use cocaine, compared to teens who do not abuse such drugs.

In 2005, 15.2 million Americans abused these drugs including more than 2 million teens. The explosion in the prescription of addictive opioids, depressants and stimulants has, for many children, made their parents' medicine cabinet a greater threat than the illegal street drug dealer. But, perhaps the most wide open substance supermarket in the world is the Internet. The Internet has become a pharmaceutical candy store, its shelves stacked with an array of addictive prescription drugs offering a high to any kid with a credit card at the click of a mouse.

For 4 years now, at CASA, in collaboration with Beau Deitl & Associates, we have been tracking online access to controlled prescription drugs. In the first quarter of each year, we have devoted 210 hours to documenting the number of Internet sites advertising and dispensing controlled drugs. These findings are a snapshot of availability at a given point in time and show trends from year to year. They do not capture the total number of sites advertising or selling controlled prescription drugs online, which may be many times the numbers I am using now.

Today CASA is releasing the fourth in its annual series of reports entitled "'You've Got Drugs!' IV: Prescription Drug Pushers on the Internet." Here are the report's disturbing findings. From 2006 to 2007, there has been a 70-percent increase in the number of sites advertising or selling controlled prescription drugs over the Internet, from 342 to 581; a 135-percent increase in the number of sites advertising controlled prescription drugs; a 7-percent increase in the number of sites selling controlled prescription drugs. Eighty-four percent of the sites selling controlled prescription drugs do not require a prescription from the patient's physician, and most of the remaining 16 percent of sites that ask for a prescription simply ask that it be faxed, allowing a customer to forge it or use the same prescription many times to load up on these drugs.

There are no controls—no controls—to stop the sale of these drugs to children. Over the 4-year course of our analysis, the number of selling sites has climbed from 154 to 187. Since there are no controls preventing sale of these drugs to children, all a child needs

is a credit card number and access to a computer and "You've Got Drugs!" Efforts to crack down on this illegal trafficking are complicated by outdated Federal law written before the Internet and inadequate State laws.

There is a mechanism in place for certifying Internet pharmacy practice sites. It is the National Association of Boards of Pharmacy, which verifies Internet pharmacy practice sites. However, the process is voluntary. Of the 187 sites found selling in 2007, only two were certified.

The widespread threat to the public health demands that Congress now take action to: clarify Federal law to prohibit the sale or purchase of controlled prescription drugs online without an original prescription issued by a DEA-certified physician based on a physical examination and evaluation; and require certification of online pharmacies to assure that they meet rigorous standards of professional practice.

The Feinstein-Sessions bill is a step in the right direction and an important step. We have a few suggestions to strengthen it that we can discuss with your staff, but we really applaud, Senator Feinstein and Senator Sessions, what you have done in introducing this bill.

The report we are releasing today makes other recommendations that I hope you will consider.

Mr. Chairman, just in closing, substance abuse and addiction—involving prescription drugs, alcohol, nicotine, all of it—is the Nation's most serious domestic problem. It is implicated in most crimes, most killing and crippling illnesses, most domestic violence, most child abuse, most homelessness, poverty, most teen pregnancy, and the wildfire spread of AIDS and other sexually transmitted diseases. I have titled my book on this subject "High Society," and I will give you one simple fact. We Americans are 4 percent of the world's population; we consume two-thirds of the world's illegal drugs.

This problem is all about kids. A kid who gets through age 21 without smoking, using illegal drugs, or abusing prescription drugs or alcohol is virtually certain never to do so. Over the past 12 years, the fastest growing drug abuse among our Nation's children involves prescription drugs. I applaud the work of this Committee to curb the availability of these drugs. We will do anything to help.

We are submitting our report along with my statement for the record, and we really appreciate, Senator Leahy, you and this Committee attending to this incredibly important problem.

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

Chairman LEAHY. Thank you very much, and the report will be part of the record.

Professor Philip Heymann is currently the James Barr Ames Professor of Law at the Harvard University Law School. Professor Heymann has served at high levels in both the State and Justice Departments during the Kennedy, Johnson, Carter, and Clinton administrations, including serving as the Deputy Attorney General for the Justice Department from 1993 to 1994. He served as the Assistant Attorney General in charge of the Criminal Division from 1978 to 1981. He spent a lot of time in this room, I might add. He

was Acting Administrator of the State Department's Bureau of Security and Consular Affairs, Deputy Assistant Secretary of State for the Bureau of International Organizations, and numerous other high-level positions in Government. He was also a former associate prosecutor and consultant on the Watergate Task Force. He also helped establish the Keep Internet and Neighborhoods Safe project and developed proposals to reduce illegal Internet prescription drug sales to youth. He is a graduate of Yale University and Harvard Law School and clerked for former Supreme Court Justice John Harlan.

Professor, the floor is yours.

STATEMENT OF PHILIP B. HEYMANN, JAMES BARR AMES PROFESSOR OF LAW, HARVARD LAW SCHOOL, AND FORMER DEPUTY ATTORNEY GENERAL, CAMBRIDGE, MASSACHUSETTS

Mr. HEYMANN. Thank you very much, Mr. Chairman and members of the Committee.

With Mathea Falco, the Director of Drug Strategies, who is sitting behind me, we assembled a group of people from the major facilitators of this traffic and from the major enforcement agencies. On page 6, we list them in short: Verizon, AOL, AT&T, Earthlink, Microsoft, Comcast, Google, Yahoo!, UBS, Morgan Chase, MasterCard, Visa, Paypal; UPS, DHL, FedEx, the DEA with Joe as their representative, the Department of Justice, and so on.

Because we wanted to address one aspect of this problem—which has been so well described that I am not going to repeat it. We find it of the same size and importance and danger that the others have described. But we saw in it the prospect of a new form of sale of contraband which is, we think, the world of globalization merged with the world of Internet. And we think that is going to change everything, limiting the reach of drug law enforcement no matter how important that may be, too.

The fact of the matter is the Internet service provider may be in the Ukraine, the drugs may be in Somalia, the credit card user—the seller of the drugs, the receiver of the money may be in Turkmenistan. We are dealing with a brand-new world out there, and the aspect of this problem that engaged us was the international aspect—not yet the largest, probably. Most people probably get their prescription narcotics out of their parents medicine cabinet. But it will be the largest, and it will be the future. And we wanted to tackle the future, and we did in six full-day meetings.

Now, the secret, we discovered, was that we could—that this traffic in Internet globalized contraband can only take place with the cooperation of credit card companies, Paypal, Internet service providers, search engines. If you think of it from the beginning, a search engine is out there advertising the sale of the drug. You cannot get to the advertisement—I am sorry. You click on the Google advice, and it will send you to thousands and thousands of responses to the search by OxyContin without prescription. And they will all be selling it without prescription at all. Of course, it is just as bad if they use a phony prescription, but they will not even bother to use a phony prescription. It will be sent in in a brown bag that looks like 2 trillion others coming into the customs

offices in New York, and it will get through. And if it does not get through, the drugs will be replaced.

So what can you do about this? The Judiciary Committee is looking at a brand-new problem, a brand-new dimension of a very old problem—a massive dimension—and it will be the same with everything that can be sold over the Internet, and it will be worldwide.

OK. Here is what you can do. There is no reason why Internet service providers should be putting—they can easily remove from your household Internet connection anybody who is promising to sell OxyContin, Vicodin, any of a list of drugs, without prescription. It is no burden to them. They know how to do that. They are doing it now as to other things, such as pornography. They can do it in a minute. No cost.

Google and Yahoo! and Microsoft can, when somebody puts in, as I did on Mother's Day, "Buy OxyContin without prescription," and got 800,000 responses, including a chat room run by Google where you can talk to friends about where to buy OxyContin without prescription. When anybody searches for OxyContin without prescription, there can be a banner at the top of the Google, Yahoo!, or Microsoft search saying it is illegal to buy this without prescription. That message ought to come right away.

MasterCard, Visa, Paypal, American Express should trace anybody who is offering to use their credit card as a device to pay for the purchase of one of these prescription narcotics without a prescription. They can do that, too. They do it if somebody is misusing their credit card. They do it if someone is cheating on their credit card. They can do it in a minute, no problem.

So why aren't they doing it? In other words, we have powerful local companies, thankfully local, facilitating the sale of powerful narcotics to children over the Internet. They say they have two big problems. One problem is they do not know who they are dealing with. The other problem is that they are worried about legal liability.

With this large group—and without them necessarily all agreeing with all of our recommendations, by a long shot, but generally in the same ballpark—we put together a model bill that would solve those two problems by: No. 1, creating a small, inexpensive but technically sophisticated organization, an Internet monitoring group that would go onto the Internet and see who is advertising the sale of powerful narcotics without a prescription, and notify the Internet service providers, the search engines, the carriers, like Federal Express, and the credit card companies. That would send them all into action, and we would not have to worry about their not being able to know. We can tell them who, if the Congress will create this small unit.

Second of all, they need a safe harbor from liability if they act on the basis of the recommendations of the Internet monitoring group.

With those two things, the only thing that we think is—right now we believe that the finance companies are bound by Treasury regulations to act vigorously to stop the use of credit cards in these sales. We believe that the Internet service providers are serious

about their willingness to do this on their own, but we do not like the idea of not monitoring them and the finance companies.

We, therefore, propose that there be an annual accounting to the Congress of the number of children—we take those figures every year—who are continuing to use narcotics over the Internet and an annual accounting of the cooperation of these large companies in their delivery.

Thank you, and sorry for being over.

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

Chairman LEAHY. That is all right. It is an important subject, and I have allowed time for everybody to go over.

Senator Feinstein is leaving for a vote that has started, and I don't know whether, Senator Sessions, if you want to go. I am going to stay here and ask some questions. I will go to vote. When she comes back, she will reconvene it, or whichever one of us gets back first, we will reconvene it.

Joseph Rannazzisi is the Deputy Assistant Administrator for the Office of Diversion Control at the Drug Enforcement Agency. He is responsible for overseeing and coordinating major diversion investigations, establishing drug production quotas and conducting liaisons with the pharmaceutical industry, international governments, State governments, other Federal agencies, and local law enforcement agencies. He has a degree in pharmacy from Butler University, received his J.D. degree from the Detroit College of Law at Michigan State University. He is a registered pharmacist in the State of Indiana.

Thomas McLellan, Ph.D., is a professor of psychiatry at the University of Pennsylvania and Founder and Executive Director of the Treatment Research Institute in Philadelphia. He has published more than 300 articles and chapters in addition research, recently became the editor-in-chief of the journal Substance Abuse Treatment. Dr. McLellan is well known for his leading role in creating the Addiction Severity Index and the Treatment Services Review, two of the most widely used instruments in the field of substance abuse. His work at TRI is dedicated to reducing the devastating effect of alcohol and other drug abuse on individuals and families. He is a graduate of Colgate, Bryn Mawr College, and Oxford University.

They will be available to answer questions. Their statements will be placed in the record. Under our rules, it did not arrive in time for statements to be given at this hearing.

[The prepared statements of Mr. Rannazzisi and Mr. McLellan appear as submissions for the record.]

Chairman LEAHY. Ms. Haight, if I might—and, again, I emphasize, as both Senator Feinstein and Senator Sessions have said to me, I know this is painful. First, let me compliment you for speaking out. Those of us who can speak out from theoretical knowledge or reading the statistics is one thing. You speak out from personal knowledge. I think that is a far more compelling story. Unfortunately, I believe there are other people that could give the same kind of testimony, as you have discovered.

What is the most important thing young people should know? Assuming somebody is actually watching this, what is the most im-

portant thing they should know about the dangers of purchasing prescription drugs over the Internet?

Ms. HAIGHT. Well, first of all, I think quite a few of the kids today, they are not aware of how prescription drugs are very dangerous and that they can cause death or addiction. And the kids really need to be aware and be educated upon prescription drugs because they are mostly afraid of cocaine or meth and those type of drugs and thinking that they are dangerous. And there has been a lot of education out there about that. But prescription drugs really is kind of the new trend for our youth to be using, and so I think it is really important that they are educated how dangerous these drugs really are.

Also, they need to be educated that some of these drugs on the Internet are not what they are. A lot of them can be counterfeit. They have actually found that some drugs have been laced with heroin. Some drugs are twice the potency of what they say they are because they want them to become addicted. These drug dealers want them to come back and buy.

Chairman LEAHY. Do we change the law then? Do we have to change the law to protect the public from these kinds of online—

Ms. HAIGHT. Yes, and, therefore, we need a law. And these doctors that are writing prescriptions are saying, hey, it is not illegal.

Chairman LEAHY. You would like to see us make it illegal?

Ms. HAIGHT. Absolutely. Absolutely. We need to do everything we can to protect our youth, and adults as well, that are finding themselves in this situation.

Chairman LEAHY. Mr. Rannazzisi, would you agree with that?

Mr. RANNAZZISI. Yes, absolutely. The perception of children, the perception of adults that controlled substances that are pharmaceutical are safe and effective because they are manufactured—or safe because they are manufactured by a drug company is really -it is a misperception that could be deadly. We have seen this over and over again. There was a study done where a large percentage of adolescents showed—basically reported that they thought—their perception was that these drugs were safe to take, where they would rather take those drugs than cocaine or heroin. So that perception is out there. So that is absolutely correct.

Chairman LEAHY. Secretary Califano?

Mr. CALIFANO. I think that what Joe just said is absolutely right. We survey teens every year. We have been surveying 12- to 17-year-olds for 11 years, Mr. Chairman, and it is quite clear that they think these drugs are safer than street drugs. They do not understand that they aren't.

I think it is very important, in addition to law, the kind of legal suggestions that Professor Heymann made, which are very similar to the ones in the CASA report released today to also think parents are very important here. I think parents have really got to understand they are the front line, until we get a law passed, in terms of how their kids use the Internet, what they are using the Internet for. And it is very difficult. It is very difficult, but they—

Chairman LEAHY. Well, and I think there, I think if parents are watching this, this may be an eye opener to them, what is available there. If we have prescriptions to be filled, we go to the same pharmacy. They make it easy. You can call up on a touch-tone phone

or a computer, but it is a pharmacy and it is the same pharmacist, it is with the records. We will get questions asked when we go there, and I am delighted to see it. I mean, they know who I am. They will ask for an ID just the same. And I think this should be done. And a lot of parents are used to that same thing.

I think this may be an eye opener to a lot of parents. You know, we have—going on computers, these kids are pretty smart, and it is pretty easy to hide what they are doing, the chat rooms, the number of chat rooms. The professor raised about on OxyContin, I mean, the back-door way you can go. Professor, I assume you feel we should be changing the law to make this tighter.

Mr. HEYMANN. Mr. Chairman, we believe that the law should be changed and tightened, and certainly the doctors who issue prescriptions without ever seeing the patient should be subject to sanctions of some sort. But we keep seeing the end game as a question of companies spread across the globe dealing highly anonymously with kids in—

Chairman LEAHY. Azerbaijan.

Mr. HEYMANN. And the only way to deal with that is to enlist the cooperation—and I think it will be forthcoming—of the search engines, the Internet service providers, and the financing companies.

Chairman LEAHY. But don't you need something beyond just a banner that says "Caution, this is an illegal″—I mean, you have got to have the site blocked, don't you?

Mr. HEYMANN. That is correct. The banner comes from the search engine. The Internet service provider should block the site at the request of any parents.

Chairman LEAHY. I think it should be blocked, period, I mean, if you are doing it this way.

Mr. HEYMANN. It should be blocked, period. There is some remote First Amendment problems. It is easy, otherwise.

Chairman LEAHY. I think we can handle that part. I yield to nobody in the defense of the First Amendment, but I think there is a way of doing that. I think you are getting very close to yelling "Fire" in a crowded theater here.

Dr. McLellan?

Mr. MCLELLAN. One thing I would like to add is that in a sort of darkly paradoxical way, it is safer to buy drugs over the Internet; at least the drugs are much more dangerous than commonly perceived. But if your choices are to go—I live in Philadelphia—to 52nd and Baltimore and purchase something from a thug versus have it delivered into the comfort and privacy of your home with virtual certainty, it is safer.

So in many ways, it is an enticement to start drug use, and that is something that I think has not been brought out. A lot of policy in this country is considered around starting drugs, like cigarettes and marijuana. There are kids today starting drug abuse with Vicodin, starting drug abuse with OxyContin, because it is easier.

Chairman LEAHY. Thank you. Doctor, I am not trying to cut you off, but I just got handed a note I have 4½ minutes to get to the floor to vote. We will stand in recess until either Senator Feinstein or I come back, and we will pick up where we left off.

[Recess at 10:56 a.m. to 11:04 a.m.]

STATEMENT OF HON. DIANNE FEINSTEIN, A U.S. SENATOR FROM THE STATE OF CALIFORNIA

Senator FEINSTEIN. [Presiding.] We will reconvene the hearing and continue on.

Mrs. Haight, I just want to say welcome. It is wonderful to have you here again. As you know, it was the death of your son that really brought my attention to this issue. And as Mr. Califano has continued on with it, we see how extensive it is and how many people are able to really receive drugs that otherwise would require the prescription of a physician. So I thank you, and although Ryan is not with us, he has made a major contribution to this effort. I want you to know that.

Mr. Califano, I think your report is excellent. I would certainly recommend it to everyone to take a look at this and read it. And Senator Sessions and I have put forward a bill which, as you say, does certain basic things. I believe I would be supportive of adding that banner that you spoke of, Mr. Heymann, to the legislation, and I will talk with Senator Sessions about doing that, see if we can do it. As you know, we have changed some sentences in this. I think you have raised what for me is a very disturbing part of this, and that is, the world community is now such that the Internet facilitates all kinds of criminal enterprises as well as legitimate enterprises, and Government becomes not able to regulate.

I had to leave to vote, and it was a big vote. This is a vote on Iraq. If any of you have any other suggestions of how Senator Sessions and I might tighten up our legislation, the floor would be open to you.

I will start with you, Dr. Heymann.

Mr. HEYMANN. Thank you very much, Senator Feinstein. Of our recommendations, the banner is in some sense the least important. Again, our total focus is on the international aspect. That is where we think it is going, where it substantially is, and we think that is the growth area, and we are very anxious, careful to urge you not to close one of two doors and just let the traffic go through the second door. That will not reduce anything.

Our most important recommendation is that a monitoring group inform MasterCard, Visa, American Express, Paypal whenever it finds their logos at the bottom of an offer to sell a prescription drug over the Internet without prescription.

Senator FEINSTEIN. In other words, that our bill create this group and empower this group to at least inform—is this what you are saying?

Mr. HEYMANN. We think that one the financing companies are informed, present Treasury regulations require them to take action to stop the transaction and to report the transaction to law enforcement, the purported transaction.

Mr. MCLELLAN. And they do it every day.

Mr. HEYMANN. And they do it. But they say—we do not believe that they know who it is—they are not monitoring the website with the rigor—the websites, the Internet, with the rigor that they have to if we are going to make it dangerous for someone to sell in exchange for a credit card payment.

So we would like perhaps Treasury to make it perfectly clear that that is required whenever they get information, a lead that

someone is selling narcotics without a prescription over the Internet using their credit card, and we would like to have an organization, a very small one—we called it an Internet monitoring group—whose full-time business it would be to monitor the Internet and, with the push of a button, send to the credit card companies, to Paypal—to the Internet service providers, too, because we want something from them—information about who is offering to sell without a prescription.

Senator FEINSTEIN. I would invite Senator Sessions to become involved in this, too, and sort of open it up. My concern is the term "monitoring group," which is not an official organ of Government, that it seems to me it would be the responsibility of a Government agency to do this and be empowered with authority to even shut down the site?

Mr. HEYMANN. Shutting down the site is, let's say, our second most important option. But that will be less useful because it will quickly be replaced. And to monitor sites even now will require a medium sophisticated program because apparently most of the sites are hijacked websites. I was working on it with Mathea Falco a month or two ago, and we played it out, and the site turns out to be the University of Oregon. Somebody has just hacked into the University of Oregon, put up there an offer to sell drugs, and so you have to get behind that offer, which will only, I am told, last for hours. It is a hijacked front. You have to get behind that to who is the real seller, and for that it takes a medium sophisticated program.

Senator FEINSTEIN. Yes, sir, would you like to add something? Then Mr. Califano.

Mr. MCLELLAN. If I could just add to that, the Treatment Research Institute has worked with Drug Strategies and Harvard in doing this, and we think the simplest of all strategies is to simply follow the money. The reflex impulse is to close something down and have a Government action. Please keep in mind now 88 percent of these sites and the figures behind the sites are offshore in countries where it is not necessarily illegal for them to sell drugs to Americans. It is illegal for us to buy.

Please keep in mind also that there are issues of entrapment and less than perfect boundaries about authority for the Government agencies. That is why we specifically suggested a nongovernmental group provide actionable evidence. If you had somebody going on a site and actually attempting to purchase and the credit card number were exercised by that company, that is actionable evidence. And in hearings that were conducted by Professor Heymann, we have heard nothing but support from the credit card companies, the delivery agencies, the whole chain of supply, the money supply. So we think that may be the strongest, if imperfect, way of bringing this to a restricted end.

Senator FEINSTEIN. Mr. Califano, did you want to say something?

Mr. CALIFANO. I share your concern. I would not have it as an independent agency. I think if something like this is going to be done, it should be done by Government that is going to be responsive, not a private agency.

I do want to second something that Phil said, though. If you notice in our CASA report, just on the sampling of sites we took, of

the 152 sites we identified in 2004, by 2005 all but 29 of them were gone. As we have done this in that 210-hour period, in the course of just those 210 hours, sites disappear and pop up again. So that is a very difficult problem.

I do think that it should be against the law to have on the Internet any pharmacy that has not been certified, and I think that alone can have a substantial impact here. And there is a system in place for certifying pharmacies, and that can be helpful.

I think the other parts of your law are—I think it is a good statute, and my instincts would be to give a good portion of this authority to the DEA, which is the right agency to go after this stuff. I think it is terribly important. And I also think there is an education campaign here that is important, that we need, whether through the Internet or other places, to educate parents and children about the dangers of abusing these prescription drugs. That is one thing.

I think we need to have the Food and Drug Administration be required to press these pharmaceutical companies to formulate these drugs in ways that make them much harder to abuse. OxyContin, all you have to do is crush it, and you could snort it, and you have got your heroin high. That is an inexcusable kind of approval, and I think also when there are addictive drugs that are being allowed to come on the market, before they come on the market, the Food and Drug Administration should have a plan—require the pharmaceutical company to have a detailed plan about what to do on the first indication of abuse. That was not true with respect to OxyContin. The plan came afterwards.

Aside from all the criminal conduct of those individuals, I think things like that are necessary as well.

Senator FEINSTEIN. Thank you.

Mr. Rannazzisi, do you have a comment to make on this, specifically whether it be a Government responsibility or some private entity?

Mr. RANNAZZISI. Well, ma'am, we reviewed that proposal, and at this moment in time we are not prepared to provide a recommendation or comment. But I would like to get back to something that we have discussed before with certification in the pharmacies.

We look at this as two separate problems. There is a our domestic problem and our international problem. Obviously, we have no regulatory control over international pharmacies, and most of these are not even pharmacies. They are just storefront operations. But we do have regulatory control over the domestic pharmacies, and as we talked about certifying, DEA does not certify pharmacies to operate on the Internet. DEA registers pharmacies to procure and dispense controlled substances pursuant to a legitimate or valid prescription.

If you look at the first placard up there, that is a comparison of a brick-and-mortar pharmacy, your normal brick-and-mortar pharmacy that operates in your community every day. That is an average number. They dispense about 88,000 tablets of hydrocodone a year, hydrocodone combination products. Now, if you look at the 2.9 million, that is a rogue Internet pharmacy. Now, remember, a rogue Internet pharmacy is a DEA registrant. Somewhere down the line on that Internet site, they are going to have to get their

drugs, if they are domestic, from a brick-and-mortar pharmacy that is servicing that Internet site. The 2.9 million is the average. We took 34 known and suspected Internet pharmacies and looked at their purchase records for 2006. Nearly 99 million hydrocodone combination products were sold out of those pharmacies 99 million. So you could see the great difference.

If you look at the second placard, the cyber pharmacies, as compared to the brick-and-mortar pharmacies, your average brick-and-mortar pharmacy does about 89 percent of noncontrolled substances as compared to 11 percent of controlled substances. Now, if you look at those cyber pharmacies, about 95 percent—they are not full-range pharmacies 95 percent of their sales are controlled substance sales as compared to about 5 percent, about 425 prescriptions a day. So you could see there is a major difference between the brick-and-mortar cyber pharmacies and—

Senator FEINSTEIN. What are you saying? I mean, do not mince words. What are you saying?

Mr. RANNAZZISI. What I am saying is that those are rogue pharmacies that are dispensing outside the scope of good practice. They are doing something illegally.

Senator FEINSTEIN. So are you saying do not worry about them, just let them continue?

Mr. RANNAZZISI. No. I am saying that we have to do something about, yes, absolutely, and we are.

Senator FEINSTEIN. I am sorry. I am not aware of what you are doing.

Mr. RANNAZZISI. OK. For starters, we are starting to look at their purchase records. Every Internet pharmacy that we have seen has a purchase footprint. We know based on their sales that they are Internet pharmacies. So what are we doing? In addition to going after them criminally, we are also going after them—we are taking their registrations—

Senator FEINSTEIN. How many have you gone after criminally?

Mr. RANNAZZISI. Organization-wise, I could not tell you the exact number. I could get back to you on the exact number.

Senator FEINSTEIN. Yes, we would like to have the number.

Mr. RANNAZZISI. Absolutely. But I can tell you that we have been shutting these pharmacies down using our regulatory authority and immediate suspension authority. We have gone after them and immediately taken their registration so they cannot dispense and procure controlled substances.

Senator FEINSTEIN. Let me just say something. I introduced this bill with Senator Sessions in 2004. We have heard nothing from you. There is no comment on the bill, there are no suggestions, there is nothing—which indicates to me that it is an agency that is not taking this very seriously, to be very candid with you.

Mr. RANNAZZISI. Well, I take exception to that, ma'am. We do take it seriously. In fact, you know, as you can see, using our regulatory authority, we are shutting these down. We are going after the distributor instead of the—

Senator FEINSTEIN. I would like to know how many you have shut down, and today you cannot answer that question.

Mr. RANNAZZISI. I will give you an exact number.

Senator FEINSTEIN. I appreciate that.

Senator Sessions, would you like to take over? I know a second vote has been called. Or perhaps we should recess again?

Senator SESSIONS. I may not be able to come back after this vote, so I would appreciate the opportunity to share a few thoughts with the panel.

Senator FEINSTEIN. You go ahead.

Senator SESSIONS. And thank you for your work on this legislation, your commitment to it. These charts up here are stunning to me. I thought it was bad, but it is worse than I thought.

Senator FEINSTEIN. It is.

Senator SESSIONS. That is a stunning, stunning chart, and I really should not be surprised based on the experience that I have had in which you see people want these drugs, they learn how to make money off of them, they may be personally addicted to them, they just want to try them, whatever.

Senator FEINSTEIN. Senator, will you continue then?

Senator SESSIONS. Yes.

Senator FEINSTEIN. I will go and vote and try and come back. Senator Leahy may be back in the interim.

Senator SESSIONS. Thank you.

Senator FEINSTEIN. Thank you.

Senator SESSIONS. [Presiding.] All right. Let me ask this. Mr. Rannazzisi, you talked about—I believe, Mr. Heymann, you served as Deputy Attorney General. I remember him here a number of times, know his experience. He has indicated that there are sites up all over saying "OxyContin without a prescription." Now, how can you get OxyContin without a prescription? I mean, how can this be? Publicly or all over the Internet, hundreds of sites, apparently.

Mr. RANNAZZISI. From our experience, those sites are probably operating overseas because OxyContin or oxycodone products are Schedule II. The level—

Senator SESSIONS. Which means they have to have a—

Mr. RANNAZZISI. A written prescription.

Senator SESSIONS. And if you go to a physician and the pharmacy, they account for every single pill.

Mr. RANNAZZISI. That is absolutely correct.

Senator SESSIONS. Everything is done to the nth degree. The prescriptions have to be maintained and kept so your people can—now, Mr. Secretary, Mr. Heymann, you have been through this Government rigmarole over the years. Both of you have. I am aware of how hard it is for the DEA to get a foreign country to cooperate or move quickly against these sites. It is just a nightmare for agencies. Could the State Department, if they made it a high priority, a condition of good relations or trade, is it a feasible thing to think that we could pressure these companies in the foreign countries?

Mr. CALIFANO. I think the odds of the State Department giving this a high priority are very, very low, and I will just give you—I go all the way back to the Johnson years. When we first saw heroin coming out of the ghettos and into broader society, I talked to Dean Rusk, and I said, you know, "We have got to do something with Turkey." That is where all the heroin was coming from in 1967. And he said, "Well, we have to be very careful about Turkey.

We need Turkey as an ally in the cold war, and we have to be very measured in our response."

The same attitude existed when I was Secretary of HEW. In that 2½ years, trying to get the State Department—with someone as distinguished and as special as Cyrus Vance being the Secretary—we could not get the State Department to give this subject any priority.

Senator SESSIONS. Secretary Shultz was not very interested in it, either.

Mr. CALIFANO. Secretary Shultz was not interested in it. And I dare say that if you went to Condoleezza Rice and said, you know, "We are getting killed by all this stuff coming in"—it is prescription drugs. It is all illegal drugs, the marijuana, the heroin, the cocaine pouring in here, heroin from Afghanistan. We are going to have the cheapest heroin in the history of the country because of what is happening, the way it is coming out of there. If you said, "Make that a priority," I do not think it is real. That is why I think we need something like this statute—

Senator SESSIONS. Now, you think it is impractical—Dr. McLellan, you nodded, and I think Professor Heymann—to expect that we could solve this problem in that fashion. We probably should not go into the details of it because our time is short. But is it being shipped from these foreign countries?

Mr. MCLELLAN. One of the things that is being missed is it is not just registered pharmacies in Afghanistan. Remember, they are called "rogue pharmacies." These are little factories that are making Vicodin and OxyContin knock-offs. By all means, they have opiate in them, but they are very difficult to regulate, too. And as Phil said, they pop up and they shut down.

I repeat, taking nothing away from all the typical Federal ways to go at this, I suggest right now follow the money. Get the source of the dollars and squeeze that neck with the cooperation of existing—and they are very cooperative. The credit card companies, the banks behind those companies, and the delivery agencies want to stop this.

Senator SESSIONS. Well, we have a group of people—a small group, maybe—who think the Internet is a crime-free zone; that is, nothing is a crime on the Internet. And it is religion with them and that to mess with it at all is a heresy of some kind, a sinful act. But do not want to mess up the Internet and turn it into a lawsuit-creating mishmash of regulations and all.

Professor Heymann, your idea was that the credit card companies could work with this in a way that they would be happy with?

Mr. HEYMANN. The answer, Senator, is yes. But we simply do not think that law enforcement—we think DEA has the least chance of being effective as a law enforcement agency operating in the Ukraine or in Somalia because it would require an extradition for DEA to make a case. So, first of all, we will not get any cooperation. Second of all, DEA's concern is making a case before an American court.

The State Department will also have difficulty, but now and then it may very well be able to press the Ukraine or Somalia to bring a case against a rogue seller in those places. But we think the problem is one of scale. My calculation is that every year, just

OxyContin and Vicodin are going to more than half a million high school students. Every year.

Senator SESSIONS. A half a million?

Mr. HEYMANN. Half a million. And so we have to find a way to deal with that problem with scale. One case is not going to help much. That is why we want the credit card companies to systematically go after everybody who is—and they are trained to do this. They are doing it under money-laundering legislation that you have passed, and they are very good at it, and they are very accustomed to it. We want them to track down which is the bank that is making payment to a dealer. And if they find the bank, they can have a contract, which it is very hard for us to regulate a bank, the United States to regulate a bank in the Ukraine.

Senator SESSIONS. My vote time has expired. I hope I have not missed it. If you do not mind, we will return, I am sure.

Mr. HEYMANN. I would appreciate that, Mr. Sessions.

[Recess at 11:28 a.m. to 11:46 a.m.]

Chairman LEAHY. [Presiding.] You know, it is interesting. This is an example of C–SPAN. While I was on the floor voting—and this last vote is still going on—I had two or three Senators in both parties come up to me and talk about this hearing and what they have been seeing, some of the information they are getting and saying, "We have got to talk with you and with Senator Feinstein and Senator Sessions about this." They did not realize what the problem is. So in case you are wondering, even with this back and forth whether it carries, it does.

Now, we have learned today—and this is a question for everybody on the panel. We have learned today about online rogue pharmacies. They are using electronic forms rather than in-person consultations to give out bogus prescriptions for prescription drugs, including highly addictive painkillers. And it appears that one of the loopholes used by what are, I think we would all agree, unscrupulous online pharmacies that allow access to drugs illegally on the Internet.

I want to emphasize that the drug store my family and I go to, and others, if you have tight controls in there, it can be very helpful, both to be able to go online or to call and use a touch-tone phone. But what Senator Feinstein has done is introduce legislation to require in-person consultation with doctors for any purchase of controlled drugs over the Internet. I cannot imagine how that would in any way inconvenience—it certainly would not inconvenience anybody in our family. I think Senator Feinstein's legislation could be a first step in attacking the serious problem.

So let me ask the person from DEA, do you support legislation to require in-person consultations for prescriptions used to buy controlled drugs over the Internet?

Mr. RANNAZZISI. DEA, the Department of Justice, and the administration are looking at all different measures that could be implemented. At this point in time, we are not prepared to make a recommendation of a specific measure.

Chairman LEAHY. When will you be?

Mr. RANNAZZISI. I cannot give you an answer right now, sir. I could tell you right now that all levels of the Department, the Do-

mestic Policy Council, HHS, we are all looking at this together. We are having regular meetings to discuss these issues.

Chairman LEAHY. Do you have any recommendations that have been made?

Mr. RANNAZZISI. Not at this point in time, sir, no.

Chairman LEAHY. Thank you.

Secretary Califano?

Mr. CALIFANO. Let me just note—and it is in our CASA report we are releasing today. This is the American Medical Association. "Physicians who prescribe medications via the Internet shall establish or have established a valid patient-physician relationship. The physician shall obtain a reliable medical history and perform a physical examination on the patient."

Chairman LEAHY. So by this you would agree with Senator Feinstein?

Mr. CALIFANO. There is no question about that. The four elements of a doctor-patient relationship are that the patient has a medical complaint, that a medical history is taken, that a physical examination has been performed, and that some logical connection exists between the medical complaint, the medical history, the physical examination, the drug prescribed. So it is right on. And the Federation of State Medical Boards agrees with you, too, Senator Feinstein.

Chairman LEAHY. Professor Heymann?

Mr. HEYMANN. As I remember Senator Feinstein's proposal, it requires at least one meeting, one live meeting with a doctor. That seems to me to be exactly right.

Chairman LEAHY. Ms. Haight?

Ms. HAIGHT. Yes, I agree with that totally. That is how it has always been in hospitals.

Chairman LEAHY. Dr. McLellan?

Mr. MCLELLAN. Well, I think it is completely appropriate for all legitimate pharmacies, all legitimate physicians, and especially those in the United States. I remind you that more than 80 percent of everything we are talking about has essentially nothing to do with the United States—

Chairman LEAHY. I understand. I am trying to figure out, though, what kind of laws are in place that make it easier to block those others, which goes to what Professor Heymann has said about the First Amendment things. You are going to have to have certain legal requirements if you are going to block activity which then becomes illegal and do it constitutionally.

Mr. HEYMANN. Senator Leahy, our answer to that was to have Internet access blocked for sellers of prescription narcotics only at the request of the households. In other words, any Internet service provider would have to ask every household to which it provides Internet service, "Do you want this to be blocked?" If they said yes, they would then block any further offers to sell drugs.

Chairman LEAHY. How many did you find on Mother's Day when you went on?

Mr. HEYMANN. Well, they have not done that yet, but I literally—you know, the Google number at the top—

Chairman LEAHY. Someone has a BlackBerry nearby.

Senator FEINSTEIN. Me. Sorry.

Chairman LEAHY. You are getting a lot of supportive testimony, Senator Feinstein. Do not block that.

[Laughter.]

Chairman LEAHY. Go ahead.

Mr. HEYMANN. The google number at the top was 800,000. I looked and my search was for "Buy OxyContin without prescription." It was not Vicodin. It was not steroids. It was a single drug, though many of them would overlap. And I only looked at the first 20 or 30, but each of them looked to me like a purchase—like an offer to sell a highly addictive narcotic to anybody without bothering with a prescription.

Chairman LEAHY. Well, the thing that gets me—I mean, I want to find some way to stop it. I think everybody agrees, parents would agree, we do not want pornography to go to our kids. But kids can move around pretty quickly, usually a lot better than parents can, on the Internet because they live on it. I told the story of a 4-year-old grandson wanting to do an interactive—I think it was Disney or something like that, a perfectly appropriate thing where you could draw pictures, do interactive things. He wanted to use the computer to do it. And I said, "Fine, but I have to get the site for you," because I wanted to make sure that is exactly the site. The site came up, and he said, "Yes, that is the one," took the mouse out of my hand and said, "I better take over now because it gets very complicated."

[Laughter.]

Chairman LEAHY. You mentioned OxyContin. We know how they misrepresent how addictive their drugs were in marketing and advertising. The press has been full of this, especially the last couple of weeks. According to court records, the makers of the drug, Purdue Pharmaceuticals, agreed to pay more than $600 million in fines and penalties. And three of its top executives admitted they were responsible for misleading those who bought and prescribed the drugs.

Do we need to change how we regulate these kinds of painkillers? We will go one, two, three, four, five. Go ahead, Mr. Califano.

Mr. CALIFANO. I would make a note of a couple of things.

One, a quarter of these sites we know claim to be in the United States. That has been consistent over the 4 years we have done this sample. About half of them say they are overseas, and about a quarter of them are unknown origin. So there are sites in the United States.

Two, with respect to what happened with Purdue Pharma, my own view is if those guys had been street drug dealers, they would be in jail, and they did just as much damage as street drug dealers. So they walked.

And, last, vis-a-vis Senator Feinstein's point, I would like to quote—we have a quote from Joe Rannazzisi in our report that we are releasing today, and let me read it. "A legitimate doctor-patient relationship includes a face-to-face consultation where a licensed physician can examine the physical symptoms reported by a patient before making a diagnosis and authorizing the purchase of a prescription medicine. Filling out a questionnaire, no matter how detailed, is no substitute for this relationship." And I realize he

does not have authority to support in a formal way what you propose in your bill, but that certainly supports it.

Mr. HEYMANN. We think that there has to be somewhere—and I am about ready to concede to Senator Feinstein and to Joe that perhaps it should be a governmental responsibility. There has to be someone who is monitoring the Internet to see if somebody—to see the long list of people who are offering to sell prescription narcotics without a prescription.

Once that is done—and I suggest you put it in the Office of Justice Programs, Senator Feinstein. I do not think it is DEA because it is not law enforcement, and the law enforcement is the focus for DEA. And Mr. Califano has already commented on the likelihood that the State Department would be very vigorous. It will not be very vigorous. I would give it to OJP, the Office of Justice Programs, and tell them to set up a small unit. We are talking about five, ten people. A few thousand dollars will create the programs, and then whenever they get information, send it to the credit card companies and expect the credit card companies to cutoff the credit and track down who is getting it, and send it to the Internet service providers and expect the Internet service providers to add it to their list that is cutoff from any family that does not want these ads coming into their house.

Chairman LEAHY. I have actually gone beyond my time. I am on Senator Feinstein's time. I am going to hand it over to her. Does anybody wish to add very, very briefly to what was said?

[No response.]

Chairman LEAHY. OK. Thank you.

Senator Feinstein, I cannot thank you enough for bringing up this subject, and I can assure you we will work on it, and the Committee will followup on it.

Senator FEINSTEIN. [Presiding.] Well, thank you very much, Mr. Chairman, and thank you for having the hearing because I think it was very constructive. I myself think that we have to develop this second part of it, and we will proceed to do so.

I do not know what is wrong with DEA, but something is. All during the methamphetamine discussion, which has gone on for 10 years from when I introduced the first bill in 1996 to the last bill that we did with Senator Talent, I have asked for DEA help, and DEA is nowhere. And now once again, on this issue, which clearly by your own chart is a big issue and clearly by the statement that Secretary Califano read, you have got to agree with it. And yet I do not know whether it is partisan or what it is, but I cannot get help on these matters from DEA. So I would like to just publicly ask for help. I would welcome DEA's suggestions. I know Senator Sessions will as well. We would like to make this as strong a bill as possible; that people who sell drugs illegally over the Internet without a physician's prescription, without a physician visit, should be prevented from doing so; and if they continue, shut down. That is my view, and we are trying to get as close to that as we possibly can.

I do not know that the Internet should be able to facilitate acts which are not legal in this country. But when you have young people who, as Senator Leahy testified and Mrs. Haight testified with her son, are so facile on the Internet, are young, want to try any-

thing, can have exposure to a whole illegal field of very powerful drugs, it is extraordinarily dangerous.

Dr. Heymann, I am amazed. This was on Mother's Day that you pulled up 800,000 sites? Or was it hits?

Mr. HEYMANN. Let me send you what I pulled up, Senator Feinstein.

Senator FEINSTEIN. Well, could you define for me again what it was?

Mr. HEYMANN. I put into Google, "Buy OxyContin without prescription." I believe the number was 800,000 hits. In an instant, 800,000 hits. I looked through the first 20 to make sure we were not picking up a lot of other things, and the first 20 were overwhelmingly offers to sell OxyContin using a credit card to whoever pushed a button on that website.

Senator FEINSTEIN. Do you remember how many of these were in country as opposed to out of country?

Mr. HEYMANN. You cannot tell from the website, though Dr. McLellan has some judgment on that.

Mr. MCLELLAN. Yes, in fact, our group was the group that discovered this. Dr. Robert Forman had the first article about this, and we have been tracking it scientifically since then. And, by the way, 800,000 is about the same number for that substance since 2002. And I say that because, to the credit of DEA and the credit of a lot of law enforcement, there have been a lot of busts in this country, and they have knocked out huge rings, and it does not stop because they pop up just as fast. The market is overwhelming. There is a very brisk business in this, and it is not going to go away simply by local law enforcement.

You can tell the registry of a site by digging into, you know, where it is—that takes a lot more work. It is almost not worth it because literally tomorrow, if you stopped my website today, literally tomorrow, and in another country, in the snap of a finger, I would have another one up.

Senator FEINSTEIN. And the drug, Dr. Heymann, that you were looking for was OxyContin?

Mr. HEYMANN. It was OxyContin, and Vicodin would have been many more, I suspect. Many more than 800,000. It was OxyContin.

Senator FEINSTEIN. All right. Does—

Mr. MCLELLAN. Two million nine hundred thousand.

Senator FEINSTEIN. Two million nine hundred thousand?

Mr. MCLELLAN. For Vicodin.

Senator FEINSTEIN. Hits for Vicodin?

Mr. MCLELLAN. If you put "No prescription Vicodin"—

Senator FEINSTEIN. Would you turn on your microphone, please?

Mr. MCLELLAN. Sorry. If you put the words "No prescription Vicodin" in Google, right here, right now, you will have no less than 2,500,000 hits.

Senator FEINSTEIN. So, clearly, I mean—

Mr. MCLELLAN. And 88 percent of them are direct offers to sell. I should just say one quick thing. Remember, a telephone is a computer. Now it is clear that if you have a purchase and you give them your website, they will text message you. Some of these pharmacies will text message you, "Need a refill?" And if the kid says "Yes," you get billed in ring tones, almost as though they are trying

to make it impossible for Mom and Dad to check as to what is actually being bought.

Senator FEINSTEIN. Clearly, there is a big problem, and clearly, DEA ought to be producing some solutions. I would like to ask for those solutions. I would like to ask, respectfully, for DEA's views, any suggestions you might have as to how we can take actions which can effectively stop this. I just hate to think that we have to throw up our hands and say it cannot be stopped.

Mr. RANNAZZISI. Ma'am, if I may, we have never said that it cannot be stopped, and we will provide any technical advice that you need, and I think we have to your staff in the past. But the fact remains that when you do a search like that, most of those are portals or informationsites. When you get right down to it, when you get right down to the anchor sites that are selling the drugs, there are far fewer than 800,000, or whatever the number is. And domestically those sites are being serviced by one pharmacy or two pharmacies or a hundred pharmacies. Each pharmacy is servicing—I do not know how many. They could be servicing 30, 40, 50 websites. So the key is not the sites. The key is those pharmacies. The key is to hit the pharmacies and to shut them down. The sites are going to regenerate.

Senator FEINSTEIN. Well, then, why doesn't DEA shut them down in this country?

Mr. RANNAZZISI. We are. We are using our regulatory authority—

Senator FEINSTEIN. Again, I have asked you how many have you shut down, and you cannot give me a number.

Mr. RANNAZZISI. And I told you, ma'am, I will give you an exact number that we have shut down.

Senator FEINSTEIN. I was just handed your written remarks, which during 2006, SOD has coordinated over 90 investigations resulting in the arrest of 64 individuals and the seizure of approximately 14 million dosage units of controlled substances and approximately $30.9 million in United States currency.

Mr. RANNAZZISI. Yes, ma'am. You wanted the number of pharmacies.

Senator FEINSTEIN. So at least you were doing something.

Mr. RANNAZZISI. Well, in all of our investigations, we follow the money, and we put people in jail. That is what our job is. But you wanted an exact number of pharmacies that we shut down, and I told you I would get back to you on that.

Senator FEINSTEIN. OK. Fair enough. Fair enough.

Mr. RANNAZZISI. OK.

Senator FEINSTEIN. I think the other thing is any suggestions DEA might have for legislation which is aimed at shutting them down. I recognize the Constitution, I recognize the difficulties, but we have to find a way to do this.

Mr. RANNAZZISI. Yes, ma'am.

Senator FEINSTEIN. I think that is probably it, unless somebody else has something that they would like to say. I would like to thank you all very much. I know some of you came from long distances, and it is very much appreciated.

So thank you, and this hearing is adjourned.

[Whereupon, at 12:05 p.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

The National Center on
Addiction and Substance Abuse
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June 6, 2007

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Ms. Jennifer Leathers
Hearing Clerk
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Jennifer:

In response to Chairman Leahy's request, attached is the hearing transcript with edited comments of my statement and responses to the Senator's questions. Also attached are my responses to specific questions from Senators Leahy and Specter.

If you have any additional questions, please feel free to contact me or Susan Foster, CASA's Vice President and Director of Policy Research and Analysis, at 212 841 5240 or sfoster@casacolumbia.org.

Sincerely,

Joseph A. Califano, Jr.

Joseph A. Califano, Jr.

Attachments

Responses to Questions from Chairman Patrick J. Leahy

1.a. ***Approximately how many Web sites currently offer to sell controlled substances illegally over the Internet?***

Because these sites can appear and disappear sometimes in the space of a day or two, it is impossible to provide a precise answer to this question. In order to provide a reasonable estimate, it is important to distinguish between sites that advertise these drugs and sites that actually sell them.

Several times during the hearing, the total number of Web sites mentioned as potentially selling drugs was in the range of 850,000 to 2+ million per drug. These numbers are meaningless. They only are a count of items that appear in response to a particular online search and may or may not be sites advertising or selling controlled drugs online. If you type any word set into a search engine, you get many related and unrelated 'hits'. The same is true here.

Among those 'hits', however, are two types of sites:

- Advertising (portal) sites. These sites do not actually sell drugs; they act as a conduit to another Web site--an anchor site--that makes the sale. Multiple portal sites feed one anchor site. Many of the 'hits' referred to above come from the same advertising site.

- Sale (anchor) sites. On these sites, the customer places an order and pays; the online pharmacy fills the order and ships the drugs. The pharmacy itself may operate the Web site or the Web site may send the order to the pharmacy. Often, different anchor Web sites use the same pharmacy to fill prescriptions. The operator of the anchor Web site may not be located in the same geographic region as the pharmacy.

Both types of sites are important, but the anchor sites (and of course their drug sources) are the main concern since these are the sites selling the drugs.

Each year CASA devotes 210 hours in the first quarter of the year to sorting through the long list of 'hits' and identifying portal and anchor sites. Toward the end of the 210 hours we devote to this analysis, we always have reached a point of diminishing returns where the 'hits' and portal sites keep linking us to the same anchor sites.

While we cannot tell exactly how many sites exist at any one time that actually sell these drugs, we have found between 154 (in 2004 and 2005) and 187 (in 2007) such sites.

The estimate of the number of sites offering to sell these drugs provided by Tom McClellan also confuses the important distinction between advertising and sale sites. For example, McClellan references a study where they identified a total of 302 sites. Further review of his published work, however, reveals that 277 of these sites were portal or advertising sites and 25 were anchor or sale sites.

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1.b. ***Approximately how many Web sites offer to provide prescriptions for controlled substances over the Internet?***

Of the 187 anchor sites we identified, 83 (44 percent of anchor sites) offered to provide an online consultation in lieu of a prescription. Another 22 (12 percent of anchor sites) made no mention of the need for a prescription, and 52 (28 percent of anchor sites) clearly stated that no prescription was needed. Thirty sites indicated that a prescription was required; 17 (9 percent of anchor sites) asked that the prescription be faxed (potentially allowing a customer to tamper with a prescription or use a single prescription multiple times); 9 (5 percent of anchor sites) said that the patient's doctor would be contacted; and 4 (2 percent of anchor sites) asked that a prescription be mailed. We have no way of knowing whether these reported requirements were actually enforced.

1.c. ***Of the Web sites identified in answer to Questions 1.a and 1.b, approximately how many are currently operating in the United States subject to U.S. law?***

CASA identified 48 anchor sites (26 percent) which indicated that the drugs would be shipped from a U.S. pharmacy. While the anchor sites operating offshore may be beyond the direct jurisdiction of U.S. law, obviously those U.S. citizens purchasing the drugs are not. And Internet search engines, financial institutions and shippers that aid in illegal purchases also bear responsibility.

2. ***Do you support the Feinstein-Session Online Pharmacy Consumer Protection Act's requirement of in-person consultations for prescriptions used to buy controlled drugs over the Internet? If not, why? If so, why would such a provision be critical to curbing rogue Internet pharmacies?***

Yes, I strongly support the Feinstein-Session Online Pharmacy Consumer Protection Act's requirement of in-person consultations for prescriptions used to buy controlled drugs over the Internet and believe these provisions should be further strengthened. In-person consultations are critical elements of professional practice. CASA concurs with many state authorities and medical societies that consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established, and recommends that these elements be reflected in the law:

- A patient has a medical complaint;
- A medical history has been taken;
- A face to face physical examination and consultation have been performed;
- Some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed.

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We further recommend that an Original Copy (not a fax or photocopy) of a prescription from the patient's doctor be required to purchase controlled prescription drugs over the Internet and that confirmation with the patient's doctor also be required to confirm the legitimacy of the prescription.

These changes would provide the required clarity to state law enforcement that online consultations are illegal, as are no prescription requirements and prescription faxing. It would require due diligence on the part of an Internet pharmacy to meet required standards of practice of a brick and mortar pharmacy.

3. ***Do you support creating a state and federal cause of action to bring injunctions to shut down non-complying Web sites?***

Yes.

4a. ***Given that teens report gaining access to prescription drugs from their parents' medicine cabinet, rather than online, why is the Internet a cause of growing concern?***

We do not know the actual share of abused controlled prescription drugs that comes from the Internet relative to other sources. While children may in fact have easier access to these drugs through their own parent's medicine cabinets and those of their parent's friends, it does not mean that the Internet is not a potential threat. The Internet is an uncontrolled channel of distribution for adults and teens alike that can be accessed in relative privacy without the same chances of detection of acquiring drugs on the street. As the Internet grows as a site for financial transactions of all sorts, it stands to reason that without intervention it also will grow as a site for access to controlled substances.

4b. ***What are the most seriously abused prescription drugs that are available on the Internet?***

A wide variety of drugs, from Schedule II through Schedule V, are available on the Internet. Our analyses have found that the drugs most frequently offered online are the benzodiazepines, like Valium and Xanax. The second most frequently offered class of drugs is the opioids, like Vicodin, Lortab, Darvocet and Darvon. Stimulants, like Ritalin, Concerta and Adderall are next in line followed by the barbiturates.

5.a. ***How common is the misperception that prescription drugs are safe to abuse among young people and how serious is the problem?***

We do not know what percent of young people consider controlled prescription drugs to be safer than street drugs. The *Monitoring the Future* survey has some data on perceived risk of using, for example, amphetamines or barbiturates once or twice or regularly compared with other drugs, but they do not specifically ask the question about the difference between prescription drugs and others. Our research has found anecdotal evidence that many teens view these drugs as relatively safe either when abused alone or in combination with alcohol or other drugs. Because controlled prescription drugs are approved by the FDA, prescribed by physicians, and taken regularly by

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family members and friends, teens and adults alike may think they are safe to use and to abuse. Perceptions of safety are tightly linked to abuse.

5.b. ***What should be done to educate young people and minors about the dangers of prescription drugs?***

Government sponsored public awareness campaigns that focus on alcohol, marijuana and other illicit drugs should include the abuse of controlled prescription drugs and should inform parents of the need to safeguard their prescription drugs from children.

Schools and communities should incorporate prescription drug abuse, including steroid abuse, into evidence-based substance use prevention programs. Health care professionals should address the issue in the context of prevention and treatment and educate young people on the dangers of prescription drug abuse.

Parents should educate themselves about the dangers of controlled prescription drug abuse and take steps to educate their children and keep controlled prescription drugs prescribed for them our of the hands of children. Parents also should take steps to make sure that their children are not using the Internet to acquire controlled prescription drugs.

5.c. ***Do you believe that the DEA's media campaign is adequate in addressing the misperception among the public that prescription drugs are less dangerous than street drugs? If not, why not?***

We have not analyzed the DEA's efforts in this regard and therefore are not in a position to comment.

6a. ***Do you support the effort to force a reformulation of OxyContin to alleviate its addictive qualities?***

We do support such an effort, but are cognizant of the fact that a reformulation may impact the drug's efficacy for those who use it as properly prescribed to control pain. Pain historically has been under treated in this country and we believe that steps must be taken to balance the control of diversion and abuse with effective pain management. We recommend that steps be taken before a drug is brought to market to require pharmaceutical companies to:

- Demonstrate they have made every effort to formulate the drug in a way that avoids or at least minimizes its potential for abuse; and,
- Include proactive risk management plans in all new applications for controlled drugs.

We also recommend that pharmaceutical companies submit promotional materials for controlled drugs to the FDA for review and approval prior to use.

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7. ***Do you support S.980? If so, please elaborate on how S.980 may be improved.***

We support S.980 as an important step in the right direction. To strengthen the Bill, we recommend that the Controlled Substances Act be amended to require that:

- The following elements be present in order to define the meaning of "the usual course of professional practice."
  - A patient has a medical complaint;
  - A medical history has been taken;
  - A face to face physical examination and consultation have been performed;
  - Some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed.

- An Original Copy (not a fax or photocopy) of a prescription from a DEA certified physician, licensed in the state of purchase, be required to purchase controlled prescription drugs over the Internet and that confirmation with the patient's doctor also be required to confirm the legitimacy of the prescription.

We suggest removal from the Bill of the following language which seems to imply legitimacy to the provision of online consultations in lieu of a prescription from the patient's physician:

> *Section 311 (d) (4) requires that each online pharmacy post on its homepage "The name, address, professional degree, and licensure of practitioners who provide medical consultations through the website for the purpose of providing prescriptions."*

We recommend that stronger penalties be applied for the online sale of controlled drugs to children.

We recommend that the following section be clarified to prohibit advertisement and direct to consumer marketing of controlled prescription drugs online in accordance with Article 10 of the 1971 International Convention on Psychotropic Substances:

> *Section 401 (3) (B) of the Bill exempts from penalty "the placement on the Internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance."*

We also recommend that:

- Internet search engines should provide warnings that sale and purchase of controlled prescription drugs over the Internet from unlicensed pharmacies and physicians and without valid prescriptions are illegal and block sites that are not certified.

- The Office of National Drug Control Policy (ONDCP), DEA and Food and Drug Administration (FDA) should develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and

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illegality of making online purchases of controlled prescription drugs from non-certified sites.

- The DEA and financial institutions (credit card and money order issuers) should collaborate to restrict purchases of controlled prescription drugs from non-licensed and accredited providers.

- Postal and shipping services should train counter and delivery personnel to recognize potential signs of pharmaceutical trafficking and know how to respond in the event of suspicious activity.

- The State Department should encourage and assist foreign governments to crack down on Internet sites illegally selling controlled prescription drugs to U.S. citizens.

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Responses to Questions from Senator Arlen Specter

1.a ***Are you saying that the DOJ and the DEA have not provided enough staff or resources to deal with this problem?***

We have no knowledge of the staffing levels or other resource allocations within the DOJ or the DEA in particular, to address this problem. Our study of the diversion and abuse of controlled prescription drugs revealed that enforcement of Internet diversion is a labor intensive operation, and we recommended in our report that the federal government assure adequate staffing to pursue cases of diversion.

1.b ***What resources and staff are they providing?***

We do not know.

1.c ***Do you know if the DOJ and the DEA have increased their staffing and resources in proportion to the explosive growth of the problem that you have documented?***

We do not know.

2. ***How is it possible to verify that a purchaser possesses an original copy of a prescription when he makes a purchase over the Internet?***

An online pharmacy can verify that a purchaser possesses an original copy of a prescription by requiring that the original copy be mailed to the Internet pharmacy and by confirming its legitimacy with the prescribing physician.

3.a. ***Are the statistics on illegal drug use trending in the same direction as those involving controlled prescription drugs, and what are the numbers/percentages?***

We have not conducted a comparative analysis for illicit drugs and controlled prescription drugs. However, while America was congratulating itself on curbing increases in illicit drug use and seeing some declines in use, the abuse of controlled prescription drugs rose sharply between 1992 and 2003.

3.b. ***Is there a trade-off or relationship between the two? (i.e., does the rate of illegal drug use go down when drug abusers shift to controlled prescription drugs?)***

The question of whether this "replacement hypothesis" is true is an interesting one, but there is no one data source that can answer this question definitively; an extensive data analysis strategy would be required to get near the answer.

3.c. ***Do the DOJ and the DEA fairly apportion their resources between these two problems?***

We do not know.

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4.a. ***What sort of rigorous standards do you suggest should be implemented in order to assure that the practices of these online pharmacies are adequate to prevent controlled substances from getting into the wrong hands?***

We recommend that an online pharmacy be required to be certified as an Internet Pharmacy Practice Site in order to operate (as proposed in the Feinstein-Sessions Bill).

We recommend that Internet Pharmacy Practice Sites obtain a special Web domain name and post proof of certification on their home page so that users can know immediately whether the site is legitimate.

We recommend that the Controlled Substances Act be amended to require that:

- The following elements be present in order to define the meaning of "the usual course of professional practice:"
    - A patient has a medical complaint;
    - A medical history has been taken;
    - A face to face physical examination and consultation have been performed;
    - Some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed.

- An Original Copy (not a fax or photocopy) of a prescription from a DEA certified physician, licensed in the state of purchase, be required to purchase controlled prescription drugs over the Internet and that confirmation with the patient's doctor also be required to confirm the legitimacy of the prescription.

4.b. ***Are the current standards for certification by the National Association of Boards of Pharmacy sufficient?***

We have not done an in-depth analysis of these standards so we cannot comment.

5. ***Do you support S.980, the Online Pharmacy Consumer protection Act of 2007?***

We support S.980 as an important step in the right direction. To strengthen the Bill, we recommend that the Controlled Substances Act be amended to require that:

- The following elements be present in order to define the meaning of "the usual course of professional practice."
    - A patient has a medical complaint;
    - A medical history has been taken;
    - A face to face physical examination and consultation have been performed;
    - Some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed.

- An Original Copy (not a fax or photocopy) of a prescription from a DEA certified physician, licensed in the state of purchase, be required to purchase controlled prescription drugs over

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the Internet and that confirmation with the patient's doctor also be required to confirm the legitimacy of the prescription.

We suggest removal from the Bill of the following language which seems to imply legitimacy to the provision of online consultations in lieu of a prescription from the patient's physician:

Section 311 (d) (4) requires that each online pharmacy post on its homepage "The name, address, professional degree, and licensure of practitioners who provide medical consultations through the website for the purpose of providing prescriptions."

We recommend that stronger penalties be applied for the online sale of controlled drugs to children.

We recommend that the following section be clarified to prohibit advertisement and direct to consumer marketing of controlled prescription drugs online in accordance with Article 10 of the 1971 International Convention on Psychotropic Substances:

Section 401 (3) (B) of the Bill exempts from penalty "the placement on the Internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance."

We also recommend that:

- Internet search engines should provide warnings that sale and purchase of controlled prescription drugs over the Internet from unlicensed pharmacies and physicians and without valid prescriptions are illegal and block sites that are not certified.

- The Office of National Drug Control Policy (ONDCP), DEA and Food and Drug Administration (FDA) should develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making online purchases of controlled prescription drugs from non-certified sites.

- The DEA and financial institutions (credit card and money order issuers) should collaborate to restrict purchases of controlled prescription drugs from non-licensed and accredited providers.

- Postal and shipping services should train counter and delivery personnel to recognize potential signs of pharmaceutical trafficking and know how to respond in the event of suspicious activity.

- The State Department should encourage and assist foreign governments to crack down on Internet sites illegally selling controlled prescription drugs to U.S. citizens.

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6.a. ***Are you finding that a significant proportion of pharmaceutical companies are negligent in minimizing their drug's potential for abuse?***

We have no data to quantify the size of this problem.

6.b. ***Are you finding that a significant proportion of pharmaceutical companies are producing misleading or false advertising?***

We have no data to quantify the size of this problem.

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WRITTEN QUESTIONS OF CHAIRMAN PATRICK J. LEAHY TO PROFESSOR PHILIP B. HEYMANN, HARVARD LAW SCHOOL

HEARING ON "ROGUE ONLINE PHARMACIES: THE GROWING PROBLEM OF INTERNET DRUG TRAFFICKING" MAY 16, 2007

1. At the hearing, witnesses testified about fraudulently obtaining prescriptions over the Internet, and how individuals can obtain prescriptions for controlled substances without a face-to-face meeting with a doctor.

   a. Do you support legislation to require in-person consultations for prescriptions used to buy controlled drugs over the Internet?

2. One of the new tools that can be used to shut down rogue online pharmacies would be to allow states attorneys generals and federal authorities to bring injunctions against those who do not follow the strict letter of the law in dispensing controlled substances over the Internet.

   a. Do you support creating a state and federal cause of action to bring injunctions to shut done non-complying websites?

3. What are your views on the pending legislation introduced by Senator Feinstein, S. 980, the Online Pharmacy Consumer Protection Act of 2007?

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Questions for Philip Heymann

From Senator Arlen Specter

May 23, 2007

1. Do you think that the DOJ and the DEA have ensured adequate staffing, and resources, of law enforcement and prosecutors to pursue cases of controlled prescription drug diversion?

2. In light of what has happened with OxyContin and Purdue Pharma L.P:
   a. Are you finding that a significant proportion of pharmaceutical companies are negligent in minimizing their drug's potential for abuse?
   b. Are you finding that a significant proportion of pharmaceutical companies are producing misleading or false advertising?

3. As part of your proposed initiative to prompt credit card companies & financial institutions to contractually prohibit the use of their financial networks for any illicit purchase or sale of controlled substances, you say that "the drug merchant's bank would be contractually obligated to know its customer and to take steps to penetrate any pseudonyms used by the drug dealer." What are the steps that you propose these companies should be taking to discover pseudonyms used by the drug dealer?

4. In your recommendations, you testify that the strategy to significantly reduce illegal Internet sales of controlled substances should: 1) allow parents to block ads for illegal sales of controlled substances from their Internet service (i.e. a v-chip for drug ads); 2) prompt credit card companies & financial institutions to contractually prohibit the use of financial networks for any illicit purchase or sale of controlled substances; and 3) sponsor a nationwide education campaign.
   a. All of these have been tried before in other areas – to mixed results. Are these recommendations enough to stem the problem?
   b. What do you think of CASA's recommendation to clarify federal law related to the sale or purchase of controlled prescription drugs on the Internet?

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5. One of the functions of the proposed Internet Monitoring Group you propose is to identify websites offering to illicitly sell controlled substances, and then to furnish that information to American companies that are now unwittingly facilitating these illegal sales.
    a. You say that you believe "cooperation of e-commerce businesses is so likely that there is no need for legal directives at this time," but what makes you so confident?
    b. Can you recommend anything that would create additional incentives for any companies?

6. Do you support s.980, the Online Pharmacy Consumer Protection Act of 2007?

43987.014

To: Jennifer Price, Judiciary Committee

As to the first question, we strongly support legislation to require at least one in-person consultation to obtain a prescription to buy controlled drugs. As we will report to you within the next few weeks, there has been movement among the "black" websites toward fraudulent prescriptions and away from simple and blatant offers to sell without any prescription. Thus, this is a crucial step.

As to the second question about bringing injunctions against rogue, online pharmacies, our focus has been on overseas sellers, both because a great deal of internet drug trafficking occurs that way already and because we think the traffic will continue to move overseas. Overseas rogue pharmacies have little to fear from an injunction which can hardly be enforced against them. Third and finally, we think Senator Feinstein's bill, S988, could be quite useful but shares the limitations of an injunctive remedy. There is no effective way for the United States to prevent sales from abroad in the new, globalized economy without securing the cooperation of the internet service providers, the search engines, and the financing agencies.

As to Senator Specter's first question, we do not think that the DOJ and the DEA have given adequate consideration to the problem of prescription drugs, one of the two or three major narcotics problems for minors in the United States and elsewhere. But we think that law enforcement will inevitably have a limited impact in the places to which rogue pharmacies will increasingly move – the most lawless places in the world. So we would

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like to see them increase their commitment of law enforcement resources but also direct their attention to building a public/private partnership with the search engines, the internet service providers, and the financing organizations.

In his second question, Sen. Specter then asks about the responsibility of the pharmaceutical companies. Frankly, we have paid less attention to them, in part because we think that much of the overseas problem may involve illegal rip-offs of their drugs. Similarly, we have not examined the accuracy of their advertising.

As to Sen. Specter's third question, overseas merchant banks already employ extensive diligence procedures to prevent terrorist financing and other types of money laundering. We recommend that on-line narcotics dealers be included as targets for this type of diligence. Included here are pattern recognition techniques and other methods to establish that an individual or business is seeking credit on false pretenses or for unstated purposes. Importantly, our proposal does not seek to create extensive new regulatory obligations, but already builds on the framework that is in place and widely accepted in the industry.

Senator Specter's fourth question is why we would expect our recommendations to prove effective. An offer by internet service providers to block, on customer request, ads on a home computer for all controlled substances or for illegal sales of controlled substances would, we recognize, not provide protection against the use by minors of internet cafes or other computers. The same issue arises with efforts to break up street drug dealing on a

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particular corner. It will move elsewhere. Still, in both cases, we believe these efforts decrease adolescent's exposure to and ultimate use of illegal and dangerous drugs.

As to the credit card companies and financial institutions, we intend to furnish them with the names used on the internet by their customers offering to make sales without a prescription of controlled substances within the United States. That should, and legally does, trigger an obligation under the money laundering statutes to cease doing business with whatever front is receiving payment through a particular credit card company or financial institution. To the extent that the financing company will be able to identify who is the ultimate recipient of the money, it would also have an obligation to notify law enforcement authorities. A simple monitoring device would allow us to keep track and report to the Congress, on what the companies have done with our referrals.

These steps plus an understanding that the major search engines should warn of illegality whenever a user requests information about nonprescription sales of controlled substances or "prescription-without-visit" sales of controlled substances will not end the problem. But they can make a major dent in it. We are planning to report to the committee within the next month on steps that are already being taken in this area. Senator Specter also asks about CASA's recommendation to clarify federal law related to the offer to sell or purchase controlled prescription drugs on the internet without a valid prescription. We think that would be a good idea, although we believe that the better reading is that such offers are already illegal.

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The reason we are optimistic that monitoring alone will cause major corporations with extensive businesses in western democratic nations to take the necessary steps to end their facilitation of illegal sales of narcotics (substantially identical to heroin) is because of the impact on their reputations of being considered dealers -- businesses profiting from illegal sale of narcotics. Being seen in that way would be likely have a huge effect on business. But that requires someone keeping track of the extent to which they are continuing to facilitate illicit drug sales and making that information public. And that requires some protection against lawsuits for the monitoring agency.

Finally, we do support the online pharmacy consumer protection act.

With best regards,

Philip Heymann

43987.018

Response to Written Questions by Senator Leahy
A. Thomas McLellan, Ph.D.
Treatment Research Institute, Philadelphia, PA

1. How easy is it for youth and others to obtain prescription drugs legally over the Internet?

a. Approximately how many websites currently offer to sell controlled substances over the Internet? The total number of retail and portal sites we have identified as of April 1, 2007 is 1075, 73 of which are retail and 1002 are portal sites.

b. Approximately how many sites offer to provide prescriptions for controlled substances. Note - If you mean" prescriptions" as in pills etc: Whenever we mention "drugs," "narcotics," or "medications," we always mean prescription medications. If you mean" prescriptions" as in the actual paper-script or the like, I cannot recall a site that offered to provide a script without being the profit maker on the medications.

c. Of these sites, how many are operating in the U.S. subject to U.S. law? Of this total, 571 (about 50%) are registered in the United States. However, site registration is no indicator of shipping location or where the operator of the website resides. As demonstrated by Dr. Forman working with suburban Philadelphia law enforcement personnel, and by the GAO study, all drugs were shipped from overseas as indicated by their postage.

2. Do you support the Online Pharmacy Consumer Protection Act's requirement for in-person consultation for prescriptions used to buy controlled drugs over the Internet? TRI supports prohibiting the sale or purchase of controlled drugs without a prescription issued by a DEA-certified physician based on a physical examination. However, we also support a congressionally sanctioned Internet monitoring group to identify rogue online pharmacies, along with liability protection for credit card companies, Internet service providers, search engines, etc. who act on information supplied by the monitoring group to disclose or to impede sale/purchase of prescription drugs. Because this is an international problem with confounding jurisdictional and legal issues, we believe only a non-traditional approach – one that "follows the money" – may be the only effective solution.

3. Do you support creating a state and federal cause of action to bring injunctions to shut down non-complying websites? On this issue we defer to our partners in the Keeping Internet Neighborhoods Safe coalition.

4. The Partnership for a Drug-Free America reports that prescription medicines are increasingly available to teens from household medicine cabinets.

a. Given that teens have access via parents' medicine cabinets, why is the Internet a cause of growing concern? There has been no systematic study of the number of sales to minors from rogue Internet pharmacies –

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only the research referred to in my testimony and others which documents the availability and ease of access to these sites. As your own hearing witness tragically confirmed, however, there is anecdotal evidence that teenagers are purchasing dangerous drugs from the Internet. Even as we develop educational material warning parents of the dangers – and work to develop an effective interdiction strategy – a systematic survey documenting the scope of the problem should be commissioned, if for no other reason than providing baseline data against which the success of the response can be measured.

b. What are the most seriously abused drugs available online? Opioids including oxycodone (active ingredient in *Oxycontin, Percocet*) and hydrocodone (*Vicodin*) are the most abused and most abusable drugs available online. It is important to remember that while opioids differ in potency, even the weakest opioids (i.e., codeine, propoxphene) can match the effects of the most potent opioids if taken in large enough doses. This is known as the equi-analgesic principle of opioids. The addition of non-opioid painkillers to prescription opioids (e.g., Tylenol, Advil) makes them less abusable and less attractive to drug abusers. For many abusers Tylenol is considered to be a contaminate that interferes with injecting and snorting, and it can cause severe liver damage when used excessively. Pure opioid preparations such as *Oxycontin* (oxycodone continuous release) come in preparations of up to 160mg (a typical Percocet has 5mg) and have no non-narcotic painkillers to inhibit their abuse through non-oral modes.

5. ***At the hearing witnesses testified that young people believe that prescription drugs are safe because they are seen as medicine and not as dangerous as illicit drugs.***

a. How common is this misperception among teens and how serious is the problem? Results of the 2006 Partnership for a Drug-Free America parent and teen tracking survey revealed some disturbing trends. Released in March, 2006 (with new data scheduled for release early summer), PDFA reported that abuse of Rx/OTC medicines is now so prevalent it is "normalized" among teens:

- Every day 2,700 teens try a prescription medicine to get high for the first time;
- (One in five) or 4.5 million teens have tried prescription medication to get high;
- (One in 10) or 2.4 million teens report abusing cough medicine to get high.

Results also indicated teens mistakenly believe abusing Rx/OTC medicines is safe:

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- Half of teens did not see a great risk in abuse;
- 40 percent of teens (2 out of 5) agreed that Rx and OTC medicines, even those not prescribed by a doctor, are much safer to use than illegal drugs;
- 51 percent of teens said they abuse Rx and OTC medicines because "they are not illegal drugs;"
- 35 percent of teens gave "they are safer to use than illegal drugs" as a reason why teens would abuse Rx and OTC medicines;
- 32 percent of teens gave "fewer side effects than street" as a reason why teens would abuse Rx and OTC medicines.

b. What should be done to educate young people and minors? Several good websites have been launched, including the DEA site mentioned in your next question. Some of this material should be incorporated into school-based prevention programs. But the most effective educational program will be one aimed at parents (see below).

c. Is DEA's media campaign adequate to address the misperception that prescription drugs are less dangerous than street drugs? The DEA website is a good start. And there are others out there, including sites hosted by the Partnership for a Drug-Free America and National Institute on Drug Abuse. Groups like Parent Corps, an affiliate of the National Families in Action, are doing very good work using parent volunteers in schools to educate other parents and inform them of the dangers and ways to take action. It is very important that evidence-based educational information geared to a teenage audience be developed and broadly disseminated. But it is equally important that educational programs for parents also be widely disseminated – research shows that while the adolescent brain is still developing, parents must provide monitoring and supervision and they cannot be effective if they are not themselves aware of the dangers of prescription drugs.

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Response to Written Questions by Senator Specter
A. Thomas McLellan, Ph.D.
Treatment Research Institute, Philadelphia, PA

1. Have DOJ and DEA secured adequate resources to pursue cases of prescription drug diversion? It is not clear that any domestic agency acting alone has the legal authority or resources to effectively confront this problem which, at its core, begins with overseas pharmacies that are highly portable and operate in countries where no-prescription sale of controlled substances is not illegal. The Treatment Research Institute (TRI) is a member of the "Keeping Internet Neighborhoods Safe" coalition advocating for a congressionally sanctioned Internet monitoring group. One role of this group would be to share information with federal agencies on the names, numbers, locations and types of Internet pharmacies – and with this information, domestic agencies could better plan for and deploy the staff and resources to mount international action.

2. Your testimony indicates that most online pharmacies are overseas, hence there is not much that U.S. law enforcement can do to police them.

> ***a. Is this true?*** It is true that all of the no-prescription websites TRI has identified are located outside of the U.S. The total number of retail and portal sites we have identified as of April 1, 2007 is 1075, 73 of which are retail and 1002 are portal sites. Of this total, 571 (about 50%) are registered in the United States. However, site registration is no indicator of shipping location or where the operator of the website resides. As demonstrated by Dr. Forman working with suburban Philadelphia law enforcement personnel and the GAO study, all drugs were shipped from overseas as indicated by their postage.
>
> ***b. Does this suggest more effective solutions lie in national educational campaigns, or "blocking" software?*** Until a more effective enforcement/interdiction approach is developed, the best strategy is to mount an educational campaign. However, at this time, there is no parental control software (PCS) that includes narcotics or prescription drug filtering capabilities. TRI is working with Spectorsoft, a leading PCS developer, to add anti-narcotics features to their products. Without an adequate educational campaign, parents will be unaware of the potential dangers and the need to purchase and install this or a similar product.

3. You say there is evidence that teenagers think these drugs are safer than street drugs.

> ***a. How much is being done in public schools to curb this myth?*** National organizations such as the Partnership for a Drug-Free America and Parent Corps have done excellent work alerting parents to the dangers and myths surrounding prescription drug use, whether acquired from family medicine cabinets or from Internet pharmacies. We are not aware

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that any of these educational efforts have led to revised, school-based prevention programs, however. With regard to the unique issues surrounding Internet drug purchases, TRI is working with a Philadelphia school district to survey parents on their knowledge of the issue and to develop a training that both warns of and provides tools for combating the problem (see below).

b. How important is it for public schools to properly educate students as to the serious dangers of these drugs. Schools will never be a substitute for parental action. But schools are essential in the mix of agents that must be employed on a continual basis, beginning when children enter the "at risk" years, as early as age ten or eleven when they are first bombarded with pro-drug/alcohol messages and peer pressures. It is important for school personnel and parents to be educated regarding this problem. Directly educating students raises legitimate concerns that children will misuse the information to obtain drugs, a concern that must be addressed.

4. Regarding parental awareness:

a. Are there research findings pointing to the level of parental awareness of the ease to which teenagers can gain access to controlled substances over the Internet? TRI is conducting research into the level of parent awareness about the threat of Internet-based drug sales utilizing funds from Pennsylvania's tobacco settlement funding. Our initial impression is that most parents are not aware of the problem. Some have knowledge of Internet-drug "busts," but they do not relate this knowledge to the availability of Internet-based narcotics sales or to their children's safety. We have preliminary data from our ongoing study in the Philadelphia school district regarding the level of parental awareness about the problem. We have developed an entire curriculum and face-to-face training for parents. Although the data have not yet been analyzed as the study is still underway, most parents cite little or no awareness of the availability of no-prescription websites prior to our training.

b. How effective have we been in communicating concerns to parents? In general, substance abuse researchers, clinicians, national professional organizations, law enforcement agencies, as well as public health institutes and agencies have not communicated the message about the threat of online narcotics drug sales to the public. Educating parents about the scope of the problem is fairly easy once they have come to the conclusion on their own that a problem exists. As shown by the low recruitment rates into our ongoing research, we have had some difficulty attracting parents into our Internet-narcotics trainings with some of them citing 1) they do not believe a problem exists, or 2) that their child is too young to be at risk for prescription drug abuse. We have come across no data that suggests any significant movement

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by parents, schools, or government agencies to prevent access to prescription drugs of abuse over the Internet.

c. Is there any way to determine whether parents are heeding the message? Spectorsoft will be able to tell us how many copies of the PCS program we distribute are actually activated by study participants. Again, national educational projects have been undertaken by advocacy groups and it may be possible to add questions to national surveys – the National Household Drug Abuse Survey, for example – to determine whether the messages have taken hold in individual households. Finally, in collaboration with the Partnership for a Drug Free America, Comcast, Verizon and WGBH Boston we are developing a Parents Resource Center that will assist parents of children entering the at risk years, parents of kids who have begun to experiment with drugs like this, and parents of kids who have serious problems and need help. We will be providing unbiased, scientific information and concrete tools and skills to parents of all three of these kinds of kids to help them deal with the issues - and in the course of this we will be collecting information to inform us regarding whether we are getting through to parents.

d. Is there any indication parents are doing substantially more to prevent their children from purchasing controlled substances over the Internet? On the small scale of our study, we have anecdotal information that parents intend to take precautions in the household and we will confirm this when we administer follow-up surveys and through the results of our work on the Parents Resource Center (see above).

5. ***What more should be done to educate parents?*** In part because of our work in this area we have come to the realization that parents have been left out of the prevention efforts - these efforts have been relegated to schools primarily. We believe parents can play a very important role but they need the tools to do so. Described above is our initial effort in this arena and we could use additional support to develop it. In principle we believe that education is necessary but not sufficient. These direct-to-parent efforts should also be supplemented by a public awareness campaign. Only a clear, concise public awareness campaign utilizing all forms of media will give the public the impetus they need to take the next step and find ways to protect their children. Just as parents comprehend the Internet as a hiding place for sexual predators, so too must they begin seeing it as a potential source of illicit drugs that can be just as lethal as "street" drugs.

6. ***Do you support the Online Pharmacy Consumer Protection Act of 2007?*** TRI supports prohibiting the sale or purchase of controlled drugs without a prescription issued by a DEA-certified physician based on a physical examination. However, we also support a congressionally sanctioned Internet monitoring group to identify rogue online pharmacies, along with liability protection for credit card companies, Internet service providers, search engines, etc. who act on information supplied by the monitoring group to disclose or to impede sale/purchase of prescription drugs. Because this is an international problem with confounding jurisdictional and legal issues, we believe only a non-traditional approach – one that "follows the money" – may be the only effective solution.

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U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

August 5, 2008

The Honorable Patrick J. Leahy
Chairman
Committee on Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Please find enclosed a response to questions arising from the appearance of Deputy Assistant Administrator Joseph Rannazzisi before the Committee on May 16, 2007, hearing entitled "Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking".

We hope that this information is of assistance to the Committee. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Keith B. Nelson
Principal Deputy Assistant Attorney General

Cc: The Honorable Arlen Specter
Ranking Member

43987.025

"Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking"

May 16, 2007

Questions for the Hearing Record
for
Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
United States Department of Justice

QUESTIONS FROM CHAIRMAN LEAHY:

1) At the hearing, witnesses provided testimony about how easy it is for youth and others to obtain prescription drugs illegally on the Internet.

a. Approximately how many websites currently offer to sell controlled substance illegally over the Internet?

RESPONSE:

There is no definitive answer as to the actual number of websites that currently offer to facilitate the illegal sale of controlled substances.

Operationally speaking, an illicit "Internet pharmacy" is a DEA-registered brick and mortar location, illegally selling controlled pharmaceutical products ordered through the Internet. This characterization is based on our experience over the last several years of investigating these pharmaceutical Internet traffickers. We have found that the vast majority are linked with DEA-registered pharmacies tied to DEA-registered doctors. As far as DEA investigations are concerned, international sources of supply for controlled pharmaceuticals have been limited. One of these physical locations may service one or more websites. It should be noted that there are legitimate pharmacies that provide controlled substances via the Internet and operate daily within the boundaries of the law. However, as a point of clarification, there are many websites on the Internet that "offer" to sell controlled substances illegally. A "Google" keyword search such as "hydrocodone no prescription needed" reveals thousands upon thousands of hits. Many websites that "offer" to sell controlled substances do not in fact sell controlled substances at all but merely link the drug seeker to yet another website. This secondary site may also be a portal to yet another website. Eventually, the drug seeker will be linked to the anchor website that DEA has coined the "Internet Facilitation Center." DEA attempts to focus on the Internet Facilitation Centers, even though they are not required to register with DEA, because they are the linchpin in the criminal scheme. They link drug seekers to rogue doctors and rogue brick and mortar pharmacies, or illicit "Internet pharmacies," in exchange for huge profits.

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It must be made clear that a single website operated by a single "Internet Facilitation Center" may use multiple brick and mortar pharmacies to service its list of drug seekers. Similarly, one illicit Internet pharmacy may service multiple Internet Facilitation Centers. Moreover, websites can fluctuate in number minute by minute. A website can easily be de-activated one day and resurface under a different address the very next day. Again, as such, there is no definitive answer as to the actual number of websites that currently offer to facilitate the illegal sale of controlled substances.

b. Approximately how many websites offer to provide prescriptions for controlled substances over the Internet?

RESPONSE:

Presently, there is no proven method to determine how many websites offer to provide illicit prescriptions for controlled substances over the Internet. Many websites claim to offer prescription drugs, but do not actually provide the drug; rather, they link the drug seeker to other websites. Websites are easily put up and taken down and the actual owner(s) may be the same or entirely different individuals.

c. Of the websites identified in answer to Questions 1(a) and 1(b), approximately how many are currently operating in the United States subject to U.S. law?

RESPONSE:

DEA cannot determine the number of websites operating in the United States that serve as Internet Facilitation Centers. Within the United States and its territories, there are more than 1,024,900 DEA-registered practitioners who can provide prescriptions, and 64,900 DEA-registered brick and mortar pharmacies that can dispense controlled substances. While the vast majority do so legally everyday, there is no special registration that identifies any of the pharmacies as dispensing controlled substances on the basis of Internet-based prescriptions. Because of this, there is no proven method to determine exactly how many rogue websites are operating in the United States.

2) At the hearing, you were asked to estimate the number of enforcement actions against online pharmacies, and you wanted the opportunity to check you records before providing an answer. Now that you have had time to check your records, I am sure you can provide answers to the following questions:

a. Over the last three years, how many criminal arrests have the Drug Enforcement Administration ("DEA") made of individuals operating online pharmacies engaged in illegally distributing controlled substances?

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RESPONSE:

From Fiscal Year 2005 through Fiscal Year 2007, 211 individuals have been arrested by DEA as a result of investigations of the illegal distribution of controlled substances over the Internet.

From FY 2005 through FY 2007, approximately $80 million has been seized, to include cash, bank accounts, property, and computers.

Other examples of DEA Internet investigations:

Operation Baywatch: The DEA Office of Diversion Control developed information that a major wholesale drug distributor had distributed over two million dosage units of schedule III controlled substances (generic and brand name hydrocodone combination products) to seven illicit Internet pharmacies located in the Tampa, Florida area during a three-week period in October 2005.

In January 2006, DEA deployed a team of diversion investigators to the Tampa District Office to support the operation. This investigative team served seven Administrative Inspection Warrants on the targeted pharmacies. As a result of these warrants, investigators seized large volumes of documentary evidence.

From this enforcement operation, investigators learned that numerous doctors and 33 websites were associated with these illicit Internet pharmacies. The investigation of the owners of these Internet sites/pharmacies is still ongoing. As a result of the investigation to date, three of the seven pharmacies' DEA registrations have been suspended; two pharmacies ceased distributing controlled substances for Internet Facilitation Centers; and two other pharmacies ceased their businesses altogether.

Operation Lightning Strike: Based on the foundation established by Operation Baywatch, from January 22 to February 21, 2007, agents and diversion investigators from several DEA offices joined together to execute search warrants, administrative inspection warrants, and administrative subpoenas on eight Internet pharmacies in the Tampa Bay area. (Two pharmacies were original targets of Operation Baywatch). These pharmacies illegally distributed controlled pharmaceuticals for rogue Internet websites. As a result, DEA registrations were suspended for all eight pharmacies. To date, this initiative has resulted in the seizure of 907,328 dosage units of generic and brand name hydrocodone combination products, and enough bulk hydrocodone to yield an additional 600,000 dosage units. Furthermore, in the aftermath of Operation Lightning Strike, two other Operation Baywatch pharmacies voluntarily surrendered their DEA registrations. In 2006, these 10 pharmacies purchased 45 million dosage units of generic and brand name hydrocodone combination products, representing 64 times the amount 10 legitimate pharmacies would normally dispense in a one-year period.

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Operation CybeRX: The Johar Saran pharmaceutical controlled substance Internet trafficking organization operated 22 "store-front" pharmacies in the Dallas/Ft. Worth area that shipped Schedule III-V pharmaceutical controlled substances nationwide to Internet customers who did not have a legitimate doctor-patient relationship with their prescribing physicians. From August 2004 to September 2005, the Saran drug trafficking organization was responsible for the illegal distribution of approximately 3.5 million dosage units of Schedule III-V controlled substances per month. From January 2005 to July 2005, Saran's gross income was approximately $19 million. Saran, his associates, and his corporations were indicted on 201 counts, including charges of illegal distribution, conspiracy, healthcare fraud, mail and wire fraud, and money laundering. Saran subsequently pled guilty to several offenses, including conspiracy to commit healthcare fraud, mail fraud, and conspiracy to distribute controlled substances. In addition to his own guilty plea, Saran entered guilty pleas on behalf of 20 corporations, including 17 pharmacies that he controlled and used in the criminal conspiracy. The Pharmacist in Charge of Saran's pharmacies also pled guilty to conspiracy to commit healthcare fraud, wire fraud, and money laundering, and conspiracy to distribute controlled substances. In addition, immediate suspension orders were served against 22 pharmacies and 14 physicians in Texas, Florida, Arizona, Washington, and Puerto Rico. Orders to Show Cause were also served on 11 physicians. Seizures included $17 million in cash, bank accounts and property.

Operation Cyber Chase: An investigation of the Brij Bansal drug trafficking organization concluded with the dismantlement of the organization and the arrest of 20 individuals in New York, Philadelphia, India, Costa Rica, Austria, and Hungary. Those arrested were distributing drugs worldwide using rogue Internet pharmacies to dispense controlled substances directly to customers who were never medically evaluated by a physician. The Bansal organization was responsible for the distribution of more than 2.5 million dosage units of Schedule II through IV pharmaceutical controlled substances per month. The Bansal organization supplied controlled substances to eight other drug organizations that operated over 200 websites. As of June 30, 2006, this investigation has resulted in 26 arrests, and seizure of 5.8 million dosage units of Schedule II through IV controlled substances, 105 kilograms of ketamine (a Schedule III controlled substance), and $8.6 million in cash.

a. (1) In those cases, how many defendants were charged, convicted, and sentenced, and what was the approximate length of sentence for the defendants?

RESPONSE:

Twenty-three of the 68 arrests in Fiscal Year 2005 have been adjudicated. Of those, ten individuals were sentenced to prison: one received a sentence of 45 years confinement, another received 30 years, and the remaining defendants received an

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00059 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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average sentence of 15.9 months confinement. Seven other individuals received probation for an average term of 34.3 months; another was fined $1,500; and five other cases were either declined for prosecution or dismissed.

Sixteen of the 38 arrests in Fiscal Year 2006 have been adjudicated. Of those, ten individuals were sentenced to prison for an average term of 36.8 months; and six other individuals received probation for an average term of 22 months.

Eight of the 105 arrests in Fiscal Year 2007 have been adjudicated. Four individuals were sentenced to prison for an average term of 20.5 months. Four cases were declined for prosecution or dismissed.

a. (2) In those cases, how many minors were involved in obtaining controlled substances over the Internet?

RESPONSE:

DEA does not know, nor can it ascertain how many minors were involved in obtaining controlled substances over the Internet. This question addresses one of the more serious issues involving the diversion of controlled substance pharmaceuticals over the Internet. DEA's experience from investigating rogue Internet pharmacies has shown that the Internet Facilitators frequently use a "medical questionnaire" that the customer or "patient" fills out. The questionnaire may be sent to a doctor for review: however, because the Internet by its nature is anonymous, and the doctor never directly evaluates the online "patient" (either in person or through a legitimate telemedicine consultation meeting appropriate criteria), the online patient's age cannot be determined with any certainty. Additionally, DEA typically does not investigate the purchase of controlled substances. DEA focuses its limited manpower and resources on the organizations that illegally sell these drugs.

b. Over the past three years, how many civil actions have the DEA undertaken to suspend an individual's or a company's authority to distribute controlled substances for misuse of the Internet?

RESPONSE:

In 2005, DEA served Immediate Suspension Orders (ISOs) against 26 pharmacies. Twenty-two of the pharmacies ceased operation, and three pharmacies entered into Memorandums of Agreement (MOAs) to cease Internet distribution. An administrative hearing was conducted concerning the remaining pharmacy, and the DEA Deputy Administrator subsequently issued a Final Order revoking its registration.

That same year, 13 physicians were served with ISOs; and 11 physicians were served with Orders to Show Cause (OTSCs). Of the physicians who received ISOs, one physician surrendered his DEA registration; the DEA Deputy Administrator issued one Final Order revoking a physician's registration; three are pending a Final Order by the

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00060 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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Deputy Administrator; seven reached settlement agreements with DEA that include a prohibition from issuing controlled substance prescriptions via the Internet; and one physician's registration expired without renewal. Of the physicians who received OTSCs, two physicians surrendered their DEA registrations; the DEA Deputy Administrator issued one Final Order revoking a physician's DEA registration; one is pending a Final Order by the Deputy Administrator; two reached settlement agreements with DEA that include a prohibition from issuing controlled substance prescriptions via the Internet; and five allowed their registrations to expire.

In 2006, five pharmacies were served with ISOs and 10 with Orders to Show Cause (OTSCs); a total of 15 administrative actions. Of the pharmacies served with ISOs, four subsequently ceased operation; and one surrendered its registration. Of the 10 pharmacies issued OTSCs, three either surrendered their registrations or ceased business; four reached settlement agreements with DEA that include a prohibition from dispensing controlled substance prescriptions via the Internet; and three are pending a recommended decision from the Administrative Law Judge. Three pharmacies that were served with OTSC were also served with ISOs while pending hearings due to their continued illegal distribution of controlled substances.

Additionally, in 2006, one DEA-registered distributor was served with an ISO for illegal sales to Internet pharmacies. The hearing concluded and the Deputy Administrator revoked its registration. Another DEA-registered distributor was issued an OTSC for illegal sales to Internet pharmacies. That matter was settled.

In 2007, 11 pharmacies were served with ISOs. Eight pharmacies either surrendered their DEA registrations or ceased their business practices. The DEA Deputy Administrator issued Final Orders revoking the remaining three pharmacies' DEA registrations. Additionally, two physicians were served with ISOs in 2007. One physician surrendered his DEA registration; and the Deputy Administrator issued a Final Order revoking the registration of the other physician. Two more physicians were issued OTSCs in 2007. One is pending a hearing and the other is pending a recommended decision from the Administrative Law Judge.

In 2007, six distributors were served with ISOs for illegal sales to illicit Internet pharmacies. Two distributors surrendered their registrations; one distributor reached a settlement agreement with DEA; and three are pending a hearing. Additionally, two other distributors were served with OTSCs in 2007. One distributor reached a settlement agreement with DEA; the other case is stayed pending settlement discussions between DEA and the registrant.

Finally, thus far in 2008, two distributors have been served with an OTSC. Those cases are pending a hearing.

b. (1) In those cases, how many individuals or companies were subject to fines or other civil penalties as a result of those actions?

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00061 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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RESPONSE:

One distributor consented to a fine of $800,000 for failing to report to DEA suspicious orders for controlled substances placed by pharmacies engaged in Internet diversion schemes. No other fines have been imposed on distributors to date. It should be noted that DEA does not have the direct authority to levy fines against DEA registrants. The United States Attorney's Office has the authority to bring a civil action against a registrant that may result in a fine.

b. (2) In those cases, how many minors were involved in obtaining controlled substances over the Internet?

RESPONSE:

See above answer in question 2 a (2).

3) **The DEA has responsibility for regulating the distribution of controlled substances through pharmacies and investigating the diversion of controlled substances. In 2002, the Justice Department Inspector General found that despite the widespread problem of controlled pharmaceutical diversion and abuse, "the DEA had been slow to commit resources to address this problem." In a July 2006 follow up review, the Inspector General found that "from FY 2002 to FY 2005, the DEA increased the percentage of time that diversion investigators spent investigating Internet diversion from 3 percent to 11 percent."**

a. What percentage of time has DEA diversion investigators spent investigating Internet diversion from FY 2005 to the present?

RESPONSE:

Diversion investigations, including Internet investigations, are worked not only by Diversion Investigators, but also by DEA Special Agents, Task Force Officers, and Intelligence Analysts.

DEA is very concerned about the diversion of pharmaceutical drugs via the Internet and has devoted an increasing amount of man-hours and resources towards this issue. For example, from FY 2003 to FY 2005, DEA increased Special Agent (SA) work hours devoted to pharmaceutical investigations by 114 percent; increased the number of Intelligence Analyst work hours by 235 percent; and increased the total number of work hours expended on Internet diversion investigations by more than 71 percent.

Specifically, in FY 2005, the combined number of work hours devoted to Internet investigations was 163,597 hours; in FY 2006, the combined number of work hours was 195,408 hours; and in FY 2007, the number of combined hours was approximately 200,000 hours.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00062 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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During FY 2006, 72 percent of Diversion Investigator (DI) work hours were for criminal and complaint investigations, 15 percent were for regulatory investigations, and 13 percent were for other work functions. During FY 2007, 76.15% percent of Diversion Investigator (DI) work hours were for criminal and complaint investigations. 18.46% percent were for regulatory investigations, and 5.40% were for other work functions. This workload shift, from regulatory to criminal, has increased the complexity of diversion investigations.

b. Are any of the DEA's investigative resources focused specifically on the illegal distribution of controlled substances over the Internet? If so, what resources and how many full-time positions are devoted to enforcement and investigation of activities over the Internet?

RESPONSE:

DEA recognizes that illegal distribution of controlled substances over the Internet is a serious threat. As these Internet drug trafficking organizations evolve, so must our investigative capabilities and techniques. DEA has and will continue to leverage all its resources to attack not only Internet drug trafficking organizations, but all drug trafficking organizations. DEA has dedicated a variety of resources and personnel to address the growing threat posed by Internet drug trafficking organizations. In addition to having a unit within DEA's Special Operations Division to specifically coordinate Internet investigations with field elements, other efforts include the following:

i. DEA has provided all field divisions with undercover credit card accounts in order to make online purchases of controlled pharmaceuticals for use as evidence in Internet investigations.

ii. DEA's Diversion Control Program is using all administrative and regulatory tools possible to identify and shut down Internet pharmacies violating the Controlled Substances Act.

iii. DEA is using the Automated Reports and Consolidated Order System (ARCOS) to identify suspicious purchasers of narcotics and determine which retail pharmacies and practitioners are most likely involved in the illicit distribution of controlled substances over the Internet. Again, it should be noted that pursuant to 21 U.S.C. § 827(d), distributors are required to report the sale, delivery, or other disposal of narcotic controlled substances to ARCOS.

iv. DEA's Office of Diversion Control has begun an Internet Distributor Initiative to focus on the more than 800 DEA-registered distributors of controlled substances.

1. As part of this initiative, DEA has created a presentation explaining the laws, regulations, and DEA policies for the

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00063 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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wholesale distributors. This presentation advises wholesale distributors of the common characteristics of illegal Internet pharmacies. The presentation is designed to emphasize to wholesale distributors that they are required to maintain effective controls against diversion, and to report suspicious orders of controlled substances when discovered.

2. When educational efforts do not yield the desired result of cutting the supply lines to these illicit operations, DEA will implement administrative, civil, or criminal sanctions against the registrant.

- DEA's Outreach Initiatives
  - i. Establish hotlines the public can use to report suspicious online pharmacies.
  - ii. Use DEA Internet sites to educate the public about the dangers of abusing controlled pharmaceuticals.
  - iii. Provide timely, accurate, and persuasive information to a variety of audiences in order to build support for effective drug enforcement.
  - iv. DEA has worked with Internet search engines such as Google, AOL, and Yahoo to create Public Service Announcements (PSAs) designed to appear when consumers attempt to illegally buy controlled substances online.
- DEA's Internet Industry Initiative
  - i. Internet traffickers of illicit pharmaceuticals rely extensively on the commercial services of three principal legitimate business sectors:
    - Providers of Internet services including web hosting, domain name registration, and search engines;
    - Express package delivery companies;
    - Financial services companies, including major credit card companies and third party payment service providers.
  - ii. Since 2003, DEA has been working with Internet-related businesses regarding the diversion of controlled pharmaceuticals.
  - iii. In 2005, DEA sponsored three interagency Internet industry conferences attended by Internet companies, parcel carriers, financial companies, and other federal agencies.
  - iv. DEA has continued to develop progressively closer working relationships with leading companies in each sector.
- DEA's Training Initiatives
  - i. AUSA Training - In 2005, DEA and the Department of Justice's (DOJ) Narcotics and Dangerous Drugs Section hosted the first-ever training for

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00064 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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approximately 100 Assistant United States Attorneys, Diversion Investigators, and Special Agents focusing on the Internet diversion of controlled substance pharmaceuticals. DOJ conducted a second training seminar for AUSAs in 2005; and a third seminar was held in May 2007.

ii. Internet Investigations Training - Implemented online investigations training program for Special Agents, Task Force Officers and Intelligence Analysts covering specialized communication exploitation techniques used to identify and target Internet traffickers of controlled pharmaceuticals.

iii. Special Agent Diversion Training - Implemented pharmaceutical diversion training for DEA Special Agents assigned to Tactical Diversion Squads and other major pharmaceutical investigations.

c. Does the DEA have any unit that is responsible for searching the Internet to find websites that offer to sell controlled substances illegally? If not, why not?

RESPONSE:

. Again, as a point of clarification, DEA, for purposes of its enforcement activities, defines "Internet pharmacy" as a brick and mortar location which utilizes websites to facilitate transactions. Although many Internet pharmacies legally operate such websites, other websites merely serve as the portal which may eventually connect the drug seeker to a rogue brick and mortar pharmacy and rogue doctor by way of the Internet Facilitation Center. Consequently, DEA focuses its resources on identifying, disrupting and dismantling the organizations and individuals behind the websites who profit from the illegal sale of these highly dangerous substances. To accomplish this, DEA has dedicated sections whose mission it is to coordinate pharmaceutical investigations that include Internet investigations.

One of those sections, within our Office of Enforcement Operations, is devoted to assisting field operations regarding investigations and administrative actions related to the diversion of pharmaceuticals. This section helps to accomplish this by working with private industry in tracking websites, financial leads, and shipments of controlled substances. We are also using all current regulatory tools possible to identify and shut down those that choose to operate outside of the Controlled Substance Act. Additionally, DEA is using the Automation of Reports and Consolidated Orders System (ARCOS) to identify suspicious purchases and determine which retail pharmacies and practitioners are likely to be involved in the illicit distribution of controlled substances via the Internet. Both manufacturers and distributors are required to provide information to the ARCOS database pertaining to any sale, delivery, or other disposal of narcotic controlled substances. DEA is able to develop leads and augment investigations using this information.

DEA's Special Operations Division also has a unit that coordinates Internet investigations with field elements. As part of their coordination and investigative efforts

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00065 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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they routinely check internal databases to determine whether or not websites under investigation are linked to other investigations.

d. *In its 2006 report, the Inspector General examined several investigative tools that are part of DEA's overall operational strategy, including the Online Investigations Project (OIP), telephone and online hotlines, undercover equipment, and training in conducting Internet diversion investigations. The Inspector General found that although the OIP has become a valuable investigative tool, "it cannot automatically identify websites with the highest volume of suspect pharmaceutical sales as originally intended."*

d. (1) Are you concerned that, contrary to the original intent of OIP, DEA may not possess the resources or capacity to identify rogue online pharmacies with the highest volume of suspect sales?

RESPONSE:

Since rogue online pharmacies were first encountered, DEA has made great strides in dealing with this phenomenon. Presently, DEA is able to identify and target numerous rogue online pharmacies. As with other criminal schemes, however, DEA must continue to modify its investigative techniques as these schemes evolve and adapt to actions taken by law enforcement.

d. (2) Do you believe that a DEA or a nongovernmental organization should regularly search the Internet to identify these websites and other locations that offer to sell controlled substances without a prescription?

RESPONSE:

Presently, DEA is able to identify rogue Internet sites through a variety of investigative means and techniques and does not believe that a non-governmental organization is necessary to unilaterally search the Internet and identify websites. Nor do we believe it would be wise to delegate an investigative responsibility such as identifying potential rogue Internet sites to a non-governmental organization. It is important to stress that to DEA, an "Internet pharmacy" is a brick and mortar location which sells controlled substances through Internet websites. Furthermore, it is important to clarify that DEA's focus is on the individuals and organizations that use the Internet to sell highly potent and dangerous controlled substances behind a cloak of legitimacy. We allocate our resources towards targeting and identifying the organizations using the websites as a front to conceal nothing more than a 21st century drug trafficking operation.

e. *Since 2002, the DEA has established telephone and online hotlines for reporting suspicious Internet pharmacies. The Inspector General's 2006 report found that "these hotlines have yielded few leads that resulted in diversion investigations." Equally troubling,*

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00066 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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the Inspector General found that while the DEA has started to provide undercover equipment to its diversion groups, "as of May 2006 most diversion groups still did not have this equipment."

e. (1) Are you concerned that DEA lacks the resources to ensure that its intelligence, technological, and investigative tools operate effectively?

RESPONSE:

As a matter of practice, DEA routinely evaluates its needs and its resources. Criminal organizations evolve and adapt and so too must DEA to effectively target and attack these organizations. As of December 2006, DEA has provided all of its field division offices with undercover credit cards and continues to deploy undercover computers. DEA has enhanced its training efforts related to diversion and Internet related crimes. DEA is also adding 40 Intelligence Analysts who will be devoted full-time to diversion investigations.

e. (2) What percentage of diversion investigators receive specialized training that can prove useful for conducting Internet investigations?

RESPONSE:

Diversion Investigators, Special Agents, Intelligence Analysts and Task Force Officers all assist and work in diversion investigations as needed. As resources dictate, all of these components receive diversion related training.

Specifically, Diversion Investigator training includes, but is not limited to:

- Internet/Financial Training for Diversion Investigators (DIs): As of the end of FY 2007, 458 of the 520 Diversion Investigators have completed Internet training conducted by DEA's Special Operations Division (SOD). Training for the remaining DIs will be coordinated through SOD as funding becomes available. SOD has scheduled 25 Internet Telecommunication Exploration Program (ITEP) classes for FY 2008.

- Advanced Internet Training: A newly developed Advanced Internet Investigation training course expands the information taught at the SOD Internet class. The Advanced Internet Investigations class provides students with more practical and investigative-based training while utilizing advance Internet exploitation tools. This class also covers the preparation of subpoenas and is offered to DIs, IRSs, and SAs who have some basic computer knowledge. Three A-ITEP classes were conducted in FY 2007.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00067 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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- Diversion Financial Techniques: In addition to the Advanced Internet Investigations course, DEA conducted two Diversion Financial Investigation Technique Schools during FY 2007. This four-day training program is designed to present field skills that allow personnel to effectively use financial information to document the money trail of drug crimes. Specialized financial investigation methods are presented to identify targets and drug networks. Sixty-six DIs attended the two Diversion schools conducted at the DEA Training Academy. In addition, twelve DIs also attended a Financial Investigation Technique School.

- Diversion Conspiracy and Complex Investigations:
  During FY 2007, the Office of Training, Diversion Operations Unit, conducted one Diversion Conspiracy and Complex Investigations School. This three-day school is designed to train DIs in the art of developing complex, long term, and historical investigations. The course places emphasis on case histories to enhance the learning process, including case development and the use of special investigative techniques, such as wire intercepts and the use of financial data bases. Twenty-eight DIs were trained on May 15, 2007 in a school conducted at the DEA Training Academy. Additionally, a Diversion Conspiracy & Complex Investigation School was held on February 20, 2008 at the DEA Training Academy.

- Money Laundering Seminar:
  During FY 2007, DEA conducted two Money Laundering Seminars. This three-day school is offered to DEA Special Agents, Task Force Agents, Intelligence Research Specialists, and Diversion Investigators. This seminar provides specialized money laundering training to increase students' investigative abilities to identify, gather, and document drug-money laundering organizations in the United States and internationally. In addition, students will increase their knowledge of the financial services industry, how to target money laundering systems, and seize and forfeit the revenues generated by the drug-money laundering organizations. Two DIs attended this training.

- Financial Investigation Seminars
  During FY 2007, DEA conducted ten Financial Investigations Seminars. This four-day school is co-sponsored with the Department of Justice and is offered to DEA Special Agents, Task Force Agents, Intelligence Research Specialists, and Diversion Investigators. This seminar is designed to present field skills that

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00068 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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allow personnel to effectively use financial information to document the money trail of drug crimes. Specialized financial investigation methods are presented to identify targets and drug networks, corroborate charges, and locate and forfeit assets. Seven DIs attended this training in FY 2007.

- Asset Forfeiture Training
  During FY 2007, DEA conducted six Asset Forfeiture Training Schools. This 4 1/2 day program is offered to DEA Special Agents, Task Force Agents, Intelligence Research Specialists, and Diversion Investigators. This program is designed to enhance the participant's investigative abilities in recognizing and conducting financial investigations. Through lectures combined with audiovisual presentations, participants learn how to identify, track, evaluate, and seize financial assets. Fourteen DIs participated in this training.

4) **At the hearing, witnesses testified about fraudulently obtaining prescriptions over the Internet, and how individuals can obtain prescriptions for controlled substances without a face-to-face meeting with a doctor.**

a. Does the DEA support legislation to require in-person consultations for prescriptions used to buy controlled drugs over the Internet?

RESPONSE:

DEA believes that any legislation that would effectively address the fraudulent prescribing of controlled substances via the Internet must include the requirement of a legitimate medical evaluation by the prescribing practitioner, either through an in-person meeting or a valid telemedicine consultation meeting appropriate criteria. At present, criminal Web entrepreneurs thrive on the anonymity of the Internet by hiring unscrupulous practitioners to write prescriptions for controlled substances to "patients" with whom the practitioners have no bona fide doctor-patient relationship. The invalid prescriptions are filled by unscrupulous brick-and-mortar pharmacies, which have found it lucrative to partner with the operators of the rogue websites. In the absence of the legitimate medical evaluation requirement, both the prescribing practitioners and the unscrupulous pharmacies knowingly turn a blind eye to this fraudulent and medically unsound method of dispensing controlled substances via the Internet. The practitioners who write prescriptions for these rogue websites typically rely solely on an online questionnaire filled in by the drug-seeking customer, and/or faxed medical records from the customer, with no meaningful examination of the information contained in such documents to determination whether it is fraudulent. The legitimate medical evaluation

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00069 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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requirement would eliminate this practice and thereby thwart the primary method of operation employed by most rogue Internet pharmacy operations.

The Administration supports the Senate-passed version of S.980, the "Ryan Haight Internet Pharmacy Consumer Protection Act of 2008", and calls on Congress to pass it.

5) According to court records, the makers of Oxycontin, Purdue Pharmaceuticals, recently agreed to pay more than $600 million in fines and penalties, and three of its top executives admitted they were responsible for misleading those who bought and prescribed the drug.

a. What role did the DEA play in the investigation and prosecution of this case?

RESPONSE:

Though DEA was consulted at the onset of this investigation, it did not participate in the investigation because the resulting charges/convictions fell under the Food, Drug, and Cosmetic Act, and not the Controlled Substances Act.

b. If the DEA did not participate, why not?

RESPONSE:

We respectfully refer you to the above answer.

6) One of the new tools that can be used to shut down rogue online pharmacies would be to allow states attorneys general and federal authorities to bring injunctions against those who do not follow the strict letter of the law in dispensing controlled substances over the Internet.

a. Does the DEA support creating a state and federal cause of action to bring injunctions to shut down non-complying websites?

RESPONSE:

The Administration supports the Senate-passed version of S.980, the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008" which provides for a State Cause of Action pertaining to online pharmacies.

7) What are the most seriously abused prescription drugs that are available on the Internet?

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00070 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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RESPONSE:

DEA investigations of rogue online pharmacies have centered primarily on Schedule III controlled substances, such as hydrocodone combination products, and Schedule IV controlled substances, such as alprazolam and phentermine. This is consistent with the 2006 National Survey on Drug Use and Health. According to that survey, 7 million Americans used psychotherapeutic drugs non-medically, with 5.2 million abusing pain relievers.

a. What, if any trends, has the DEA seen in prescription drug abuse over the last three years?

RESPONSE:

Although the Internet has provided a valuable service in supplying legitimate prescription drugs to consumers (who benefit from the ease of having valid prescriptions filled online), the Internet has also provided illegal drug traffickers with a means of diverting powerful controlled substances from the legitimate marketplace for illicit use.

8) At the hearing, witnesses testified that young people too often believe that prescription drugs are safe, because they are seen as medicine, and teenagers consider them not as dangerous as other illicit drugs.

a. How common is this misperception among young people and how serious is the problem?

RESPONSE:

According to the Partnership for a Drug Free America's 2005 Partnership Attitude Tracking Study:

- Nearly one in five teens (19 percent or 4.5 million) report abusing prescription medications to get high;
- Two in five teens (40 percent, or 9.4 million) agree that Rx medicines, even if they are not prescribed by a doctor, are much safer to use than illegal drugs;
- Nearly one-third of teens (31 percent, or 7.3 million) believe there's "nothing wrong" with using Rx medicines without a prescription once in a while;
- Nearly three out of 10 teens (29 percent or 6.8 million) believe prescription pain relievers – even if not prescribed by a doctor – are not addictive.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00071 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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. According to the most recent University of Michigan, Monitoring the Future study, OxyContin® (OxyContin) use increased steadily among 12th graders from when it was first measured in 2002 until 2005, with annual prevalence rising from 4 percent to 5.5 percent. In 2007 5.2% of 12th graders reported past year use. Hydrocodone [brand name Vicodin] is another specific narcotic drug used for pain control, and has an even higher prevalence rate than OxyContin. In 2007 it showed an annual prevalence among 8th, 10th and 12th graders of 2.7 percent, 7.2 percent, and 9.6 percent, respectively.

b. What has the DEA done to educate young people and minors about the dangers of prescription drugs?

RESPONSE:

In 2005, DEA established a website designed for teenagers called "justthinktwice." Launched in August 2005, www.justthinktwice.com is devoted to and designed by teenagers to give them the hard facts about illicit drugs, including the illicit use of prescription drugs. Through the website, DEA is telling teens to "think twice" about what they hear from friends, popular culture, and adults who advocate drug legalization. Information is also provided regarding the harm drugs cause to their health, their families, the environment, and innocent bystanders. Since its creation, the website has had over 152 million hits. DEA Demand Reduction also produced a teacher's guide for use in schools and by parents to accompany the website.

In June, 2006, DEA Demand Reduction hosted the first-ever *Vigil for Lost Promise*, which brought together parents and siblings who had lost loved ones to drugs. One of the *Vigil*'s participants, Francine Haight, also provided testimony at this hearing regarding the loss of her son Ryan. DEA Demand Reduction continues to work with parents.

Whenever possible DEA works with and continues its support for grassroots organizations that reach out to teens and youngsters regarding drug abuse.

9) In December 2006, the University of Michigan released a national survey, called "Monitoring the Future" – the largest and most in-depth survey of youth drug use in the nation measuring drug, alcohol and cigarette use and related attitudes among teenagers. The study revealed, among other things, that there was a thirty percent increase in the use of the prescription drug OxyContin last year. I understand that in April of 2001 the DEA implemented a comprehensive National Action Plan to reduce the diversion and abuse of OxyContin.

a. How many DEA investigations and arrests have led to successful prosecutions in OxyContin cases since 2001?

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00072 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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RESPONSE:

OxyContin is a controlled release formulation of the generic drug oxycodone. From April 2001, when the OxyContin National Action Plan was implemented, to the end of FY 2006, DEA initiated 970 oxycodone (both brand name and generic) investigations. In FY 2007, another 253 oxycodone investigations were initiated. From 2001 through FY 2007, DEA made 1,249 oxycodone-related arrests. Though DEA databases do not track prosecutions, the majority of DEA arrests result in successful prosecutions.

b. For years now, DEA publications have claimed that DEA is "working closely" with FDA to urge the reformulation of OxyContin.

b. (1) Does the DEA support the reformulation of Oxycontin to alleviate its addictive qualities? If so, what has the DEA done to urge the FDA to require this reformulation?

RESPONSE:

DEA does not have regulatory or statutory authority for involvement in the drug approval process; the FDA is the Federal agency responsible for review and approval of pharmaceuticals. Moreover, information such as drug formulations are trade secrets and/or confidential commercial information, and FDA is prohibited under statute and regulation from disclosing such information. However, DEA does have the authority to schedule drugs and has experience and knowledge in how formulations have been or might be defeated. DEA has had, and will continue to have, meetings with FDA and industry to provide its expertise or assistance as needed.

10) I am concerned that curbing Internet prescription drug abuse may take collaboration between law enforcement and private sector companies (*i.e.*, credit card companies, payment systems, Internet Service Providers, common carriers, etc.). What current methods of collaboration with private sector entities does DEA use to combat rogue online pharmacies? Please describe in detail.

RESPONSE:

Due to the sensitive nature of these discussions, DEA is not at liberty to divulge the details of these collaborative efforts. By doing so, we would compromise methods and techniques being utilized today. However, we can convey that since 2003, DEA has been working with Internet-related businesses regarding the diversion of controlled pharmaceuticals. DEA's Internet Industry Initiative was established to exploit the weaknesses inherent to the schemes used by Internet traffickers who rely extensively on the commercial services of three principal legitimate business sectors: Internet service providers; express package delivery companies; and financial services companies, including major credit card companies and third party payment service providers.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00073 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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DEA has also worked with Internet search engines such as Google, AOL, and Yahoo to create links to DEA's Diversion Website. These links are designed to appear when consumers attempt to buy controlled substances online without the required legitimate physician-patient relationship.

11) Information sharing between private sector entities and the DEA may be critical to preventing online prescription drug abuse. While the number of occasions may be limited, the willingness for private sector entities to share information with DEA about locations to sell pharmaceuticals illegally and to act upon them may be diminished by the threat of law suits.

a. Do you think that the private sector can play an important role in assisting DEA reduce online drug abuse?

RESPONSE:

As stated above, DEA has been working closely with various private sector businesses to reduce drugs being diverted via the Internet. DEA would not have been as successful as it has been without the cooperative efforts and assistance provided by these businesses.

12) What are the DEA's views on the pending legislation introduced by Senator Feinstein, S. 980, the Online Pharmacy Consumer Protection Act of 2007?

RESPONSE:

The Administration supports the Senate-passed version of S. 980, the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008", and calls on Congress to pass it.

QUESTIONS FROM SENATOR DURBIN:

1) In your testimony you mention the key role that distributors of controlled substances play in controlling illicit Internet pharmacies. Your testimony also mentions that the DEA has initiated administrative, civil and criminal sanctions against some distributors of controlled substances because they were distributing to illicit Internet pharmacies.

a) How many enforcement actions has the DEA initiated?

RESPONSE:

We respectfully refer you to the response to Chairman Leahy's Question 2(a).

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00074 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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b) How many distributors have received administrative, civil or criminal sanctions? Please break down your answer by type of sanctions received.

RESPONSE:

Administrative/Civil Actions:
In 2006, one DEA-registered distributor was served with an ISO for illegal sales to Internet pharmacies. The hearing concluded and the Deputy Administrator revoked this distributor's registration. Another distributor was served with an Order To Show Cause (OTSC) for similar conduct. That matter was settled.

In 2007, six distributors were served with ISOs for illegal sales to Internet pharmacies. Of these six, one surrendered its registration; two other distributors reached settlement agreements with DEA. The remaining three distributors are pursuing settlement negotiations with DEA. Also in 2007, two more distributors were served with OTSCs for illegal sales to Internet pharmacies. Both distributors reached settlement agreements with DEA.

To date in 2008, two distributors have been served with OTSCs for illegal sales to Internet pharmacies. DEA is actively engaged in negotiating settlement agreements with these distributors.

Criminal Actions:
There were no criminal sanctions put forth on any distributors during this timeframe.

2) Professor Heymann's testimony emphasized the importance of having a monitoring group to search the Internet for rogue pharmacies and keep track of them as they pop up.

a) How does the DEA become aware of a new suspected illicit Internet pharmacy?

RESPONSE:

It must be made clear that a single website operated by a single "Internet Facilitator" may use multiple brick and mortar pharmacies to service its list of drug seekers. Similarly, one Internet pharmacy may service multiple Internet Facilitation Centers. Moreover, websites can fluctuate in number minute by minute. A website can easily be de-activated one day and resurface under a different address the very next day.

For purposes of DEA enforcement activities, DEA considers an illicit "Internet pharmacy" as a DEA-registered brick and mortar location, illegally selling controlled pharmaceutical products ordered through the Internet. One of these physical locations may service one or more websites. It should be noted that there are legitimate pharmacies that provide controlled substances via the Internet and operate daily within the legal boundaries of the law. However, as a point of clarification, and subject to other definitions DEA uses, there are many websites on the Internet that "offer" to sell

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controlled substances illegally. A "Google" keyword search such as "hydrocodone no prescription needed" reveals thousands upon thousands of hits. Many websites that "offer" to sell controlled substances do not in fact sell controlled substances at all but merely link the drug seeker to yet another website. This secondary site may also be a portal to yet another website. Eventually, the drug seeker will be linked to the anchor website that DEA has coined the "Internet Facilitation Center." DEA attempts to focus on the Internet Facilitation Centers, even though they are not required to register with DEA, because they link drug seekers to rogue doctors and rogue brick and mortar pharmacies (some of which may be registered with DEA), or illicit "Internet pharmacies," in exchange for huge profits.

That said, DEA has and will continue to leverage all its resources to attack not only Internet drug trafficking organizations, but all drug trafficking organizations. DEA has dedicated a variety of resources and personnel to address the growing threat posed by Internet drug trafficking organizations. All of these efforts help assist us in targeting, identifying, investigating, and ultimately dismantling the organizations operating behind these illicit websites.

Some of these efforts include the following:

- DEA's Diversion Control Program is using all administrative and regulatory tools possible to identify and shut down Internet pharmacies violating the Controlled Substances Act.
- DEA is using the Automated Reports and Consolidated Order System (ARCOS) to identify suspicious purchasers of narcotics and determine which retail pharmacies and practitioners are most likely involved in the illicit distribution of controlled substances over the Internet. Again, it should be noted that pursuant to 21 U.S.C. § 827(d), distributors are required to report the sale, delivery, or other disposal of narcotic controlled substances to ARCOS.
- DEA's Office of Diversion Control has begun an Internet Distributor Initiative to focus on the more than 800 DEA-registered distributors of controlled substances.

  i. As part of this initiative, DEA has created a presentation explaining the laws, regulations, and DEA policies for the wholesale distributors. This presentation advises wholesale distributors of the common characteristics of illegal Internet pharmacies. The presentation is designed to emphasize to wholesale distributors that they are required to maintain effective controls against diversion, and to report suspicious orders of controlled substances when discovered.

  ii. When educational efforts do not yield the desired result of cutting the supply lines to these illicit operations, DEA will implement administrative, civil, or criminal sanctions against the registrant.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00076 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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- DEA's Outreach Initiatives

  i. Establish hotlines the public can use to report suspicious online pharmacies.

  ii. Use DEA Internet sites to educate the public about the dangers of abusing controlled pharmaceuticals.

  iii. Provide timely, accurate, and persuasive information to a variety of audiences in order to build support for effective drug enforcement.

  iv. DEA has worked with Internet search engines such as Google, AOL, and Yahoo to create Public Service Announcements (PSAs) designed to appear when consumers attempt to illegally buy controlled substances online.

- DEA's Internet Industry Initiative

  i. Internet traffickers of illicit pharmaceuticals rely extensively on the commercial services of three principal legitimate business sectors:

     a. Providers of Internet services including web hosting, domain name registration, and search engines;

     b. Express package delivery companies;

     c. Financial services companies, including major credit card companies and third party payment service providers.

  ii. Since 2003, DEA has been working with Internet-related businesses regarding the diversion of controlled pharmaceuticals.

  iii. In 2005, DEA sponsored three interagency Internet industry conferences attended by Internet companies, parcel carriers, financial companies, and other federal agencies.

  iv. DEA has continued to develop progressively closer working relationships with leading companies in each sector.

b) Does the DEA have agents who monitor the Internet to keep track of these websites?

RESPONSE:

DEA does not have individual agents assigned to monitor the Internet. As stated before, it's vitally important to note that, for purposes of DEA enforcement activities, an illicit "Internet pharmacy" is a brick and mortar location (some of which may be registered with DEA) that utilizes websites (sometimes multiple websites) to facilitate the sale of controlled substances. These sites can be, and often are, put up and taken down with little effort. DEA concentrates its investigative efforts on attacking, disrupting, and dismantling the organizations and individuals hiding behind websites and diverting controlled substances.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00077 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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c) Does the DEA rely on tips from DEA registrants to identify new rogue internet pharmacies?

RESPONSE:

On occasion DEA does receive information from its registrants regarding possible diversion. DEA also receives information from informants and through investigative efforts that identify potential sources of diversion.

3) **Along with the concerns about illicit sales of prescription drugs on the Internet, I am concerned about Internet sales of drugs that can be used as ingredients for making methamphetamine.**

As you know, we have a huge methamphetamine ("meth") problem in the country today. I have introduced legislation that would promote the use of electronic logbooks in brick and mortar pharmacies, in order to keep better track of sales of meth precursor drugs like pseudoephedrine.

This is an important bill, because meth cooks in Illinois and elsewhere have learned to get around the limits on pseudoephedrine purchases by hopping from pharmacy to pharmacy and buying legal amounts at each one. Electronic databases of pseudoephedrine sales will help stop these meth cooks from getting their ingredients in this way.

But as we clamp down on the ability of meth cooks to get their ingredients from brick-and-mortar retailers, they will turn increasingly to the Internet to try to buy meth precursor drugs.

a) What data can the DEA provide regarding illicit sales of pseudoephedrine and other meth precursor drugs on the Internet? Please provide such data.

RESPONSE:

Presently, DEA does not have intelligence indicating that illicit sales of pseudoephedrine are being conducted on the Internet to or within the United States. Internationally, individuals or organizations may pose as a chemical company and meet with a representative from a foreign distribution company. The "customer" would then order a bulk quantity of pseudoephedrine and ask that it be shipped to, as an example, the Congo. Once the shipment reaches the Congo it is then diverted to a production/manufacturing site in North America. During the course of the negotiation for this shipment the two parties may communicate via e-mail, but that would be the only connection with the Internet.

b) What steps should be taken specifically to clamp down on Internet sales of meth precursors?

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00078 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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RESPONSE:

Other than the method described in question 3(a), DEA has not been seeing the Internet used as method to illegally sell meth precursors. DEA recognizes that there is a danger that such sales could reemerge in the future and will respond as needed.

c) What steps are being taken by the DEA, either by itself or in conjunction with other federal agencies, to prevent illicit Internet sales of meth precursor drugs from foreign suppliers who ship the precursors in from abroad?

RESPONSE:

DEA, operating under the auspices of ***Project Prism*** (a United Nations program), hosted a meeting in Hong Kong in February, 2006, for law enforcement and regulatory officials of producing countries of ephedrine/pseudoephedrine and 3-4 methylene dioxy phenyl-2-proponone (PMK). The purpose of this meeting was to develop and enhance systems for voluntary cooperation in data collection and exchange in law enforcement channels to build a consensus towards exchange of information on pharmaceutical preparations containing ephedrine and pseudoephedrine as well as bulk precursors. This was the first time that almost all of the countries that produce these chemicals and those countries affected by methamphetamine have sat down together to discuss this problem. While there were some differences of opinion as to the manner and channels in which information regarding the licit trade in these substances should be exchanged, it was important to bring precursor chemical producing nations together in concert with countries in which illicit drug manufacturing occurs in order to have a candid discussion regarding the diversion of these licit chemicals. The communication that occurred between countries attending the open forum was encouraging and led to more constructive action and subsequent forums. While we were disappointed that China chose not to send a delegation, the DEA, in cooperation with the Department of State, will continue discussions with all involved countries to determine the worldwide production of these chemicals, identify producers and distributors, gain better insight as to what form (bulk v. tablets) the chemicals are manufactured and distributed at various stages, and learn where the chemicals are destined.

The Hong Kong meeting also helped to lay a foundation for the discussions and negotiation amongst concerned governments which led to the passage of a resolution, entitled "Strengthening Systems for Control of Precursor Chemicals Used in the Manufacture of Synthetic Drugs", at the 49th Commission on Narcotic Drugs (the CND) in Vienna, Austria, in March of 2007. The resolution involves the synthetic drug precursors previously mentioned, as well as preparations containing these substances, and phenyl-2-propanone (P2P) as well. The resolution calls on all nations who are signatories to the various UN conventions dealing with drugs and precursor chemicals to provide to the International Narcotics Control Board (INCB), annual estimates of their legitimate requirements for these substances, and preparations containing these substances, and to ensure that its imports of these substances are commensurate with their respective nation's legitimate needs. The resolution also urges countries to continue to provide to the INCB, subject to their national legislation and taking care not to impede legitimate international commerce, information on all shipments of these substances, to include pharmaceutical preparations, and further requests countries to permit the INCB to share the

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00079 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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shipment information on these consignments with concerned law enforcement and regulatory authorities to prevent or interdict diverted shipments.

DEA is also working with CBP and their database systems to identify and seize suspect shipments of chemicals that enter U.S. port facilities. DEA is also providing training related to precursor chemicals, methamphetamine labs, and enforcement procedures to its Mexican counterparts.

QUESTIONS FROM SENATOR SPECTER:

1) **Does the DEA need more staffing, and other resources, to pursue cases of controlled prescription drug diversion?**

RESPONSE:

Staffing and resources needs of one particular agency are expenditures which must be considered among those of every Department and agency within the Federal Government. Consequently, DEA must coordinate the resources and staffing at our disposal as effectively and efficiently as possible.

To address the growing problem of the illegal diversion of prescription drugs, the Administration in its *2006 Synthetic Drug Control Strategy* specifically set as one of its goals to reduce prescription drug abuse by 15 percent over the next three years with 2005 as the base year. According to the 2005 National Survey on Drug Use and Health, there were approximately 6.4 million Americans who abused psychotherapeutic drugs non-medically; in 2006 this number was 7.0 million, as compared to 3.8 million in 2000. In doing its part, the DEA has taken a comprehensive approach and redirected additional resources towards this issue. Over the past several years, the number of investigations, work hours, and expenditures have increased.

From FY 2003 to FY 2005, DEA increased Special Agent (SA) work hours devoted to pharmaceutical investigations by 114 percent; increased the number of Intelligence Analyst work hours by 235 percent; and increased the total number of work hours expended on Internet diversion investigations by more than 71 percent.

Specifically, in FY 2005, the combined number of work hours devoted to Internet investigations was 163,597 hours; in FY 2006, the combined number of work hours was 195,408 hours; and in FY 2007, the number of combined hours is approximately 200,000 hours.

During FY 2006, 72 percent of Diversion Investigator (DI) work hours were for criminal and complaint investigations, 15 percent were for regulatory investigations, and 13 percent were for other work functions. During FY 2007, 76.15% percent of Diversion Investigator (DI) work hours were for criminal and complaint investigations, 18.46% percent were for regulatory investigations, and 5.40% were for other work functions. This workload shift, from regulatory to criminal, has increased the complexity of diversion investigations. DEA also increased the number of diversion investigations by 23 percent, from 770 in FY 2002 to 950 in FY 2005.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00080 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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Historically, most diversion of pharmaceutical controlled substances occurs at the retail level as a result of illegal prescribing, prescription forgery, or 'doctor shopping.' The Internet has become the fastest growing source of diversion. As trafficking patterns have changed, so has DEA. DEA is conducting ever-increasing numbers of investigations surrounding the diversion of controlled pharmaceuticals via the Internet. These investigations are, however, time consuming and costly.

Compounding the situation is the fact that DIs presently do not have law enforcement authority when conducting criminal investigations. DIs must rely on DEA Special Agents to make arrests, conduct surveillance or execute search warrants. To address this issue, and support these criminal investigations of pharmaceutical traffickers, DEA received congressional authority in December 2007 to reprogram 108 vacant Diversion Investigators to Special Agent positions. The conversion of the 108 positions is only an initial step towards resolving the lack of law enforcement authority.

Additionally, DEA has invested significant resources in training Diversion Investigators, Special Agents, Intelligence Analysts and Task Force Officers.

Special Agent/Task Force Officer Training

The Special Agent Diversion Schools provides Special Agents with an in-depth understanding of diversion investigations, focusing on the Controlled Substance Act as it pertains to regulated pharmaceuticals, methods of diversion, required records and reports, pharmacology, addiction, and undercover and investigative techniques used in diversion investigations. In FY 2007, a total of 106 Special Agents, 19 Task Force Officers, and one agent from the Naval Criminal Investigative Service have received this training.

Intelligence Analyst Training

DEA incorporated its diversion training into the Basic Intelligence Research Specialist (BIRS) training program which began in July 2006. DEA provided a two-hour block of instruction titled "Diversion Overview," as well as a four-hour block of instruction on various databases including ARCOS. The aforementioned blocks of diversion training will be incorporated into all future BIRS training.

DEA is also developing a new training course for BIRS. This new course of instruction will focus on the necessary job tasks/standards, as well as the skills, knowledge, and abilities needed by Intelligence Research Specialists (IRS) to effectively support diversion investigations. In October 2005, DEA's TR conducted an informal electronic assessment that was sent, via e-mail, to all Diversion Program Managers (DPM) to determine the necessary skills, knowledge, and abilities needed by IRSs to support criminal diversion investigations. The responses provided by DPMs were used in determining the topics to be included in a training program for IRS who will be assigned to diversion groups.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00081 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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Advanced Intelligence Training: The Office of Training created a five-day course for IRS to include topics that would effectively support diversion investigations. The course will include investigative tools, such as ORACLE and ARCOS, that are used to gather intelligence in furtherance of criminal diversion cases. This course will be offered to IRS who are assigned to or assist with criminal diversion investigations. The first class was held in July 2007, and trained 35 Intelligence Research Analysts. A follow up class was held in April 2008 and in addition to 10 Intelligence Research Specialists, was expanded to include 8 Special Agents and 30 Basic Intelligence Research Specialist trainees.

Diversion Investigator Training

- Internet/Financial Training for Diversion Investigators (DIs): As of March 1, 2007, 369 of the 520 Diversion Investigators have completed Internet training conducted by DEA's Special Operations Division (SOD). Training for the remaining 164 DIs will be coordinated through SOD as funding becomes available. SOD scheduled 26 Internet Telecommunication Exploration Program (ITEP) classes for FY 2007, in which a majority of the remaining DIs were in attendance. In addition, DEA trained 33 DIs on Internet investigations in August 2007, and will continue training through FY 2008.

- Advanced Internet Training: A newly developed Advanced Internet Investigation training course will expand the information taught at the SOD Internet class. The Advanced Internet Investigations class will provide students with more practical and investigative-based training while utilizing tools such as "Netwitness" and other advanced Internet exploitation tools. This class will also cover the preparation of subpoenas and will be offered to DIs, IRSs, and SAs who have some basic computer knowledge.

- Diversion Financial Techniques: In addition to the Advanced Internet Investigations course, DEA has added two Financial Techniques courses into the FY 07 training schedule. They were held on March 12, 2007, and June 25, 2007. The Financial Investigations course is designed to provide DIs with the skills and knowledge to enhance their investigative techniques pertinent to financial investigations. Each class trained 30 DIs.

- Diversion Conspiracy and Complex Investigations: DEA conducted one Diversion Conspiracy and Complex Investigations class for DIs on May 15, 2007. The Conspiracy and Complex Investigations School is designed for DIs with at least two years' experience with DEA and addressed the elements necessary to successfully develop complex investigations. The curriculum includes courses on investigative resources, telephone number recognition and analysis, case studies, Title III investigations, and case organization. Another Diversion Conspiracy & Complex Investigation School took place on February 20, 2008 at the DEA Training Academy. Twenty-two DIs and three Intelligence Research Specialists attended.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00082 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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The Diversion Control Program is funded by fees collected from DEA registrants. Title 21 U.S.C. § 886a establishes the Diversion Control Fee Account. Specifically, under Title 21 U.S.C. § 886a(C) "Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program."

The diversion of controlled pharmaceuticals continues to threaten the safety and well-being of Americans. Nevertheless, the DEA is committed to bringing to bear all of the resources and the necessary tools at its disposal to fight this growing problem while simultaneously ensuring an uninterrupted supply of controlled pharmaceuticals for legitimate demands.

2) **In May 2007 Purdue Frederick pled guilty to resolve criminal and civil charges related to the drug OxyContin's "misbranding," and agreed to pay $600 million in settlement payments to the federal and state governments. Meanwhile, three executives of Purdue Pharma, including its president and its top lawyer, pleaded guilty as individuals to misbranding, a criminal violation. Purdue Frederick and Purdue Pharma are independent, associated companies. In his statement, U.S. Attorney John Brownlee of the Western District of Virginia said that Purdue Frederick is the "manufacturer and distributor" of OxyContin. However, it turns out that Purdue Frederick is no longer the manufacturer and distributor; now, it is Purdue Pharma.**

a. *Why did Purdue Frederick plead guilty and not Purdue Pharma?*

RESPONSE:

On May 20, 2007, the U.S. Attorney (USA) for the Western District of Virginia announced that "this morning . . . the Purdue Frederick Company, the manufacturer and distributor of OxyContin, pleaded guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers." The USA explained that "Purdue and its top three executives have pleaded guilty to illegally misbranding OxyContin from 1996 thru 2001." The USA, prior to providing a brief summary of the government's evidence against Purdue, noted that the "main violations of the law revealed by the government's criminal investigation are set forth in detail in the [Agreed] Statement of Facts . . . ."

Pursuant to the Agreed Statement of Facts that was filed with the Court along with the Plea Agreements and other related documents, the corporate defendant was defined as follows:

> Defendant The PURDUE FREDERICK COMPANY, INC. ("PFC"), doing business as The Purdue Frederick Company, was a New York corporation, headquartered in Connecticut. It was created in 1892 and was purchased by its current owners in 1952. At all times relevant to this Agreed Statement of Facts, PFC and other related and associated entities were engaged in the pharmaceutical business throughout the United States. PFC and the other related and associated entities were frequently referred to as "Purdue."

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00083 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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PFC developed and originally marketed OxyContin Tablets ("OxyContin"), a controlled-release form of oxycodone, which is a Schedule II controlled substance. OxyContin is an opioid analgesic that is intended to be taken every twelve hours. (Agreed Statement of Facts, ¶¶ 1 & 2). As explained by the USA, the Purdue Frederick Company, Inc. pled guilty because it was a manufacturer and distributor of OxyContin during the time period of the offense (January 1996 - June 2001). The current manufacturer and distributor of OxyContin, Purdue Pharma L.P., was required to enter into a comprehensive Corporate Integrity Agreement with HHS that mandated changes in Purdue's corporate operations to prevent future violations of law. With these agreements, the government was able to hold the responsible corporate entity accountable for its criminal conduct and protect the public from future criminal conduct by the current distributor and manufacturer of OxyContin.

b. Why did Purdue Pharma executives plead guilty if Purdue Pharma did not?

RESPONSE:

Each one of the executives who pled guilty was an executive of both the Purdue Frederick Company, Inc. and Purdue Pharma L.P.

c. Is it true that if Purdue Pharma had pled guilty, OxyContin would have been excluded from Medicare coverage?

RESPONSE:

Had Purdue Pharma L.P. pled guilty, to a felony misbranding charge, the company would have been subject to mandatory exclusion from all Federal health care programs by the HHS Office of the Inspector General (OIG). Pursuant to Title 42, United States Code, Section 1320a-7(a)(3), any "entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, in connection with the delivery of a health care item or service . . . of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct" shall be excluded from participation in any Federal health care program." (If Purdue Pharma L.P. had pled guilty to a misdemeanor misbranding charge, the company would have been subject to permissive exclusion under 42 U.S.C. § 1320a-7(b)(1).)

Notwithstanding this mandatory exclusion, OIG may grant a waiver of the effect of exclusion if the excluded entity is the sole source of specialized services. OIG has stated that it would consider requests from Federal health care programs for a waiver of exclusion with respect to a pharmaceutical product for which there is a particularized patient need. If Purdue Pharma had been excluded from participation in Federal health care programs and no waiver had been granted, no payment could have been made by Medicare, Medicaid, or any other Federal health care program for any items (such as OxyContin) that were furnished by Purdue.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00084 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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3) In light of what has happened with OxyContin and Purdue Pharma L.P:

a. Are you finding that a significant proportion of pharmaceutical companies are negligent in minimizing their drug's potential for abuse?

RESPONSE:

DEA has no legal or regulatory authority to demand or force the development or reformulation of products that might deter abuse. Factually, most formulations are easily defeated by individuals who are determined to extract the chemical(s) for illicit use. It is a daunting task to formulate a drug that will both prevent abuse and still deliver the desired legitimate medical effect.

b. Are you finding that a significant proportion of pharmaceutical companies are producing misleading or false advertising?

RESPONSE:

Violations of misbranding, false advertising, and "off-label" marketing fall under the jurisdiction of the Food and Drug Administration (FDA). That said, the DEA stands ready to assist the FDA to the extent appropriate to investigate such offenses.

4) It is my understanding that a number of so-called rogue Internet pharmacies continue to be licensed by the DEA, even though you have identified them internally as suspicious. It is also my understanding that the DEA does not revoke the DEA registrations of rogue Internet pharmacies if the DEA does not have clear cut evidence of wrongdoing.

a. What kind of evidence do your require for "suspicious pharmacies" and "clear cut evidence of wrongdoing?

RESPONSE:

DEA educates the regulated community on how to recognize rogue Internet pharmacies, while at the same time making its own decisions about whether the conduct of the rogue pharmacy rises to the level of a criminal or civil violation.

The DEA may revoke a pharmacy's DEA registration if there is a statutory basis to do so. *See* 21 U.S.C. §§ 823(f), 824(a). In instances where a pharmacy diverts controlled substances to customers who request the substances via the Internet, the basis for revocation is usually that the pharmacy's continued registration is inconsistent with the public interest. There are five factors that must be considered when determining the public interest. *See* 21 U.S.C. § 823(f)(1)-(5). The DEA has revoked the registrations of many pharmacies that unlawfully dispense controlled substances to customers who request the substances via the Internet. *See United Prescription Services, Inc.*, 72 Fed. Reg. 50,397 (Aug. 31, 2007); *CRJ Pharmacy and YPM Total Care Pharmacy*, 72 Fed. Reg. 30,846 (June 4, 2007); *Trinity Health Care Corp.*, 72 Fed. Reg. 30,849

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00085 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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(June 4, 2007). These Final Orders describe the numerous facts that can support the basis for revocation, as well as an important regulation that specifies a pharmacy's responsibilities regarding controlled substance prescriptions. The regulation states that a prescription for a controlled substance is unlawful unless it has been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). While "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* "[T]he person knowingly filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*

DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for controlled substances when he or she either "knows or has reason to know that the prescription was not written for a legitimate medical purpose." In other words, a pharmacist has a "corresponding responsibility" to ascertain whether a prescription has been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04 (2005).

The government's burden of proof at the administrative revocation proceeding is by a preponderance of the evidence. If the investigation reveals evidence that can support a statutory basis for revocation, by a preponderance of the evidence, the pharmacy's registration would likely be revoked.

b. Do you notify pharmaceutical manufacturers and distributors once the DEA has determined that an Internet pharmacy is suspicious?

RESPONSE:

DEA has an Internet Distributor Initiative that is designed to educate the 821 DEA-registered distributors of controlled substances and focus on those who are distributing to pharmacies that are filling illegitimate Internet prescriptions.

As part of this initiative, DEA has created a presentation explaining the laws, regulations, and DEA policies for the wholesale distributors. This presentation advises wholesale distributors of the common characteristics of illegal Internet pharmacies. The presentation is designed to emphasize to wholesale distributors that they are required to maintain effective controls against diversion, and to report suspicious orders of controlled substances when discovered.

That said, this initiative goes beyond simply explaining the statutory and regulatory requirements each distributor must follow as a DEA registrant. The presentation emphasizes that, simply by virtue of being authorized by DEA to handle controlled substances, every distributor has a responsibility to use due diligence to detect and prevent the diversion of the controlled substances it sells.

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From August, 2005 through February 2008, DEA briefed 27 corporations with over 131 controlled substance distribution sites concerning illegal Internet pharmacy operations. As a result, some distribution sites have voluntarily stopped selling or voluntarily restricted sales of controlled substances to numerous domestic pharmacies.

When educational efforts do not yield the desired results of cutting the supply lines to these illicit operations, DEA will implement administrative, civil, or criminal sanctions against the registrant. It is important to note that one of the most significant elements of S.980, the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008," is the increase in the penalties associated with the illegal distribution of Schedules III, IV, and V substances. Current penalties are inadequate, out of sync with penalties associated with other CSA violations, and do not serve as an effective deterrent.

c. *If not, why not?*

RESPONSE:

DEA is mindful of its obligation to afford due process to the pharmacy that is believed to be engaged in suspicious activity. DEA has no authority to tell a manufacturer or distributor not to sell controlled substances to a properly registered, albeit suspicious, pharmacy, and, in another context dealing with listed chemicals, DEA was enjoined from "blacklisting" a suspicious distributor. *See* Chemicals for Research & Industry v. Thornburgh, 762 F. Supp. 1364 (N.D. Cal. 1991).

5) **It is my understanding that the DEA believes that pharmaceutical manufacturers and pharmaceutical distributors should be responsible for sales to suspicious pharmacies, even if DEA has not revoked the licenses of these pharmacies. Why do you think it is appropriate for manufacturers and distributors to make judgments that the DEA cannot make, and for manufacturers and distributors to be civilly and criminally liable for failing to make the judgments that the DEA cannot make?**

RESPONSE:

Federal regulations impose a duty on controlled substance manufacturers and distributors to maintain effective controls against diversion, *see* 21 U.S.C. 823, and to report suspicious orders to DEA. *See* 21 U.S.C. § 842(a)(5)(imposing civil penalty for negligently failing to file required reports; 21 C.F.R. § 1301.74(a),(b)(imposing regulatory duty on manufacturers and distributors to report suspicious orders). As an enforcement and regulatory agency, DEA provides guidance to industry on how to recognize suspicious orders, and through its Internet Distributor Initiative, DEA advises wholesale distributors of the common characteristics of illegal Internet pharmacies, and reminds them of their obligation to maintain effective controls against diversion. DEA recognizes that it cannot police every transaction between registrants. Like every regulatory agency, it must set parameters and then expects registrants to comply with their due diligence requirement.

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This does not mean that DEA does not make judgments about whether a particular pharmacy has engaged in illegal activity. DEA routinely makes those decisions and pursues such cases criminally, administratively or through civil sanctions, whichever is appropriate.

DEA has no statutory authority to direct a manufacturer or distributor not to do business with a suspect pharmacy. Moreover, it would violate the suspect-pharmacy's due process rights to be subjected to a DEA "blacklisting" campaign without the opportunity to dispute the Government's assertions.

In sum, DEA educates the regulated community on how to recognize rogue Internet pharmacies, while at the same time making its own decisions about whether the conduct of the rogue pharmacy rises to the level of a criminal or civil violation.

6) What type of inspections or other review does the DEA undertake before issuing DEA controlled substance registration to a pharmacy? What type of follow up does the DEA perform? How frequently do you follow up? Do you follow up with all pharmacies that you have identified as suspicious?

RESPONSE:

When DEA receives an application for registration from a pharmacy, DEA contacts the appropriate state licensing agencies (pharmacy board, state controlled substance agency) to review and verify all required information and the status of state pharmacy registrations. DEA also checks its internal databases to ascertain if the applicant has a history of regulatory non-compliance or has been registered previously. If negative information is discovered, DEA may contact local law enforcement authorities to conduct further background checks.

DEA has no program for routine on-site visits to pharmacy applicants. On-site visits to a pharmacy applicant may be conducted if information is developed during the registration process that raises suspicions of illegal activity.

7) Do you support s.980, the Online Pharmacy Consumer Protection Act of 2007?

RESPONSE:

The Administration supports the Senate-passed version of S. 980, the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008", and calls on Congress to pass it.

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SUBMISSIONS FOR THE RECORD

Statement
of the
American Pharmacists Association

Submitted to the Senate Committee on the Judiciary

on "Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking"

May 16, 2007

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Statement of the American Pharmacists Association

Before the Committee on the Judiciary
United States Senate

Hearing on

Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking

May 16, 2007

The American Pharmacists Association (APhA) appreciates the Committee's efforts to improve patient safety through regulation of Internet access to prescription medications. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the military.

Legitimate Internet Pharmacy vs. Rogue Internet Drug Sellers
Internet pharmacy is a growing element of our drug distribution system. Unfortunately, unscrupulous Internet drug sellers are manipulating this process and threatening the safety of our nation's drug supply. The value of prescription medications doesn't materialize if patients receive sub-standard care. As the medication experts on the health care team, and the health professionals dedicated to partnering with patients to improve medication use, we fully support efforts to reign in this dangerous practice of drug distribution.

The ability to access medications through the Internet provides convenient access to patients. But patients need assistance distinguishing between a rogue Internet drug seller and a legitimate Internet pharmacy. Legitimate Internet pharmacies can provide patients safe and effective medications as well as access to the most critical member of the patient's health care team when it comes to medications — their pharmacist. Conversely, illegitimate Internet drug sellers operate outside these protections and pose safety risks to patients. Examples of these safety risks include:

- Failure to provide access to pharmacists. Patients who bypass the expertise of a pharmacist could find themselves taking a new medication that conflicts with another medication, creating a dangerous drug-to-drug interaction. It is always best for a patient's medication regimen to be reviewed by a pharmacist to reduce the likelihood of these occurrences.
- Offering medications "without a prescription", a serious breach of our regulatory system, which circumvents the assistance of doctors and pharmacists.
- Offering to "prescribe" medications without a physical examination, or any interaction with the patient, bypassing the traditional prescriber-patient relationship. As a result, consumers may receive inappropriate medications because of a misdiagnosis.

Evidence of the need to regulate Internet drug sellers can be found as far back as 2004 in two reports by the Government Accountability Office (GAO) that demonstrate the "buyer beware" environment that Internet pharmacy creates for American patients. The report, "Internet Pharmacies: Some Pose Safety Risks for Consumers"[1] details how GAO was able to obtain prescription drugs from domestic and foreign Internet drug sellers and identifies problems associated with the handling, FDA-approval status, and authenticity of the drug samples received from non-Canadian foreign Internet drug sellers. The report, "Internet Pharmacies: Hydrocodone, an Addictive Narcotic Pain Medication, is Available without a Prescription through the Internet"[2] details the ease with which the GAO was able to purchase hydrocodone on the Internet without providing a prescription or being examined by a physician. The report concludes that Internet drug

[1] http://www.gao.gov/new.items/d04820.pdf
[2] http://www.gao.gov/new.items/d04892t.pdf

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sellers appear to be in the business of knowingly servicing, and profiting from individuals who may purchase pain medication for illicit purposes.

Catching the "Bad Guys"
Nothing suggests that problems associated with Internet access to prescription medications have been remedied since these reports were released. In fact, data suggests that these sites have proliferated. These situations support the need for review and refinement of our existing safety net, not the expansion of efforts to circumvent or relax the system. Therefore, APhA supports creating requirements, new "hooks" with which we can catch illegitimate web sites and prevent their proliferation. We support the creation of uniform certification standards, which require Internet pharmacies to:

- comply with all State pharmacy practice laws and all laws relating to controlled substances;
- ensure a prescription drug is dispensed only pursuant to a valid prescription even in circumstances when a prescription is not required for the drug by the country from which it is mailed;
- display on their website several pieces of critical information including contact information for the pharmacy, information about the pharmacist in charge or supervising pharmacist, information regarding its ownership and management, the seal provided to certified pharmacies (for example, the National Association of Boards of Pharmacy's VIPPS program[3]), and a statement that the pharmacy will not dispense a prescription medication without a prescription;
- provide opportunities for patients to consult with a licensed pharmacist;
- create systems for adverse drug event and medication error reporting, for patient complaints, to facilitate communication between the pharmacy and consumers regarding drug recalls, and to address patient confidentiality; and,
- develop quality assurance standards.

Furthermore, we support limiting the source of payments to rogue Internet drug sellers by prohibiting credit card payments for illegal Internet drug purchases, prohibiting website advertising that "no prescription is needed", and prohibiting websites from accepting advertising from uncertified (and therefore also unlicensed) Internet drug sellers.

However, while supportive of regulating the rogue Internet drug industry, we caution against creating new federal requirements for pharmacies that are already licensed by State Boards of Pharmacy or as a federal pharmacy (e.g. pharmacies that serve the Department of Defense). For legitimate Internet pharmacies to remain a viable option, we recommend working within the current pharmacy regulatory infrastructure that retains State Boards of Pharmacy as the primary regulatory authority for State licensed pharmacies. Creating new federal licenses, instituting new federal licensing fees, or creating new reporting requirements could cause domestic pharmacies to remove the Internet as an access point for their patients.

Important Collaborations
Our commitment to proper medication use continues through the life of the medication and is not limited to ensuring appropriate Internet access to prescription medications. As the largest professional society of pharmacists and an organization dedicated to promoting the proper use and distribution of life saving medications, APhA is also committed to ensuring that medications are handled responsibly. Through the daily work of pharmacists, abuse and illegal diversion abuse is limited.

Recently, APhA's work in this area has included establishing important collaborative relationships. For example, APhA is working with the White House Office of National Drug Control Policy (ONDCP) to ensure that law enforcement officials, educators and other healthcare providers have the necessary resources to educate the public about the risks associated with medication misuse. APhA is also working with the U.S. Fish & Wildlife Service, the Environmental Protection Agency, and other government organizations to address the proper disposal and handling of unused medications in the home and workplace. This approach not only ensures the medications don't end up back in the distribution chain or are used for illicit purposes, but helps safeguard public health and the environment by curbing disposing of these medications in our waterways.

[3] http://www.nabp.net/

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APhA also supports educating parents about the dangers of prescription drug abuse by children. In recent years, prescription drug abuse has risen due to what appears to be a false perception by children that prescription drugs are safer than street drugs and are therefore safe for recreational use. In recognition of the essential role parents play in the prevention of drug abuse in children, APhA has partnered with the Partnership for a Drug-Free America as they begin developing new resources to help parents become better educated about prescription drug abuse.

Conclusion

APhA strongly agrees that enough safety concerns arise with patients accessing prescription medications through the Internet to warrant regulatory oversight. As beneficial as some of the deals may appear for medications purchased through the Internet, some of these deals have a price — significant health risks. These potential risks require immediate attention and we commend you for drawing attention to this public health issue. We support efforts to help patients in distinguishing between legitimate pharmacies and illegitimate Internet drug sellers and that may curb abuses by illegitimate Internet drug sellers.

Medications, a critical aspect of patient care, are only safe and effective when patients understand how to use them appropriately and for what side effects they should watch. Legitimate Internet pharmacy can provide a service to those homebound, or with challenges to receiving their medications from their local pharmacist, or who prefer this mechanism. Any efforts to regulate Internet access to prescription medications must strike a balance between shutting down illegitimate drug sellers and allowing the legitimate Internet pharmacies to continue to serve patients.

APhA looks forward to working with the Committee as you seek ways to better ensure patient safety within the realm of Internet access to prescription medications.

Statement of Joseph A. Califano, Jr.
Chairman and President
The National Center on Addiction and Substance Abuse
(CASA) at Columbia University

Senate Committee on the Judiciary
Hearing on
Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking

May 16, 2007

Mr. Chairman Leahy and Members of the Committee:

Thank you for the invitation to testify today.

The National Center on Addiction and Substance Abuse (CASA) at Columbia University has studied the nation's problem of controlled prescription drug abuse and has documented for four consecutive years the Internet availability of these drugs.

In 2005, CASA released its landmark report, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* This report revealed that our nation is in the throes of a growing epidemic of controlled prescription drug abuse involving opioids like OxyContin and Vicodin, depressants like Valium and Xanax, and stimulants like Ritalin and Adderall.

From 1992 to 2002, prescriptions written for such controlled drugs increased more than 150 percent, 12 times the rate of increase in population and almost three times the rate of increase in prescriptions written for all other drugs.

Mirroring this increase in prescriptions has been an increase in abuse of these drugs. From 1992 to 2003, the overall number of people abusing controlled prescription drugs increased 94 percent, seven times faster than the increase in the U.S. population. The number of 12- to 17-year olds who abused controlled prescription drugs jumped 212 percent and the number of adults 18 and older abusing such drugs climbed 81 percent.

In 2003, 15.1 million Americans abused controlled prescription drugs, exceeding the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (.3 million). Abuse of controlled prescription drugs has grown at a rate twice that of marijuana abuse; five times that of cocaine abuse; 60 times that of heroin abuse.

Particularly troubling are the implications for our children. From 1992 to 2002, new abuse of prescription opioids among 12- to 17-year olds was up an astounding 542 percent, more than four times the rate of increase among adults. In 2003, 2.3 million 12- to 17-year olds (nearly one in 10) abused at least one controlled prescription drug; for 83 percent of them, the drug was an opioid. Teens who abuse controlled prescription drugs are twice as likely to use alcohol, five

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times likelier to use marijuana, 12 times likelier to use heroin, 15 times likelier to use Ecstasy and 21 times likelier to use cocaine, compared to teens who do not abuse such drugs.

In 2005, 15.2 million Americans abused these drugs including 2.1 million teens.

The explosion in the prescription of addictive opioids, depressants and stimulants has, for many children, made their parents' medicine cabinet a greater threat than the illegal street drug dealer. But, perhaps the most wide-open substance supermarket in the world is the Internet, which has become a pharmaceutical candy store, its shelves stacked with an array of addictive prescription drugs offering a high to any kid with a credit card number at the click of a mouse.

For four years now, CASA, in collaboration with Beau Deitl & Associates, has been tracking online access to controlled prescription drugs. In the first quarter of each year, we have devoted 210 hours to documenting the number of Internet sites advertising and dispensing controlled drugs, the prescription requirements if any, the types of drugs sold, the advertised country of origin and any controls on sale to children. These findings are a snap-shot of availability at a given point in time and show trends from year to year. They do not capture the total number of sites advertising or selling controlled prescription drugs online.

Today CASA is releasing the fourth in its series of annual reports entitled "*You've Got Drugs!" IV: Prescription Drug Pushers on the Internet*. Here are the report's disturbing key findings:

- From 2006 to 2007, there has been:
  - A 70 percent increase in the number of sites advertising or selling controlled prescription drugs over the Internet, from 342 to 581;
  - A 135 percent increase in the number of sites advertising controlled prescription drugs, from 168 to 394;
  - A seven percent increase in the number of sites selling controlled prescription drugs, from 174 to 187.
- Eighty-four percent of the sites selling controlled prescription drugs do not require a prescription from the patient's physician. Most of the 16 percent of sites that ask for a prescription (57 percent) simply ask that it be faxed, allowing a customer to forge it or use the same prescription many times to load up on these drugs.
- There are no controls stopping sale of these drugs to children.
- Over the four year course of our analysis, the number of selling sites has climbed steadily from 154 in 2004 and 2005 to 187 in 2007.

Since there are no controls preventing sale of these drugs to children, all a child needs is a credit card number and access to a computer and *You've Got Drugs!* Online purchase of controlled prescription drugs happens beneath the radar screens of Internet providers, financial institutions,

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shippers and parents. Attempts to crack down on this illegal trafficking are complicated by outdated federal law written before the Internet and inadequate state laws.

Although there is a mechanism in place for certifying Internet pharmacy practice sites--the National Association of Boards of Pharmacy, Verified Internet Pharmacy Practice Sites™ (VIPPS®)--the process is voluntary. Of the 187 selling sites found in 2007, only two were certified.

The widespread threat to the public health demands that Congress now take action to:

- Clarify federal law to prohibit sale or purchase of controlled prescription drugs on the Internet without an original copy of a prescription issued by a DEA-certified physician, licensed in the state of purchase, based on a physical examination and evaluation; and,

- Require certification of online pharmacies to assure that they meet rigorous standards of professional practice.

The Feinstein-Sessions Bill--S.980, the Online Pharmacy Consumer Protection Act of 2007--is a step in the right direction. We have some suggestions to strengthen that Bill that we can discuss with your staff.

The report we are releasing today makes other recommendations that I hope you will consider as well, including actions that can be taken in collaboration with Internet search providers, financial institutions and shipping services.

Mr. Chairman and members of this Committee, substance abuse and addiction--involving alcohol, nicotine and illegal and prescription drugs--is the nation's most serious domestic problem, implicated in crime, most killing and crippling illnesses, domestic violence, child abuse, homelessness, poverty, teen pregnancy and the wildfire spread of AIDS and other sexually transmitted diseases. I have titled my new book, *High Society: How Substance Abuse Ravages America and What to Do About It*, because this problem permeates our social problems. We Americans are four percent of the world's population and we consume two-thirds of the world's illegal drugs.

This problem is all about our children. A child who gets through age 21 without smoking, using illegal drugs or abusing prescription drugs or alcohol is virtually certain never to do so. Over the past 12 years, the fastest growing drug abuse among our nation's children involves prescription drugs. I applaud the work of this Committee to curb the availability of these drugs to our children and pledge to do anything I can to help in your important endeavors.

I am submitting our report along with my Statement for the record.

Thank your for attending to this critical problem and for the opportunity to speak with you today.

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"You've Got Drugs!" IV:
Prescription Drug Pushers on the Internet

A CASA* White Paper

May 2007

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Table of Contents

Accompanying Statement of Joseph A. Califano, Jr. i
"You've Got Drugs!" IV: Prescription Drug Pushers on the Internet 1
The Internet: A Growing Source of Drugs 1
The Regulatory Framework 2
Verified Internet Pharmacy Practice Sites™ (VIPPS®) 3
The CASA Analysis 3
The Internet: A Wide-Open Channel of Distribution 4
Prescriptions Not Needed 6
Trends in Prescription Requirements 6
No Controls Blocking Sale to Children 7
Advertised Source of Drug Shipments. 8
Lifecycle of Web Sites Selling Controlled Prescription Drugs 8
Next Steps 8
Appendix A: Detailed Methodology 11
Notes 15

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"You've Got Drugs!" IV: Prescription Drug Pushers on the Internet

Accompanying Statement of Joseph A. Califano, Jr.

For four years, The National Center on Addiction and Substance Abuse (CASA) at Columbia University has been tracking the availability of controlled prescription drugs over the Internet. This work is designed to examine the online availability of dangerous and addictive prescription opioids like OxyContin and Vicodin, depressants like Valium and Xanax, and stimulants like Ritalin and Adderall.

Our first report, *You've Got Drugs! Prescription Drug Pushers on the Internet,* was released in February of 2004. We updated the analysis in 2005 and 2006. This report is the fourth in our series. Each analysis was conducted in the first quarter of the year and involved 210 hours of staff time devoted to searching the Web for sites that advertise or offer for sale controlled prescription drugs. As a result, CASA now has four years of trend data which are included in this report.

Despite CASA's previous reports, other research, Congressional testimony, DEA investigations, press attention and even fatalities, access to controlled prescription drugs online continues unabated. Our findings this year show a 70 percent increase over 2006 in the number of Web sites identified that advertise or sell controlled prescription drugs. There was a 135 percent increase in Web sites advertising these drugs and a seven percent increase in sites offering to sell them. Eighty-four percent of sites offering controlled prescription drugs do not require that the patient provide a prescription from his or her doctor. Of those sites that do require prescriptions, 57 percent only require that the prescription be faxed allowing significant opportunity for multiple use and other types of fraud.

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Most disturbing, there are no controls limiting access to children and of the 187 sites offering controlled prescription drugs for sale, only two are certified by the National Association of Boards of Pharmacy as Verified Internet Pharmacy Practice Sites™, meaning that they are legitimately operating over the Internet.

In 2005, the latest data available, 15.2 million people age 12 and over (6.2 percent) report abusing* controlled prescription drugs in the past year. Today, more adults and teens report abusing these drugs than the number abusing all illicit drugs combined except marijuana.

This report lays out, for the fourth time, the nature of this growing threat to the public health, and recommendations that can and should be implemented to address this problem. Leadership from the federal government is required; further delays cannot be justified.

In previous years, Beau Dietl & Associates (BDA) conducted this analysis for CASA. This year CASA staff conducted the analysis working with Stephen Heskett of BDA to assure methodological consistency with previous years. I would like to thank Bo Dietl and Stephen Heskett for remaining committed to their partnership with CASA as we continue to shine a spotlight on this serious public health problem.

This White Paper was prepared under the direction of Susan E. Foster, MSW, CASA's Vice President and Director of Policy Research and Analysis. She was assisted by Harold Wenglinsky, PhD, a CASA Research Associate. Roger Vaughan, DrPH, head of CASA's Substance Abuse and Data Analysis Center (SADAC℠), Associate Professor of Clinical Public Health, Department of Biostatistics, Mailman School of Public Health at Columbia University and associate editor for statistics and evaluation for the *American Journal of Public Health,* conducted the data analysis with Elizabeth Peters, Senior Data Analyst at SADAC. Jane Carlson and Jennie Hauser handled the administrative details.

While many people and organizations were involved in this effort, the findings and opinions expressed herein are solely the responsibility of CASA.

* The definition of abuse provided in the *National Survey on Drug Use and Health* is using a drug not prescribed for you or taken only for the experience or feeling it caused.

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"You've Got Drugs!" IV: Prescription Drug Pushers on the Internet

In 2004, The National Center on Addiction and Substance Abuse (CASA) at Columbia University published the first report *You've Got Drugs! Prescription Drug Pushers on the Internet.* This report documented the widespread advertising and offers of sale for controlled prescriptions drugs--pain relievers like OxyContin and Vicodin, depressants like Valium and Xanax, and stimulants like Ritalin and Adderall--online and without a prescription. Research for the 2004 report was contributed by Beau Dietl & Associates (BDA) and was inspired by findings from CASA's research into the diversion and abuse of these drugs. CASA and BDA replicated the work in 2005 and 2006; this report is the fourth in the series.

Over the four years of analyses, the number of Web sites identified that offer controlled prescription drugs for sale has increased.* Eighty-four percent of these sites do not require prescriptions from a patient's physician; of those that do indicate that a prescription is required, 57 percent simply ask that the prescription be faxed--increasing the risk of multiple use of one prescription or other fraud. Over the four year period of CASA's analysis, the total number of sites requiring no prescription has increased. And, there are no controls to limit the sale of these drugs to children.

The Internet: A Growing Source of Drugs

Today an estimated 200 million people in the U.S. are Internet users; 125 million access the World Wide Web at least weekly. Internet users are disproportionately young, including nearly 100 percent of college students and 78 percent of 12- to 17-year olds. Sixty-three percent of adults have access to the Internet. The fact that

* CASA did not attempt to purchase any controlled prescription drugs online. This report identifies those sites that advertise and offer to sell the drugs.

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children, teens and college students are likelier to be online than adults makes online access to controlled prescription drugs even more troubling.[1]

With the click of a mouse, the Internet offers a convenient and private means of purchasing controlled prescription drugs. Not surprisingly, online access has grown rapidly since the first Internet pharmacies began in 1999.[2]

"freedom-pharmacy.com"

This Web site offers controlled prescription drugs "prescription free…at the freedom of your finger tips." The site offers over a thousand different drugs, and advertises its location as Nicosia, Cyprus. Drugs are shipped in "unmarked packaging: orders arrive within 10-14 days in discrete unmarked parcels via registered international air mail."[3]

With increased availability has come increased abuse of these drugs. CASA's landmark 2005 report, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.*, documented the enormous increase in the manufacture and distribution of controlled prescription drugs. Between 1992 and 2002, while the U.S. population increased 13 percent, prescriptions filled for controlled drugs increased 154 percent.[4]

The number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003--by 94 percent--seven times faster than the increase in the U.S. population. In 2003, the number of people abusing prescription drugs exceeded the combined number who were abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (.3 million).[5] By 2005, 15.2 million people were abusing these drugs.[6]

Children are especially at risk. In 2005, 2.1 million teens between the ages of 12 and 17 (8.2 percent) admitted abusing a prescription drug in the past year.[7] A 2005 survey of teens found that nearly one in five (19 percent or 4.5 million) admit abusing prescription drugs in their lifetime. More teens have abused these drugs than many illegal drugs, including Ecstasy, cocaine, crack and methamphetamine. More than half (56 percent) believe that prescription drugs are easier to obtain than illicit drugs and 52 percent believe that prescription opioids are "available everywhere."[8]

With access to a credit card, an easy form of prescription drug access--completely lacking in scrutiny from parents, other family members, and law enforcement--is over the Internet. Teens' easy access to the Internet and insufficient regulation of rogue Internet pharmacies contribute to the easy availability of these drugs to teens.[9]

The Regulatory Framework

Online pharmaceutical sales by state licensed, legitimate and reputable Internet pharmacies can provide significant benefits to consumers.[10] Legitimate online pharmacies operate much like traditional drugstores where drugs are dispensed only on receipt by the pharmacy of a valid prescription from the consumer or directly from the consumer's physician.[11] But many pharmacies, so-called rogue pharmacies, do not obey the laws.

According to federal law outlined in the Controlled Substances Act (CSA), "it shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice...."[12]

Federal regulation further states, "a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[13] Although the exact meaning of "acting in the course of professional practice" is not explicitly defined by law or regulation, the Drug Enforcement Administration (DEA) indicates that "for a doctor to be acting in the usual course of

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professional practice, there must be a bona fide doctor-patient relationship. For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A physical examination has been performed; and,
- Some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed."[14]

Illegal Internet pharmacies have introduced a new avenue through which unscrupulous buyers and users can purchase controlled substances for unlawful purposes. These pharmacies--based both inside and outside the U.S.--sell a variety of prescription medications including controlled drugs. Many dispense controlled drugs advertising that no prescription is needed. Others dispense them after a patient completes an online questionnaire that may or may not be reviewed by a physician or a "script doctor" whose job is to write hundreds of prescriptions a day without ever seeing a patient.[15] In any event, such sales do not constitute a legitimate doctor-patient relationship as described above.[16]

The Federation of State Medical Boards states that "electronic technology should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship."[17] Thus online prescriptions, generated without a physical examination of the patient by the doctor, are not considered legitimate.

Not all state laws, however, reflect these conclusions. Because of the lack of clarity in federal and state law over what constitutes a legitimate prescription, attempts on the part of law enforcement to bring rogue sites or "script doctors" working with them to justice are hampered.[18]

Verified Internet Pharmacy Practice Sites™ (VIPPS®)

In an attempt to address the issue of online access to controlled prescription drugs and provide some assurance to consumers of legitimate online pharmacy practice sites, the National Association of Boards of Pharmacy established a process for certifying sites as legitimate. This process is known as becoming a Verified Internet Pharmacy Practice Site™ (VIPPS®). The program "identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have completed successfully a rigorous criteria review and inspection." Certification is voluntary. To date there are 13 such sites. This year, CASA's analysis included two of these sites.

Verified Internet Pharmacy Practice Sites™ (VIPPS®)

Web Business Name	Web Site Address
Anthem Prescription	www.anthemprescription.com
Caremark.com	www.caremark.com
DrugSource, Inc.	www.drugsourceinc.com
drugstore.com	www.drugstore.com
Familymeds.com	www.Familymeds.com
HOOK SUPERX, Inc., dba CVS/pharmacy	www.cvs.com
Liberty Medical Supply, Inc.	www.libertymedical.com
Medco Health Solutions, Inc.	www.medco.com
Omnicare, Inc. dba Care for Life	www.careforlife.com
Prescription Solutions	www.rxsolutions.com
Tel-Drug, Inc./CIGNA	www.teldrug.com
Walgreen Co.	www.walgreens.com
WellDyneRx	www.welldynerx.com

The CASA Analysis

This year CASA conducted the analysis of Internet sites advertising and selling controlled prescription drugs online. In previous years BDA had conducted the analysis for CASA. To assure conformance with methods and procedures, BDA staff responsible for

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conducting the analysis in previous years worked with CASA. (See Appendix A, Detailed Methodology) As in previous years, a total of 210 hours was devoted to documenting the number of Internet sites dispensing the following controlled substances:

- **Opioids:** Codeine (Schedule II or III versions), Diphenoxylate (Lomotil), Fentanyl (Duragesic), Hydrocodone (Vicodin), Hydromorphone (Dilaudid), Meperidine (Demerol), Oxycodone (OxyContin, Percocet) and Propoxyphene (Darvon)

- **CNS Depressants:** Benzodiazepines including Alprazolam (Xanax), Chlordiazepoxide hydrochloride (Librium), Diazepam (Valium), Estazolam (ProXom), Lorazepam (Ativan), and Triazolam (Halcion); and barbiturates including Mephobarbital (Mebaral), Pentobarbital sodium (Nembutal) and Secobarbital (Seconal)

- **Stimulants:** Amphetamine-dextroamphetamine (Adderall), Dextroamphetamine (Dexedrine), Dexmethylphenidate HCl (Focalin) and Methylphenidate (Ritalin)

For each site, dispensing patterns were identified including:

- Dispensing controlled substances without any consultation or prescription;

- Dispensing controlled substances with an "online consultation," which typically involves completing a questionnaire; and,

- Dispensing controlled substances with a valid prescription.

CASA also sought to document from where the site advertised that the drugs would be shipped, whether from the U.S or another country, and any controls blocking the sale of these drugs to children.

The Internet: A Wide-Open Channel of Distribution

While estimates of Internet pharmacies have reached as high as 1,400,[19] it is virtually impossible to identify the precise number offering prescription drugs for sale--especially controlled substances--directly to consumers.[20] Web sites easily can be created or removed, or change their names or Web addresses; they also may offer no identifying information that can assist in tracking them to a particular location or source. Many large Internet pharmacies have multiple, seemingly independent, advertising sites that all connect to one online pharmacy.[21]

This year CASA identified a total of 581* Web sites offering Schedules II through V† controlled prescription drugs--up 70 percent from 342 in 2006. (Table 1) Of these sites:

- 394 (68 percent) were portal sites. Portal sites do not offer drugs for actual sale; they simply act as a conduit to another Web site--an anchor site--that does make the sale possible.

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* This number represents the sites that could be identified in a similar period of time each year; it does not represent the total number of sites advertising or selling controlled prescription drugs online.

† The Controlled Substance Act (CSA) assigns drugs with the potential for abuse to one of five categories or "schedules," depending on the drug's medical usefulness, its potential for abuse and the degree of dependence that may result from abuse. Schedule I substances have no currently accepted medical use in the U.S. and are not available by prescription, and include illicit drugs with a high potential for abuse such as heroin and marijuana. Schedule II through V substances have accepted medical use and varying potentials for abuse and dependency, with Schedule II drugs having the highest abuse potential and Schedule V the lowest abuse potential of the controlled substances. Schedule II includes drugs like OxyContin and Percodan; Schedule III includes drugs like Vicodin and Lortab; Schedule IV includes drugs like Xanax and Valium; and Schedule V includes drugs like codeine-containing analgesics.

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- 187 (32 percent) were anchor sites. At an anchor site, the customer places an order and pays; the online pharmacy fills the order and ships the drugs. The pharmacy itself may operate the Web site or the Web site may send the order to the pharmacy. Often, different Web sites use the same pharmacy to fill prescriptions. The operator of the anchor Web site may not be located in the same geographic region as the pharmacy.

Table 1
Internet Sites Advertising or Selling Controlled Prescription Drugs*

	2004	2005	2006	2007
Sites selling drugs (anchor sites)	154 (31%)	154 (39%)	174 (51%)	187 (32%)
Sites advertising drugs (portal sites)	338 (69%)	242 (61%)	168 (49%)	394 (68%)
Total sites	492	396	342	581

From 2006 to 2007, the number of portal sites found--sites that advertise the drugs--increased by 135 percent, while the number of anchor sites found--sites that actually sell the drugs--increased by seven percent. Over the four years that CASA has tracked online access to these drugs, the number of anchor sites found has increased by 21 percent.

As in previous years, benzodiazepines are the controlled prescription drugs most frequently offered for sale; in 2007, 79 percent of the anchor sites (147) offered these drugs. (Table 2) The percentage of sites offering to sell benzodiazepines has declined from 93 percent in 2004; the total number of sites offering benzodiazepines has ranged from a low of 143 in 2004 and 2005 to a high of 154 in 2006. In all years, the most frequently offered benzodiazepines were Xanax, alprazolam (generic), Valium and diazepam (generic).

The second most frequently offered class of controlled prescription drugs is the opioids. In 2007, 64 percent (120) of anchor sites offered these drugs for sale compared with 66 percent (101 sites) in 2004, 75 percent (115 sites) in 2005 and 72 percent (125 sites) in 2006. The most frequently offered opioid drugs include hydrocodone (e.g., Vicodin, Lortab) and propoxyphene (e.g., Darvocet, Darvon).

Table 2
Internet Availability of Controlled Prescription Drugs by Class

	2004	2005	2006	2007
Benzodiazepines	143 (93%)	143 (93%)	154 (89%)	147 (79%)
Opioids	101 (66%)	115 (75%)	125 (72%)	120 (64%)
Stimulants	42 (27%)	34 (22%)	14 (8%)	21 (11%)
Barbiturates	2 (1%)	15 (10%)	2 (1%)	4 (2%)
Total anchor sites	154	154	174	187

In 2007, 11 percent of sites (21) offered stimulants, up from eight percent in 2006 (14 sites), but down from the high of 27 percent (42 sites) in 2004. The most frequently offered stimulant is methylphenidate (e.g., Ritalin, Concerta) followed by dextroamphetamine (e.g., Adderall, Dexedrine).

In 2007, two percent (4) were identified that offered barbiturates. From 2004 through 2006, these drugs were offered for sale at one percent (2), 10 percent (15) and one percent (2) of sites respectively.

* Several adjustments were made in classification of data from previous years to assure consistency of reporting.

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Prescriptions Not Needed

Of the 187 sites identified in 2007 that offer to sell controlled prescription drugs on the Internet, 84 percent (157) did not require any prescription. (Table 3) Of those sites not requiring prescriptions:

- 33 percent (52) clearly stated that no prescription was needed;
- 53 percent (83) offered an "online consultation;" and,
- 14 percent (22) made no mention of a prescription.

Only 16 percent (30) of all the sites offering controlled prescription drugs required that a prescription be faxed or mailed or that the patient's doctor be contacted for the prescription. (Table 4) Of those sites stating that some type of prescription was required:

- 57 percent (17) asked that a prescription be faxed (potentially allowing a customer to tamper with a prescription or to fax a single prescription to several Internet pharmacies);
- 13 percent (4 including 1 VIPPS® site) asked that a prescription be mailed; and,
- 30 percent (9 including 1 VIPPS® site) indicated that a doctor would be contacted prior to dispensing the drug.

Table 3
Internet Pharmacy Anchor Sites Not Requiring Prescriptions

	2004	2005	2006	2007
Sites not requiring prescriptions	144 (93%)*	147 (95%)*	155 (89%)*	157 (84%)*
No prescription needed	63 (44%)	53 (36%)	49 (32%)	52 (33%)
Online consultation	76 (53%)	84 (57%)	90 (58%)	83 (53%)
No mention of prescription	5 (3%)	10 (7%)	16 (10%)	22 (14%)
Total anchor sites	154	154	174	187

* of total anchor sites

Table 4
Internet Pharmacy Anchor Sites Requiring Prescriptions

	2004	2005	2006	2007
Sites requiring prescriptions	10 (7%)*	7 (5%)*	19 (11%)*	30 (16%)*
Patient faxes	7 (70%)	1 (14%)	14 (74%)	17 (57%)
Patient mails	3 (30%)	4 (57%)	3 (16%)	4 (13%)
Doctor contacted	0 (0%)	2 (29%)	2 (11%)	9 (30%)
Total anchor sites	154	154	174	187

* of total anchor sites

Trends in Prescription Requirements

The percentage and number of sites clearly stating that no prescription was required have decreased from 41 percent of *all sites* (63) in 2004 to 28 percent of *all sites* (52) in 2007 while the percentage and number making no mention of prescription requirements have increased from three percent of all sites (5) in 2004 to 12 percent (22) in 2007.

The tendency of a drug to be offered without a prescription varies with the class of drug. Web sites are more likely to advertise some type of prescription requirement for opioids than for benzodiazepines. The numbers were too small to draw meaningful conclusions for stimulants or barbiturates.

Between 2004 and 2006, there was an increase in the number of Web sites that offered an "online consultation" in lieu of a prescription from a patient's physician--from 76 sites in 2004 to 90 sites in 2006. In 2007, 83 sites were found offering online consultations. In this case, the consumer fills out an online questionnaire that is reportedly evaluated by a physician affiliated with the online pharmacy. Without ever

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meeting the patient face-to-face, allegedly a physician reviews the questionnaire and then authorizes the Internet pharmacy to send the drug to the patient.[22] Tens of thousands of "prescriptions" are written each year for controlled and non-controlled prescription drugs through such Internet pharmacies, which do not require medical records, examinations, lab tests or follow-ups.[23] Online consultation is the primary method for obtaining prescription drugs over the Internet.

Some rogue Internet pharmacies provide online consultations free of charge; others refer customers to "script doctors" who are willing to write prescriptions for a fee.[28] CASA's analysis identified fees ranging from $10 to $180. Some sites claim that a physician will contact the patient via telephone or email. Others attempt to distance themselves from the consultation process by claiming that they merely are providing a referral service.

The Federation of State Medical Boards of the United States, Inc., the American Medical Association, the National Association of Boards of Pharmacy and the Drug Enforcement Administration (DEA), all agree that online consultations cannot take the place of a face-to-face physical examination with a legitimate physician.

No Controls Blocking Sale to Children

As in previous years, there is no evidence of any mechanisms in place to block children from purchasing addictive prescription drugs online. In fact, in a previous analysis BDA found that it was possible to order drugs by providing true information that should have warned any legitimate provider against supplying the requested drug. For example, a supervised 13-year old ordered and received Ritalin by using her own height, weight and even age when filling out the form.[30] While several Web sites required that purchasers identify their age, access to the site was easily gained by typing in a fake age.

Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.[24]

--Federation of State Medical Boards of the U.S.

Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient physician relationship...The physician shall...obtain a reliable medical history and perform a physical examination of the patient...[25]

--American Medical Association

Online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination.[26]

--National Association of Boards of Pharmacy

A legitimate doctor-patient relationship includes a face-to-face consultation, where a licensed physician can examine the physical symptoms reported by a patient before making a diagnosis and authorizing the purchase of a prescription medicine. Filling out a questionnaire, no matter how detailed, is no substitute for this relationship.[27]

--Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Deputy Chief, Office of Enforcement Operations
Drug Enforcement Administration

Congress & Ryan Haight

Ryan Haight died in 2001 from an overdose of hydrocodone. He had been a California high school honors student and athlete. He had purchased the drug over the Internet with an online consultation. In memory of Ryan Haight, Senators Dianne Feinstein and Jeff Sessions are proposing legislation to limit the sale of controlled substances over the Internet. Feinstein stated the rationale of the Act: "Ready access to controlled substances over the Internet is helping to fuel addictions."[29]

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Advertised Source of Drug Shipments

The physical location of the anchor sites from which controlled prescription drugs are sold often is difficult to discern; however, of the 187 sites selling the drugs in 2007:

- 26 percent (48) indicated that the drugs would be shipped from a U.S. pharmacy;
- 48 percent (91) indicated that they would be coming from outside the U.S.; and,
- 26 percent (48) gave no indication of the geographic source of the drug. (Table 5)

Table 5
Origin of Drug Shipment

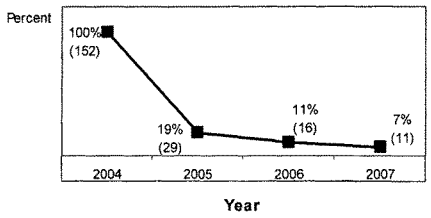
	2004	2005	2006	2007
U.S.	43 (28%)	57 (37%)	62 (36%)	48 (26%)
Non-U.S.	71 (46%)	61 (40%)	57 (33%)	91 (48%)
Unknown	40 (26%)	36 (23%)	55 (31%)	48 (26%)
Total Web sites	154	154	174	187

Lifecycle of Web Sites Selling Controlled Prescription Drugs

Web sites that sell controlled prescription drugs have an extremely high turnover and may attempt to avoid detection by changing their Web names and addresses. Of the non-VIPPS® anchor sites identified in 2004 (152), only 19 percent (29 sites) remained in business one year later. Only seven percent (11 sites) were still operating when CASA conducted this year's study--four years later. (Figure 1) CASA and BDA also found that it was not unusual for sites to have multiple names* or to disappear entirely even within the period of analysis. This fluidity in Web sites increases the difficulty of tracking and closing down rogue sites.

* Sites with multiple names were counted as one site.

Figure 1
The Persistence of Non-VIPPS® Anchor Sites Found in 2004



Next Steps

While legitimate online pharmacies can provide access to medications for patients who need them, this snapshot of the wide availability of dangerous and addictive drugs on the Internet reveals a wide-open channel of distribution. This easy availability has enormous implications for public health, particularly the health of our children, since research has documented the tight connection between availability of drugs to young people and substance abuse and addiction.[31]

Although Congress has held hearings on the subject and legislation has been introduced to help curb availability, no action has been taken to date. Because Internet access to controlled prescription drugs transcends state lines, federal action is key. The extensive availability of controlled prescription drugs online poses a threat to our nation's health and a challenge for law enforcement. To address these concerns, CASA recommends the following key actions:

- Congress should clarify federal law to prohibit sale or purchase of controlled prescription drugs on the Internet without an original copy of a prescription issued by a DEA-certified physician, licensed in the state of purchase and based on a physical examination and evaluation. Congress also should impose higher penalties for illegal sale to minors.

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- Congress should require that in order to advertise or sell controlled prescription drugs online, an offerer must be certified as an Internet pharmacy practice site. Such certification would identify legitimate online pharmacy practice sites, and clearly identify non-certified cites as illegal. Such sites could obtain a special Web domain name so that users can know immediately whether the site is legitimate. One mechanism might be certification by the National Association of Boards of Pharmacy as a VIPPS® site.

- Internet search engines should provide warnings that sale and purchase of controlled prescription drugs over the Internet from unlicensed pharmacies and physicians and without valid prescriptions are illegal and block sites that are not certified.

- The Office of National Drug Control Policy (ONDCP), DEA and Food and Drug Administration (FDA) should develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making online purchases of controlled prescription drugs from non-certified sites.

- The DEA and financial institutions (credit card and money order issuers) should collaborate to restrict purchases of controlled prescription drugs from non-licensed and accredited providers.

- Postal and shipping services should train counter and delivery personnel to recognize potential signs of pharmaceutical trafficking and know how to respond in the event of suspicious activity.

- The State Department should encourage and assist foreign governments to crack down on Internet sites illegally selling controlled prescription drugs to U.S. citizens.

- The federal government, Internet search providers, shippers, financial institutions and non-profit organizations concerned with controlled prescription drug abuse should cooperate in creating a national non-profit clearinghouse to identify and shut down illegal Internet pharmacies.

EMBARGOED FOR RELEASE: Wednesday, May 16, 2007, 12:01 AM, EDT

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Appendix A
Detailed Methodology

The National Center on Addiction and Substance Abuse (CASA) at Columbia University replicated Beau Dietl & Associates (BDA) methodology that was developed for its initial investigation in 2004. This methodology was as follows:

Time Devoted to Project

This analysis is conducted in the first quarter of each year. Total staff time devoted to documenting online sites that advertise or sell controlled prescription drugs is approximately 210 hours.

Database Information

The database created for this report contains detailed records for all Web sites uncovered during the 210 hours devoted to the analysis. Each record contains the following information: distinction between anchor and portal sites, and for each anchor site, dispensing information, advertised country of origin and the list of drugs offered by the Web site.

Customer Emulation

Throughout this investigation, CASA attempted to duplicate the approach that an individual seeking to order controlled prescription drugs might use. At all times, CASA investigators asked themselves the following question: How would a typical individual approach the search to buy a controlled substance over the Internet? What would a customer think when viewing this Web page?

Target Drugs

CASA worked from a list of drugs which included only controlled substances as defined by the DEA, Schedules II through V; primarily Schedules II and III. Each investigator was assigned several of these drugs to research.

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Web Site Discovery

The goal of the investigation was to uncover as many Web sites as possible involved in the sale of the target drugs. To this end, CASA employed the following methods:

Method 1--Internet Search

CASA searched the Internet using several popular search engines such as *google.com* and "*meta*" search engines; i.e., engines that search several search engines at once, such as *dogpile.com*, *hotbot.com*, etc. Combining the word "buy" with the drug being investigated (e.g., "buy Valium") narrowed the number of hits obtained and excluded potential informational pages.

The domain names from the resulting hits were added to the master database created for this purpose unless it was obvious they were of no interest to this investigation, such as news articles or technical or academic papers.

Method 2--Email Advertisements

Another method used was to pull Web sites from any e-mail advertisements, a.k.a. spam, that many people receive on a daily basis. One investigator was assigned the task of researching the Web sites advertised in these emails.

Web Site Investigation

Once a Web site was identified as a seller of a drug, investigators looked for the following information:

Site Classification: Portal vs. Anchor Sites

It is important to consider the relationship between what customers see on the screen when a Web site is accessed and which Web servers actually are being accessed.

For example, Internet surfers might think they are visiting only one site when in fact they might be forwarded multiple times to separate sites. Or the page they are visiting might appear to be selling pharmaceuticals when in fact it does not but rather is linked to other Web sites that do. Bearing those distinctions in mind, CASA categorized Web sites as either *anchor sites* or *portal sites*. An anchor site is one that sells drugs directly to the potential buyer while a portal site only refers the potential buyer to the anchor site.

Site Classification: Advertised Country of Origin

Web sites exist in cyberspace and not in the real world. It is therefore important to define what is meant when discussing the "location" of a Web site selling drugs. One can mean the location the Web site advertises as to the origin of the drugs it sells; the physical location of the computers holding the Web site data; the location of the business or individual running the Web site; or the location from where the drugs actually are shipped.

The second definition provides little information because data in the Internet can be transmitted from anywhere in the world. The third presents a host of problems because registration information for a Web site can intentionally or unintentionally be inaccurate. And even if accurate, it does little to help us understand the origin of the drugs as the Web site operator can exist anywhere in the world separate from the location from where the drugs are shipped. The fourth definition would by far be the most accurate since the postage and return address would provide all the information one requires. However, that information is available only when drugs are ordered, something CASA investigators did not do.

The first option is the only remaining possibility. Thus, investigators relied on information provided by the Web site as to the country from which the drugs were to originate.

CASA investigators looked for:

- Text in the body of the Web page that stated the source of the drug(s);
- Graphics, such as a country's flag, that might lead a visitor to believe the drugs were from a certain location; or,

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- The title of the site itself which would lead a visitor to believe the drugs were from a certain location.

Site Classification: Dispensing Pattern

Given the information provided by each Web site, investigators were able to determine each site's prescription requirements. This was done either by browsing through each site looking for such sections such as "FAQs" or "How to Order" or by beginning the ordering process and noting if and when a prescription requirement was requested. The dispensing patterns of all the Web sites discovered fell into these categories:

- **Pre-written prescription.** Some Web sites required that the patient submit a prescription already written by a doctor. In most cases, this was to be done via fax (potentially allowing an individual to use the same prescription at several sites). Occasionally, a site required the original prescription to be mailed or advised that the prescribing doctor would be contacted prior to dispensing the drug. These cases were noted in the master database.

- **Online consultation.** Other Web sites did not require a prescription. However, they required answers to a questionnaire that often was referred to as an "online consultation." These sites asked the patient to fill out some form of medical questionnaire. Frequently a consultation fee was charged for this service.

- **No prescription.** Several sites made no mention of any type of prescription requirements and neither did they include a medical questionnaire. Other sites advertise that no prior prescription was needed.

Site Classification: Drugs Available

Investigators noted any target drugs available at the Web site, even if a particular drug was not one assigned to them. If an investigator discovered a Web site selling their assigned drug and it already was entered into the database by another investigator, he/she checked to be sure the assigned drug was recorded.

Site Classification: Other Information

Investigators also noted any other information that might be of interest to the investigation such as if the site seemed to be a copy or similar to another site.

Notes on Analysis

Several adjustments were made in classification of data from previous years to assure consistency of reporting.

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Notes

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Statement of the
Federation of State Medical Boards

Senate Committee on the Judiciary

Submitted by James N. Thompson, MD
President and Chief Executive Officer

Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking

May 16, 2007

I. The Federation of State Medical Boards (FSMB)

The FSMB is a non-profit organization of the 70 state medical licensing and disciplinary boards of the U.S. and its Territories. Established in 1912, the FSMB is a known and authoritative resource on issues related to medical regulation, including research, policy analysis and development, education, and state by state licensing and disciplinary statutes, rules and policy. FSMB's mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice and to support state medical boards in protecting the public. As a collective voice for state medical boards, the FSMB monitors state and federal legislative initiatives, works collaboratively with federal and state regulatory agencies, and offers legislative assistance to and on behalf of our member medical boards.

II. Model Guidelines and Key Concerns

The Internet has had a profound impact on society, including the practice of medicine and pharmacy, and offers opportunities for improving the delivery of health care. The appropriate application of technology can enhance medical care by improving patient access to specialty care, facilitating communication with physicians and other health care providers, filling prescriptions, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information and clarifying medical advice. At the same time, new technologies can create opportunities for individuals and entities to exploit technological advancements for personal gain without regard for patient safety. The simultaneous increase in telemedicine technologies/applications and "rogue" Internet pharmacies, those that prescribe and dispense medication based on online consultations or questionnaires, have created complex regulatory challenges for state medical boards in protecting the public.

The primary mission of state medical boards is patient protection through the regulation of the practice of medicine, regardless of the treatment modality. Regulation becomes more complicated as patients interact with physicians electronically rather than in a

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traditional face-to-face setting. Accordingly, the FSMB has been active in addressing regulatory issues associated with the use of telecommunications and the Internet in the practice of medicine for more than a decade. In 1996, the FSMB published *A Model Act to Regulate the Practice of Medicine Across State Lines.* In 2000, it published guidelines for Internet prescribing. In 2002, it published *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, one of the first national standards established for Internet medical practice.

Those guidelines, which the FSMB recommends be adopted by all state medical boards, emphasize the key position of the FSMB and its member boards with respect to Internet pharmacies: *An appropriate relationship between the patient and the physician must exist before a prescription is written and medication dispensed.* Failure to have an appropriate physician-patient relationship poses serious health risks including: (1) adverse drug reactions and/or interactions, (2) misdiagnosis or delay in diagnosis, (3) failure to identify complicating conditions, and (4) misuse, abuse and diversion of prescription medications, including controlled substances.

III. National Clearinghouse on Internet Prescribing

In addition to policy development and promulgation, the FSMB has aggressively sought to identify Internet pharmacies that are dispensing drugs on the basis of prescriptions written by health care providers whose relationship with the patient does not appear to meet minimal standards. In September 2000, the FSMB established its National Clearinghouse on Internet Prescribing, to collect and disseminate information on "rogue" Internet sites offering prescribing and dispensing services for prescription drugs to consumers.

The Clearinghouse is uniquely qualified to coordinate information between regulatory and enforcement entities because of its formal relationship with state medical boards. The FSMB has well established lines of communication with state and federal regulatory agencies, including the Department of Justice, the Drug Enforcement Agency, the Food and Drug Administration, Immigration and Customs Enforcement, and the Federal Trade Commission, as well as the National Association of Boards of Pharmacies, the National Association of Drug Diversion Investigators, the National Association of Attorneys General, representatives of the pharmaceutical industry, and the media.

To date, approximately 39 physicians have been disciplined by their licensing board based on Clearinghouse data. The Clearinghouse has supplied information for more than 300 cases on the federal level and more than 600 cases on the state level. Additionally, information regarding Internet prescribing has been shared with the Medical Council of New Zealand and the Ministry of Health in Germany.

IV. State Regulation

The Federation strongly supports state-based regulation of the practice of medicine. With regard to Internet prescribing, state medical boards have the authority to discipline

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licensed physicians prescribing and dispensing medications inappropriately. Forty-six (46) boards have taken disciplinary action against licensees, twenty-nine (29) states have adopted rules/policies, and seventeen (17) states have enacted legislation to clarify this authority. An additional nine (9) states have introduced legislation this year to regulate the practice of medicine via the Internet. Further, state medical boards have communicated among themselves regarding physicians licensed in multiple states. These cooperative efforts have been effective in closing several Internet sites and causing a number of physicians to cease their affiliation with questionable operations.

V. Federal Legislation – Online Pharmacy Consumer Protection Act

The FSMB supports the development of federal legislation to protect patients ordering prescriptions over the Internet but cautions against any legislation that would have the unintended consequences of restricting patient access to legitimate telehealth services. The FSMB supports legislation that would strengthen the enforcement authority of state and federal regulators against Internet pharmacies and those associated health care professionals.

S.980, the Online Pharmacy Consumer Protection Act of 2007, would provide significant protection for consumers who utilize the Internet to obtain pharmaceuticals.

S.980 addresses issues crucial to the protection of patients ordering prescriptions over the Internet. First, the bill requires a pharmacy that seeks to deliver, distribute, or dispense by means of the Internet a controlled substance to obtain a registration specifically authorizing such activity from the Attorney General. The pharmacy would be required to disclose information in a visible and clear manner on its homepage, including contact information for the site owner, a list of States in which the pharmacy has any operations, information relating to pharmacies and pharmacists associated with the website, the name, licensing information and contact information for practitioners who provide medical consultations through the website, and a compliance statement. Patients should know with whom they are dealing. Disclosure will not only be beneficial to patients but will allow state medical boards to identify individuals against whom they may take disciplinary action.

Second, S.980 defines the term "qualifying medical relationship" to mean a medical relationship that exists when a practitioner has conducted at least one medical evaluation with the user in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals; or conducts a medical evaluation of the patient as a covering practitioner and is not prescribing a controlled substance in schedule II, III, or IV; and shall not be construed to imply that one medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice. This requirement for conducting at least one in-person physical examination prior to issuance of a prescription is similar to requirements in much of the country. A clear, national standard would greatly support law enforcement and administrative efforts to regulate this burgeoning practice via the Internet. However, vigilance must be maintained to make certain this bill

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does not negatively impact the practice of telemedicine. As this legislation moves forward, FSMB would be pleased to work with the Committee and the sponsors to address these concerns.

Third, state attorneys general are not able to enjoin the operations of an Internet pharmacy that affect citizens in their particular states if that pharmacy is operated out of another state. Many of our member boards believe that a number of Internet sites that dispense drugs in an inappropriate manner could be shut down if the attorneys general had nationwide injunctive powers as well as the ability to pursue other civil remedies including damages, restitution or other compensation across state lines. S.B. 980 authorizes those injunctive powers.

VI. Model Guidelines on Physician-Patient Electronic Communication

In its *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*, the FSMB addresses physician use of electronic communications and the Internet in the delivery of patient care. Portions of the guidelines are excerpted below: ***Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings.*** Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care. A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

Patient-physician electronic mail should be maintained with written policies and procedures addressing (1) privacy, (2) health-care personnel who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, (6) archival and retrieval, and (7) quality oversight mechanisms.

Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. All patient-related electronic communications, including patient-physician e-mail, prescriptions, lab results, evaluations and consultations should be stored and filed in the patient's medical record.

Turnaround time should be established for patient-physician e-mail. E-mail systems should be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients should be encouraged to confirm that they have received and read messages.

VII. Conclusion

In conclusion, the Internet offers tremendous opportunities for improving the delivery of health care. However, it is the position of the FSMB that the use of the Internet in

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providing medical services, including prescribing and dispensing medications, should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship. The misuse of the Internet in providing medical services and dispensing dangerous drugs to consumers is risk to the public health, safety and welfare and warrants the passage of federal legislation that can distinguish legitimate telemedicine practice from those associated with "rogue" Internet pharmacies.

Federation of State Medical Boards; page 5

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Testimony to Judiciary Committee

Good afternoon. My name is Francine Haight. Thank you for inviting me to testify at this hearing about a very important topic that tugs at my heartstrings everyday. Many of the speakers here today will be giving you statistics and numbers. I am here to put a face to those numbers. I am very sad to say that face is Ryan's, my son. Unfortunately he was a victim of illegal sales of pharmaceuticals through the Internet.

Ryan was born on December 28, 1982 and died on February 12, 2001 from an overdose of prescription drugs he had purchased on the Internet. He was only 17 when he ordered the drugs, and only 18 when he died.

Ryan was an incredible boy. From the time he was little, I always believed that he would make a difference in this world. He was very intelligent and excelled in school. He loved math and science, was at the top of his class, was a GATE (Gifted and Talented Education) student in the elementary years, and then went on to take honors classes. He was an A student and maintained a 4.0 or above during his years in high school. He looked forward to going to college.

Ryan was athletic and loved the thrill of competition. In elementary school he played Little League Baseball and then became a top player in the Majors and made the All Star Team. He played Open Junior Tennis tournaments, and went on to play Varsity tennis for Grossmont High School in La Mesa, California. He loved to ski, snowboard, water ski, kneeboard, and attempted all sports with great enthusiasm. He loved to play billiards, bowl, and play ping-pong.

Ryan loved using the computer. He was thrilled to find out that he could easily chat online with his friends from school. He could send and receive email everyday. He could enter chat rooms and talk about educational and current events. He learned to surf the Internet. It was a perfect place for him to use for his papers in school, or to seek information he was curious about. Ryan used the computer to play games. He enjoyed trading baseball cards on EBay. Ryan was taking a computer graphics class in high school. He was considering a possible career with computers. But on February 12, 2001 that all stopped.

On February 12, 2001, I found Ryan in his bed, lifeless. I tried to resuscitate him, but could not bring him back. Ryan had died. I was in shock. Just the night before we had dinner together, after he came home from working at a nearby retail store. At midnight I kissed him goodnight and he said "Love You, Mom." Those were the last words I would hear from him. Ryan died from an overdose of Vicodin, a prescription drug. They also found small amounts of Valium and Morphine. I thought, how? How did he get these drugs? After one of his friends told us he got them off

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the Internet, we gave our computer to the DEA to investigate. Through their investigation, they found how Ryan had ordered the drugs. A medical doctor, Robert Ogle, whom Ryan never saw and was never examined by, prescribed them, and an Internet pharmacy, Clayton Fuchs of Mainstreet Pharmacy, delivered them to our home. I was in shock. I thought how could this be possible? I am a registered nurse; Ryan's father is a physician. We know that all controlled substances have to be accounted for. We count each drug everyday, and all are charted when administered to a patient. They are under lock and key. How could he get them off the Internet so easily? At a time when we were worried about our children being exposed to pornography and predators, marijuana and alcohol, we did not know that drug dealers were in our own family room. Ryan did not have a computer in his bedroom; we always believed it should be in the main part of the house so that we could keep an eye on what our children were doing.

Through the DEA's investigation we also learned about web sites that have chat rooms that glorify the use of drugs. It was on one of these web sites where Ryan was confronted by a "drug dealer," who told him where he could go on the Internet to purchase drugs for experimental purposes, fun, and to make him feel better. I am appalled that these web sites are still up and running. It's still shocking to see kids go online to write about their "trips" on drugs. After a long investigation and trial, Dr. Robert Ogle and Clayton Fuchs, who together made millions by their drug dealings, were prosecuted by the United States Attorney in Dallas, Texas and are now in federal prison for the next 20 years. I attended the sentencing of Clayton Fuchs, and although it does give me some peace that justice was served, it does not bring Ryan back. I am still shocked at the ease and availability of buying controlled substances on the Internet. I still receive emails to purchase drugs daily. I was contacted by a woman who together with her 14 year old son decided to just see how easy it really was to buy drugs off the Internet. She was shocked to see how easy it was to get mind-altering, very addictive controlled substances. I receive messages like these from teenagers and adults often. Over the last few months, Ryan's story has been told in a documentary called "Online Nightmares" and produced by E Entertainment has aired about 15 times. I have received numerous emails from teens and adults. I feel it is important to read a few of these today to let you know how many people are affected by this on a daily basis.

1. I didn't know your son at all.. I saw you on T.V just about 1 hour ago and I know how it feels to loose a family member from drugs. I know that in your case it was a son but in mine it was a brother and my mother. All though my mom didn't die from drugs, she was in the car with my brother driving it under the influence of zanex. My mother did not know that he was under the influence but she thought something was wrong but she gave him the benefit of the doubt. I just

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want to let you know that everything your doing about stopping all these drug online sites that are giving them to kids is appreciated not only to me but too many. Thank you for holding in there and being so strong. I am 13 years old and I never thought that I could even live without my mother nor my brother but I've been getting through it everyday. Even though there is not a day goes by that I do not think of either of them nor cry about them. I guess you can say it just made me stronger. It also makes me believe drugs are not the answer to ANYTHING! Nothing at ALL. It also made a lot of other people in my town know that too. My brother was a very popular kind and sweet brother and just knowing that we can never have our bonds we used to have kills me inside. Everyday I fight to stay alive. Because everyday I think about killing myself. But i know that's not what my mom or brother would want me to do. Well thank you once again.

2. Just finished watching the E special of which a portion was about your son. I am so sorry to hear about his death. I am a youth pastor with my wife, and we have had a similar loss in our church. I think that there should have been some regulation and verification of his age on delivery.

3. I heard about your story on the special on E Entertainment, personally I feel part of the problem with online drugs sites is the spam that goes with it. Congress needs to take further action to stop this. Someone who is depressed who doesn't want to see anyone for help may get an email advertising Anti-depressents, if you notices in these types of emails that is what these drug sites mostly advertise and that is their target audience.

4. I was Ryan!! I didn't know how prolific these web sites were until I saw your program. I also ordered from them to feed my addiction to Tramadol. It ruined my marriage, and almost my career. I am not a teen, I am now 42 years old and there isn't a day that goes by that I don\t think what could have happened. I now teach 8th grade English at a metro middle school in Oklahoma City.

Thank you for sharing Ryan's story. We shared it with our 16 year old daughter who we believe is experimenting with prescription medication. We too are shocked at how easy it is for children to get access to drugs. Rather it be school, the Internet, friends or all of the above.

5. Dear Francine: I definitely want to get on board with this issue and will contact my congressman.
I am actually not a youth. My story is that I was a 35 years old single mother with 9 years of sobriety from all mood altering substances when I started getting spam advertising "V I C O D I N" (just like that, all caps etc.). Of course, having been particularly fond of opiates but

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never really abusing them due to what I thought at the time was the difficulty of obtaining them, I checked out the sites. When I found that often no prescriptions were necessary, I was intrigued and began my relapse. I obtained codeine and ultram on line, neither as strong as vicodin or percocet but I would take up to 12 at a time. It was a nightmare. I was in school for a Masters degree in mental health counseling and would often be nodding out through class, and I'm ashamed to say, through my internship working with clients (I don't share this detail at a local level, due to the nature of the counseling profession). Eventually, I started drinking again as well and within a week my behavior was such that I was asked to take a leave from the grad program. This turned out to be a huge blessing because I did check myself into rehab and in my re-gained sobriety, I got my life back and so much more. Through what I can only call grace I did not lose my child, I did not get into an accident (which is so lucky because I was often very impaired when driving, again, I am deeply ashamed to say), I did not get arrested, and most importantly, I did not die (and leave my son motherless). But I so easily could have. Sometimes I felt like my heart muscle would burst. And although ultram is marketed as a narcotic alternative, it most certainly is addictive, induces a similar high, and is known to cause seizures, even at the prescribed level of one or two pills. I was very lucky and I shutter when I look back now, especially when I hear of stories such as your son's. I finished school and am working as counselor in the chemical dependency field. I love it because I understand my clients. For me, the story has a happy ending but so often I see in my work and elsewhere, it does not. I have lost several clients to oxycontin and other narcotics and that they are available on line still makes me insane with rage and frustration. And that these pharmacies continue to call me and tell me that my "medicine" is ready to be shipped out reminds me often of the nightmare. The scary thing is, this disease of addiction is something recovering addicts have to fight everyday, and on days where I'm vulnerable, I could be in great danger when these peddlers call me. This is VERY SERIOUS. I don't think I would have relapsed had I not received that spam email.

I am so very sorry for your loss, Francine. God bless,

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I told Ryan's story before the United States Senate Permanent Subcommittee on Investigations on June 17, 2004, after the introduction of the "Ryan Haight Act"[1] by Senator Dianne Feinstein and Senator Norm Coleman. This bill would counter the growing sale of controlled prescription drugs on the Internet without a valid prescription. It would 1) require the Internet pharmacy website to display information identifying their business, pharmacists and physicians for consumers; 2) bar the selling of drugs via the Internet when the website has referred the customer to a doctor who then writes a prescription based solely on an online questionnaire without ever seeing the patient; and 3) provide states with new enforcement authority that will allow a state's attorney general to shut down a rogue site across the country, rather than only bar sales to consumers of his or her own state.

Since Ryan's death others have died after purchasing controlled drugs over the Internet. Linda Surks who I met last year, lost her son Jason to prescription drugs. He used the Internet to research the safety of certain drugs and how they react with others. He ordered drugs from one Mexican pharmacy on the Internet that automatically renewed his order each month.

Prescription drug usage is up among our teens. Prescription drug addiction is up all across America. The Ryan Haight Internet Pharmacy Consumer Protection Act was reintroduced by Representative Tom Davis in 2005. The passing of this Bill authorizes states to shut down rogue virtual drug sites and makes it difficult to obtain dangerous and addictive drugs online. This bill is supported by the Federation of State Medical Boards and the National Community Pharmacists Association. I encourage all of you present to pass this bill. Ryan is far from an isolated incident. Americans of all ages have discovered powerful addictive drugs like Vicodin, Codeine, OxyContin, and Valium are only a click away. This is one way to start to protect our youth from having an easy way to get drugs and to protect them from dying as Ryan did.

A Registered Nurse, Jennifer Stephenson, recently wrote her Master's paper called "The Ryan Haight Internet Pharmacy Consumer Protection Act, An attempt at Regulation of Internet Pharmacies. She is just one of many professionals in the medical field that is concerned about this issue. I have the paper with me today, but it is too long to read but is available for you to read if you like.

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I would like to see that Ryan's bill be possibly added as a noncontroversial amendment to "the prescription drug user fee act (PDUFA), which governs FDA issues and prescription drug review" and address the safety issue incumbent in drug sales.

After Ryan died, it took me almost three years to get strong enough to do what I know Ryan would have wanted me to do. I started "RYAN's Cause" - RYAN stands for "Reaching Youths Abusing Narcotics." The website is *http://www.ryanscause.org.* Since then I have been dedicated to educating and providing information to parents, families, schools, and our communities on issues concerning the Internet and drug abuse. I have shared my story with numerous local and national news stations and television programs such as Dateline News, Fox News, Good Morning America, the Today Show, and the Montel Williams Show. I have interviewed with several newspapers including the Washington Post and magazines such as Reader's Digest in hopes to raise awareness of this growing drug problem in hopes to prevent other families from suffering such a devastating loss. I am here today, because I want to help fight this war against drugs. Too many people are dying.

I am a parent that belongs to a club I never wanted to join. I am an ordinary person who could be your neighbor, your co-worker, or member of your house of worship. But drugs took my son from me and some days the grief is still unbearable. Drug abuse is an equal opportunity killer. It is not confined to one kind of neighborhood, one socioeconomic group, or one kind of kid. Ryan was the boy next door. We need to do everything we can to protect our children. Tighter regulations on the sale of controlled substances on the Internet will not totally solve the drug problem, but I guarantee it will help and it's a good place to start. Thank you for allowing me to speak, and for listening to this very important issue. Ryan continues to make a difference. I just did not know he would be so far away.

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"Keep Internet Neighborhoods Safe"
Preventing the Illegal Internet Sales of Controlled Substances to Youth

Testimony of
Philip Heymann, Professor of Law, Harvard Law School
(Prepared with Mathea Falco, President, Drug Strategies)
U.S. Senate Committee on the Judiciary
May 16, 2007

Chairman Leahy, Senator Specter and other members of the Committee, we are pleased to testify before you today about a significant but still largely unaddressed threat to our young people --- the growing tragedy of addiction and death from powerful narcotic painkillers bought without prescription over the Internet. Although the problem has received considerable press coverage, including a major series in the *Washington Post* in 2003, no sustained action has been taken to curtail expanding illegal internet drug sales. This is all the more surprising because taking action would not involve freedom of speech issues nor invoke opposition from either political party or the business sector. In short, no one supports selling controlled substances without valid prescriptions over the internet to our youth, and yet nothing is happening to stop this traffic.

We commend the Senate Committee on the Judiciary for taking the lead in developing effective responses to the growing problem of illegal drug sales over the internet, which is one example of the many ways the internet can and will be used in the future for criminal activities. We share with you the conviction that it is time to take action to

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curtail cyber-trafficking of dangerous drugs before it expands even further. We believe that the most effective way of doing so is by engaging the active cooperation of the legitimate businesses that now unwittingly facilitate this traffic. Only the Congress can assure this cooperation.

The Problem

Our "Keep Internet Neighborhoods Safe" (KINS) initiative began in early 2005, when we learned of the extensive research conducted by the Treatment Research Institute (TRI) at the University of Pennsylvania that specifically identified more than 300 unique websites offering to sell prescription narcotics like Vicodin and Oxycontin without prescription. A seventh-grader researching a paper for health class might enter the term "Oxycontin" or "Vicodin" in any major search engine and see sites that aggressively market the availability of narcotic painkillers without the required prescription on two-thirds or more of the listings provided. TRI verified that these websites actually deliver what they promise and will even replace without cost any shipments that are intercepted.

Prescription narcotics, like Vicodin and Oxycontin, are now widely abused by young people. The most recent national surveys report that in 2006, 9.7% of high school seniors said they had used Vicodin at least once in the past year, compared to 9.3 % in 2003. The even more powerful narcotic Oxycontin was used by 4.3% of 12th graders and 3.8% of tenth graders. Particularly alarming is the rapid rate of initiation of

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Oxycontin and Vicodin use among the youngest adolescents. In 2006, 2.6% of eighth graders reported having used Oxycontin in the past year, a 100% increase since 2002 (when only 1.3% reported using the drug). Vicodin use among this group jumped from 2.5% in 2002 to 3% in 2006, an increase of 20%. ***After tobacco, alcohol and marijuana, Vicodin is now the most widely reported drug abused by 12th graders.*** By way of contrast, heroin has an annual prevalence rate of less than 1 percent among 12th, 10th, and 8th graders.

Most young people (and their parents) don't realize that these drugs are as addictive as heroin and that they can lead to overdose and even death, particularly when combined with alcohol. (The dangers of these drugs were the basis of last Thursday's multiple convictions of Oxycontin's makers for hiding that the drug is as addictive and produces a high as powerful as heroin. See Appendix D, http://www.nytimes.com/2007/05/11/business/11drug.html?ex=1179547200&en=f09f0937cd2f845a&ei=5070&emc=eta1) Although there is not yet solid data on the magnitude of internet sales of narcotic drugs without prescription -- and non-internet sources may still be greater -- both DEA and treatment centers report that adolescents are increasingly relying on the internet as a source of supply. Although key government agencies are aware of this growing problem and have undertaken several enforcement operations in the U.S. to try to curtail internet drug traffic, the tragic costs in terms of wasted lives and teen deaths continue to mount.

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We believe that familiar law enforcement techniques directed at the sources, transporters, and retail sales networks of drug dealing will prove ineffective to deal with a globalized, internet-based system of sales and distribution of drugs (and also with offers of other contraband including child pornography, gambling opportunities, and illegal weapons). Online stores can be hosted and registered anywhere in the world -- advertising, selling, and delivering products internationally with considerable anonymity and convenience. The sellers and their goods are extremely difficult to identify and locate. Even if these difficulties can be overcome, the countries in which they operate are unlikely to be willing partners in suppressing a trade that may be wholly unregulated in their country. For one of the many countries that, unlike the United States, leaves the sale of narcotic painkillers such as Oxycontin and Vicodin unregulated, there is little incentive to undertake enforcement efforts at the cost of their own sellers, simply to benefit American consumers.

Many of the websites selling such narcotic painkillers as Oxycontin and Vicodin are located abroad and will not be deterred by U.S. threats of increased penalties. They do, however, have one critical vulnerability to U.S. control. To advertise, finance, and deliver these drugs, they must and do rely on the unwitting cooperation of such major legitimate businesses as search engines, internet service providers, and credit card companies. If these legitimate businesses, which do wish to remain within the boundaries of U.S. law, withdraw their assistance -- or advise law enforcement to whom, in this category, their services are being provided - the dealers in internet sales of controlled substances without a prescription will find it far more difficult to continue

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their businesses. It was for this reason that we decided that a new, unique collaboration between the private and public sectors could make a critical difference. By engaging the support of the global businesses that unintentionally facilitate cybertraffic in dangerous drugs, we can substantially reduce that traffic and its costs to American teenagers.

For some businesses, such as the providers of financial services, regulatory obligations already require a far greater effort than is often now being made to end facilitation of illegal sales of narcotics. For others, such as internet service providers and search engines, there is no present legal obligation (other than whatever remote dangers there are of being found to be accomplices to the sale). But they express great willingness to cooperate in an effort to end these illegal sales. Both groups claim difficulty in identifying which of their customers are involved in this internet trade in narcotics and both worry about liability if they act to end that trade. If the Congress can solve both those problems – which, we will show, it easily can – then cooperation should be forthcoming. If it is not, and we propose reporting requirements which will promptly reveal any such failure, then the Congress can legislate enforceable regulations.

Creation of KINS

In January 2005, the Center for International Criminal Justice at Harvard Law School, Drug Strategies, the Treatment Research Institute at the University of Pennsylvania, and the Weill Medical Center at Cornell University formed a core leadership group to

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00130 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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develop strategies to "Keep Internet Neighborhoods Safe". Since then, we have held six plenary meetings at Harvard Law School involving more than fifty participants and we have met with government officials and private company executives in Washington, D.C. On July 6-7, 2006, we convened a major conference at Harvard to discuss new strategies to curtail illegal Internet sales of controlled substances to youth by targeting key points of control. (A list of participants is attached as Appendix A.)

Our collaboration has brought together leaders of companies that play key roles in internet commerce. These include Internet Service Providers (ISPs), such as Verizon Online; AOL; AT&T, Earthlink; Microsoft, and Comcast; search engines, such as Google and Yahoo; banks, such as UBS and JP Morgan Chase; credit card companies, such as Mastercard, Visa and Paypal; and private carriers, such as UPS, DHL and Fed Ex. We have also included officials of relevant U.S. government agencies, such as the National Institute of Drug Abuse, the Department of Justice, the Drug Enforcement Administration, Customs and Border Protection, the Department of State, and the U.S. member of the United Nations International Narcotics Control Board. Senior staff members from key Senate and House Committees have also participated. In addition, our collaboration has been informed by academic, legal, and technology experts as well as leaders in public education through the media, such as the Partnership for a Drug Free America.

Based on extensive discussions, we have developed recommendations designed to curtail illegal Internet drug sales by targeting key points in the chain of Internet

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00131 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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commerce that begins with a search engine, moves to a web site, and requires drugs to be produced and shipped in response to international financing of sales. Central to the success of these recommendations is the timely sharing of detailed information about the drug-trafficking websites so that their operations can be shut down. While all the participants in the "Keep Internet Neighborhoods Safe" initiative worked toward identifying effective and practical strategies, not all agreed with each of our recommendations.

How the New Strategy Would Work

Let me summarize what we believe it would take to reduce significantly the use of the internet to sell controlled substances illegally to minors within the United States.

First, we must empower parents to protect their children by giving them the means to keep illegal drug websites off their home computers. We believe that internet service providers (ISP's) should make available to their customers the opportunity to block ads for illegal sales of controlled substances from their internet service. ISPs already offer filtering features that give parents control over what comes into their home computers, and our recommendation would build on these already successful filtering programs.

Second, we believe that the credit card companies, and the financial institutions that sponsor them, should contractually prohibit (and most do now) the use of their financial networks for any illicit purchase or sale of controlled substances. This is an entirely

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00132 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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familiar obligation of financial institutions. To be specific, on receipt of information about illicit transactions from independent monitoring groups or from their own internal monitors, the financial institutions would and should be expected to identify the accounts that are being abused, presumably by putting through a "test" order of their own. The drug merchant's bank would be contractually obligated to know its customer and to take steps to penetrate any pseudonyms used by the drug dealer. The dealer's merchant bank would also cut off credit to the offending account and to those behind the account if it is really a front -- furnishing the information it learns about the illegal transaction to other credit card companies and to law enforcement. For example, with that information in hand, the State Department would notify the relevant authorities in whatever foreign state the illegal sale was located, asking for prosecution under applicable treaties.

Third, we believe that efforts to cut off illegal internet sales of controlled substances should be supplemented not only by other forms of law enforcement but, more promisingly, by a nationwide educational campaign, led by government agencies, such as the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration as well as private organizations such as the Partnership for a Drug-Free America. Again, we think a public/private partnership is essential. All these organizations should be taking steps to educate both parents and children on the dangers of using narcotic painkillers without prescription, particularly in combination with alcohol. Part of that education should be information about the firewalls and parental control software that are available from Internet service providers.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00133 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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The most direct form of warning should take place whenever a teenager asks a search engine (such as Google, Yahoo, or Microsoft) to find one of the controlled substances for sale "without a prescription" or "without questions" or any similar euphemism. The response to any such request should include a prominent banner that reminds the requestor that it is illegal to buy or sell this drug in the United States without a prescription. Search engines, such as Google, are already providing ways for users searching the internet to protect their computers from websites that inject viruses. They could easily extend these efforts to include warnings about websites illegally offering to sell controlled substances.

None of these steps is costly or technologically challenging to the industries now providing their services to illegal dealers of narcotics to children over the internet. Most members of each industry express an eagerness to help but explain that they don't know how their facilities are being used or by whom. And each expresses a fear of legal liability for terminating a relationship on these grounds. A simple step can eliminate these problems.

Thus, at the center of any comprehensive strategy would be the creation of an independent monitoring group (IMG) or organization that could identify, on a continuing, real-time basis, websites that offer to sell controlled substances without prescription. This small non-profit organization, which we estimate would cost about $2 million a year to operate, should receive funding through the Office of Justice Programs (OJP) in the

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00134 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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Department of Justice. The IMG can be imagined as a group of individuals simply using search engines to identify websites offering to sell controlled substances without valid prescriptions. But because the websites they will identify will usually be fronts linked to other websites, the IMG will need the assistance of readily designable computer programs. The IMG will furnish that information immediately, by the press of a key, to the sizeable number of honest American companies that are now unwittingly facilitating these illegal sales of drugs as well as to relevant government law enforcement agencies.

The IMG will send this information as to offers to make illegal drug sales simultaneously to the financial institutions, such as credit card companies, that finance the illegal sales. The information will also go to the carriers who unknowingly ship controlled substances into the United States and to pharmaceutical companies whose drugs are being advertised without their consent. The former could deny service and provide information helpful to Customs inspectors. The latter would have a strong interest in pursuing those misusing their formulas and brand names.

The IMG will also serve as a clearinghouse, making information from any of the private service providers available to the others. A "safeharbor" for actions reasonably taken on the basis of the findings of the IMG eliminates the fear of liability now inhibiting cooperation. Having thus eliminated the present objections to cooperation of the service providers, the Congress should satisfy itself that promised voluntary cooperation is in fact forthcoming. This can be accomplished by simply directing OJP, through the

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00135 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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IMG, to report annually on both the extent of use of these narcotics and the extent of cooperation of the service providers.

The internet service providers and the financing institutions say that they are currently monitoring the internet to detect opportunities to engage in illegal drug transactions. What they find independently would importantly supplement what the IMG finds. This public/private cooperation is the earmark of our proposal, but without the input from the IMG, the American people would lack an adequate assurance of the thoroughness of and disterestedness (or independence) of their search.

Conclusion

The structure we propose would not only be effective but would also be broadly accepted by Congress and the American public. In addition, it would create strong incentives for the cooperation of the private sector that is essential to the success of the public/private partnership that we believe is needed. With the continuing attention of Congress to illegal internet sales of controlled substances, we expect that businesses that play key roles in internet commerce would stop facilitating sales to minors. In particular, we think Treasury regulations relating to money-laundering already impose a legal obligation on the financial institutions to take action against these illegal sales. As to the other e-commerce businesses, we believe that their cooperation is so likely that there is no need for legal directives at this time. However, it is especially important to require annual reporting (as set forth in Appendix B) by the Assistant Attorney General

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00136 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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for the Office of Justice Programs to Congress on the progress—or lack of progress--made by both government agencies and private sector businesses. In the event that companies do not take voluntary steps to help curtail illegal internet drug sales to minors, Congress can impose specific new legal obligations.

Appendix C is a more detailed and carefully described outline of what each member of the public/private partnership would be expected to do and how the pieces would fit together. We believe that this structure can, at minimal cost, substantially reduce the internet availability of narcotic painkillers to minors. Fortunately, this is one of the relatively rare occasions where the results of an initiative will be immediately apparent to the Congress, both through the reporting requirements we suggest to Congress and in the form of the annual surveys which have shown, so alarmingly, the rapid increase in use of prescription painkillers by high school students.

We have attached, as Appendix B, a model piece of legislation that would require warnings of illegality to be attached to any website advertising the sale of controlled substances within the United States without a valid prescription. Granting the Independent Monitoring Group and private companies relief from liability for actions taken on the basis of its findings is all that would be required of the Congress at first.

I will be happy to answer your questions.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00137 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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APPENDIX A:

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"KEEP INTERNET NEIGHBORHOODS SAFE" CONFERENCE

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VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00138 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00139 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

43987.109

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VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00140 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00141 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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APPENDIX B:

Model Legislation to Keep Internet Neighborhoods Safe

(1) It shall be unlawful for any person or organization, whether or not located within the United States, to use the Internet to offer or to attempt to sell or purchase within the United States a controlled substance without a valid prescription.

(2) (a) It shall be unlawful for any person or organization, whether or not located within the United States, to use the Internet to sell or advertise to sell a controlled substance within the United States, unless each and every page of the website that facilitates or advertises the sale of a controlled substance bears the following warning: "It is illegal to sell or to purchase controlled substances without a legitimate prescription".

(b) The warning shall appear in conspicuous and legible type in contrast by typography, layout, or color with all other lettering on the website.

(3) (a) No person, corporation, or other entity shall be liable for refusing to do business with, or influencing others not to do business with, any organization that

(i) operates in violation of one or both of the above provisions;

(ii) encourages other persons, corporations, or entities to do business with an organization operating in violation of one or both of the above provisions;

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00142 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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(iii) assists customers in purchasing controlled substances without a legitimate prescription.

(b) No person, corporation, or other entity shall be liable for mistakenly identifying, or relying in good faith on a mistaken identification of a website as advertising or facilitating the sale of controlled substances without a valid prescription, if the mistake was made in good faith.

(4) In applying its regulations relating to violations of any prohibition of facilitating a criminal transaction, the Department of Treasury shall presume that an offer to sell controlled substances without prescription over the Internet involves transactions aggregating $5,000 or more.

(5) Creation of the Independent Internet Monitoring Group

(a) The Assistant Attorney General for the Office of Justice Programs by making a grant to a nonprofit private agency shall establish an independent Internet Monitoring Group (IMG), which shall:

(i) operate a national information clearinghouse where individuals can report by email or through a toll-free telephone line any website that is advertising or offering to sell a controlled substance without prescription over the Internet or is operating in violation of any of the provisions above;

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00143 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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(ii) monitor the Internet on a continuing basis to identify websites operating in violation of the above provisions. Monitoring will be conducted by IMG computers programmed to identify such websites as well as by technical experts who will evaluate the data to determine validity; and

(iii) provide information on a real-time basis about websites that are identified to be operating illegally to relevant government agencies as well as to key private sector companies, including financial institutions, credit card companies, internet service providers, search engines, vendors of filtering software or services, private carriers and public and private organizations that seek to curtail illegal internet drug sales through prevention and education.

(6) The Assistant Attorney General for the Office of Justice Programs shall submit a report not later than 120 days after the end of each fiscal year to the President, Speaker of the House of Representatives, and the President pro tempore of the Senate describing in detail the activities in the preceding fiscal year of the IMG established under section (4)(a). It shall include a report by the IMG on:

(a) the number and location of websites the IMG has identified as illegally advertising or offering to sell controlled substances without prescription over the internet;

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00144 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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(b) a list of the countries from which the websites identified by the IMG were found to be operating;

(c) specific actions taken by the relevant government agencies and key private sector businesses, such as credit card companies, Internet Service Providers, search engines, vendors of filtering software or services, and private carriers in response to the information provided by the IMG regarding websites identified as illegally advertising or offering to sell controlled substances without prescription over the internet; and

(d) the need for further legislation, if any.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00145 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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APPENDIX C:

Proposed New Strategies

A. Monitor the Internet to identify websites and other internet facilities, such as chat rooms, that offer to sell controlled substances without a valid prescription or that do not display a warning that a valid prescription is required.

1. One or more independent organizations should identify on a continuing, real-time basis websites that offer to sell, or sell, controlled substances without prescription. We believe that a specialized, independent nonprofit organization should be created to conduct continuous monitoring of the Internet. This Independent Monitoring Group (IMG) would develop a real-time template to identify the names of these websites, including the URL, payment mechanisms advertised (e.g., Visa, Mastercard), and any other purchase and delivery data. The IMG, which essentially would serve as a clearing house of information on illegal drug trafficking websites, would be an efficient conduit of publicly available information to credit card companies, ISPs, common carriers, and key federal agencies so that they could take appropriate actions as described below.

2. Provide the names and Internet addresses of these websites to credit card companies and other payment systems, ISPs, search engines, common

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00146 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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carriers, the U.S. Postal Service, the Drug Enforcement Administration, and other relevant federal agencies. Congress should grant immunity to any person, corporation or other entity for mistaken identification of such websites made in good faith or for refusing to do business with any of these organizations mistakenly identified in good faith. Today, the bulk of illicit drug sales are conducted in a relatively open way. As enforcement increases, new ways will emerge for connecting buyers and sellers of controlled substances without prescription. Already there is evidence that chat rooms provide forums for drug trafficking. Spam is an additional source of offers. As Internet connectivity continues to expand to cellular telephone systems, there is every reason to anticipate that these, too, will become advertising and distribution networks for the illegal sales of controlled substances. The Independent Monitoring Group, or similar nonprofit organizations, will be required to continue to develop new methods of tracking and identifying websites that offer to sell controlled substances without prescription over the Internet. On receiving reliable information that those associated with such a website have come into compliance with U.S. law, these monitoring groups will relay that information to all parties that were previously advised of its illegal practices.

B. Empower Families to Limit Home Access To Websites Illegally Selling Controlled Substances by Requiring ISPs to offer their customers a managed service or device that could be configured to block access to websites offering to sell controlled substances without prescription.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00147 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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Parents are deeply concerned about the safety of their children where they live and go to school. Parents should be able to limit their children's access to drugs in the virtual neighborhood of the Internet, whether the parents are technically savvy or not. ISPs should be required to ask each of their customers if they want technology implemented that blocks access to websites offering to sell controlled substances without prescription. The technology should be easy for customers to install and use and could be made available directly by the ISPs or through third party providers. The largest of the ISPs already offer parental controls which do, or could be adapted to, serve this valuable function. (This requirement of offering a filtering service might be waived for ISPs that do not serve minors or households with children, such as universities and corporate enterprises, ISPs to the extent that they provide wireless access points for temporary connections, and ISPs with only small numbers of clients.)
Earlier efforts by federal and state governments to mandate filtering systems in the area of pornography have failed because of spillovers to legitimate areas. These schemes have most often faltered by permitting or requiring ISPs to use Internet Protocol ("IP") based filtering. Where a filtering system is based on an ISP blocking designated IP addresses, the filter can block numerous lawful sites that share the same IP address.

Our recommendation takes a different, more effective approach by empowering parents and other customers to decide whether to implement filtering as part of their ISP service. It would give the ISP the option of providing a software or hardware filtering system implemented on the ISP end or on the customer's computer. Even when a filtering system is URL or content based, if the ISP can effect the filtering only by

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00148 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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applying it to all of its customers and not just the ones requesting it, the spillover effect could harm valued First Amendment interests of otherwise lawful Internet users. If the ISP's network configuration does not permit customer specific, URL-based filtering, or if it is simply more economical for the ISP, the ISP could provide the filtering system through software on the customer's computer, just as many ISPs presently implement anti-virus and anti-spam filters and Microsoft will implement parental controls that will enable customers to request filtering of drug sites as part of the forthcoming VISTA operating system. We do not think legislation is necessary at this time to effect our recommendation in this area, because we hope and expect that ISPs will implement this recommendation voluntarily.

Information about specific websites offering to sell controlled substances without prescription would be provided to ISPs and filtering software manufacturers by the Independent Monitoring Group (IMG), or similar organizations, and updated constantly. ISPs building their own lists of illegal and legal sites or purchasing this service from third party providers would be expected to ensure that sites identified by the IMG were contained on their lists. If ISPs were neither building independent lists nor purchasing them from third party providers, they would be expected to implement filtering systems based on those sites identified by the IMG. At the customer's request, the customer's Internet traffic would be filtered, and the filter updated in a manner similar to Microsoft's Windows Update, Symantec's Live Update, and other companies' automated update systems. If after notifying ISPs of illegal pharmaceutical sites those sites remained accessible to customers requesting filtering, the KINS/IMO would notify relevant parties.

VerDate Aug 31 2005 13:17 Sep 02, 2008 Jkt 043987 PO 00000 Frm 00149 Fmt 6633 Sfmt 6633 S:\GPO\HEARINGS\43987.TXT SJUD1 PsN: CMORC

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In the future, as technologies converge, similar requirements should apply to cell phone service providers and all other distributors of electronic communications.

ISPs alternatively may want to make a simpler and broader option available to their customers. There is no reason why parents who do not want to be able to purchase controlled substances over the Internet need to have access to websites selling them in their home. An ISP could, directly or through a third party provider such as LookSmart's Net Nanny, offer its customers a system that blocks access to any website selling prescription drugs over the Internet, whether lawfully or unlawfully.

C. Prevent Misuse of Financial Institutions to Finance Illegal Sales of Controlled Substances

The financial sector can and should play a pivotal role in combating the trafficking of illicit drugs on the Internet. All financial institutions have extensive legal obligations to ensure the integrity of the financial system. Responsibilities for monitoring the international financial system for abuse and preventing such abuse should include explicit requirements to monitor illicit drug sales. The obligations to "know your customer" and conduct due diligence have been reinforced by both anti-money laundering legislation and the USA Patriot Act. The combination provides a powerful framework that is fully applicable to sales of controlled substances without prescription.

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With the current legal framework in mind, we recommend that the Department of the Treasury assure itself that the financial sector, including credit card companies, banks and emerging Internet funding organizations, such as PayPal, adopt the following policies:

1. All financial institutions will incorporate into their Terms of Use and other analogous contractual agreements explicit prohibitions on the use of their financial networks for any illicit purchase/sale of drugs.

Most major financial institutions already include such bans in their standard contractual language. This practice should be made mandatory for the industry. Financial institutions' policies also should include a contractual due diligence requirement for any organization, including merchant banks, third party acquirers and other payment processors, to monitor their networks for any use of the financial network for illicit drug sales.

2. All financial institutions will monitor their networks for illicit drug sales and respond to credible outside information regarding such activity.

Financial institutions should ensure that the broad efforts they currently undertake to monitor networks for fraud and other abuse, explicitly include the threat of illicit drug sales. To carry out these obligations, financial institutions will identify clearly

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responsibility within the organization for meeting them as well as report semi-annually on the identification of threats and actions taken in response to information provided.

Upon the receipt of credible information related to possible abuse, financial institutions will test suspect accounts and identify those accounts that are being abused. In addition, the financial institutions will ensure that any merchant bank in the system is notified of such accounts and takes appropriate measures.

3. When financial institutions, such as credit card companies, identify an account that is being abused, they will share such information within their network and, consistent with legal obligations, law enforcement. The merchant banks and other related actors in the network should have an obligation to cut off credit to the offending account.

Financial networks share large amounts of information to ensure the integrity of the financial system. All actors within the network should be required to share information about offending accounts to ensure that businesses that are barred from credit cannot otherwise obtain it within the network. If merchant accounts and other third party actors do not respect such ban, than they, too, should be blocked from accessing the credit network.

Consistent with legal obligations relating to customer privacy, all financial institutions will share information with US law enforcement, regulators and other organizations used to

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facilitate information sharing with respect to all those participating in, or assisting in the financing of, the illicit purchase/sale of drugs.

D. Launch nationwide education and prevention campaigns

1. Enlist key government agencies, such as the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) as well as private organizations, such as the Partnership for a Drug Free America (PDFA), to educate adults and youth on the dangers of using narcotic pain-killers without prescription, including accidental injuries, dependence, overdose, and death, particularly when used in combination with alcohol.

The most recent national surveys report that adolescent non-medical use of highly addictive prescription drugs is increasing. These drugs include opiate painkillers (narcotics) such as Vicodin and Oxycontin, sedatives such as Ambien, and tranquilizers such as Valium and Xanax. These increases are occurring in the face of the otherwise encouraging news that among youth ages 12 to 17, past month illicit drug use overall has declined 19% since 2001. After alcohol and marijuana, Vicodin (without prescription) is now the most widely used drug among high school seniors. Adults and youth may not view controlled substances, like Vicodin, which can be obtained without prescription over the Internet, as equally "dangerous" as narcotics which can be bought from street dealers or classmates, especially since the drugs are widely prescribed by

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doctors for legitimate medical purposes. The ease with which these drugs are obtained over the Internet, their packaging, and their appearance of legitimacy can contribute to the belief that such drugs are relatively safe when in fact these drugs can be lethal when taken in high doses or in combination with alcohol. A recent national survey by the Partnership for a Drug Free America (2005) reported that almost half of teens said they believe that prescription drugs, even if not prescribed by a doctor, are much safer than street drugs and almost a third said that prescription pain killers, even if not prescribed, are not addictive.

2. Encourage Internet Service Providers (ISPs) to educate their customers about new technological safeguards such as firewalls and parental control software that can prevent the use of computers for the illegal purchase of addictive controlled substances.

ISPs can make technological safeguards widely available to their customers who want to block websites that offer to sell controlled substances without prescription. The ISPs should regularly notify all customers of this opportunity to create a safe Internet neighborhood for their families as well as continue to update the technology as needed.

3. Enlist all major Internet search engines to display prominently a warning whenever Internet users request a search for any controlled substance that it is illegal to purchase controlled substances without prescription over the Internet in the United States. Internet search engines should also work closely with federal

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agencies to develop effective links to drug education websites describing the dangers of non-medical use of powerful prescription drugs, such as Vicodin or Oxycontin.

To buy controlled substances over the Internet, adolescents must find sellers. Many young people use the internet to find everything from music downloads to movie tickets. Using search engines such as Google and Yahoo!, easily constructed searches readily lead to a million or more websites offering to sell controlled substances without prescription. Internet search engines can play a deterrent role by placing forceful warnings at the top of search results for controlled substances without prescription. They can also help educate Internet users about the dangers of non-prescription use of controlled substances by providing links to drug education websites, such as www.drugfree.org (Partnership for a Drug Free America) when these search requests are made.

4. Enlist web publishers that accept advertising to implement screening or third party review processes to avoid accepting advertising from sites that offer to sell controlled substances without a valid prescription.

Many large Internet search companies already employ screening or review processes to prevent advertisements for sites offering the sale of controlled substances without a prescription. Other third party advertisers, Internet portals, advertising networks, and

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marketing affiliate companies should be encouraged to implement similar screening or third party review processes.

E. Strengthen Law Enforcement and International Cooperation

1. The Department of State and DEA should each create a dedicated internal structure of an adequate size to carry out international law enforcement efforts to curtail illegal sales of controlled substances without a valid prescription over the Internet. The Department of State should be expected to act on information received from the Independent Monitoring Group (IMG) and credit card companies about Internet drug traffickers, and to use that information to work with law enforcement counterparts abroad to bring about foreign prosecution and asset forfeiture. In significant cases, DEA should seek extradition with the goals of prosecuting these traffickers in the United States and seizing their assets wherever they may be.

The Department of State and DEA should each establish an office to: receive information from the Independent Monitoring Group, credit card companies, ISPs, pharmaceutical companies and others; analyze information about illegal websites received from the IMG or private parties; and then initiate enforcement efforts. Each should also be organized to pass on to cooperating private parties information about illicit drug vendors to the extent that this is consistent with law enforcement needs. Each office should maintain public records of the reports it receives, the occasions on

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which it has requested a delay of any private action, and the actions it and its foreign counterparts have taken.

2. Build international cooperation and commitment to fighting this problem on a global scale.

The Department of State should give high priority to curtailing illicit Internet sales of controlled substances both in its bilateral relations with other governments and in its policy positions in international organizations. In addition, the Department of State and the U.S. Delegation to the United Nations Commission on Narcotic Drugs should lead an effort to strengthen enforcement of the Single Convention on Narcotic Drugs, particularly Articles 30, 31, and 36 (which together require signatories to make criminal the distribution of narcotic drugs without prescription). The Department of Justice and DEA should coordinate with the Department of State to pursue U.S. enforcement efforts under the Single Convention. These departments and agencies should urge the International Narcotics Control Board (INCB) to report annually to the United Nations General Assembly on the scope and seriousness of Internet trafficking in controlled substances.

3. The DEA should work with U.S. and multi-national pharmaceutical companies to identify the source of controlled substances offered for sale without prescription over the Internet.

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Whenever DEA obtains samples of illegally sold controlled substances through online purchases by its own agents or from U.S. Customs, the U.S. Postal Service, or private carriers who have intercepted them, it should send these samples to pharmaceutical companies to enable them to determine the source of the drug (e.g., whether it is a legitimate drug that was illegitimately diverted or a patent-infringing copy of the company's drug). The DEA should also obtain information from covert online purchases and, as soon as consistent with law enforcement, furnish that information to credit card companies so that they can identify and shut down merchant accounts being used for illegitimate purposes.

F. Enhance Border Interdiction

1. U.S. Customs and Border Protection ("CBP" or "Customs") should seek and use information from private carrier, pharmaceutical, and credit card companies and from the Independent Monitoring Group (IMG) to monitor and intercept illegal shipments into the United States of controlled substances sold without prescription.

Millions of packages coming from abroad are processed daily through Customs international mail facilities. Packages containing illegal controlled substances are likely to be designed to be generally indistinguishable from the rest. In addition to conducting random searches of incoming packages in an effort to intercept illegal drugs, Customs officials should use information provided by the IMG and credit card companies

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regarding the names and addresses used by individuals and companies who offer to sell controlled substances over the Internet without a legitimate prescription. Based on this information, Customs officials should make every effort to target and interdict these illicit shipments. Upon interdiction of illegal controlled substance shipments, Customs should notify the intended recipient, and, for interdictions considered to be in commercial quantities, the Drug Enforcement Agency for possible prosecution of the original shipper. Customs should analyze and process data taken from intercepted shipments of controlled substances (such as point of origin) to improve the effectiveness of interception of future shipments.

2. When private carrier companies have reason to believe that certain packages may contain illegally sold controlled substances, they should immediately provide to Customs officials as much identifying information as possible, including shipping account and credit card numbers.

Since private common carriers often receive or pick up packages directly from shippers, they may be able to identify transactions that appear suspicious. Under earlier recommendations, carriers will also receive information on suspicious transactions from IMOs and from credit card companies. If, on these bases, they suspect that they are transporting packages that contain illegal controlled substances, carriers should provide to Customs officials all identifying information, including shipping account and any available credit card numbers. In particular, the credit card numbers would be useful to Immigration and Customs Enforcement (ICE) and DEA in criminal investigations of

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commercial shipments. The Interagency Pharmaceutical Task Force is a vehicle to share such relevant data about suspicious shipments among CBP, ICE, and DEA. Private carrier companies should be encouraged to comply with these procedures through incentive programs; for example, Customs could use voluntary compliance in this program as a factor in determining whether a specific carrier receives enhanced customs privileges.

Keep Internet Neighborhoods Safe is a collaborative effort of the Center for International Criminal Justice at Harvard Law School, Drug Strategies, Weill Medical Center of Cornell University, and the Treatment Research Institute at the University of Pennsylvania. For additional information please contact Philip Heymann, James Barr Ames Professor of Law, Harvard Law School at heymann@law.harvard.edu, or Mathea Falco, President of Drug Strategies, at dspolicy@aol.com.

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APPENDIX D

The New York Times
nytimes.com

May 11, 2007

Narcotic Maker Guilty of Deceit Over Marketing

By BARRY MEIER

ABINGDON, Va., May 10 — The company that makes the painkiller OxyContin and three of its current and former executives pleaded guilty Thursday in federal court here to criminal charges that it had misled doctors and patients when it claimed the drug was less likely to be abused than traditional narcotics.

The company, Purdue Pharma, agreed to pay $600 million in fines and other payments to resolve the criminal charge of "misbranding" the product, one of the largest amounts ever paid by a drug company in such a case.

The three executives, including its president and its top lawyer, also pleaded guilty to misdemeanor charges of misbranding the drug. Together, they agreed to pay $34.5 million in fines.

The guilty plea — by Purdue Frederick, an affiliate of Purdue Pharma — is the latest of a number of cases brought by the Justice Department against pharmaceutical makers that accuse them of misbranding, a broad statute that makes it a crime to put false or misleading information about a drug on its label or in ads, or to promote it for unapproved use.

Another company, Bristol-Myers Squibb, pleaded guilty Thursday to making false statements to the government involving its anti-clotting medicine Plavix. [Page C3.]

The Purdue plea underscores the growing pressure on the drug industry over its marketing. On Wednesday, the Senate passed a bill to give the Food and Drug Administration power to oversee drug advertising and labels, and to restrict the distribution of risky medicines.

OxyContin is a powerful, long-acting narcotic that provides relief of serious pain for up to 12 hours. Initially, Purdue Pharma contended that OxyContin, because of its time-release formulation, posed a lower threat of abuse and addiction to patients than traditional, faster-acting painkillers like Percocet or Vicodin.

That claim became the linchpin of an aggressive marketing campaign that helped the company sell over $1 billion worth of OxyContin a year.

Purdue Pharma, based in Stamford, Conn., heavily promoted OxyContin to doctors like general

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practitioners, who often had little training in treating serious pain or in recognizing signs of drug abuse.

But experienced drug abusers and novices, including teenagers, soon discovered that chewing an OxyContin tablet — or crushing one and then snorting the powder, or injecting it with a needle — produced a high as powerful as heroin. OxyContin is a pure, high-strength version of a long-used narcotic, oxycodone.

By 2000, parts of the United States, particularly rural areas, began to see soaring rates of addiction and crime related to use of the drug.

At a news conference Thursday in Roanoke, Va., John L. Brownlee, the United States attorney for the Western District of Virginia, said the impact of Purdue's marketing of OxyContin had resulted in rising crime rates, teenage drug addiction, deaths and other problems.

"The results of Purdue's crimes were staggering," he said.

In a statement, the company said the three executives were not aware of the wrongdoing by other company employees. Misdemeanor charges of "misbranding" can be brought against corporate executives even if they are unaware of such crimes.

The three men — Michael Friedman, the president; Howard R. Udell, its top lawyer; and Dr. Paul D. Goldenheim, its former medical director — led Purdue at the time of the crimes.

The developments marked a sharp reversal for Purdue Pharma, a privately held company. Its executives had defeated hundreds of lawsuits from patients claiming that they became addicted to OxyContin. They also rebuffed critics, including some in Congress, who said that the company's aggressive marketing of OxyContin may have spurred its abuse.

The company's defenders included the former New York mayor, Rudolph W. Giuliani, whose firm was hired in 2002 by Purdue Pharma as part of a crisis management strategy and to improve security at its manufacturing plant.

More recently, Mr. Giuliani, acting as a lawyer for Purdue, took part in several meetings last year between Justice Department officials and defense lawyers for the company and individual executives.

Melanie Hillis, a spokeswoman for the Bracewell & Giuliani law firm, which is based in Houston, said that Purdue Pharma was a client of the firm. She said Mr. Giuliani had not been involved in representing the company for several months.

The company and the three executives pleaded guilty at a small courthouse in this small city at the edge of Appalachia, a region where OxyContin abuse became so widespread that the drug was dubbed

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"hillbilly heroin." Mr. Brownlee and other prosecutors decided to investigate Purdue Pharma after bringing cases against drug addicts as well as local doctors accused of illegally prescribing the drug.

"I think we had a responsibility to bring cases against everyone who was making money," Mr. Brownlee said.

The crimes to which the company and its executives pleaded guilty took place between late 1995, when the federal Food and Drug Administration approved OxyContin for sale, and mid-2001, when Purdue Pharma, facing public criticism and regulatory scrutiny, dropped all "reduced-risk" claims related to the drug.

During that period, OxyContin produced $2.8 billion in revenue for Purdue Pharma.

Federal officials said that internal Purdue Pharma documents showed that company officers recognized that, even before the drug was marketed, they would face stiff resistance from doctors concerned about the potential of a narcotic like OxyContin to be abused by patients.

As a result, prosecutors charged, the company effectively started a fraudulent and deceptive marketing campaign aimed at convincing doctors that OxyContin, because of its time-release formula, was less prone to abuse, and that it was less likely to cause addiction or to produce other narcotic side effects than competing drugs. In its plea agreement, the company acknowledged doing so.

"We accept responsibility for those past misstatements and regret they were made," the company said.

According to prosecutors, some Purdue Pharma supervisors and employees used fraudulent techniques to promote OxyContin to doctors.

For instance, when the painkiller was first approved, F.D.A. officials allowed Purdue Pharma to state the time-released nature of a narcotic like OxyContin "is believed to reduce" its potential to be abused.

But some Purdue sales representatives falsely told doctors that the statement meant that OxyContin was less likely to lead to addiction or abuse than traditional, fast-acting painkillers like Percocet.

In addition, some company sales officials gave doctors misleading scientific charts to support such fraudulent claims. Also, Purdue Pharma trained its sales representatives on how to overcome concerns by doctors that OxyContin could be easily abused, according to the transcript of a training tape made for Purdue Pharma sales official that was released by Mr. Brownlee.

Purdue Pharma also knew, prosecutors charged, that large quantities of oxycodone could be easily extracted from OxyContin so the drug could be intravenously injected by drug addicts.

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Of the $600 million in payments, Purdue Frederick will pay $470 million in fines and payments to a variety of federal and state agencies.

It also agreed to pay at least $130 million to resolve civil lawsuits brought by pain patients who claimed they became addicted as a result of having OxyContin prescribed to them. A lawyer for one company executive said that much, if not all, those funds have been paid out in the process of settling lawsuits. There are still claims against the company by private plaintiffs.

This week, Purdue agreed to pay $19.5 million to 26 states and the District of Columbia to settle complaints that it encouraged physicians to overprescribe OxyContin.

Some drug industry critics said Thursday that while the fines sent an important message, the amounts were far too low, given the vast profits from OxyContin sales and the problems caused by the drug.

"The damage to the public from these white-collared drug pushers surely exceeds the collective damage done by traditional street drug pushers," Dr. Sidney Wolfe, the director of the health research group at Public Citizen, an advocacy group in Washington, said.

Mr. Friedman, Purdue's president, agreed to pay $19 million in fines; Mr. Udell, its lawyer, $8 million; and Dr. Goldenheim, $7.5 million. A Purdue Pharma spokesman said that Mr. Friedman planned to leave the company this year but that his departure was not related to his guilty plea.

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Statement
United States Senate Committee on the Judiciary
Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking
May 16, 2007

The Honorable Patrick Leahy
United States Senator , Vermont

OPENING STATEMENT OF SENATOR PATRICK LEAHY
CHAIRMAN, SENATE JUDICIARY COMMITTEE
HEARING ON "ROGUE ONLINE PHARMACIES: THE GROWING PROBLEM OF INTERNET DRUG TRAFFICKING"
MAY 16, 2007

Today, the Committee holds an important hearing on the growing problem of rogue online pharmacies that illegally traffic in highly addictive painkillers and other controlled substances.

In many ways, the Internet has made our lives better and I have been one of its biggest proponents for those reasons. It removes the historic constraints from geography and provides access to information and knowledge that might otherwise remain unavailable to those of us from rural areas. Distance learning, access to medical knowledge at the finest hospitals and increased commercial competition are all aspects of the Internet that are important to recognize and promote. Vermont businesses sell Vermont products throughout the Nation and around the world through the Internet. At the same time, the Internet has enabled Vermonters, and others, better access to convenient and more affordable medicine.

But the online sale of pharmaceuticals presents a more complicated and problematic aspect. Rogue online pharmacies increasingly have become a source for the illegal supply of controlled substances. Dangerous and addictive prescription drugs are too often only a click away without the proper constraints of local doctors and pharmacists.

Controlled drugs, such as pain relievers, tranquilizers, stimulants, and sedatives, can too easily be bought illegally over the Internet. Anyone – including children – can readily obtain dangerous controlled substances from online pharmacies. All they need is access to a computer and a credit card. The check and security provided by our local pharmacists in local pharmacies -- those who have served Americans for generations and helped us get well and keep us well -- is not always replicated online.

The 2006 National Survey on Drug Use and Health indicates that almost 6 million people currently misuse prescription drugs and, of them, more than two-thirds -- 4.4 million people -- abuse pain relievers such as OxyContin. Some celebrities have been involved in high profile cases, but people in every state and increasingly from every age group and demographic are affected. When abused, these drugs have enormous potential to cause harm, illness, addiction, and, as we will hear this morning from one of our witnesses, tragically even death.

American teenagers are particularly vulnerable to Internet drug trafficking. Among young people, prescription drugs have become the second most abused illegal drug, behind marijuana. In fact, if you exclude marijuana, more adults and teens report abusing prescription drugs than all other illicit drugs combined.

Too many American teenagers mistakenly believe that abusing addictive narcotics is a safe way to get

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"high".

As we learned just last week, some drug companies have themselves contributed to that dangerous impression by giving consumers misleading information about the addictive qualities of these drugs. Purdue Pharmacies, the maker of the powerful painkiller OxyContin, and three of its corporate executives, pleaded guilty to intentionally misleading the public when it promoted OxyContin as less addictive than traditional narcotics. It is a sad day when pharmaceutical companies act like tobacco companies and mislead the public rather than alerting the public to the risks associated with use of its products.

We have legislation referred to this Committee that would create potent new tools for law enforcement to prosecute those who illegally sell drugs online, and allow state authorities to shut down online pharmacies even before they get started. I look forward to working with the Senators from California and Alabama on these matters.

As the longtime co-chair of the Congressional Internet Caucus, I will ask the Caucus to consider the issue of the growing danger that online pharmacies pose to youth.

Internet drug trafficking has presented another challenge for law enforcement. If drug dealers came into our neighborhoods selling these kinds of drugs, Americans would be up in arms.

I thank our distinguished panel of witnesses for appearing here today and Senator Specter our ranking member for his work in connection with this hearing.

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"Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking"

Senate Judiciary Committee
May 16, 2007

Testimony of

Jon Marshall
Kentucky State Police

Representing

National Narcotic Officer's Associations Coalition

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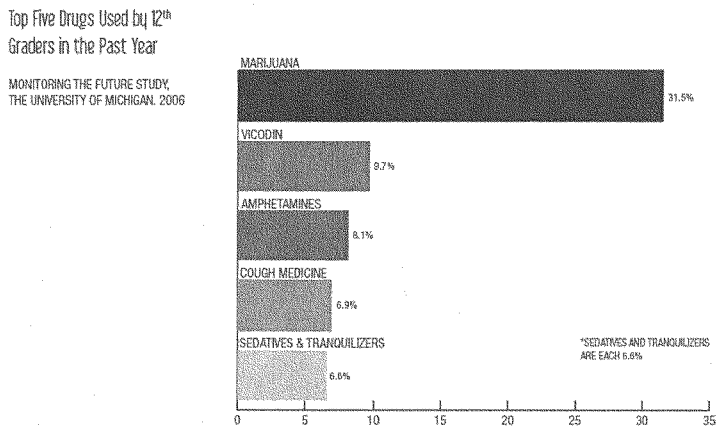
Chairman Leahy, Ranking Member Specter, and distinguished Members of the Senate Judiciary Committee, I am Jon Marshall of the Kentucky State Police, and I am testifying on behalf of the National Narcotic Officer's Associations Coalition (NNOAC), comprising individual state narcotic associations representing more than 50,000 narcotic law enforcement officers.

The NNOAC is growing more concerned about the growth of prescription drug abuse in the United States, and the use of the internet to gain access to these drugs. According to the White House Office on National Drug Control Policy, teens are turning away from street drugs and using prescription drugs to get high. Research conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), for the first time, the number of new users of prescription drugs has caught up with new users of marijuana. Among young people ages 12-17, prescription drugs as a class have become the second most abused illegal drug, behind marijuana.

Earlier this the year, the White House Office on National Drug Control Policy released a study showing that 12th graders reported that the most commonly abused drug among the age group after marijuana is Vicodin. Past-year use of Vicodin is high among 8th, 10th and 12th graders, with nearly one in 10 high school seniors using it in the past year.



Among middle school and high school-aged children, three percent, or 840,000 teens ages 12-17, reported current abuse of prescription drugs in 2005, making this illegal drug category the second most abused next to marijuana (7%). SAMHSA reported that teens ages 12-17 account for one-third of all new abusers of prescription drugs, and have

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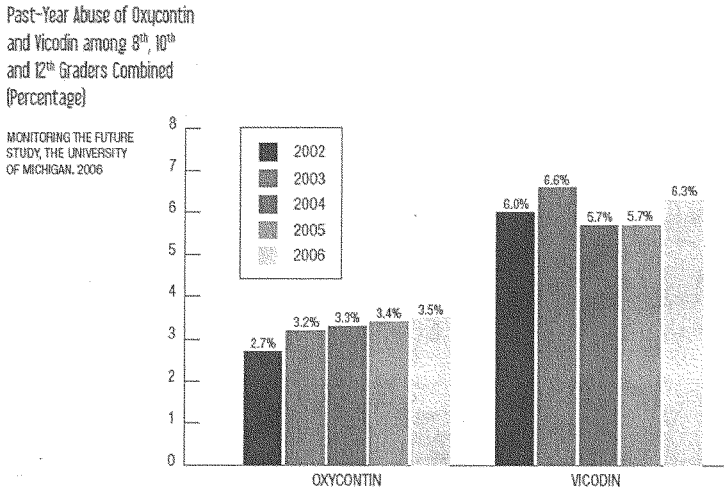
the second-highest annual rates of prescription drug abuse after young adults (18-25). Indeed, prescription drugs are the most commonly abused drug among 12-13-year-olds.

An area of growing concern is the use of prescription drugs among 8th, 10th, and 12th graders. Indeed, this year's Monitoring the Future survey shows that the use of OxyContin has continued to climb from 2002, while Vicodin abuse is at its second highest level.



The majority of teens get prescription drugs easily and for free, often from friends and relatives. Nearly half (47%) of teens who use prescription drugs say they get them for free from a relative or friend. Ten percent say they buy pain relievers from a friend or relative, and another 10 percent say they took the drugs without asking.

The White House Office on National Drug Control Policy reported past-year use of Vicodin is high among 8th, 10th and 12th graders, with nearly one in 10 high school seniors using it in the past year. Among college students, according to the National Center on Addiction and Substance Abuse, in 2005 college men were likelier than college women to report abusing prescription opioids (9.6 percent vs. 7.7 percent)--including Vicodin (13.5 percent vs. 7.4 percent).

The diversion of hydrocodone and oxycodone products Lortab, Lorcet, Vicodin® and Oxycontin continues to be a problem in the Commonwealth of Kentucky. Primary methods of diversion include pharmacy theft, "doctor shopping," prescription fraud, and purchasing large quantities of drugs from unscrupulous Internet pharmacies.

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The use of the Internet to illegitimately obtain prescription drugs affected southeastern Kentucky especially hard. Parcel delivery services had to add additional delivery trucks to established routes in the area to handle a significant increase in parcel volume. The increase in parcel volume was solely linked to an increase in parcels originating from out-of-state Internet pharmacy operations. Additionally, due to the C.O.D. nature of these deliveries, delivery drivers were increasingly carrying large amounts of cash and drugs in their vehicles. For the safety of their employees, parcel delivery services in southeastern Kentucky suspended door-to-door delivery service of packages from Internet pharmacies.

In 2005, the Kentucky Legislature passed and enacted legislation that required Internet pharmacies doing business in Kentucky to register with the Kentucky Board of Pharmacy; adhere and abide by all rules, regulations, and policies of the Board; made it a felony for an individual to order from an internet pharmacy without a legitimate doctor/patient relationship; and authorized law enforcement agencies to seize prescription drugs ordered from unlicensed Internet pharmacies. The law significantly reduced the fraudulent purchasing of controlled substances from out-of-state Internet pharmacies by Kentucky citizens. We have recently amended the law to allow for prosecution of individuals receiving such illegally acquired drugs in the Commonwealth of Kentucky.

The NNOAC believes it is critical for the 110th Congress to address prescription drug abuse, and specifically to focus on one of the main sources for drug abusers: rogue internet pharmacies. The NNOAC has six core principles we would like Congress to address in improvements to the Controlled Substances Act (CSA), presented in priority order:

Face-to-face requirement for prescribing: Ideal legislation would prohibit dispensing controlled substances via the Internet without a "valid prescription." For a prescription to be valid in the context of internet commerce, it must be issued for a legitimate medical purpose in the usual course of professional practice with a requirement that there be at least one in-person medical evaluation by the doctor.

This provision would address the primary harm caused by rogue Internet pharmacies: dispensing controlled substances on a large scale without a legitimate medical purpose. Rogue Internet pharmacies invariably operate with active participation of an unscrupulous DEA-registered practitioner who willingly issues prescriptions to "patients" throughout the country whom the practitioner never sees and without a preexisting bona fide doctor-patient relationship.

As blatantly egregious as this practice may seem to legitimate medical professionals, it is not an automatic violation of federal law. Rather, to demonstrate a violation of the CSA in a criminal or administrative proceeding, the Government must prove – in each instance – that the particular prescription at issue was not for a legitimate medical purpose. Depending on the judge and fact finder, this could be difficult and resource-intensive endeavor for the Government. The bill would eliminate this evidentiary problem for the Government by making it an automatic violation of the CSA for a

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practitioner to issue a prescription via the Internet, or for a pharmacy to fill one, if the practitioner has never conducted an in-person medical evaluation.

Controlled substances endorsement requirement – NNOAC-backed legislation would require an endorsement from DEA before online pharmacies could dispense controlled substances via the Internet. This endorsement would supplement the existing registration a pharmacy holds for its brick-and-mortar operation.

Domestic rogue Internet pharmacies are generally supplied by DEA-registered brick-and-mortar pharmacies. Typically, these brick-and-mortar pharmacies have little or no walk-in customers and do most or all of their business via rogue Internet sites. In some instances, crime organizations find legitimate "mom and pop" brick-and-mortar pharmacies and purchase them, then use them for just a few months as a supplier to rogue Internet operations, then walk away from the pharmacy after taking in substantial cash.

It is important that bill sponsors communicate that they do not want to block online pharmaceutical sales, but instead put online pharmacies on an equal regulatory footing with brick-and-mortar facilities with respect to controlled substances. Enactment of such legislation mandating a DEA endorsement will mean it will be immediately illegal (a per se violation of the CSA) for a pharmacy to fill prescriptions via the Internet unless the pharmacy has obtained the separate endorsement from DEA for that purpose. This endorsement would be added to the existing registration requirement in place for all pharmacies, and will allow DEA to carefully scrutinize all applications for such registration and only allow legitimate applicants to operate via the Internet.

Enhanced penalties for controlled substances schedule III through V – Legislation addressing internet pharmacies should enhance penalties for unlawfully dispensing controlled substances in schedules III through V, as DEA has requested in testimony for the past year. These enhanced penalties would apply equally to all unlawful distributors and dispensers of controlled substances (not just those who do so by means of the Internet).

At present, the sentencing guidelines call for relatively minimal penalties for trafficking in schedule III through V controlled substances. As a result, it is sometimes difficult to get US Attorneys interested in prosecuting rogue Internet pharmacy cases, since such rogue operations generally refrain from selling schedule II substances.

By increasing the statutory maximum sentences for trafficking in schedule III through V substances, such a provision would likely cause the sentencing commission to correspondingly increase the guideline sentencing.

Prohibition on advertising illegal sales of controlled substances – Rogue pharmacy legislation should make it a crime to use the Internet to advertise the illegal sale of a controlled substance by means of the Internet.

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This provision is targeted primarily at the tremendous volume of spam and similar solicitations that have cluttered the Internet in recent years, enticing buyers to visit Internet sites that will sell controlled substances to anyone for no legitimate medical purpose.

This provision is similar to the longstanding CSA provision that prohibits advertising the sale of schedule I controlled substances. While this provision, by itself, would not end rogue Internet sales of controlled substances, it is intended to lessen the ability of the rogue operations to lure buyers to their Web sites.

Internet pharmacy transparency and disclosure – NNOAC-supported legislation would require online pharmacies to post truthful information about their location, identity, and licensure of the pharmacy, pharmacists and prescribers, and states in which they are authorized to practice pharmacy.

This provision would assist law enforcement in investigating online pharmacies and should also provide some deterrent against noncompliance by reminding online pharmacies of their legal duties.

State Cause of Action – Internet pharmacy legislation should give the Attorney General of each state the ability to bring a civil action in a federal district court to enjoin the actions of an online pharmacy or person which/who is operating in violation of this statute. To bring such an action, the state must have served prior written notice on the Attorney General of the United States, giving the Attorney General the opportunity to intervene in the litigation.

This provision would help ensure that state and federal enforcement authorities can work in partnership with each other and that individual states are able to take effective enforcement action. Under current law, a state attorney general's enforcement authority against an online pharmacy is limited to the geographic boundaries of that state.

On behalf of NNOAC, I thank you for this opportunity to submit testimony on one of the most pressing issues facing law enforcement: shutting down rogue internet pharmacies trafficking in controlled substances. We stand at the ready to help enact strong legislation during this Congress.

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TRI | science addiction

Testimony of A. Thomas McLellan, Ph.D.
Chief Executive Officer
Treatment Research Institute
Before the U.S. Senate Committee on the Judiciary
May 16, 2007

Good morning Senators Leahy, Spector and other Committee members, and thank you for this opportunity to testify on an issue that first captured the attention of scientists at the Treatment Research Institute (TRI) in 2004, when my colleagues and I published a study on the availability of drugs for no prescription purchase over the Internet. I regret to tell you that with the exception of increased awareness and closer monitoring, not much else has changed since that time.

In 2004 our studies indicated it may be as easy to buy opiates or other abusable prescription drugs online as it is to purchase a book or CD. The same is true today. Anyone – regardless of age or medical need - can purchase pharmaceutical grade opioids, barbiturates, benzodiazepines and stimulants over the Internet without a prescription. The number of online pharmacies has remained constant since 2004 when we began our tracking studies, this despite increased awareness and vigilance. In fact, some of our data suggest that negative exposure appears to increase demand and trigger a temporary proliferation of these sites.

The concern, of course, is for the youth of America – Internet savvy teenagers with their own credit cards or access to their parents' cards – and increasingly disposed to prescription drugs to get high. According to a new analysis released in February by the White House Office on National Drug Control Policy, illicit drug use by teens has dropped 23% over the past five years, yet new users of prescription drugs have caught up with new users of marijuana. Clearly, kids are scavenging through parents' medicine chests, but if and when they begin surfing the Web, dangerous

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prescription drugs are available and there is evidence that teenagers think these drugs are safer than street drugs.

Two of these are OxyContin (active ingredient: Oxycodon) and Vicodin, and both have been shown to be drugs teenagers are increasingly using to get high. Both are in the same family of drugs as heroin. Unlike heroin, OxyContin and Vicodin are appropriate for pain management when prescribed and taken under a physician's care. Taken over long periods of time they are highly addictive, and when snorted or injected as some teenagers do, they carry the same risk of addiction and death due to overdose as heroin.

Eight to twelve tablets of Vicodin, one-quarter to one-half tablet of Oxycontin are roughly as potent as one bag of heroin. Both are frequently offered on the Internet in far larger quantities. As we speak there is at least one site offering bargain basement prices for purchases of Oxycontin, now on sale at thirty tablets for the "special members" price of only $6.00.

TRI first began investigating the online availability and demand for prescription drugs in 2004 using the commonly known "Google" search engine. Search engines are a unique way to measure demand for an Internet commodity based both on the number of successful "hits" a simple search yields (*ie,* sites offering the commodity) as well as the ranking of the sites based on their position in the search results (higher rankings reflecting, among other things, more traffic to the site.) In all of our studies we employed search terms familiar even to novice browsers and developed objective measures for categorizing sites based on ease of purchase, pro- or anti-drug content, accuracy of warning labels, and other measures. Visual inspection of each site also yielded data about pricing, marketing and delivery practices; location (domestic or international), and other variables.

TRI | science addiction

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In our initial investigation, fifty-three of the first 100 links were to sites offering to sell opiate medications without a prescription. The sites had names emphasizing their easy accessibility, customer orientation, location and illicit status. One site reassured visitors it was their right to be a "recreational user" in the privacy of a home. Another offered introductory specials to new customers who could receive codeine tablets free of charge. Those satisfied with the arrangement were asked to send $5 in cash in exchange for another twenty tablets. Thirty-five of the 53 links offered to also sell other abusable medications including barbiturates, stimulants, benzodiazepines, and "date rape" drugs such as Rohypnol and GHB. We did not find any sites offering to sell heroin, cocaine, marijuana, or Ecstasy, but many offered to sell marijuana seeds and a few advertised opium poppies and coca leaves.

In a subsequent study involving forty-seven Google searches, more than 300 websites were identified offering no prescription sale of opioids. We estimate close to 80% of these sites are registered to owners outside the United States. Some boasted sharply discounted prices due to local pricing policies. One required prescriptions but claimed they could be issued within "minutes" via online consultation with physicians. Many assured potential customers that purchases could be made with minimal risk of seizure by U.S. Customs officials. One site promised shipments with no identifying information, altered return addresses for each shipment, and promises to reship orders free of charge in case of confiscation.

Other findings suggest that neither publicity nor interdiction appear to put a dent in the Internet supply. In November 2004 the highly publicized entry of a well-known media personality into treatment for opioid dependence sparked a five-part series in the *Washington Post* on buying opioid medications on-line. Both events were followed by a dramatic increase in sites advertising no-prescription drug sales according to Google tracking mechanisms. A similar steep increase

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occurred in the three months following the April 2004 DEA arrest of a large Internet drug dealer, one found to have issued 2.5 million dosage units of Schedule II-V controlled substances *per month.*

This seemingly paradoxical increase in supply following enforcement success explains why traditional public safety response will not curb Internet drug trafficking in the United States. When the preponderance of these sites are located in other countries, outside U.S. jurisdiction and some of them legally condoning such sales; when sites can be quickly dismantled and launched again from other locations; and when American officials are understandably loathe to interfere with legitimate online drug purchases, particularly those by senior citizens, it is clear that effective response requires a blend of non-traditional measures that make it more difficult for purveyors to sell to American buyers – especially our teenagers.

Providing we are able to convince parents and family friends to lock up their medicine cabinets and monitor teens' Internet use, we absolutely can confront this online source of dangerous drugs. Failure to do so will set us back in our efforts to prevent youth substance abuse. I yield to others on the panel to discuss the many policy options available to us, including legal protection to the number of American entities interested in doing their share, such as credit card companies, banks, and shipping agents.

Addiction to alcohol and other drugs is a *preventable* disease and for the majority of people in this country suffering from addiction, the roots of the disease can be traced to adolescence. More than 95% of people who are dependent on alcohol or other drugs started before they were 20 years old. There is also reliable evidence that delaying age of first use dramatically reduces the chances of meeting diagnostic criteria for dependence or abuse later in life.

We cannot anticipate and shut down all avenues through which teenagers acquire and use drugs. Yet when there is an avenue so clear and so obviously in need of deterrence, we should do all in our power to put it out of the reach of children toward whom our best and most basic protective instincts apply.

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Statement on

Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking

Senate Judiciary Committee

Wednesday, May 16, 2007

National Association of Chain Drug Stores

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Mr. Chairman and members of the Judiciary Committee. The National Association of Chain Drug Stores (NACDS) is pleased to submit a statement for the record on the growing problem of rogue Internet drug sellers.

NACDS represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 37,000 pharmacies, employ 114,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly $700 billion.

We commend you on holding this important hearing on rogue Internet drug sellers. These rogue Internet sites, both domestic and foreign, are engaged in a pattern of illegal activity regarding the prescribing and dispensing of prescription 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. Prescription medications sold through these so-called "pharmacies" are often available to consumers without any legitimate relationship with a physician and without a valid prescription.

NACDS and its members are greatly concerned about the patient safety implications of prescription medications sold through these rogue sites. We want 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.

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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. We strongly believe that any federal legislation should not subject state-licensed pharmacies to further regulation, simply because they provide consumers the option of ordering prescriptions via an Internet site. It is critical that federal legislation 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.

For example, proposals that broadly regulate pharmacies if any part of the prescription ordering or sales transaction is conducted through an Internet site are problematic. Legitimate state-licensed pharmacies that merely operate Internet sites for the purpose of allowing patients the convenience of ordering refill prescriptions that are later picked up at the brick-and-mortar pharmacy would be subject to this type of proposal. This would place an additional and unnecessary administrative burden on pharmacies that are already regulated by the states.

Congress should also avoid legislative language that could prohibit legitimate pharmacies from the standard practice of contacting physicians for prescription refills through the Internet. For example, if Congress were to indicate that a pharmacy may not dispense a prescription if the patient did not have a prescription for the drug when the communication began, a prescription with no more refills would no longer be a valid prescription.

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.

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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.

For example, a pharmacy chain that has an Internet ordering connection might be required to post on its website licensure information about each and every one of its pharmacists in each and every one of its stores. Many pharmacists are licensed in multiple states, which require the pharmacy operator to know significant licensure information about its pharmacists beyond what is already required to practice in their own state. In addition, pharmacists often change pharmacy practice locations, making it very difficult to accurately maintain this type of information, which is of questionable value to consumers, on an Internet site.

These burdens are also duplicative, since pharmacies are already required by state boards of pharmacy to visibly post this information in each pharmacy outlet. Therefore, brick-and-mortar pharmacies with Internet sites should not have to aggregate and post this information on their sites if the information is already posted in their individual stores.

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.

The VIPPS program requires rigorous certification and recertification of pharmacies that have Internet sites. It would be redundant for pharmacies with Internet sites that are certified by VIPPS to also have to meet additional and duplicative federal requirements. The recognition of VIPPS certification should be incorporated into any legislative proposal.

Workable Solutions: As Congress considers ways to reduce the threats to health and safety that illegal Internet drug sellers pose to consumers, NACDS encourages considerations of the following strategies:

- Narrowly limit the definition of Internet pharmacy to exclude legitimate, state-licensed brick-and-mortar pharmacies, and specifically target rogue illegal Internet drug sellers.
- Encourage and empower federal and state agencies to work together to enforce existing laws against illegal Internet "pharmacies."
- Clearly identify legitimate pharmacy Internet sites through a credible and thorough certification program.

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- Educate consumers about the dangers of dealing with illegal Internet drug sellers and provide a convenient method for consumers to report suspected illegal activity.
- Require a pharmacy that maintains an interactive consumer Internet site to list on the site the states in which it maintains valid pharmacy licenses.

Conclusion

NACDS encourages Congress to develop policies that narrowly target illegal Internet drug sellers, rather than creating duplicative regulations and unnecessary administrative burdens on state-licensed brick-and-mortar pharmacies with Internet sites. We believe that rogue Internet sites can be effectively targeted without granting new authority to the FDA to regulate the practice of pharmacy, which has traditionally been the authority of the states.

While illegal Internet entities must be shut down, consumer access to prescription medications through legitimate pharmacies must be protected. We look forward to working with this Committee in defining that balance and achieving our shared goal of eliminating rogue Internet operations that threaten our drug supply and patient safety.

Thank you for the opportunity to submit this statement to the hearing record. Should you have any questions, please contact Paul T. Kelly, Vice President, Government Affairs.

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Remarks by

Joseph T. Rannazzisi,
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
United States Department of Justice

Before the

Senate Judiciary Committee

Regarding

"Rogue Online Pharmacies:
The Growing Problem of Internet Drug Trafficking"

May 16, 2007 10:00 a.m.
Room 226, Dirksen Senate Office Building
Washington, D.C. 20510

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Written Statement of

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
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United States Department of Justice

May 16, 2007

Introduction

Chairman Leahy, Ranking Member Specter, and distinguished Members of the Judiciary Committee, on behalf of the men and women of the Drug Enforcement Administration, I want to thank you for the opportunity to discuss the problem of prescription drug abuse, and in particular, the illegal distribution of controlled substance pharmaceuticals via the Internet.

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. In 2005, an estimated 6.4 million Americans age 12 and older reported past month use of prescription drugs for non-medical purposes.[1] Of these, 4.7 million used pain relievers non-medically. Nationally, the misuse of prescription drugs was second only to marijuana in CY 2005.

Part of this increase in abuse is fueled by the perception among many that prescription drugs are relatively safe when compared to what some might consider more conventional "street" drugs such as heroin or cocaine. There is relatively little stigma associated with prescription drugs. Because they are manufactured for a legitimate medical purpose, many take these drugs without the anxiety of thinking they will be ostracized for their habit.

Perhaps even more alarming is the false sense of security associated with the abuse of these substances. Many feel as though if a doctor can prescribe it, the drug can't be as harmful to your health. According to the 2005 Partnership Attitude Tracking Study, 40% believe that prescription medicines are "much safer" to use than illegal drugs.[2] Furthermore, the same study concluded that 31% believe there's "nothing wrong" with using prescription medicines without a prescription "once in awhile." The truth of the matter is, these controlled substances are not just highly dangerous, but they can prove lethal.

This study also found that teens believe a key reason for abusing prescription pain relievers is their widespread availability and easy access. This ease of access, which teens indicate is provided by parent's medicine cabinets, friend's prescriptions, and by the Internet,

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[1] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. (2006). Results from the 2005 National Survey on Drug Use and Health.
[2] Partnership for a Drug Free America, (2006) 2005 Partnership and Attitude Study (PATs), 18th Annual study of teen drug use and attitudes.

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coupled with the lack of medical supervision and lack of quality control associated with illegal pharmacies, is a dangerous combination which has led to tragic consequences.

Prescription drugs can be illegally acquired through a variety of means, depending on the type of drug. While DEA and other law enforcement investigations have shown that OxyContin® and other schedule II drugs are most commonly obtained illegally through "doctor shopping" or other, more traditional methods of illegally acquiring controlled pharmaceutical substances, this has not been the case for schedule III or schedule IV substances. Schedule III and schedule IV drugs[3] (e.g., anti-anxiety medications, hydrocodone combination products, and anabolic steroids), on the other hand, are increasingly accessible and often illegally purchased through the Internet. And unlike someone stealing a few pills out of the medicine cabinet from someone else's prescription, large, high-potency sales of 100 or more pills occur hundreds of times everyday over the Internet.

The Internet as a Method of Diversion

The Internet has become one of the fastest methods used today to divert huge quantities of controlled pharmaceuticals. Certainly there are benefits to allowing individuals with a valid prescription to get their prescriptions over the Internet, ranging from simple convenience to providing individuals in remote areas or with limited mobility with access to needed medications they may not otherwise obtain. As with many other products, the Internet affords businesses access to a customer base not possible for a traditional "brick and mortar" location. The convenience appeals to consumers as well. Legitimate pharmacies operate everyday providing services over the Internet and operate well within the bounds of both the law and sound medical practice. In support of these legitimate efforts, the National Association of Boards of Pharmacy (NABP) has established a registry of pharmacies that operate online and meet certain criteria, including compliance with licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.

Unfortunately, other so-called 'pharmacy' sites on the Internet today illegally sell controlled substance pharmaceuticals. These rogue Internet sites are not there to benefit the public, but to generate millions in illegal sales. To the uninformed individual these sites may seem convenient, cost-effective and safe, but to the investigator and the drug-seeking individual there are indicators on the rogue sites which should serve as a warning that the site is operating beyond the bounds of what's safe and legal.

A consumer will notice a level of authorization and accountability with legitimate sites that is very rare to find with a "rogue" site. Before you even access its main page, an illicit site will draw you in by advertising powerful prescription medicines. The drugs and their cost (often designed to convey the sense that the consumer is saving money, when in actuality, they're frequently spending far more via "rogue" sites) are the first pieces of information these sites typically publish in order to get the customer's attention. More often than not, a "rogue" site will also validate and process prescriptions based on the completion of a cursory questionnaire. This

[3] For a more complete listing of substances controlled under the Controlled Substances Act, please see http://www.dea.gov/pubs/scheduling.html. A full list of all controlled substances can be found in chapter 21 of the Code of Federal Regulations, section 1308.11 through section 1308.15.

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process is designed to elicit what drug the customer wants and what the method of payment will be, rather than diagnosing a health problem and establishing a sound course of medical treatment.

In contrast, a legitimate site will never authorize a prescription based merely on this criterion. There will be an expectation in working with a legitimate on-line pharmacy that a customer will have a prescription from a doctor before visiting the site—just as a customer would when visiting a brick and mortar drug store. While DEA does not certify websites or the legitimacy of Internet pharmaceutical sales, if an Internet pharmacy follows all rules applicable to their brick and mortar counterparts (including, but not limited to, ensuring a patient's right to privacy, authenticating and securing prescription orders, and adhering to a recognized quality assurance policy), then the Internet pharmacy is acting in compliance with existing law.

Rogue sites, on the other hand, may provide bogus pictures of individuals wearing white lab coats designed to imply a level of trustworthiness, but these sites have structured themselves to avoid accountability for the products they sell. DEA believes a majority of the rogue sites operating today are based in the United States and work in concert with unscrupulous doctors and pharmacies. The fact that all of these individuals are complicit in this operation defeats the important checks and balances that have been established in the legitimate process of supplying controlled substance prescriptions to patients in need. While DEA has had some law enforcement successes against these organizations, the criminals promoting this activity are becoming more sophisticated. Their business model takes advantage of the anonymity of the Internet, the ease with which new web sites can be created, and the trust of the American people in the safety and efficacy of pharmaceutical products.

While this business model has evolved significantly over time (and we expect it to keep doing so), there are three primary players that facilitate these web sites: the doctor, the pharmacy, and the Internet facilitator. These three players collaborate in an almost seamless fashion.

Illegal pharmaceutical sales are promoted by Internet facilitators who have no medical training and are not DEA registrants. These facilitators start by targeting doctors who may be carrying a significant debt, such as a young doctor fresh out of medical school, or those who have retired and are looking for some extra income. The facilitator convinces these doctors that it's OK to approve the prescriptions because they will be provided with some 'medical history' (submitted by the "patient" through a web site). Increasingly common is for the facilitator to provide an opportunity for the doctor to have a telephone conversation with the "patient" or for the "patient" to fax or email 'medical' information to the doctor. The doctor then approves a prescription for a schedule III or schedule IV substance with the mistaken belief or "justification" that these substances are not as "dangerous" as those in schedule II. (Note: The criminal penalties for violations involving schedule II substances can be significantly higher than for those involving a schedule III or IV substance.) This poorly constructed veil of medical evaluation is designed to provide added justification for the requested medicine. And for every prescription the doctor authorizes, the Internet facilitator will pay the doctor ten to twenty-five dollars. Law enforcement has discovered website-affiliated doctors who authorize hundreds of prescriptions a day.

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The Internet facilitators will also recruit pharmacies into their scheme. They often target small, independent pharmacies struggling to make ends meet. The Internet facilitator will tell the pharmacist that all they have to do is fill and ship these prescriptions to customers. The prescriptions have all been approved by a doctor, and they are only for schedule III or schedule IV substances. In addition to paying the pharmacy for the cost of the medicine, the Internet facilitator will also pay the pharmacy an agreed upon amount that may reach into the millions of dollars. DEA has seen pharmacies close their doors completely to walk-in customers and convert their entire business to filling these orders.

The Internet facilitator generates the web sites that draw customers into this scheme. Web sites used by Internet facilitators often mislead the public by advertising themselves as pharmacies, but they do not operate in the same manner as brick-and-mortar pharmacies. These rogue sites offer only a few pharmaceutical products for sale, and are typically limited to only controlled substance and life-style drugs. Advertising typically emphasizes the ability to acquire controlled substances without a prescription or an appropriate examination, and none include a face-to-face medical examination from a licensed physician. They provide the customer with a wide-variety of quick and easy payment methods, ranging from cash-on-delivery to credit 'gift' cards. Various steps of the ordering process will link and shift the buyer to different web sites, making it difficult to connect payments, products, and web providers together. Rarely is there any identifying information on the web site about where the Internet pharmacy is located or who owns or operates the web site.

Frequently, and as mentioned in previous paragraphs, these web sites offer, at best, abbreviated medical interaction. This brief interlude is not meant to elicit meaningful health information; and is generally done by way of a questionnaire filled out by the customer without meaningful interaction between the doctor and the "patient". All too often the questionnaire is a ruse constructed in a manner solely for the purpose of identifying exactly just what type of controlled substance the customer is looking to purchase. In some cases, we have seen web site questionnaires that will not allow the customer to continue unless the 'right' information is entered to "justify" the drugs being requested. For example, if someone wanted a weight-loss drug, but filled out the questionnaire saying they were five feet tall and weighed ninety pounds, the questionnaire would not allow the customer to advance until the provided height and weight were more conducive to someone needing a weight-loss drug.

The Effects of Rogue Internet Pharmacies

In calendar year 2006, thirty-four known or suspected rogue Internet pharmacies dispensed 98,566,711 dosage units of hydrocodone combination-products.[4] To put this in perspective, controlled substances account for 11 percent of dosages at legitimate "brick and mortar" pharmacies in the United States versus 95 percent at these rogue Internet pharmacies. These thirty-four pharmacies alone dispensed enough hydrocodone combination-products to supply over 410,000 actual patients with a one-month supply at the maximum amount recommended per prescription.[5]

[4] Information gathered from information reported to DEA and recorded in the ARCOS database.
[5] The 2006 Physicians Desk Reference recommends a maximum of 8 tablets per day of hydrocodone with acetaminophen.

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Controlled pharmaceuticals in the United States are legitimately prescribed and dispensed within a closed system of distribution. Importers and manufacturers of controlled substances as well as physicians who dispense or prescribe them and pharmacies that fill controlled substance prescriptions are all DEA registrants subject to the Controlled Substance Act and the Code of Federal Regulations. As a closed system there are built-in checks and balances. Each registrant has a corresponding liability to keep the integrity of the closed system intact. However, with rogue Internet pharmacies there is complicity amongst all of the participants, effectively eliminating all of the normal checks and balances. Even some major corporations may turn a blind eye to obvious warning signs when supplying these rogue pharmacies.

Common methods of drug diversion, by their nature, provide some constraints on the amount of controlled substances individuals can acquire over a given period of time. These methods place the "patient" at a greater risk of being caught by law enforcement because the DEA registrant is frequently not complicit in the scheme and will report the suspicious behavior.

The sheer volume of controlled substances being dispensed anonymously over the Internet contributes significantly to other downstream methods of diversion, (e.g. children and young adults getting controlled substances from the medicine cabinet or family and friends). While studies such as *National Survey on Drug Use and Health* indicate that only a small percentage of youth get controlled pharmaceuticals via the Internet (the majority obtaining them from family and friends), it's important to remember that when these individuals obtain these substances they generally acquire only a few pills at a time. In contrast, individuals ordering via the Internet frequently receive 100-120 pills at a time, making it a potentially much higher-volume source than friends or the family medicine cabinet.

Vigil for Lost Promise

In June of 2006, DEA hosted the Candlelight Vigil for Lost Promise, in remembrance of those who have died from drug use. Several hundred parents and family members joined together to share their tragic stories of loss in an effort to raise awareness of the dangers of substance abuse and in hope that through awareness other families could avoid the loss they have suffered.

But the consequences to those individuals who seek controlled prescription drugs illegally over the Internet can be just as dangerous and deadly as the consequences of those abusing more traditional substances, such as cocaine or heroin. Many parents of young people who died from the misuse of prescription drugs have told us that they were unaware of the source of the pills which killed their sons and daughters. However, in some cases, parents such as Francine Haight and others discovered that their children were using the Internet as the source for pharmaceuticals.

Linda Surks, mother of Jason Surks, testified before Congress last year about the tragedy which befell her family when they discovered that Jason had overdosed on prescription drugs at the age of 19. A pre-pharmacy major as an undergraduate, he had an academic curiosity about prescription drug formulas and combinations.

What they didn't know was that Jason had been drawn in by the Internet facilitators who made it far too easy to order dangerous controlled substance pharmaceuticals from illicit online

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sites. A search of his computer after he died revealed that he had visited multiple Internet pharmacies. One in particular had automatically renewed his order regardless of whether or not Jason had actually placed it himself, even after he died. The drugs just kept coming.

Enforcement Challenges

As this threat has grown, DEA has also increased its effort to go after these cyber drug dealers. There no longer needs to be a direct interaction between these modern criminals and the drug seeker, they have the ability to reach directly into every computer on the Internet. Whether temptation in the form of a cleverly worded "spam" email or someone actively seeking to acquire narcotics without seeing a doctor, the Internet has created a whole new delivery and sales system for drug traffickers.

While Internet investigations do offer the advantage of having an extensive paper trail, the amount of information generated by one web transaction is so voluminous it becomes difficult to separate the important investigative information from the routine.

The methods and structures of these online organizations continue to evolve, and we are watching some organizations adjust and shift operating methods in response to law enforcement initiatives.

In short, the Internet has provided drug trafficking organizations with the perfect medium. It connects individuals from anywhere in the globe at any time; it provides anonymity, and it can be deployed from almost anywhere with very little formal training. All of these features allow for a more rapid means of diverting larger and larger quantities of controlled substances. The proliferation of rogue Internet pharmacies has also brought new legal challenges as well.

DEA's Response

Despite these challenges, DEA has been successfully using the tools that we have to counter this growing threat. We are using all current regulatory tools possible to identify and shut down those that choose to operate outside of the Controlled Substance Act. DEA is using the Automation of Reports and Consolidated Orders System (ARCOS) to identify high or excessive volume purchases and determine which retail pharmacies and practitioners are likely to be involved in the illicit distribution of controlled substances via the Internet. Typically, a traditional independent brick and mortar pharmacy will sell about 180 prescriptions per day. Of these sales, only 11 percent will involve controlled substances.[6] Conversely, the typical 'cyber' pharmacy will sell around 450 prescriptions each day—425 of these, or 95 percent, will involve controlled substances.

Operation Cyber Chase

In 2005, the dismantlement of the Brij Bansal Internet trafficking organization resulted in the arrest of over 20 individuals distributing drugs worldwide via Internet pharmacies. Arrests were made in the U.S., India, Costa Rica, Austria, and Hungary.

[6] 2003 NCPA-Pfizer Digest New York, New York – June 26, 2003.

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Both manufacturers and distributors are only required to provide information electronically to the ARCOS data base about any sale of narcotic substances. Although this data is limited to narcotics, DEA is able to develop leads and augment investigations from this information.

In addition to trying to identify the retail pharmacies that are involved in the illegal sale of controlled substances over the Internet, DEA has also begun educating and, when appropriate, taking legal action against, the distributors who are providing these pharmacies with the huge quantities of pharmaceuticals being sold. In 2006, DEA began an Internet Distributor Initiative designed to focus on the more than 800 DEA registered distributors of controlled substances. DEA has focused on these distributors because, for any transaction involving controlled substances, whether from the manufacturer to the distributor, from the distributor to the pharmacy, or from the pharmacist to the patient, the seller has a legal obligation to ensure the substances transferred are not destined for diversion. In other words, the seller may not facilitate, or otherwise contribute to, the diversion of the substances sold. DEA's educational presentation to these distributors provides wholesalers some examples of domestic Internet pharmacies, their purchase patterns, and methods of operation. The presentation is designed to emphasize to wholesalers their obligation not to sell where diversion appears to be occurring or face the loss of their DEA registration or judicial sanctions. While these educational efforts were successful in some situations, DEA has had to initiate appropriate administrative, civil, or criminal sanctions against some distributors.

> ***Operation Click4Drugs***
>
> ***In 2006, the dismantlement of this drug trafficking organization that used over 300 websites (one pharmacy filled over 2000 Internet prescriptions per day) and passed $25 million through six bank accounts per month, resulted in 27 arrests and the seizure of $17 million in assets (including currency).***

In addition to working with DEA registrants, DEA has also developed a productive relationship with other businesses that are affected or inadvertently used to facilitate these Internet pharmacies. Since 2003, DEA has been working with Internet-related businesses regarding the diversion of controlled pharmaceuticals. DEA's Internet Industry Initiative was established to exploit the weaknesses inherent to the schemes used by Internet traffickers who rely extensively on the commercial services of three principal legitimate business sectors: Internet service providers[7]; express package delivery companies; and financial services companies, including major credit card companies and third party payment service providers. And in 2004, DEA became part of a federal interagency task force (with FDA, FBI, CBP, ICE) established to combat the increasing diversion of pharmaceuticals over the Internet.

> ***Operation CybeRX***
>
> ***The Johar Saran drug trafficking organization was responsible for the illegal distribution of approximately 3.5 million dosage units of Schedule III-IV controlled substances per month which resulted in a gross income of approximately 2.7 million in that same period. Saran and his associated were indicted on over 200 counts. Seizures included approximately $17 million in cash, bank accounts, and property.***

In FY 2004, DEA established a specialized section within its Special Operations Division (SOD) to coordinate multi-jurisdictional Title III investigations involving the diversion of

[7] Including web hosting services, domain name registration companies, and search engines.

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pharmaceuticals and chemicals over the Internet. During FY 2006, SOD has coordinated over 90 Internet investigations, resulting in the arrest of approximately 64 individuals and the seizure of approximately 14 million dosage units of controlled substances and approximately $30.9 million in U.S. currency. In FY 2006, 14.7 percent of Diversion Control Program case work hours were dedicated to diversion cases involving the Internet. This was an increase of approximately 27 percent from FY 2005 when Internet cases represented 11.3 percent of the investigative work hours and an increase of 50 percent from FY 2004 when 8.8 percent of investigative work hours were for Internet cases.

Conclusion

Drug traffickers continue to exploit the Internet and threaten the health and safety of Americans. Nevertheless, the DEA has refined its methods by which we identify, pursue, and ultimately dismantle these groups and we remain committed to bringing to bear all of the resources at our disposal to fight this growing problem while simultaneously ensuring an uninterrupted supply of controlled pharmaceuticals for legitimate demands. DEA's core mission of disrupting and dismantling drug trafficking organizations, including those who seek to illegally distribute licit drugs, is an integral component to the *2006 Synthetic Drug Control Strategy* and we will continue to implement this aspect of the *Strategy* with our inter-agency partners to combat controlled substance pharmaceutical diversion.

Chairman Leahy, Ranking Member Specter, and members of the Committee, I thank you for the opportunity to discuss this vital issue and welcome any questions you may have.

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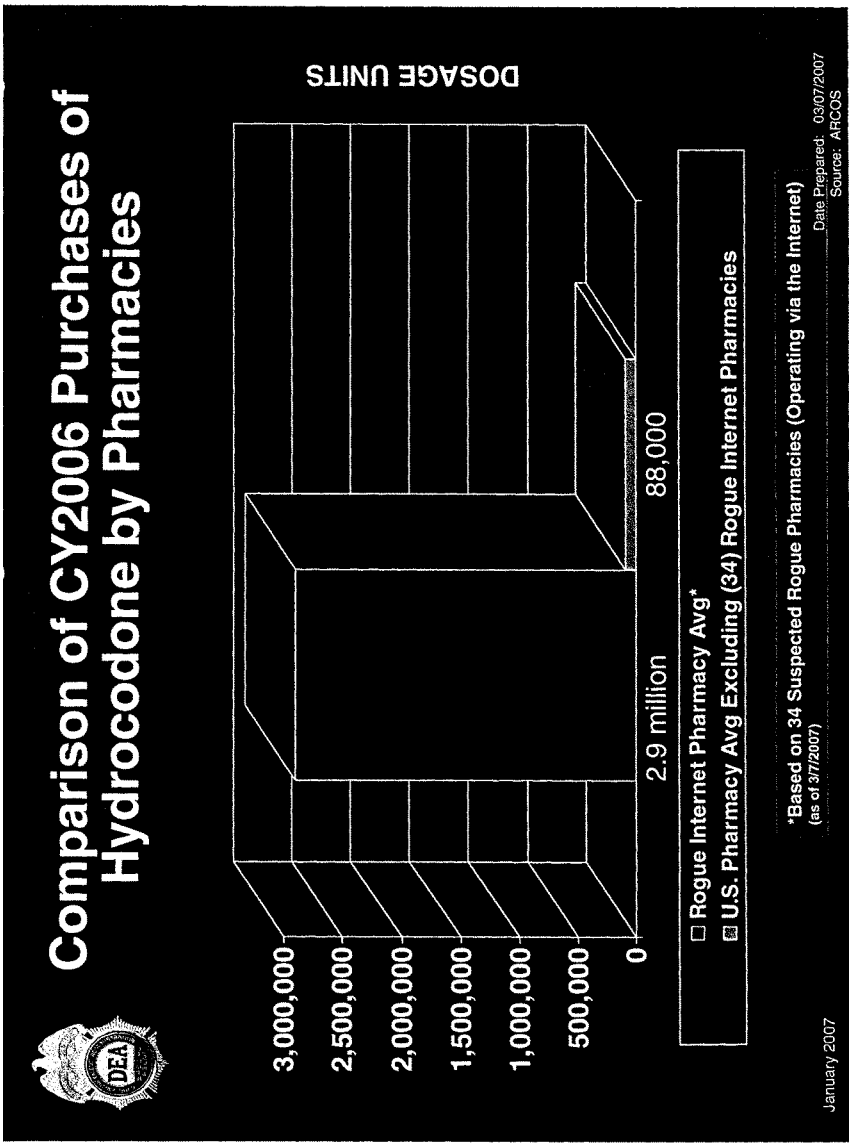
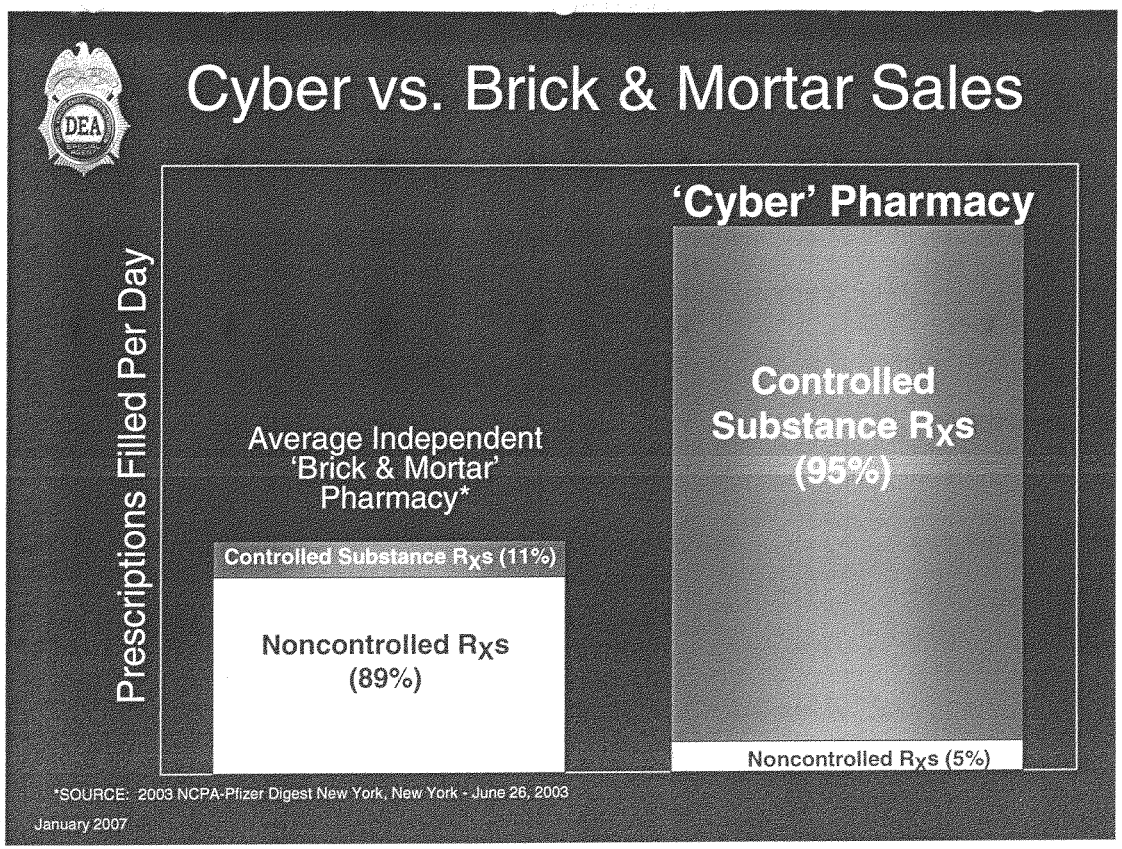
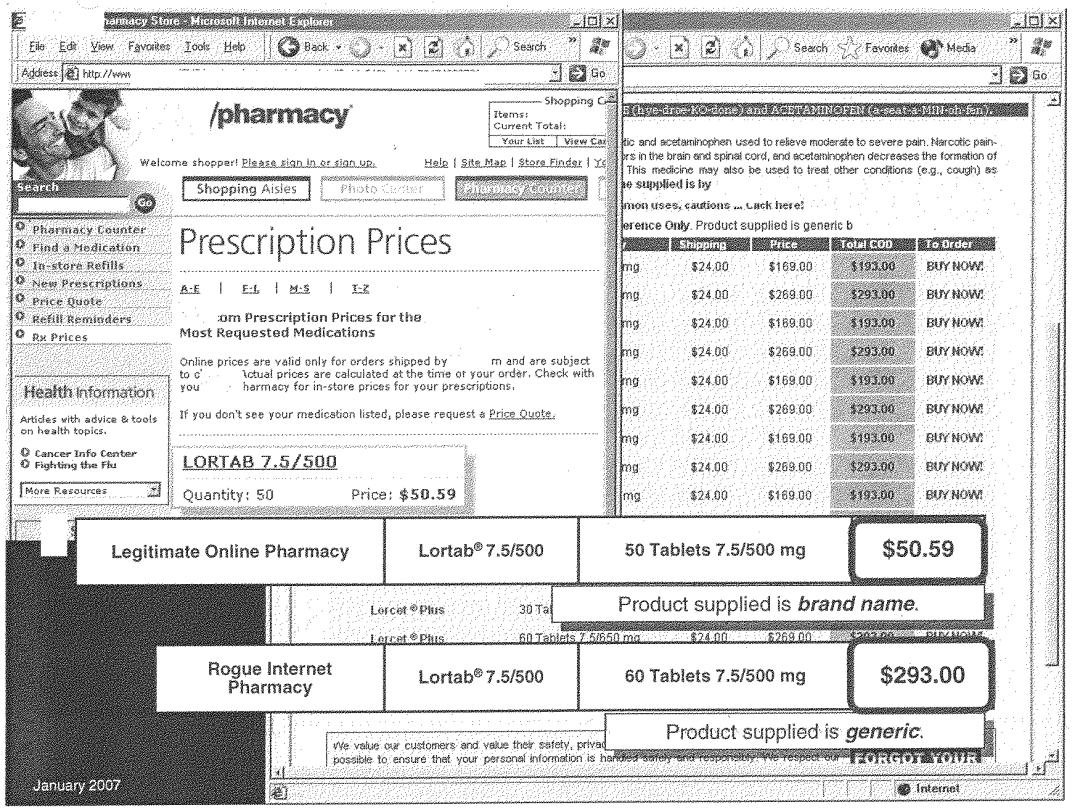

Comparison of CY2006 Purchases of Hydrocodone by Pharmacies
DEA
DOSAGE UNITS
3,000,000
2,500,000
2,000,000
1,500,000
1,000,000
500,000
0
2.9 million
88,000
Rogue Internet Pharmacy Avg*
U.S. Pharmacy Avg Excluding (34) Rogue Internet Pharmacies
*Based on 34 Suspected Rogue Pharmacies (Operating via the Internet)
(as of 3/7/2007)
Date Prepared: 03/07/2007
Source: ARCOS
January 2007


Cyber vs. Brick & Mortar Sales
DEA
Prescriptions Filled Per Day
Average Independent 'Brick & Mortar' Pharmacy*
Controlled Substance Rxs (11%)
Noncontrolled Rxs (89%)
'Cyber' Pharmacy
Controlled Substance Rxs (95%)
Noncontrolled Rxs (5%)
*SOURCE: 2003 NCPA-Pfizer Digest New York, New York - June 26, 2003
January 2007


/pharmacy
Prescription Prices
LORTAB 7.5/500
Quantity: 50
Price: $50.59
Legitimate Online Pharmacy
Lortab® 7.5/500
50 Tablets 7.5/500 mg
$50.59
Product supplied is brand name.
Rogue Internet Pharmacy
Lortab® 7.5/500
60 Tablets 7.5/500 mg
$293.00
Product supplied is generic.
January 2007