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ONLINE PHARMACIES AND THE PROBLEM OF INTERNET DRUG ABUSE

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIME, TERRORISM, AND HOMELAND SECURITY

OF THE

COMMITTEE ON THE JUDICIARY
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ONLINE PHARMACIES AND THE PROBLEM OF INTERNET DRUG ABUSE

TUESDAY, JUNE 24, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIME, TERRORISM,
AND HOMELAND SECURITY
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 11:32 a.m., in room 2141, Rayburn House Office Building, the Honorable Robert C. "Bobby" Scott (Chairman of the Subcommittee) presiding.

Present: Representatives Conyers, Scott, Smith, Gohmert, Forbes, Sensenbrenner, Coble, Chabot, and Lungren.

Mr. SCOTT. The Subcommittee will now come to order.

And I am pleased to welcome you today to the hearing before the Subcommittee on Crime, Terrorism, and Homeland Security on "Online Pharmacies and the Problem of Internet Drug Abuse."

We have a growing problem where dangerous and addictive prescription drugs can too easily be bought over the Internet by anyone, including children. All they need to get relievers, tranquilizers, stimulants and sedatives is access to a computer and a credit card.

None of the proper constraints, such as local doctors and pharmacists, exist in the Internet context. In most cases, there is no identifying information on the Web site with respect to where the actual pharmacy is located or who operates the Web site.

A questionnaire is filled out by the customer without meaningful interaction between the doctor and the patient. And you could have a situation where a pharmacy in one State fills a prescription written by a doctor in another State for a patient in yet another State.

The illegitimate practice is growing and will continue to thrive. In fact, from 2006 to 2007, there has been a 70 percent increase in the number of Web sites advertising or selling controlled prescriptive drugs over the Internet. The 2006 National Survey on Drug Use and Health indicates that almost 7 million people currently misuse prescription drugs.

I hope at this hearing we will be able to find answers to the following questions: What is the cause and nature of the problem? To the extent the problem originates from Web sites outside the United States, how do we crack down on it? How do we fight rogue Internet sites without overreaching on the legitimate ones? And are the existing laws adequate to address the problem?

With respect to the second point, I look forward to hearing about the ways the private sector can assist in combating online sales

from foreign countries. We need to address the international aspect of this problem, and strengthening the public-private-sector collaboration can help provide an effective solution.

Third point, I would like to stress that any legislation on this issue is no substitute for educational treatment and prevention programs.

In addition, before enacting legislation, we need to consult with legitimate pharmacies who have online Web sites for their customers so that we do not tread on Americans' ability to obtain easy access and convenience in seeking their prescriptions.

And finally, we need to examine whether current laws are sufficient to address the problem. While a mechanism currently exists for certifying Internet pharmacies with the National Association of Boards of Pharmacy, this process is purely voluntary.

To mandate a registration system for Internet sites, a bill has been introduced in the Senate, S. 980, the Ryan Haight Online Pharmacy Consumer Protection Act, and I understand that a House companion bill on this legislation will be introduced shortly.

The bill will require businesses who distribute controlled substances using the Internet to register with the Drug Enforcement Administration and to report on the nature of their Web sites. The bill would also prohibit the sale of controlled substances that are sold over the Internet without prescriptions and would require doctors to have at least one in-person consultation with patients for whom they prescribe controlled medication.

In addition, the bill creates a new crime that makes it unlawful for any person to knowingly or intentionally deliver, distribute or dispense a controlled substance over the Internet except as authorized by the bill. Penalties would also be in accordance with those offered under the Controlled Substances Act.

Finally, the bill increases penalties for all illegal distribution of controlled substances classified as Schedule 3, 4 or 5 drugs. It also adds a mandatory minimum sentence for trafficking a certain date-rape drug called "roofies."

Before passing any legislation, we need to examine these provisions further, as they are not directly linked to Internet sales and address drug trafficking generally. If that is the case, they should be dealt with in another bill.

I look forward to hearing from the witnesses and hope the hearing will identify the nature and problem of how we can effectively deal with illegitimate online sales while protecting the convenience of the legitimate ones.

That said, it is my pleasure to recognize the former Ranking Member of this Subcommittee, the gentleman from Virginia, my colleague, Randy Forbes, for his opening statement.

Mr. FORBES. Thank you, Mr. Chairman. It is always a pleasure to be with you, and it is great to be back on this Subcommittee.

And I, too, want to thank all of our witnesses for being here today. We appreciate your time.

Mr. Chairman, I will yield to the Ranking Member of the Committee.

Mr. SMITH. Thank you.

Mr. Chairman, are you yielding me time, or is the Ranking Member yielding me time?

Mr. SCOTT. Well, you have got the time either way. [Laughter.]

Mr. SMITH. I don't want to take up the Ranking Member's time.

Mr. Chairman, America is no stranger to illegal drugs and drug addiction. For decades, Congress has fought to curb the use of drugs such as heroin, cocaine and marijuana. Today America is facing a new threat: prescription drug abuse.

According to the Office of National Drug Control Policy, prescription drugs now rank second, only behind marijuana, as America's drug of choice. The Drug Enforcement Administration estimates that as many as 7 million Americans are addicted to prescription drugs. Today, prescription painkillers cause a higher number of overdose-related deaths than cocaine and heroin combined.

And large quantities of these drugs are just a few mouse-clicks away. Hundreds of online pharmacies peddle these highly addictive painkillers to adults and teenagers without a valid prescription. The most popular of these drugs is hydrocodone, more commonly known as Vicodin.

These rogue Web sites can link a patient from Texas with a doctor in Florida. Based on little more than an online questionnaire, the doctor writes a prescription, which is then filled by a pharmacist in a different State.

Teenagers are fast becoming addicted to prescription painkillers in large part because of their availability on the Internet. And, sadly, some of them are dying.

On February 12, 2001, Ryan Haight died of an overdose of Vicodin. He was just 18. An investigation into his death revealed that Ryan ordered the drug from a doctor he had never seen and who had never examined him. The drugs were shipped directly to his home by an online pharmacy.

Congress can and must put a stop to this. And today I join Congressman Bart Stupak and Congresswoman Mary Bono Mack in introducing the Ryan Haight Online Pharmacy Consumer Protection Act of 2008.

This legislation amends the Controlled Substances Act to address the growing sale of prescription drugs by these so-called online pharmacies. The bill prohibits the sale or distribution of all controlled substances by the Internet without a valid prescription. It requires online pharmacies to display information identifying the business and any pharmacy and doctor associated with the Web site. The bill also provides tough penalties for the illegal sale of prescription drugs.

Identical legislation sponsored by Senator Feinstein and Senator Sessions unanimously passed the Senate in April, and it is past time for the House to do the same.

I welcome our witnesses today.

And, Ranking Member Forbes, I yield back the balance of my time. Thank you for yielding.

Mr. SCOTT. Thank you.

The gentleman's time has expired. The gentleman from Michigan, the Chairman of the full Committee, Mr. Conyers.

Mr. CONYERS. Thank you, Chairman Scott.

Does Mr. Forbes have an additional comment? I would yield to him if he does.

Mr. FORBES. Mr. Chairman, I do, but I would be glad to defer to you and go after that, Mr. Chairman, if you are so inclined.

Mr. CONYERS. Oh, okay.

Well, I thought this was going to be a very simple hearing here. And then I find out two things.

One, we have got mandatory penalties all over the place. Now, maybe there is somebody on the panel that thinks that imprisoning addicts for as long as we can write the numbers in is a good idea. I think we will have to talk about that.

And, of course, the distinguished Ranking Member of the Committee, he and I are in ongoing discussions on every subject before the Judiciary Committee, so we will just add that one to the list.

But, you know, doubling—we imprison more people than anybody on Earth, and here we are dealing with a unanimously passed Senate product that says, "Hey, let's go for more." Schedule 3, from 5 years, plus 2 years, new penalty, 10 years. A schedule 3, bodily use, 10 years, 20 years. Date rape, oh, gosh, that is 20 years, easy. And so we go on down the line.

I mean, what is this? Why? What possible salutary effect can it have? And what kind of deterrent do you think it is going to have on anybody that may be thinking about doing it?

So I will be talking to my dear friend and colleague, Bart Stupak, and of course Ms. Bono about this. We need a new bill, Chairman Scott. I don't want to be fooling around trying to amend this in the full Committee. And besides, we have got to be careful how we stop these illegal Internet pharmacy sites without getting it confused with the legitimate ones.

And so I will put the rest of my statement in the record, and look forward to the testimony.

[The prepared statement of Mr. Conyers follows:]

PREPARED STATEMENT OF THE HONORABLE JOHN CONYERS, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN, AND CHAIRMAN, COMMITTEE ON THE JUDICIARY

In 2007, more than 500 internet sites advertised or sold controlled prescription drugs, such as Vicadin, Oxycontin, Valium, and Ritalin, and nearly 85 percent of these sites did not require an actual prescription.

Online pharmacies present enormous implications for the health and safety of our communities and our children. In most instances, all that a person needs to buy these drugs is access to a computer and a credit card. As a result of the absence of any meaningful controls, even children can purchase prescription drugs online.

Earlier this year, the Senate passed S. 980, dealing with online pharmacies. While a good start, the measure may have unintended consequences and impact individuals other than illegal drug dealers.

It is my hope that any bill considered in the Judiciary Committee satisfies three principal goals.

First, the legislation should not burden our already struggling health care system. Currently, there are 47 million uninsured Americans and another 50 million Americans who are under-insured. While some people buy drugs from these rogue internet sites for illegal purposes, others purchase them for legitimate medical reasons. We must carefully evaluate the impact of any measure on the cost of health care and prescription drugs for these millions of struggling Americans.

For example, my bill, H.R. 676, would establish a universal health insurance program with single-payer financing that would cover all medically necessary services, including prescription drugs. This program would significantly reduce, if not eliminate, these rogue sites. At the very least, my program would make it much easier to identify illegal conduct from legal conduct. In the meantime, though, we need to consider whether there is more focused legislation that we can implement with respect to rogue internet pharmacies.

Second, the legislation must address the problem of illegal internet drug dealers. There are many legitimate pharmacies that use the internet to serve their customers. In addition, many insurance companies work with legitimate internet pharmacies to provide prescription drugs to patients, often at a reduced rate and increased convenience of the patient. The legislation should recognize the value of these pharmacies, and seek to stop the illegal internet pharmacy sites without substantially burdening the legitimate ones.

Third, we need to recognize that the answer to substance abuse problems is not longer sentences in prison. The current penalties for controlled substance crimes—whether committed on the street or through the internet—are sufficiently harsh.

Instead of imprisoning drug addicts for even longer periods of time, we should address the underlying problem of substance abuse. To that end, we should support educational programs that teach our children about the dangers of drug use and encourage providing community activities for our teenagers so that they don't turn to drugs out of boredom. And, we should support meaningful drug treatment programs.

I look forward to hearing from all of our witnesses today and hope they will provide us with a better understanding of the problem and possible solutions.

Mr. SCOTT. Thank you. And I thank the Chairman for his comments.

The gentleman from Virginia?

Mr. FORBES. Thank you, Mr. Chairman.

And, again, we just want to point out that somewhere in America right now, a person is purchasing highly addictive painkillers from an Internet Web site. That Web site operator has no medical training. He is not licensed by the DEA of the State to dispense prescription drugs. The doctor has never examined this person, but he writes the prescription anyway, not for 10 pills or 20, but for 100.

The dangers posed by illegal online pharmacies are real. The National Center on Addiction and Substance Abuse reports a 542 percent increase in the abuse of prescription opiates among 12 to 17 year olds between 1992 and 2000.

These Web sites dispense large amounts of controlled substances, many characterized as Schedule 3 or Schedule 4 drugs under the Controlled Substances Act.

The National Association of Boards of Pharmacy operates the Verified Internet Pharmacy Practices Sites accreditation process. To receive a VIPPS accreditation, a pharmacy must comply with the licensing requirements of its State and each State in which it dispenses medication. However, this accreditation process is merely voluntary, as the Chairman mentioned earlier.

Internet pharmacies are not only a source for obtaining prescription pain medication, a good number of the drugs purchased from these illegal Web sites are counterfeit. Most counterfeit drugs come from overseas and are imported to the United States with false documentation. These drugs are often expired, diluted or mixed with other toxic substances.

Patients purchasing drugs from these Web sites have no guarantees as to the drug's safety. Moreover, they may experience a dangerous drug interaction or side effect from ingesting drugs without proper medical supervision.

More than 80 percent of packages intercepted and examined at U.S. mail facilities have contained either unapproved foreign drugs, controlled substances or counterfeit drugs. According to the Food and Drug Administration, the number of fraudulent prescription drugs intercepted by customs officials nearly doubled between 2004 and 2005.

Last year, the FDA was alerted that drugs such as Ambien, Xanax, Lexapro and Ativan ordered online were found to contain a powerful antipsychotic drug. The antipsychotic drug compound was haloperidol and is used in medications prescribed for schizophrenia.

Also last year, the FDA issued a warning against the purchase of the weight-loss drug Xenical from online pharmacists. Tests showed that capsules purchased off the Internet did not contain orlistat, Xenical's active ingredient. Some contained only talc or starch. Others included sibutramine, the active ingredient in another weight-loss drug, Meridia.

Although Xenical and its active ingredient, orlistat, are not listed on the schedule under the Controlled Substances Act, sibutramine is listed as a Schedule 4 controlled substance.

It is clear from these few examples that illegal online pharmacies pose a serious threat not only to those who have used narcotics but also to unsuspecting consumers.

I commend Mr. Smith, the Ranking Member of the Judiciary Committee, for his leadership on this issue.

Again, Mr. Chairman, I commend you for holding this hearing.

And I thank all of our witnesses for their time and expertise, and I look forward to their comments.

And I yield back the balance of my time.

Mr. SCOTT. Thank you very much.

I would ask unanimous consent that other Members' opening statements be made——

Mr. CHABOT. Mr. Chairman?

Mr. SCOTT [continuing]. Part of the record at this point.

The gentleman from Ohio.

Mr. CHABOT. Thank you, Mr. Chairman. I would ask unanimous consent to make an opening statement, and I will keep it to about a minute, if I could?

Mr. SCOTT. Without objection.

Mr. CHABOT. Thank you.

Mr. Chairman, I, again, want to thank you and the Ranking Member for holding this hearing. And I also want to welcome one of the witnesses that we have here, who is from the great State of Ohio, Mr. Winsley, executive director of the Ohio State Board of Pharmacy.

The problem of prescription drug abuse is real and it is growing. With more than 7 million prescription drug abusers in this country, according to the DEA, rogue Internet pharmacies and Web sites only compound the drug problem, giving criminals new avenues to prey on the vulnerable.

While passage of the Ryan Haight Online Pharmacy Consumer Protection Act would be a positive first step, in my view, effective communication between State and Federal law enforcement and the private sector, including the pharmacies, manufacturers and distributors, is, I believe, key to staying ahead of the criminals and using technology to our advantage.

Again, I thank the Chairman and the Ranking Member for holding this hearing. And I yield back the balance of my time.

Mr. SCOTT. Thank you.

Without objection, other Members' opening statements will be made part of the record at this point.

We have a distinguished panel of witnesses here today to help us consider the important issues currently before us.

Our first witness is Joseph Rannazzisi, who began his career with the U.S. Drug Enforcement Administration in 1986. In 2006, he was appointed to the position of deputy assistant administrator for the Office of Diversion Control. In this position, he is responsible for overseeing and coordinating major diversion investigations, drafting and promulgating of regulations, establishing drug production quotas, and conducting liaison with various State and Federal agencies. He holds a B.S. degree in pharmacy from Butler University and a J.D. from Detroit College of Law at Michigan State University.

Our next witness will be Christine Jones, general counsel of the Go Daddy Group. As general counsel, she is responsible for all legal affairs at the Go Daddy Group, as well as the Domain Services, Network Abuse, Compliance, and Legal departments. Her previous legal practice focused on complex commercial litigation. She worked for the Los Angeles District Attorney's Office prior to entering private practice. She holds a bachelor of science degree in accounting from Auburn University and a J.D. from Whittier Law School.

The next witness will be William T. Winsley, who is executive director of the Ohio State Board of Pharmacy. He has been with the Board of Pharmacy since 1988, starting as a pharmacist investigator, moving to assistant executive director in 1991, and has been serving as executive director since 1998. Prior to employment with the board, he was a practicing pharmacist and pharmacy administrator with three different hospital pharmacies for a total of 14 years. He holds a B.S. in pharmacy and an M.S. in hospital pharmacy management from Ohio State University.

And our final witness will be Patrick J. Egan, who is a partner at the Fox Rothschild Attorneys at Law, where he is chairman of the white-collar practice group. He has nearly 20 years of experience in representing businesses, executives, professionals and other individuals in Federal white-collar criminal defense matters. His experience includes defending an Internet pharmacy site in the Federal grand jury investigation. He graduated from Pennsylvania State University and received his J.D. from Temple University School of Law in 1986.

We begin with Mr. Rannazzisi.

TESTIMONY OF JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINSTRATION (DEA), U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. RANNAZZISI. Good morning, Chairman Scott, Ranking Member Forbes, Chairman Conyers, distinguished Members of the Subcommittee.

On behalf of Acting Administrator Michele Leonhart and 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 pharmaceuticals via the Internet.

As you may know, nonmedical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. According to the 2006 National Survey on Drug Use and Health, 7 million Americans used psychotherapeutic drugs nonmedically, with 5.2 million reportedly abusing pain relievers. Nationally, the misuse of prescription drugs remained second, only to marijuana.

While forged prescriptions, doctor shopping and simple theft from medicine cabinets are all means by which highly addictive pharmaceutical controlled substances are diverted, the Internet has become an increasingly common method of diverting these drugs via rogue Internet pharmacies.

The sheer volume of controlled substances being dispensed anonymously by rogue Internet pharmacies contributes significantly to the downstream methods of diversion. Illicit Internet sales of controlled sales of controlled substances commonly involve 100 or more pills per transaction. These sales occur hundreds of times per day.

For example, in 2006, DEA identified 34 known or suspected rogue Internet pharmacies that dispensed over 98 million dosage units of hydrocodone-combination products. To put this into perspective, the average legitimate pharmacy in the U.S. dispenses approximately 88,000 dosage units of hydrocodone-combo products per year.

DEA investigations of these Internet traffickers have found that the vast majority are linked to DEA-registered pharmacies and DEA-registered doctors. It should be noted that there are legitimate pharmacies that provide controlled substances——

Mr. SCOTT. Excuse me. Did you say they are or are not?

Mr. RANNAZZISI. They, for the most part, are related to DEA pharmacies that are registered DEA pharmacies and doctors.

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 Web sites on the Internet that merely offer to sell controlled substances illegally. A Google keyword search such as "hydrocodone no prescription needed" reveals thousands upon thousands of hits.

While the drug-seeker may go through several portal sites offering controlled substances, eventually the individual will be linked to the anchor Web site, or what we term the "Internet facilitation center." These facilitation centers 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.

Under current law, however, these Internet facilitation centers are not required to register with DEA. And the Controlled Substances Act did not take into account the technological advances that have taken place since the CSA was established. The anonymity afforded by the Internet poses numerous challenges to law enforcement.

Despite the challenges, DEA has identified, disrupted and dismantled several illegal operations involved in this growing threat. When we are able to identify these individuals and businesses, we

investigate and shut down those that operate outside the boundaries of the Controlled Substances Act.

DEA is also targeting the source of supply for many rogue Internet pharmacies. The DEA registered wholesalers and distributors. DEA has initiated an education program for wholesalers and distributors to explain how these rogue schemes operate and reinforce what their requirements are under the CSA.

When appropriate, DEA has taken legal action against the wholesalers and distributors who are not complying with their statutory obligations and providing rogue Internet pharmacies with huge quantities of controlled substance pharmaceuticals.

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 the Internet distribution.

Finally, we continue to build upon solid, interagency partnerships with FDA, FBI, CBP, ICE, as well as the individual State boards of pharmacy and medicine. With that, it should be noted that interagency engagement on this topic has been ongoing for years.

These discussions culminated with the Administration's formal endorsement of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. This bill updates the CSA to set both permissible and impermissible conduct for Internet Web site operators, medical practitioners, and pharmacists involved in Internet distribution of controlled substances. This bill will provide law enforcement with additional tools to identify and shut down these illegal operations, thereby helping protect the American people.

Chairman Scott, distinguished Members of the Subcommittee, drug traffickers continue to exploit the Internet and threaten the health and safety of Americans. Nonetheless, the men and women of the Drug Enforcement Administration 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 substances for legitimate demands.

Thank you for the opportunity to discuss this vital issue, and I would welcome any questions.

[The prepared statement of Mr. Rannazzisi follows:]

PREPARED STATEMENT OF JOSEPH T. RANNAZZISI

Remarks by

Joseph T. Rannazzisi,
Deputy Assistant Administrator
Office of Diversion Control

Drug Enforcement Administration
United States Department of Justice

Before the

House Judiciary Committee
Subcommittee on Crime, Terrorism, & Homeland Security

Regarding

"Online Pharmacies and the Problem of Internet Drug Abuse"

June 24, 2008, 11:30am
Room 2141 Rayburn House Office Building
Washington, D.C. 20515

Introduction

Chairman Scott, Ranking Member Forbes, and distinguished Members of the House Judiciary Subcommittee on Crime, Terrorism, and Homeland Security, 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. According to the 2006 National Survey on Drug Use and Health, seven million Americans used psychotherapeutic drugs non-medically (5.2 million reporting abusing pain relievers), up from 6.4 million reported in the 2005 Survey. Nationally, the misuse of prescription drugs was second only to marijuana in Calendar Year (CY) 2005.

Part of this increase in abuse is fueled by the fact that 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 that if a doctor can prescribe it, the drug can not be as harmful to your health when compared to what some might consider more conventional "street" drugs such as heroin or cocaine. According to the 2005 Partnership Attitude Tracking Study, 40 percent believe that prescription medicines are "much safer" to use than illegal drugs. Furthermore, the same study concluded that 31 percent believe there is "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; they can prove lethal.

This study also found that teens believe a key reason for abusing prescription pain relievers is the widespread availability and easy access to the drugs. This ease of access, which teens indicate is provided by parents' medicine cabinets, friends' prescriptions, and the Internet, 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 (e.g., anti-anxiety medications, hydrocodone combination products, and anabolic steroids[1]), are widely accessible and often illegally purchased through the Internet. Unlike someone stealing a few pills out of the medicine cabinet from someone else's

[1] 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.

prescription, illicit Internet sales of controlled substances commonly involve 100 or more high-potency pills; these sales occur hundreds of times every day.

The Internet as a Method of Diversion

The Internet has become one of the fastest growing methods of diverting controlled pharmaceuticals. Certainly there are benefits to allowing individuals with a valid prescription to fill their prescriptions over the Internet, ranging from simple convenience to providing individuals in remote areas or with limited mobility with greater access to needed medications. 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 every day 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, but they in fact operate beyond the bounds of what is safe and legal. The differences are clear to drug-seeking individuals and investigators alike.

A consumer will notice a level of authorization and accountability with legitimate Internet pharmacy 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 are 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 provide for invalid prescriptions based on the completion of a cursory questionnaire. This 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 dispense prescription drugs based merely on this criterion. There will be an expectation in working with a legitimate on-line pharmacy that a customer will have a valid 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 Web sites or the legitimacy of Internet pharmaceutical sales, if an Internet pharmacy follows the same rules as their brick and mortar counterparts (including, but not limited to, ensuring a patient's right to privacy, authenticating valid prescriptions, 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 professionalism and trustworthiness, but these sites have structured themselves to avoid accountability for the products they sell. DEA investigations indicate that 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 significant success in dismantling 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 or pharmaceutical 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 is OK to approve the prescriptions because they will be provided with some purported "medical history" (often submitted by the "patient" through completion of an online questionnaire). What has become 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. Such communications fall far short of legitimate telemedicine-based medical consultations. 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 anywhere from ten to twenty-five dollars. Law enforcement has discovered Web site-affiliated doctors who authorize hundreds of prescriptions a day.

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, that the prescriptions have all been approved by a doctor, and that 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 legitimate 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 or a legitimate telemedicine-based medical consultation. 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. Also absent is information on how to contact a physician or pharmacist for information about the drug(s) ordered, including drug interactions and adverse reaction.

Frequently, and as mentioned in previous paragraphs, these illicit Web sites offer, at best, insufficient 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 CY 2006, DEA identified 34 known or suspected rogue Internet pharmacies that dispensed 98,566,711 dosage units of hydrocodone combination-products.[2] To put this in perspective, controlled substances account for 11 percent of prescription sales at legitimate "brick and mortar" pharmacies in the United States versus 95 percent at these rogue Internet pharmacies. These 34 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.[3]

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

[2] Information gathered from information reported to DEA and recorded in the ARCOS database.
[3] The 2006 Physicians Desk Reference recommends a maximum of 8 tablets per day of hydrocodone with acetaminophen.

has a corresponding liability to keep the integrity of the closed system intact. Inside the closed system of distribution that governs the traditional doctor-patient-pharmacy relationship, there exists a system of checks and balances that make it difficult for a drug-seeker to illicitly acquire controlled substances. However, with rogue Internet pharmacies there is complicity amongst all of the participants, even if they do not all know each other, to effectively eliminate 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.

In the brick-and-mortar setting, common methods of drug diversion, by their very nature, provide some constraints on the amount of controlled substances individuals can acquire over a given period of time. For example, if an individual is visiting multiple physicians for the same ailment, there are a finite number of doctors that the individual can visit, and often doctors require new examinations before refilling a prescription. Or if an individual is going to forge a written prescription, their forgeries are limited by the number of prescription forms illegally obtained. 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. Not so for most illegal Internet pharmacies.

The sheer volume of controlled substances being illicitly 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 the National Survey on Drug Use and Health indicate that only a small percentage, less than one percent, get controlled pharmaceuticals via the Internet (the majority obtaining them from family and friends), it is important to remember that when these individuals obtain these substances illicitly from family and friends or by stealing from the medicine cabinet they typically acquire less pills than on the Internet. By contrast, DEA investigations clearly reveal that individuals illicitly ordering via the Internet frequently receive 100 to 120 pills at a time. Thus, those who receive their drugs via rogue Internet pharmacies are netting more pills than they would from friends or the family medicine cabinet. Our investigations have led us to believe that the Internet is one of the major upstream sources. For example, a 2006 DEA investigation revealed that just one rouge Internet pharmacy distributed in excess of 15 million hydrocodone tablets in a single year.

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 diverted pharmaceuticals.

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. The criminals have the ability to reach directly into every computer on the Internet. Whether through temptation in the form of a cleverly worded "spam" email or someone actively seeking to acquire narcotics without seeing a doctor (or having a legitimate telemedicine-based medical consultation), the Internet has created a whole new delivery and sales system for drug traffickers. 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.

Internet investigations do offer the advantage of having an extensive paper trail, or the cyberspace equivalent thereof. Investigations are in some respects similar to "white collar" cases. However, the amount of information generated by one Web transaction is so voluminous it becomes difficult to separate the important investigative information from the routine. DEA has gained valuable experience in working these cases in the past several years; the same is true of Department of Justice attorneys to whom we refer cases for prosecution.

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 Web sites. 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 Web sites 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 Web sites that "offer" to sell controlled substances do not in fact sell controlled substances at all but merely link the drug seeker to yet another Web site. This secondary site may also be a portal to yet another Web site. Eventually, the drug seeker will be linked to the anchor Web site, 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.

It must be made clear that a single Web site operated by a single "Internet Facilitator" 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, Web sites can fluctuate in name and number minute by minute. A Web site 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 Web sites that currently offer to facilitate the illegal sale of controlled substances.

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.

The Legislative Response

The controlled substance laws and regulations of the United States were written before the advent of fax machines, let alone "high-speed" Internet service and the Administration is fully aware of the complexities associated with the advent of this technology. It should be noted that inter-agency engagement on how best to bring the laws that protect the American people from drug traffickers up to speed with the methods these traffickers now routinely employ has been ongoing for years. These discussions culminated with the Administration's formal endorsement of the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008". Passed by the Senate in March, the bill now awaits action in this chamber. The bill updates the Controlled Substances Act to set forth both permissible and impermissible conduct for Internet Web site operators, medical practitioners and pharmacists involved in the distribution of controlled substances by means of the Internet. The bill has received the full support of the Administration. Enactment of this legislation, which balances the legitimate benefits derived from using the Internet to provide consumers with controlled substances obtained through valid prescriptions with the need to combat the illegal online diversion of these same drugs, would help address the problems associated with illicit Internet pharmacy operations. The DEA stands ready to assist the Congress in any manner possible as you consider this vitally important piece of legislation.

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.[4] Conversely, the typical "cyber" pharmacy will sell around 450 prescriptions each day—425 of these, or 95 percent, will involve controlled substances.

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 wholesale distributors of controlled substances. DEA has focused on these distributors because, for any transaction involving

[4] 2003 NCPA-Pfizer Digest New York, New York – June 26, 2003.

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 purchasing 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 proceedings against some distributors.

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[5]; express package delivery companies; and financial services companies, including major credit card companies and third party payment service providers. In 2004, DEA became part of a federal interagency task force (with the Food and Drug Administration, the Federal Bureau of Investigation, Customs and Border Protection, and Immigration and Customs Enforcement) established to combat the increasing diversion of pharmaceuticals over the Internet.

In Fiscal Year (FY) 2004, DEA established a specialized section within its Special Operations Division (SOD) to coordinate multi-jurisdictional Title III investigations involving the diversion of pharmaceuticals and chemicals over the Internet. In FY 2007, DEA initiated 132 Internet investigations, a 17 percent increase over the 113 Internet investigations initiated in FY 2006. Twenty-seven Internet investigations were initiated during the first quarter of FY 2008. As a result of these Internet investigations, DEA seized approximately $39.4 million in cash, bank accounts, property, and computers during FY 2007, a 319 percent increase over FY 2006 ($9.4 million). During the first quarter of FY 2008, DEA seized $9.2 million from Internet investigations.

Also during FY 2007, 17.1 percent of Diversion Control Program case work hours supported Internet cases. This represents an increase of 10 percent from FY 2006 and an increase of 50.4 percent from FY 2005.

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

[5] Including web hosting services, domain name registration companies, and search engines.

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 Scott, Ranking Member Forbes, and members of the Subcommittee, I thank you for the opportunity to discuss this vital issue and welcome any questions you may have.

Mr. SCOTT. Thank you. Thank you very much. I failed to advise you of the lights before you that indicate the 5 minutes. You did well and came in right under.

The green light will stay on for 4 minutes, the yellow light for 1 minute. We would ask you to summarize your testimony in 5 minutes, as best as you possibly can.

Ms. Jones?

TESTIMONY OF CHRISTINE N. JONES, GENERAL COUNSEL, GODADDY.COM, SCOTTSDALE, AZ

Ms. JONES. Good morning, Mr. Chairman.

First, thank you for the invitation to be here today. We are grateful for this Committee's attention to this problem and for recognizing that online drug sales are a problem that must end.

The purpose of my testimony is to describe the scope of the problem we all face and how Go Daddy specifically responds to those challenges.

Go Daddy is interested in this issue because we often get requests from the DEA, for example, or other law enforcement agencies to disable online drug sites, and, as of today, there is no law we can rely on to help them. And we believe there should be such a law.

So we are committed to taking whatever steps are necessary and feasible to assist in ending this practice. And we would also challenge our counterparts on the Internet to do the same.

A domain name registrar serves as, sort of, the point of entry to the Internet. So, for example, if you wanted to become ChairmanScott.com, you could go to GoDaddy.com and get that name. Well, you can't, because I registered that name in anticipation of this hearing, but if I hadn't done that, you could. I will be happy to help your staff get that afterwards. [Laughter.]

No, I won't sell it. It only cost $9.99.

A domain name registrar is different from an ISP like AOL or MSN or EarthLink in that the ISP provides access to the Internet; the registrar provides the registration service for a dot-com name and the like.

Once you have ChairmanScott.com, you would have to build a Web site, and then you would have to find a place to actually put the files for your Web site. Again, you could go to GoDaddy.com for that service. And we call that "hosting" service.

A hosting provider differs from an ISP in that the hosting provider provides space on a computer; the ISP provides access to the computer that has the data on it.

The Go Daddy Group devotes considerable time and resources to working with law enforcement on preserving the integrity and security of the Internet by quickly closing down Web sites and domain names engaged in illegal activities.

We work with law enforcement agencies at all levels—Federal, State and local—and routinely assist in a wide variety of criminal and civil investigations. We also work with groups like the Anti-Phishing Working Group, Digital Phish Net, and so on.

We have made it a high priority to use our position as the world's largest registrar to try to make the Internet a better and safer place.

Often we end up investigating sites involving online drug sales. They come in many forms and degrees of severity. And they include things like sites with invalid contact data; sites depicting counterfeit or copycat drugs purporting to be drugs produced by major pharmaceutical companies, and you alluded to those in your opening statement; sites selling advertising advocating or promoting the use of drugs by minors; sites which admit to filling orders without a prescription.

Our investigations also uncovered sites containing offers to provide controlled substances via prescription provided by a "doctor" employed by the Web site operator. These sites typically don't verify age, medical history or medical necessity. The result is that any 14-year-old can go on the Internet and have a supply of recreational drugs sent to their home via overnight courier with no questions asked.

We take each instance of this seriously and devote high-priority attention to ensuring full cooperation with law enforcement in their attempts to remove such Web sites from our network.

We have nearly 30 million domain names. In fact, tomorrow we are going to go across the threshold of 30 million domain names under management. We can't look at all of them. But what we can do is work with law enforcement to try to address this problem.

Within the first 6 months of 2008, we have shut down or suspended over 6,000—6,000—online pharmacy domain names, in the first two quarters of 2008. When I say "shut down," that means if it were a brick-and-mortar store, it would be like putting a lock on the door so you can't do business with those people anymore.

Six thousand in 6 months—we think that is a lot. And the trend is growing. For all of 2007, we had 1,300. So the problem is getting big, and the scale is huge.

And, you know, this isn't just about people trying to save money on prescription drugs by unknowingly buying counterfeit brand-name pills. This is about young kids who use their parent's credit card, they tell them they are buying music or a videogame or some legitimate purchase; instead, they are able to stock the weekly party with enough ecstasy for them and all their friends. It is very, very serious.

The good news about having—well, what we have discovered is that there is a small core of vendors who run a very large number of Web sites. And I think Mr. Rannazzisi alluded to that. The good news is that, for the most part, if you can get to them and get them to stop, you have a large benefit on the other end. The bad news is that one company's actions—for example, Go Daddy—regardless of how much we may help, isn't enough.

So effective legislation in this area, we think, may help overcome this problem. If we can either convince the illegitimate pharmacy sites that it is not going to be in their best interest to continue the same practices or if we can standardize the level and type of responses from providers—for example, our counterparts—we may all be able to see success for the Internet, much like we have seen within Go Daddy as we have responded to these.

Again——

Mr. SCOTT. Can you wrap up?

Ms. JONES. Yes. I just want to say thank you for the opportunity to be here and to be heard on these issues. And I will be happy to answer any questions.

[The prepared statement of Ms. Jones follows:]

PREPARED STATEMENT OF CHRISTINE N. JONES

Before the House Committee on the Judiciary
Subcommittee on Crime, Terrorism, and Homeland Security
United States House of Representatives

Online Pharmacies And
The Problem of Internet Drug Abuse

Statement of Christine N. Jones
General Counsel and Corporate Secretary
The Go Daddy Group, Inc.

June 24, 2008

Introduction

Good morning Mr. Chairman and Members of the Committee. I am Christine Jones, General Counsel and Corporate Secretary of The Go Daddy Group, Inc.

First, I would like to thank you, Chairman Scott, for the kind invitation to testify today regarding online pharmacies and the problem of drug abuse on the Internet. We are grateful for this Committee's attention to this important issue and for recognizing that the problem of online drug sales generally, and illegal sales to minors specifically, is a growing and unacceptable problem that must end. The purpose of this testimony is to describe the scope of the problem we all face and how Go Daddy responds to these challenges. Go Daddy is committed to taking whatever steps are necessary and feasible to assist in ending this practice, and we would challenge our counterparts on the Internet to make the same commitment.

Background

The Go Daddy Group, Inc. consists of eight ICANN Accredited registrars, including GoDaddy.com. When I joined Go Daddy in early 2002, it was a very small registrar with well under 100 employees. Today, we have thirty million domain names under management, and are the number one registrar in the world. That means we register a domain name once every second or less. Go Daddy is also a large hosting provider. We currently employ over 2,000 people and do not utilize offshore outsourcing of any kind.

A domain name registrar serves as the point of entry to the Internet. If, for example, you wanted to register the domain name www.ChairmanScott.com, you could go to www.GoDaddy.com to register that domain name. A domain name registrar is different from a traditional Internet Service Provider (ISP), such as AOL, MSN, or EarthLink, in that the ISP provides access to the Internet whereas the registrar provides the registration service for .com names and the like.

Once the domain name www.ChairmanScott.com is registered, you would need to build a website and find a place to store, or "host," that website. Again, you could go to

www.GoDaddy.com for storage, or hosting, services. A hosting provider differs from a traditional ISP in that the hosting provider supplies space on a computer that is accessible from the Internet rather than access to a computer which is provided by the ISP.

How Go Daddy Deals With Online Pharmacies

The Go Daddy Group devotes considerable time and resources to working with law enforcement on preserving the integrity and safety of the Internet by quickly closing down websites and domain names engaged in illegal activities. We work with law enforcement agencies at all levels and routinely assist in a wide variety of criminal and civil investigations. We are also quick to respond to complaints of spam, phishing, pharming, and online fraud and work closely with anti-fraud and security groups such as the Anti-Phishing Working Group, Digital Phish Net, the National Center for Missing and Exploited Children, and CyberTipLine. I personally, and the company in general, have made it a high priority to use our position as a registrar to make the Internet a better and safer place.

We routinely investigate sites involving online drug sales. They come in many forms and degrees of severity. These include, but are not limited to, the following: 1) sites with invalid contact data for the operators; 2) sites depicting counterfeit or copycat drugs purporting to be drugs produced by the major pharmaceutical companies; 3) sites selling advertising, advocating, or promoting use of drugs by minors; and, 4) sites which admit to filling orders without a prescription. Our investigations have further uncovered sites containing offers to provide Level I controlled substances via a prescription provided by a "doctor" employed by the website operator. These sites typically do not verify age, medical history, or medical necessity. The result is that any 14 year old can go on the Internet and have a supply of recreational drugs sent to their home via overnight courier with no questions asked. We take each instance seriously and devote high priority attention to ensuring full cooperation with law enforcement in their attempts to remove such websites from our network, as described in more detail below.

The Domain Name Registration Process

The domain name registration system is entirely automated. There is no human intervention into the process. Because many words have multiple meanings and combinations of words can be used for both legitimate and illegitimate purposes, no domain names are automatically prohibited from registration. As mentioned above, Go Daddy registers a domain name once every second or less. This makes it virtually impossible for a human to verify the legitimate use of every domain name registration, particularly on an ongoing basis. Thus, we have developed a notification system for reporting instances of all types of network abuse, including online pharmacies, to our Network Abuse Department.

The Notification Process

With nearly 30 million domain names under management, we must rely on information from third party complaints or notices. The Go Daddy Network Abuse Department receives information that an online pharmacy site may be residing on our network in several ways: 1) a direct complaint from a third party via email; 2) a direct complaint via telephone; 3) a tip from employees who have become aware of drug sales on a customer site; and, 4) a notification from law enforcement and other "watchdog" groups.

The Investigation Process

Within the first six months of 2008, we received thousands of complaints on sites that were related to pharmaceuticals. These included sites with invalid contact data, legal disputes by legitimate drug producers, trademark disputes, spam, phishing, and of course, criminal investigations.

The most common situation we see is "pill spam," or email advertising the sale of prescription drugs. The most common pill spam situation is spam email being sent to Go Daddy customers or our customers' customers. Our email team estimates that our extremely effective spam filters block more than an estimated 2,400 separate spam attacks every day, many of which are related to selling drugs online.

The Results

Despite our spam filters, our Network Abuse Department still receives between 30 and 50 pharmacy related spam emails every day, with the majority of them hitting on Friday nights. This is a new permutation of an old spam and phishing trick designed to lengthen the amount of time a site that is likely fraudulent or abusive would remain online. The theory is that the ISP providing the service may have gone home for the weekend.

Of the 30 to 50 pill spam emails we receive every day, over 95% of the pharmacy sites mentioned in the spam emails do not have services with Go Daddy. This may well indicate that many pill spammers tend to favor other registrars or hosting providers who are not as active in combating abuse as Go Daddy is, or who are known to have slower response times in dealing with abuse issues. It also tends to show that other registrars could do more to combat this growing problem.

To put the remaining 5% in some perspective, those sites where Go Daddy does provide services, our Abuse Department suspended over 1,300 domain names in 2007 that were involved in online drug sales. In other words, in one year, we disabled more than 1,300 separate websites where drugs were available for purchase, mostly without a prescription, and almost always without any age verification or parental oversight required. We believe this statistic shows how easy it is for Internet users who are also drug users to get drugs, some of them dangerous Schedule I drugs, with no verification that the online pharmacy or its customer has any legal business in the drug transaction. This should concern all of us.

For 2008, the trends are much more severe. Go Daddy has suspended over 6,000 online pharmacy domain names so far in the first two quarters of 2008 alone. That is six thousand in six months! This huge increase provides one of the main reasons Go Daddy has been so vocal and active in bringing attention to this issue. Drugs are too easy to buy online. This is about more than just people trying to save money on prescription drugs by unknowingly buying counterfeit brand name pills. This is about young kids who use

their parents' credit card, tell them they are buying music or video games, and instead are able to stock the weekly party with enough ecstasy for them and all their young friends. This is very, very serious.

What the data means

Based on our data, it appears that illegitimate pharmacy sites, just like phishing and spam sites, are likely primarily operated by a relatively small core of offenders who do so on a large scale and organized basis. When we took action on some of these larger offenders, effectively stopping their use of Go Daddy products and services, we saw an immediate and sustainable reduction in pharmacy site abuse here at Go Daddy. The numbers of pharmacy sites we are seeing advertised in spam, however, has continued to increase. So, it would be very helpful to have cooperation from our peers in the industry to fight this issue.

The good news about having a small core of offenders responsible for most of the problems is that if you can get to them and stop them, you see large benefits. The bad news is that any one company's actions to combat this, regardless of how much it may help our specific situation, will not stop the problem. It will only cause the problem to shift to another provider. Effective legislation in this area may help overcome this problem. If we can either convince the illegitimate pharmacy sites that it is not going to be in their best interest to continue the same practices, or if we can start to standardize the levels and types of responses from providers, we should see overall success for the Internet much like we have seen within Go Daddy.

How Go Daddy Deals With Private Domain Name Registrations

Go Daddy offers privacy services for domain name registrations. A private domain name registration is recorded through a proxy registrant, thus enabling a domain name registrant to avoid publication of their personal information in the public WHOIS data base. We find that most of the users of the private registration service are legitimate users; bad actors typically do not want to pay extra to hide their WHOIS data when they are probably going to provide false WHOIS data, anyway. Most online pharmacies do

not have privacy protection on them. More often than not, the registrant simply provides false, but typically valid looking, WHOIS data, upon registration.

The registration process for a domain name is exactly the same regardless of whether the customer chooses to enable privacy. While we do not have different rules for registering a domain name with privacy, we do use our terms of service broadly to cancel privacy when it is being used for ANY improper purpose. We also give law enforcement the proxy registrant information on private domain name registrations when they are investigating a domain name with privacy. In the case of online pharmacy sites, this information is voluntarily provided to law enforcement during the notification process described above.

Conclusion

Thank you again, Mr. Chairman, for the opportunity to be heard on these important issues. Your commitment and the commitment of the Members of this Committee, to bringing attention to this troubling problem is sincerely appreciated. Go Daddy is committed to working with law enforcement and others in the industry to remove illegitimate online pharmacies from the Internet. I would be happy to answer any questions you may have.

Mr. SCOTT. Thank you.
Mr. Winsley?

TESTIMONY OF WILLIAM T. WINSLEY, EXECUTIVE DIRECTOR, OHIO STATE BOARD OF PHARMACY, COLUMBUS, OH

Mr. WINSLEY. Thank you, Mr. Chairman, for allowing me the honor of presenting oral and written testimony before you today.

I am here primarily to describe the limited progress that the States have made in dealing with the overwhelming problems presented by the ready access of drugs via the Internet, with my primary focus of course being on what Ohio has done in this regard.

I would first like to say that, in my opinion, the people that I talk about here today are not accurately described by the term "Internet pharmacies." To me, an Internet pharmacy is one that is properly licensed to fill legitimate prescriptions written by a doctor who is practicing in a valid doctor-patient relationship and they comply with all the laws, rules and regulations that are necessary, just like most of the brick-and-mortar pharmacies do. In other words, my concern today is not with those sites like Walgreens.com, CVS.com, Medco.com or the many other legitimate pharmacies that are out there doing business on the Internet.

The Web sites I have problems with are those that I describe as Internet drug dealers or, more appropriately, Internet drug traffickers. These sites are responsible for pouring millions of doses of prescription drugs, controlled substances, into the hands of consumers with little or no regard to the possible harm they could be doing.

If that description makes them sound like street-corner drug dealers, then I have accomplished my purpose here today. In many cases, there is more similarity to street-corner drug dealing than there is to legitimate medical care. The advantage to using the Internet, as Mr. Rannazzisi pointed out, is that it is easier for the principals to hide.

My written testimony contains brief descriptions of four investigations that we have conducted in Ohio since 1998. The methods used by the Internet drug dealers are constantly changing to counteract the enforcement processes of local, State and Federal agencies. And it is getting a lot harder to track them down and even harder to convict them.

Federal help is needed to help slow down this flood of illicit drug sales.

To demonstrate what I mean by using the word "flood," let me just talk about the last two cases that we have done in Ohio. They are described in more detail in my written testimony.

But each case involved a small, independent pharmacy who filled illegal prescriptions from the Internet for only 4 months each, only 4 months for each of the pharmacies. And yet, together, they managed to fill over 14,000 illegal prescriptions and dispense over 1.2 million doses of hydrocodone products to people all over the United States. Four months, two small, independent pharmacies, 1.2 million doses of hydrocodone products. They also shipped other drugs, but hydrocodone was the major one.

Now, both of the pharmacists involved had their licenses revoked by the Board of Pharmacy in Ohio, but the principals in the scheme

were safely tucked away in another State, where we had no jurisdiction and little ability to get to them.

These cases involved only two pharmacies in Ohio, one in Columbus and one in Nelsonville, Ohio, which is a small town about an hour southeast of Columbus. I know there are more pharmacies in Ohio doing this. We have multiple investigations going on even as we speak.

From talking to my colleagues around the country, I know that Ohio is not unique and every State is facing problems like this. Every State has small, independent pharmacies that are shipping millions of doses out via illegal Internet prescriptions. It just boggles my mind to imagine how much hydrocodone is hitting the streets.

There are some activities going on that will help deal with this problem. As an addendum to my written report, I have provided some information about VIPPS, which you have already heard about, and a new program that NABP has started, known as the Internet Drug Outlet Identification program.

A review of this report on the Internet drug outlet program will identify for the Committee a lot more problems than I have time to talk about today. There are about 139 Internet drug outlets that NABP has identified as problem sites. Many of them appear to be linked to one common network. Many of them are foreign. And most of them do not require a valid prescription.

The States and the Federal agencies charged with dealing with this problem need some help. I would suggest to you that Senate 980 appears to provide some of that help for controlled substances. I would encourage the Committee to carefully review this bill and move it along so it could become law. With the addition of the language contained in this bill, Federal and State agencies will have a lot greater ability to deal with the people causing all these problems.

Mr. Chairman, Committee Members, thank you for the opportunity to testify today. I look forward to discussing the issue with you further when it is time for questions. Thank you, Mr. Chairman.

[The prepared statement of Mr. Winsley follows:]

PREPARED STATEMENT OF WILLIAM T. WINSLEY

OHIO STATE BOARD OF PHARMACY

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TESTIMONY BEFORE THE COMMITTEE ON THE JUDICIARY, SUBCOMMITTEE ON CRIME, TERRORISM, AND HOMELAND SECURITY

Hearing on Online Pharmacies and the Problem of Internet Drug Abuse
June 24, 2008

William T. Winsley M.S., R.Ph.
Executive Director

Mr. Chairman and members of the Subcommittee, it is my pleasure to submit this written testimony that will outline our experiences with some Internet drug dealers masquerading as legitimate Internet pharmacies, and the problems that the states have faced in dealing with those who are operating illegally, using Ohio as an example. I will also describe some independent processes that have been started to attempt to deal with this problem and provide you with my opinion of things that Congress can do to help us resolve these issues.

Introduction

By way of introduction, the Ohio State Board of Pharmacy was established by the Ohio Legislature in May of 1884 and has been in continuous service to the citizens of Ohio since that time. The duties of the Board have grown over the years and, at this time, encompass the enforcement of the following chapters in the Ohio Revised Code:

2925. – Criminal Drug Laws
3715.– Pure Food and Drug Law
3719. – Controlled Substance Act
4729. – Pharmacy Practice Act & Dangerous Drug Distribution Act

The State Board of Pharmacy consists of nine members (eight pharmacists and one public member) appointed by the Governor to serve four year terms. Each member may be re-appointed one time at the Governor's discretion.

Like all other professional licensing boards, the Ohio State Board of Pharmacy is responsible for the licensing of the professionals that practice under the Board's authority. In our case, this includes pharmacists and pharmacy interns. In addition, the Board licenses sites where Dangerous Drugs (primarily those requiring a prescription) are purchased and stored prior to the delivery to a patient. The site licenses are issued by the Board as either a Terminal Distributor of Dangerous Drugs (mainly retail type settings) or a Wholesale Distributor of Dangerous Drugs. Terminal Distributor sites include, but are not limited to, retail pharmacies, hospitals, nursing homes, prisons and jails, emergency medical squads, clinics, medical gas distributors, etc.

In addition to the licensing function just discussed, the Ohio State Board of Pharmacy is also a law enforcement agency, unlike most other licensing boards around the country.

Until recently, we were the only agency in Ohio that had statewide jurisdiction to enforce the criminal drug laws. Therefore, we have conducted criminal investigations of doctors, nurses, dentists, veterinarians, and other individuals far removed from our licensing functions as outlined above.

As an example, in the last seven years (January, 2001-December, 2007), agents of the Board of Pharmacy conducted investigations leading to the arrest of over 750 professional individuals for violations of the criminal drug laws, including:

Pharmacists (RPh)	128
Pharmacy technicians	109
Pharmacy Interns	7
Registered Nurses (RN)	286
Licensed Practical Nurses (LPN)	184
Physicians (MD or DO)	46
Dentists (DDS)	7
Certified RN Anesthetists (CRNA)	5
Police Officers	4
Medical Assistants	10

It is our law enforcement activities that lead to this written testimony. We have completed several investigations involving Internet transactions and it is interesting how the process has changed and become more difficult and expensive to investigate and prosecute over the years.

Ohio's History With Internet Drugs

Our first experience with Internet drug trafficking was in 1998. We became aware that a doctor in the Columbus, Ohio area had set up his own website, www.get-it-on.com, where lifestyle drugs and controlled substances could be obtained by means of an on-line questionnaire. In one of the first cases of this type in the country, we investigated the doctor, Dr. Daniel Thompson, and his partner, Vincent Chabra. As far as I know, this was also the first investigation in the country to buy controlled substances for a cat. We did this to prove the inability of the physician to determine the legitimacy of the patient with his on-line questionnaire without a physical examination. Drugs were being shipped all over the country from this one company and its website. After our investigation, the doctor and the company were indicted. The doctor was indicted on 64 felony counts of illegal drug sales (both controlled substances and non-controlled substances).

Unfortunately, right before the trial was to begin and immediately after a motions hearing where the defense attorney told the judge that he could not defend his client against the charges since he had just lost on every motion he made, the elected county prosecutor stepped in. Over lunch with the defense attorney between the motions hearing in the morning and jury selection in the afternoon, he made a deal with the defense attorney. Dr. Thompson was allowed to plead to two misdemeanors instead of going to trial on the 64 felony counts. The Prosecutor made this deal without consulting with the Assistant Prosecutor handling the case, the attorney from the Pharmacy Board who had been appointed special prosecutor to assist in the case, or the Board investigators. Therefore, Dr. Thompson and Vincent Chabra were free to go on their way to bigger and better things. It's my understanding that both Vincent Chabra and Dr. Thompson had dealings

with DEA and other agencies a few years later for the same type of activities. I believe that Chabra surrendered about $130 million from off-shore accounts as part of his federal settlement. That's a lot of illegal drug sales that might have been prevented had the Prosecutor in our case done his job.

After it became obvious that a company with an on-line questionnaire who also provided the drugs was too easy for investigators to track, the Internet drug traffickers modified their techniques. They began using multiple websites with apparently unrelated domain names that all fed back to one company. This company would then contract with physicians to review the questionnaires and sign off on prescriptions, paying them by the prescription. These "prescriptions" would then be transmitted to a pharmacy that was either owned by the Internet company or contracted to them. In some cases, like our next Internet case, the companies even went so far as to contract with doctors who were licensed in the state where the person requesting drugs was located. The doctor never saw the patient, although in some cases there were very short telephone conversations between the doctor and the person requesting drugs before the doctor approved the prescription. Rarely, if ever, did these conversations result in the doctor refusing to issue a prescription.

Since it was extremely difficult to identify and link the various websites with the company behind the scheme(to say nothing about the doctors, pharmacies, and patients involved with them), and since we had limited resources, we did not pursue any more Internet cases for some time. However, in May of 2000, we became aware of a pharmacy that was shipping drugs into Ohio and one of our agents managed to buy some drugs. The pharmacy (website address www.1stonlinepharmacy.com) was in North Carolina and the doctor, Warrick Barrett, MD who was also licensed in Ohio, was in Indiana. The pharmacy was actually licensed with Ohio, as well as several other states. They were operating under the guise of a legitimate mail order pharmacy. In a settlement with us, they surrendered their Ohio license and agreed to refrain from shipping drugs to Ohio or pursuing any further licensure until they were able and willing to function legally. The State Medical Board of Ohio revoked the doctor's Ohio medical license.

In the latest change that we have seen, the Internet companies are now contracting with local pharmacies (usually independent, not chain pharmacies) to fill the prescriptions. We have recently had two cases involving Ohio pharmacies who were filling prescriptions written by doctors from another state for patients living in a third state. Pharmacies in Ohio and, I assume, other states are being bombarded with offers from companies looking for someone to fill "legitimate" prescriptions. The pharmacists are being offered a significant dispensing fee, far higher than they normally make, to fill these prescriptions. While most pharmacists realize the illegal nature of these transactions, we have unfortunately found several who have agreed to participate. We have had two Board hearings so far, but there are several other active investigations going on at this time.

Based on our investigation of Caringwell Pharmacy, located in Columbus, Ohio, and its owner, Jae-Seung Lee, R.Ph., the Board found that the pharmacist sold the following amounts of drugs by filling illegal prescriptions from the Internet between November 29, 2006, through March 29, 2007, a period of 120 days:

CONTROLLED SUBSTANCE	# of Rxs	QTY. OF DRUG
hydrocodone/APAP 10/325 mg tablets	3,231	348,480
hydrocodone/APAP 10/500 mg tablets	1,412	154,336
hydrocodone/APAP 7.5/500 mg tablets	109	11,010
hydrocodone/APAP 7.5/750 mg tablets	193	19,530
hydrocodone/APAP 10/650 mg tablets	550	62,570
hydrocodone/ APAP 10/660 mg tablets	15	1,800
TOTAL hydrocodone products	**5,510**	**597,726**
alprazolam 1 mg tablets	82	6,330
alprazolam 2 mg tablets	527	46,890
TOTAL alprazolam products	**609**	**53,220**
diazepam 10 mg tablets	**205**	**16,265**

Please note that hydrocodone/APAP is the generic name for products such as Vicodin, Lortab, Norco, etc. Alprazolam is the generic name for Xanax and diazepam is the generic name for Valium.

The Board revoked the pharmacist's license and the pharmacy's license.

We also investigated Stoltz Leader Drug, located in Nelsonville, Ohio, and its owner, Steven Holtel. After hearing about our investigation, the Board revoked Holtel's pharmacist license for filling Internet prescriptions during the time period of October 17, 2005, through February 14, 2006. The following table lists only the hydrocodone containing prescriptions filled, although there were many prescriptions filled for other drugs as well.

Drug	Strength	# of Rxs	QTY. OF DRUG
hydrocodone/APAP	10/500	1,815	169,680
hydrocodone/APAP	10/650	553	52,020
hydrocodone/APAP	5/500	1,795	9,870
hydrocodone/APAP	7.5/500	623	54,060
hydrocodone/APAP	7.5/750	924	79,590
hydrocodone/APAP	10/325	3,180	296,280
hydrocodone/ibuprofen	7.5/200	98	9,270
Total hydrocodone products		**8,988**	**670,770**

Both of these pharmacies were small, independent pharmacies. However, they were shipping these large quantities of controlled substances to individuals all over the country. In most cases, the doctor, patient, and pharmacy were all separated by large distances. There were no physical examinations, there was no valid doctor-patient relationship, there was no valid pharmacist-patient relationship.

These were just two small pharmacies in Ohio. We will have more pharmacies to add to our list soon. I know from talking to my colleagues from around the country that Ohio is not unique; this is taking place all over the country. The amount of controlled substances being sold illegally must be staggering. Something needs to be done soon.

Please note that all of our cases have involved people and companies located within the United States. Even though websites and drug sales emanating from foreign countries are

a large part of the problem, we cannot deal with those sites. That will take a concerted federal effort by DEA, FDA, Customs, and other federal agencies.

Current Efforts To Combat The Problem

Currently, the National Association of Boards of Pharmacy (NABP), whose membership is made up of all of the Boards of Pharmacy in each state and territory plus several Pharmacy Boards from outside of the U.S., has two programs operating to help consumers determine whether the website offering to sell them prescription drugs is legitimate. These programs are the Verified Internet Pharmacy Practice Sites (VIPPS) and the Internet Drug Outlet Identification Program. On the NABP website (www.nabp.net) is a selection for "Internet Pharmacies" which will take the reader to a page with a header that reads: **Buying Medicine Online -How do I decide which pharmacy to use?**

By reading about the VIPPS program and by reviewing the list of suspect Internet sites, it is hoped that consumers will be able to make a more informed choice when they choose their Internet pharmacy.

Documentation describing these two programs is attached to this testimony as Addendum 1. It should be noted that NABP started the Internet Drug Outlet Identification Program without any outside funding after learning about the serious problems faced by consumers and regulators alike when they were trying to deal with the large number of Internet drug sites and determine which were legitimate and which were not. A review of the list of questionable sites will reinforce the need for federal action to provide DEA, FDA, other federal agencies, and the States with the tools needed to deal with this proliferation of drug dealing websites.

REQUEST FOR FEDERAL ASSISTANCE

Currently, the federal laws and regulations that exist do not go far enough to deal with this problem effectively. State laws and rules vary widely, see Addendum 2 for some of Ohio's current laws and rules, which has led to some states almost seeming to be safe havens for the people operating these websites. The changes proposed in Senate Bill 980 would go a long way to remedying that problem. Much of the wording of this bill is very close to language already existing in several states. By making this change federally, federal agencies will be able to operate effectively even in states that have weak laws and rules or no laws or rules on this topic at all. This bill would give the federal agencies more ability to stop these websites from operating and would also provide a better chance of getting consistent and better prosecution if they persist.

Having appropriate laws in place is not enough, however. In order to enforce the laws, it takes personnel, equipment, and expertise. In addition to strengthening the laws that deal with the problem, Congress needs to allocate adequate funding to the various agencies involved in the enforcement of these new laws. While the states can often conduct their own investigations, resources are even more limited on that level. Cooperation between the states and the federal agencies would be very beneficial to resolving this issue.

Ohio Testimony - Addendum 1

NABP's Verified Internet Pharmacy Practice Site program and Internet Drug Outlet Identification Program

VIPPS

In response to public concern of the safety of pharmacy practices on the Internet, the Association developed the Verified Internet Pharmacy Practice Sites (VIPPS) program in the spring of 1999. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria that VIPPS-accredited pharmacies follow.

To be VIPPS accredited, a pharmacy must comply with the licensing and survey requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP 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.

VIPPS pharmacy sites are identified by the VIPPS hyperlink seal displayed on their Web sites. By clicking on the seal, a visitor is linked to the NABP VIPPS site where verified information about the pharmacy is maintained by NABP. The public is also welcome to access the VIPPS site to search for a VIPPS Internet pharmacy that matches their needs.

Recommended Internet Pharmacies

Web Business Name	Web Site Address
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
Prescription Solutions	www.rxsolutions.com
Prime Therapeutics, LLC	www.primetherapeutics.com
Rx Direct, Inc	www.rxdirect.com
Savon.com	www.savon.com
Tel-Drug, Inc/CIGNA	www.teldrug.com
Walgreen Co	www.walgreens.com
WellDyneRx	www.welldynerx.com
WellPoint NextRx	www.wellpointnextrx.com

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Internet Drug Outlet Identification Program

Progress Report for State and Federal Regulatory Bodies: June 2, 2008

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INTERNET DRUG OUTLET IDENTIFICATION PROGRAM
PROGRESS REPORT: JUNE 2, 2008

I. INTRODUCTION

NABP is pleased to announce that our Internet Drug Outlet Identification program is well under way. The new Internet Pharmacies section of the NABP Web site went live on May 16, 2008, its primary purpose, to educate patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of May 29, the Web site lists 139 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby posing a significant risk to the public health.

II. OBJECTIVE

The main objective of this program is to review and monitor Web sites selling prescription drugs and to distinguish those sites that do, and do not, comply with state and federal laws and/or NABP patient safety and pharmacy practice standards. NABP has developed these standards with input from several industry, professional, and regulatory groups, including the US Food and Drug Administration (FDA) and the US Drug Enforcement Administration (DEA). Internet drug outlets that appear to operate in conflict with these criteria are listed on the NABP Web site as "not recommended."

At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the Verified Internet Pharmacy Practice Sites™ (VIPPS®) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended." These lists, along with program criteria and related patient information, are accessible in the new Internet Pharmacies section of the NABP Web site, *www.nabp.net*. The program criteria are also included as Appendix A of this report.

III. RESULTS

As of May 29, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 148 Internet drug outlets selling prescription medications. Of these 148 sites, 139 (94%) appear to be in conflict with state and federal laws and NABP patient safety and pharmacy practice standards. These sites are listed as "not recommended" on the NABP Web site. Complete findings on these sites are included in Appendix B of this report (see attached spreadsheet). Only nine (6%) of those 148 sites have been found to be potentially legitimate, pending verification of licensure and other criteria.

NABP has identified another 317 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Staff has identified another six potentially legitimate sites and, likewise, is in the process of verifying these findings.

The 139 Internet drug outlets currently listed as "not recommended" on the NABP Web site are characterized as follows:

- 61 have a physical address located outside of the United States
- 128 do not require a valid prescription
- 65 offer foreign or non-FDA-approved drugs
- 114 do not offer medical consult with a pharmacist
- 39 do not have secure sites
- 131 do not accept insurance
- 39 have server locations in foreign countries
- 84 appear to be affiliated with a network
- 62 dispense controlled substances
- 39 sell precursor products

Potentially legitimate sites appear to meet program criteria that could be verified solely by looking at the site. Staff has not verified licensure or DEA registration or requested attestation of compliance with the remaining criteria for any potentially legitimate sites at this time. These sites are not posted on the NABP Web site.

Sites encountered that appear to sell only over-the-counter products or herbal supplements, that are displayed in an indecipherable foreign language, or that

appear to be based in a foreign country and not selling prescription medications to customers in the United States have been deferred for possible review at a later date.

NABP obtained leads for the sites we have reviewed thus far from the following sources:

- PayPal: PayPal sends NABP lists of suspiciously operating Internet drug outlets and related Web sites based on customer complaints
- Suspicious sites compiled from 2001-2004: Information on these sites was obtained by NABP staff in previous years. Staff revisited these sites (a) to see if they still exist, and (b) to evaluate them according to current program criteria.
- Customer inquiries and Report a Site: These suspiciously operating sites were reported by customers either to Customer Service staff or via the electronic "Report a Site" tool on the NABP Web site.
- Google key-word search for common prescription drugs of abuse
- Unsolicited e-mail messages (ie, spam) advertising Internet drug outlets
- February 2008 *Ohio State Board of Pharmacy Newsletter*
- Pfizer news release, "Microsoft and Pfizer Target Sellers of Illegal Generic Viagra and International Pharmacy Spam Rings," describing legal proceedings in which Pfizer is suing Internet drug distributors for selling fraudulent versions of its brand-name drug
- Reverse IP look-ups (search conducted using a Web site's IP address or domain name that provides a listing of all sites hosted on the same IP address)
- Internet drug outlets named on previously reviewed Web sites

In our research, NABP staff continues to come across many sites that appear to be affiliates of one another. For example:

- Twenty-one sites are subsidiaries of Alliance Health Group/Handy Healthcare Group;

- Twenty-eight sites appear to be affiliates of Health Network Solutions LLC/Millennium Pharmaceuticals;
- Five sites appear to be affiliated with Trusted Tab/Trusted Tabs;
- Fourteen sites appear to be affiliates operating with 877-479-2455 listed as the toll-free number;
- Twelve sites appear to be affiliates of UltraMeds;
- Thirty-one sites appear to be affiliates with DesktopDrugs;
- Five sites appear to be affiliates of Real-medical.com;
- Ten sites appear to be affiliates of CanadaMeds;
- Six sites appear to be affiliates of Secure Medical; and
- Nine sites appear to be affiliates of UnitedPharmacies

NABP will investigate these networks of affiliated rogue sites and will provide further information in a future report.

IV. DISCUSSION

NABP will continue evaluating Internet drug outlets and will continue to list sites that appear to be in conflict with state and federal laws and NABP patient safety and pharmacy practice standards as "not recommended" on the NABP Web site. We also will provide the boards of pharmacy, federal regulatory agencies, and other interested stakeholders with periodic updates of our findings. Our hope is that regulators will find the information helpful in their efforts to crack down on illegally operating Internet drug outlets. We also welcome any partnership opportunities to help us spread the word to the public about the potential dangers of buying medicine online and about the information available on the NABP Web site, *www.nabp.net.*

In addition, we ask that you share with NABP any knowledge or concerns you might have pertaining to illegally or unprofessionally operating Internet drug outlets, so that we may pass this information along to the public, as well as to the state and federal regulatory bodies and interested stakeholders. By working in concert, we can make considerable progress toward curbing the illegal trade

of prescription drugs and protecting the public health from illegal operators of Internet drug outlets.

For further information, please contact Melissa Madigan, Policy and Communications Senior Manager, via e-mail at mmadigan@nabp.net or by phone at 847-375-4487.

APPENDICES

APPENDIX A (CONT.)

Internet Drug Outlet Identification Program Criteria

Patient Safety and Pharmacy Practice Standards

Licensure and Residency

1. The pharmacy, in accordance with applicable state and federal laws and regulations, must be licensed or registered in good standing to operate a pharmacy or engage in the practice of pharmacy in all applicable jurisdictions.

2. The pharmacy, in accordance with applicable state and federal laws and regulations, must not be or not have been subject to significant disciplinary action.

3. The pharmacy, in accordance with applicable state and federal laws and regulations, must be registered with Drug Enforcement Administration (DEA) if dispensing controlled substances.

4. The pharmacy, in accordance with applicable state and federal laws and regulations, must be domiciled in the United States.

Prescriptions

5. The pharmacy, in accordance with applicable state and federal laws and regulations, must assure the legitimacy and authenticity of all prescription drug orders. A legitimate and authentic prescription drug order must be based upon a valid patient-prescriber relationship, which requires the following to have been established: a) The patient has a legitimate medical complaint; b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through a telemedicine practice approved by the appropriate Practitioner Board; and c) Some logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

6. The pharmacy, in accordance with applicable state and federal laws and regulations, must adhere to the Federal Controlled Substances Act and DEA rules regarding prescriptions for controlled substances, including but not limited to the following: a) Prescriptions for Schedule II controlled substances must be provided in writing by the prescriber; b) Prescriptions for Schedule III - V controlled substances must be provided in writing by the patient or prescriber, or verbally or by facsimile by the prescriber; c) Schedule II controlled substance prescriptions may not be refilled; a new prescription must be issued for each quantity of the substance.

7. The pharmacy, in accordance with applicable state and federal laws and regulations, must *not* dispense or offer prescriptions originating from telephonic, electronic, or online medical consultations without a pre-existing

patient-prescriber relationship that has included a face to face physical examination.

8. The pharmacy, in accordance with applicable state and federal laws and regulations must *not* offer to dispense or dispense medications that have not been approved by FDA.

Patient Privacy

9. The pharmacy, in accordance with applicable state and federal laws and regulations, must maintain a secure Web site and ensure patient identifiable information and prescription transactions are encrypted per industry standards.

10. The pharmacy, in accordance with applicable state and federal laws and regulations must have and provide patients with a statement of patients' rights to privacy and attempt to obtain from patients signed confirmation of receipt of such statement.

Patient Services

11. The pharmacy must provide, on the Web site, a 24-hour toll free number for patients who experience or believe they have experienced an adverse event involving their medication.

12. The pharmacy must provide, on the Web site, the US street address of the pharmacy that dispenses prescription medications on behalf of (or through) the Web site.

13. The pharmacy must provide, on the Web site, the US street address of the site's corporate headquarters or primary place of business.

14. The pharmacy must provide, on the Web site, instructions to patients describing how to submit complaints or concerns.

15. The pharmacy must offer pharmacist medication consultation via secure means through the Web site, via telephone, or in person for walk-in patients.

Professional Practices

16. The pharmacy must attest and provide documentation to NABP that they obtain medications from US licensed wholesale drug distributors and/or US licensed or FDA registered pharmaceutical manufacturers.

17. The pharmacy must maintain a currently registered domain name that is not anonymous or private.

APPENDIX B

Internet Drug Outlets Evaluated and Listed as 'Not Recommended'

Not Recommended Sites : These Internet drug outlets appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards.

***Not* Recommended Sites**

Web Business Name	**Web Site Address**
1 Stop Pharmacy	http://1stop-pharmacy.e-trusted.com
111 Drugstore.com	www.111drugstore.com
1800-Viagra.com	www.1800-viagra.com
1drugstore-online.com	www.1drugstore-online.com
24HoursPPC	www.24hoursppc.org
4Rx.com	www.worldexpressrx.com
4Rx.com	www.4rx.com
800-MEDS	www.800-meds.com
800-Pharmacy.com	www.800-pharmacy.com
90-day Supply	www.90-daysupply.com
ABCOnline Pharmacy	www.abconlinepharmacy.com
AccessRx	www.blue-pill.com
AccessRx	www.bigmeds.com
AccessRx	www.privatepills.com
AccessRx	www.coloradomeds.com
AccessRx	www.radiomeds.com
AccessRx	www.consumermeds.com
AccessRx	www.peoplemeds.com
AccessRx	www.tvmeds.com
AccessRx	www.medstoday.com
AccessRx	www.accessrx.com
Aclepsa.com	www.aclepsa.com
Aclepsa.com	www.viagraclones.com
AdvCare Pharmacy	www.adv-care.com
AFFORDAPHARMA	www.affordapharma.com
AlliedPharmaWorld	www.alliedpharmaworld.com
America Pharmacy World	www.americapharmacyworld.com
America1rx.com	www.america1rx.com
American Drug Club	www.americandrugclub.com
American Nutrition Inc.	www.americannutrition.com
Americanameds.com	www.americanameds.com
Anabolic Labs	www.anaboliclabs.co.uk
Anabolics Supplementary	www.anabolics-steroid.net
Anabolics-Supplements.com	www.synthethic-androgen.com
Ananbolics-supplement.com	www.anabolic-supplement.com
ApexRx.com	www.pilldrugstore.com
Avoidmiddleman.com	www.avoidmiddleman.com
BM Pharmacy	www.budgetmedicines.com
Bodybuilding.com	www.bodybuilding.com/store
BolixHolix	www.bolixholix.com
Burrendah Pharmacy	www.burrendahpharmacy.com
Buy Viagra Online	www.buy-viagraonline.com
BuyDeca Durabolin	http://buydecadurabolin.com
Buyephedraonline.com	www.buyephedraonline.com

BZPSupply.com	http://bzpsupply.com
Canada Discount Rx	www.canadascript.com
Canada Drugs	www.canadadrugs.com
Canada Drugs	www.smartmed.ca
Canada Drugs	www.pharmacycan.com
Canada Drugs	www.libertymeds.com
Canada Drugs	www.economicalrx.com
Canada Drugs	www.directpharmacyrx.com
Canada Drugs	www.usapharmacyservices.com
Canada Drugs	www.redwooddrugs.com
Canada Drugs	www.rx1.biz
Canada Drugs	www.rxcarecanada.com
Canada Drugs	www.valuemartpharmacy.com
Canada Drugs	www.pricemartpharmacy.com
Canada Drugs	www.universalmeds.com
Canada Drugs	www.europeanmeds.com
Canada Drugs	www.onlinerxdrugstore.com
Canada Drugs	www.rxnorth.com
Canada Drugs	www.onlinecanadiandrugstore.com
Canada Pharmacy	www.canadapharmacy.com
Canadian Meds World	www.canadianmedsworld.com
Canadian Pharmacy	www.I-pharmacy24.com
Canadian Pharmacy	www.simple-op.com/index.php
CheapDrugs.com, CheapMeds.com	www.cheapmeds.com
CheapDrugs.com, CheapMeds.com	www.cheapdrugstoday.com
Cipro Pharmacy.com	www.cipropharmacy.com
CrazyMuscle.com	www.crazymuscle.com
Cross Border Pharmacy	www.affordableprescriptions.com
Cross Border Pharmacy	www.crossborderpharmacy.com
CutPriceChemist.com	www.cutpricechemist.com
Cybermedsrx.com	http://cybermedsrx.com
Desktop Pills	www.desktoppills.com
DirectDocLink.com	www.directdoclink.com
Discount Drugs from Canada	www.discountdrugsfromcanada.com
DISCREET-PHARMACY.com	www.discreet-pharmacy.com
DoctorSolve	www.doctorsolve.com
dotcomScripts.com	www.dotcomscripts.com
dotdrugstore.com	www.dotdrugstore.com
DrugsFromCanada.com - Prescriptions Direct	www.drugsfromcanada.com
DrugsWell	http://drugswell.com
E Prescribe	www.eprescribe.com
E3R Information System Pvt. Ltd.	www.1vermainfo.e-trusted.com
Easierrxmeds.com	www.easierrxmeds.com
Easy MD	www.discount-rx.net
elegalhighs.com	www.elegalhighs.com
Elitepharmashop	http://elite-pharmashop.com
e-Pharmacity	www.e-pharmacity.com
Eprescriptions.com	www.eprescriptions.com
Eprescriptions.com	www.americanpharmacy.com
European Rx Pharmacy	www.europeanrxpharmacy.com
EverythingPills.com	http://everythingpills.com
Express Pharmacy	www.express.expresspharmacyonlin e.com

EzDocLink.com	www.ezdoclink.com
EzDocOnline.com	www.ezdoconline.com
EzMedLink.com	www.ezmedlink.com
EzPharmaLink.com	www.ezpharmalink.com
Finpecia/Generic Finasteride	http://generic-finasteride.tripod.com
FitnessMed.net	www.fitnessmed.net
Freedom-Pharmacy.com	www.freedom-pharmacy.com
FrontierPharmacies.com	www.frontierpharmacies.com
FrontierPharmacies.com	www.feelingfattoday.com
Generic-Pharmacy.net	www.generic-pharmacy.net
genuinegenerics	www.genuinegenerics.com
Gererics.ws	www.generics.ws
Group-Rx.com	www.group-rx.com
Guaranteed Supplements.com	www.guaranteedsupplements.com
HBEES	www.hbees.com
Health Solutions Network	www.PrescriptionsKeyWest.com
Hello Pharmacy.com	www.pharmacyworldwide.biz
Imperialpills.com	www.imperialpills.com
International Antiaging Systems Ltd (IAS Offshore Pharmacy)	www.antiaging-systems.com
Israel Online Meds	www.israelonlinemeds.com
just ephedrine	http://sankuarydesign.com/justephe
drine	
KIMS Pharmacy	http://stores.kimspharmacy.net
Littlebluepill.net	www.littlebluepill.net
LowCostMeds24-7.com	www.canadianpharmacy24-7.com
Main Meds Online.com	www.yourprescriptionforless.com
Main Meds Online.com	www.mainmedsonline.com
MedHaven.net	www.medhaven.net
Medical Discounts International Inc.	www.wecaremedicalmall.com
MedicalTouch.net	www.medicaltouch.net
MedPrescribe.com	www.medprescribe.com
Meds Discount	www.meds-discount.com
MedStore	http://www.medstore.biz
MedzOnline.com	www.medzonline.com
MexicoRXstore.com	www.mexicorxstore.com
mexmeds4you.com	www.mexmeds4you.com/contactus.
asp	
MK Medical Services	www.mkmedicalservices.com
My Pharma Stop	www.mypharmastop.net
MyDrugstorePlus	www.mydrugstoreplus.com
MyFirstPharma	www.myfirstpharma.com
MyPharmaCentral	www.mypharmacentral.com
MyPharmaNow	www.mypharmanow.com
MyPharmaOne	www.mypharma1.net
MyRxScripts	www.myrxscripts.com
MySaveMeds.com	http://mysavemeds.com
neopills	www.neopills.com
NetPrescribe.com	www.netprescribe.net
NoPrescriptionPharma.com	www.noprescriptionpharma.com
Offshore Pharmacy	www.offshorepharmacy.net
Online Health Pharmacy	www.online-health-pharmacy.com

Online Ordering and Consulting for Prescription Drugs	www.aplusviagra.com
Order-Rx	www.order-rx.com
PharmSite	www.canadian-drugs-shop.com
PharmSite	www.allpills.net
PHD PharmacyRX	http://phdpharmacyrx.com
Phentermine	www.phentermine-discreet.com
pill quest	www.pillquest.com
PillDeals.com	www.pilldeals.com
Pillman.com	www.idealmeds.com
Pills for all	www.pillsforall.com/
Pills-For-Less.com	www.pills-for-less.com
Pillsourcemd.com	www.pillsourcemd.com
Planetdrugsdirect.com	www.planetdrugsdirect.com
PlanetSkunk	www.planetskunk.com
Pot Seed Bargains.com	www.potseedbargains.com
PremiumRx.com	www.premiumrx.com
PrescripNet.com	www.PrescripNet.com
PricePills.com	www.pricepills.com
PriorityDrugs.com	www.prioritydrugs.com
PriorityPills.com	www.prioritypills.com
PrivacyPharmacy.com	www.privacypharmacy.com
ProFarmacia	www.profarmacia.com
Propecia For Less	www.propeciaforless.com
PropeciaPharmacy	www.propeciapharmacy.com
ProzacPharmacy	www.prozacpharmacy.com
RapidMedsOnline.com	www.rapidmedsonline.com
Raremeds.com	www.raremeds.com
Real Medical	www.real-medical.com
Renee Boje Legal Defense Fund	www.reneeboje.com/donations.html
RFDrugstore.com	www.realfastdrugstore.com
RFDrugstore.com	www.rfdrugstore.com
RoyalCanadianMeds.com	www.royalcanadianmeds.com
Rx Go Express	http://rxgoexpress.es.tl
Rx2world.com	www.rx2world.com
Rx4Us	www.rx4us.com
Rxdirectdrugs.com	www.rxdirectpharmacy.com
RxMart.com	www.rxmart.com
RxMedsCanada	www.RxMedsCanada.com
Rx-now	www.rx-now.com
RxUSA.com	www.rxusa.com
Rx-Web	www.rx-web.com
Safe Pharmacy	www.safepharmacy.com
Safe Web Medical.com	www.safewebmedical.com
Salvia World	www.salviaworld.com
Senior Rx Care	www.canadianpharmacyservice.com
Senior Rx Care	www.seniorrxcare.com
Ship Rx Canada	www.shiprx.com
Shop Anabolic Online Steroids Store	www.shopanabolic.com
SILAGRA 100	www.silagra100.com
SimplePharmacy.com	www.simplepharmacy.com
Smart Choice Pharmacy	www.smartchoicepharmacy.com
Spanien Express	www.spanienexpress.org
Steroids Express	http://steroids-express.com
Summitmeds	www.summitmeds.com

supreme-pharmacy.com	www.supreme-pharmacy.com
SureDocLink.com	www.suredoclink.com
Sureway	www.sureway.com
The Canadian Drug Store	www.tcds.com
The Free Garage Sale	www.freegaragesale.net/medic.htm
ThriftyMedsNow.com	www.thriftymedsnow.com
Top-Pharmacies.com	www.rx-product.com
Top-Pharmacies.com	www.rx-list.com
Top-Pharmacies.com	www.prescription-drug.net
Total Meds	www.xanax4less.com
TriChrome World	www.trichomeworld.co.uk
Turbo Drugs	www.turbodrugs.com
Turbo Meds	www.turbopills.com
Turbo Meds	www.turbomeds.com
Turbo Pharmacy	www.turbopharmacy.com
UltimateRx.com	www.ultimaterx.com
United Pharmacies	www.menspharmacy.com
United Pharmacies	www.unitedpharmacies.com
United Pharmacies	www.hairpharmacy.com
United Pharmacies	www.slimmerspharmacy.com
United Pharmacies	www.womenspharmacy.com
United Pharmacies	www.lifepharmacy.com
United Pharmacy	www.united-pharmacy.com
Universal Drugstore	www.medisavecanada.com
UPS - United Prescription Service	http://unitedprescriptionservice.com
Urban Shaman Etheobotanicals	www.urbanshaman.net
US Can Pharmacy	www.uscanpharmacy.com
US Value Pharm	www.drug-store-outlets.com
US Value Pharm	www.us-value-pharm.com
USA Prescription	www.usaprescription.com
USADrugonline.com	www.usadrugonline.com
USARx.com	www.usarx.com
ValMeds	www.valmeds.com
Value Pharmaceuticals	www.valuepharmaceuticals.com
Viagra Online Pharmacy .com	www.viagraonlinepharmacy.com
Viagra.com.ua	www.viagra.com.ua
ViagraOnlinePharmacy.net	www.viagraonlinepharmacy.net
viagraonlinestore.com	www.viagraonlinestore.com
ViaMedic	www.viamedic.com
Viapro.com	www.via100.com
Viapro.com	www.viapro.com
Vidrin	www.vidrin.com
Vidrin	www.vidrin.biz
Watson's Pro	www.watsonspro.com
WorldCheapestGenerics.com	www.herbalviagracialis.com
Worldwide Value Meds	www.canadavaluemeds.com
XL Pharmacy	www.xlpharmacy.com
XL Pharmacy	www.supervalue-rx.com
Yartook.com	www.yartook.com
Yasmin	www.buyyasmin.com
YourSafeMed.com	www.yoursafemed.com
Zopiclone4sale	www.zopiclone4sale.com

Ohio Testimony - Addendum 2

OHIO REVISED CODE (Laws)

4729.551 Licensing of retail sellers.

Each person, whether located within or outside this state, who sells dangerous drugs at retail for delivery or distribution to persons residing in this state, shall be licensed as a terminal distributor of dangerous drugs pursuant to sections 4729.54 and 4729.55 of the Revised Code.

The board of pharmacy may enter into agreements with other states, federal agencies, and other entities to exchange information concerning the licensing and inspection of terminal distributors of dangerous drugs who are located within or outside this state and to investigate any alleged violations of the laws and rules governing the legal distribution of drugs by such persons.

Effective Date: 07-21-1994

OHIO ADMINISTRATIVE CODE (Administrative Rules)

Rule 4729-9-24 Retail And Wholesale Sales Of Dangerous Drugs On-Line (Ohio Pharmacy Board Rule)

(A) All persons selling or offering to sell dangerous drugs at retail or wholesale in Ohio must be licensed or registered with the Ohio state board of pharmacy as a dangerous drug distributor.

(B) All dangerous drug distributors registered or licensed with the Ohio state board of pharmacy and who sell or offer to sell dangerous drugs at retail or wholesale on the "Internet" to persons located in Ohio or any other state must make such sales only in compliance with all state and federal laws governing the legal distribution of dangerous drugs.

(C) "Internet" sites owned and/or maintained by Ohio registered or licensed dangerous drug distributors must provide the following information to the public on the "Internet" site and no drugs are to be shipped at wholesale or retail except in accordance with Ohio's drug laws:

(1) Name dangerous drug distributor is licensed to do business as in Ohio.

(2) Full address of licensed or registered site.

(3) Name of responsible person as it appears on the dangerous drug distributor license.

(4) Telephone number where responsible person may be contacted.

(5) A list of the states in which the dangerous drug distributor may legally sell prescription drugs at wholesale or retail.

(6) The name, address, and how the drug law enforcement agency may be contacted in each state in which the person is authorized to do business. This may include a link to the drug law enforcement agency's "Internet" site and/or their e-mail address.

(D) Any Ohio licensed or registered dangerous drug distributor requesting personal information from the public by way of the "Internet" site (questionnaire forms or e-mail) must provide for security and confidentiality of the information. This portion of the "Internet" site must also provide information regarding how the personal information will be used, pursuant to all federal and state laws, rules, and regulations, and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

HISTORY: Eff 3-1-99; 1-1-04

4731-11-09 Prescribing to persons not seen by the physician. (Ohio Medical Board Rule)

(A) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

(B) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any dangerous drug which is not a controlled substance to a person who the physician has never personally physically examined and diagnosed, except in accordance with the following requirements:

(1) The physician is providing care in consultation with another physician who has an ongoing professional relationship with the patient, and who has agreed to supervise the patient's use of the drug or drugs to be provided; and

(2) The physician's care of the patient meets all applicable standards of care and all applicable statutory and regulatory requirements.

(C) A physician shall not advertise or offer, or permit the physician's name or certificate to be used in an advertisement or offer, to provide any dangerous drug in a manner that would violate paragraph (A) or paragraph (B) of this rule.

(D) Paragraphs (A) and (B) of this rule do not apply to or prohibit the provision of drugs to a person who is admitted as an inpatient to or is a resident of an institutional facility. For purposes of this rule, "institutional facility" has the same meaning as in rule 4729-17-01 of the Administrative Code. This paragraph does not authorize or legitimize practices that would violate other applicable standards or legal requirements.

(E) Paragraphs (A) and (B) of this rule do not apply to or prohibit:

(1) The provision of controlled substances or dangerous drugs by a physician to a person who is a patient of a colleague of the physician, if the drugs are provided pursuant to an on call or cross coverage arrangement between the physicians;

(2) The provision of controlled substances or dangerous drugs by a physician to a person who the physician has accepted as a patient, if the physician has scheduled or is in the process of scheduling an appointment to examine the patient and the drugs are intended to be used pending that appointment;

(3) The provision of controlled substances or dangerous drugs by emergency medical squad personnel, nurses, or other appropriately trained and licensed individuals, in accordance with protocols approved by the state board of pharmacy pursuant to rule 4729-5-01 of the Administrative Code; or

(4) The provision of controlled substances or dangerous drugs by a nurse practicing in accordance with a standard care arrangement that meets the requirements of Chapter 4723. of the Revised Code and rules promulgated by the board of nursing pursuant thereto.

(5) The provision of controlled substances or dangerous drugs by a physician who is a medical director or hospice physician of a hospice program licensed pursuant to Chapter 3712. of the Revised Code, to a patient who is enrolled in that hospice program. This paragraph does not

authorize or legitimize practices that would violate other applicable standards or legal requirements.

(F) For purposes of this rule, "controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(G) For purposes of this rule, "dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(H) A violation of any provision of this rule, as determined by the board, shall constitute "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

Effective: 08/31/2006

R.C. 119.032 review dates: 05/18/2006 and 08/31/2011

Promulgated Under: 119.03

Statutory Authority: 4731.05

Rule Amplifies: 4731.22

Prior Effective Dates: 10/1/99

Mr. SCOTT. Thank you.

I want to recognize the fact that the gentleman from North Carolina, Mr. Coble, and the gentleman from California, Mr. Lungren, have joined us.

Mr. Egan?

TESTIMONY OF PATRICK J. EGAN, ATTORNEY-AT-LAW, FOX ROTHSCHILD, LLP, PHILADELPHIA, PA

Mr. EGAN. Good afternoon, Mr. Chairman and distinguished Committee Members. Thank you very much for the opportunity to present this testimony. It is with great honor that I do this, and I appreciate the invitation very much.

I would like to note that the views that I am expressing are my personal views and not those of the firm that I practice with.

I am here to discuss the big picture of the Internet pharmacy and how it works into the overall health-care issues that this country faces. Because, for every action, there is an equal and opposite reaction. We have all been taught that since we were children. And the fact of the matter is that the Committee and Congress has focused, I believe, and certainly the bill in the Senate focuses on one area of the issue without looking at the bigger picture.

At this particular time, what we really need to address is whether the Internet pharmacy system, as it presently exists, is one which is benefiting only those who wish to abuse controlled substances and those who wish to deal drugs to them, or whether it is also benefiting the larger public who has health-care issues that need to be addressed.

And I believe that there has not been any type of empirical research done which would indicate that the majority of people who purchase prescription drugs via the Internet are doing so to abuse them or whether they are individuals who could not otherwise avail themselves to access to those prescription drugs.

For instance, in this country there are many people who live in rural areas where it is a long way to go to get to a doctor. In this country, as we know all too well, there are many uninsured and underinsured individuals who do not have access to go to a doctor and obtain a visit when they need to get prescription drugs.

We have two major problems in this country on the health-care level. One of them is obesity, and another is pain. Many, many thousands of people die from obesity every year. What Congress appears to be doing here is focusing on the issue of drug abuse and those individuals who suffer from drug abuse, which is indeed a tragedy, without considering what the actions that might be taken, what effect they may have on the ability of others to obtain health care.

An additional concern that I believe should be addressed is whether, by passing legislation which criminalizes this type of behavior, what you are really doing is forcing those who would obtain prescription drugs and controlled substances illicitly through the Internet away from sites that are run by legitimate, licensed pharmacies in the United States to sites that are run offshore, where we have no control, where all of the evidence indicates that the majority of the drugs are often counterfeit.

And, indeed, if you look at the particular bill that was passed by the Senate, essentially what it does is it asks the DEA to go and take a look at what happens with regard to these offshore Web sites.

But there is no means for any control over them, because they are offshore. What you are going to do is take the model that is presently taking place in this country and you are going to take that model away, which is going to drive people who either need pain medication or diet medication to these offshore sites and away from sites that are presently operated in what might not appear to be traditionally the way that it would have been done but, with the issues that are facing this country and the technological advances, may well turn out to be a model that might work for the future.

There are presently Internet pharmacies operating in this country where you are able to obtain a prescription drug without a face-to-face visit with a doctor. The DEA has termed that not a valid prescription. The question is whether you want to codify that in the law. And that is what is being suggested to you by some of the other distinguished people on this panel.

I would suggest that when you look at the best approach that it would be to regulate further those pharmacies, rather than to criminalize their behavior. For instance, there are computer programs whereby pharmacies can have a check on addresses and make sure that they are not sending back to the same address any sooner than they should within the period that those drugs would be used. So if an individual at this address orders a drug on day 1 and tries to come back and order on day 3, they are refused.

There are pharmacies that are run by licensed pharmacists and there are doctors who are licensed doctors reviewing these questionnaires, and they are not being paid more to grant every single description. They are being paid by the review. If you have that in place, you have licensing authorities who can exercise control over these people. But if you criminalize that behavior, that particular section of the industry will disappear, and, instead, what you will have is only offshore pharmacies.

Moreover, I would like to echo the statements that were made at the start of this by some of the distinguished Members of Congress. For decades, Congress has fought to curb drug abuse. I would suggest that, for decades, Congress has fought to curb drug abuse through the imposition of more serious penalties and mandatory minimum sentences. And I would suggest that the empirical evidence is that, for decades, that has failed.

The time has come to look at appropriate regulations that can actually handle these problems without locking up millions, thousands, whatever the numbers are, of people. And the mandatory minimum that is attached to this bill has nothing to do with Internet pharmacies. And, to me, the legislation smacks of the 1980's, not of 2008, when we need to take an intelligent approach to these problems.

[The prepared statement of Mr. Egan follows:]

PREPARED STATEMENT OF PATRICK J. EGAN

Testimony of Patrick J. Egan, Esquire
"Online Pharmacies and the Problem of Internet Drug Abuse"
June 24, 2008

Overview

The "Ryan Haight Pharmacy Consumer Protection Act" S.980[1] (hereinafter the "Proposed Bill"), if implemented, would have a negative impact on the policy issue of safe delivery of controlled substances to United States patients at a reasonable cost. Additionally, the Proposed Bill through criminalization of the sale of controlled substances without a "valid prescription" by "online pharmacies" fails to attack the source of addiction to prescription medication. Drug users have multiple superior sources to acquire prescription medication and do not receive adequate treatment while incarcerated.

The Proposed Bill would disproportionately effect millions of Americans who cannot afford medical care and prescription medicine by impacting the significant benefit U.S. patients receive from the purchase of medications through online pharmacies without what the bill and DEA term a "valid prescription." Furthermore, the Proposed Bill directly impacts the ability of Americans to treat chronic pain, which affects up to 85% of adults at some point in their lives,[2] and obesity, which affects 66% of the population.[3] An estimated 300,000 premature deaths are caused by obesity each year[4], while an estimated 146,377 deaths from the period 1979-1998 are caused by arthritis.[5] We do not seek to marginalize the 26,000 citizens [6]who die from the total effects of all drugs each year (Nonmedical use of prescription medicine included), however for the greater pubic good, the ability to purchase prescription medication from "online pharmacies" without the need to visit a doctor grossly outweighs the cost to society.

Finally, the Proposed Bill follows the erroneous policy path of increased prison sentences for drug offenses that has so clearly been the hallmark of the failed "War on Drugs". As such the provisions of the Proposed Bill which call for increasing maximum sentences and a review of the guidelines by the Sentencing Commission reflect thinking that is more in tune with 1980 than 2008.

I. The Proposed Legislation Detracts From The Policy Goal of Safe Delivery of Controlled Substances To Patients At Reasonable Cost

The Proposed Bill would negatively impact the safe delivery of controlled substances to patients at a reasonable cost because many Americans would be forced to purchase medication from offshore sources which have a higher propensity to purchase counterfeit medication.[7] Additionally, the restrictions would raise the cost of obtaining prescription medication. In 2005 , the United States spent 16%, 1.7 trillion dollars (up from 14% in 2000) of Gross Domestic

[1] S. 890, 110 th Congress § 2 (as passed by Senate, April 1, 2008).
[2] Joseph Curran, *Prescription For Disaster*, State Office of Attorney General (September 2005) (internal citations omitted).
[3] *Health, United States, 2007*, U.S. Department of Health and Human Services, 40 (2007) *available at* http://www.cdc.gov/nchs/data/hus/hus07.pdf. (Internal Citations Omitted)
[4] *Id. Health, United States, 2007.*
[5] *Arthritis Types- Overview* (2008), http:www.cdc.gov/arthritis/generic.htm
[6] S. 890, 110 th Congress § 2 (as passed by Senate, April 1, 2008).
[7] Mary Shepard, *Vulnerable Points In the U.S. Drug-Distribution System,* Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).

Product (GDP) on health care.[8] Of this money, 12% was spent on prescription drugs, 25% on physician care. Out-of-pocket expenditures for health care cost Americans $236 billion.[9]

The majority of Americans choose not to report healthcare problems to health care providers due to costs. Over 40 million (19%) Americans 18 years of age and over failed to receive one or more of the following health care services in the past year because they could not afford them; medical care, prescription medicines, mental health, dental care, or eyeglasses. From 1997-2005, the percentage of adults rose from 6%-9% because of the inability to afford prescription medicine.[10]

These combined financial considerations make "online pharmacies" that do not require doctors visits an attractive source of healthcare for millions of Americans. Therefore, the Proposed Bill is not the appropriate response to drug abuse in the United States.

A. The Proposed Bill Would Increase U.S. Patient Costs.

The Proposed Bill would negatively impact millions of Americans that are presently unable to afford medical care and prescription medicine. The act would contribute to the disparity between Americans that can afford medical care through the traditional channels and those that cannot. In total, Americans spend an estimated $1.7 trillion in health care.[11] Specifically, an estimated $236 billion was spent out-of-pocket because of lack of insurance coverage, deductible, or copayment. Furthermore, an estimated $200 billion was spent on prescription medication, including an estimated $40 billion being spent out-of-pocket.[12] Interestingly, Americans have spent $650 million dollars a year in purchases from Canadian Internet Pharmacies.[13] This is attributed to the significant aging of the U.S. population, a U.S. pharmaceutical free market that permits drug manufactures to determine the market price, and the limited U.S. public and private health insurance plans.[14] 77% percent of Americans deem it unreasonable for Congress to stop Canadian pharmacies form selling drugs to Americans over the internet.[15] The following are significant groups that would be adversely affected by the Proposed Bill.

1. Nonmetropolitan Areas

Americans that live in nonmetropolitan areas have substandard access to physicians and have no other alternative than to forego medical care and prescription drug use or make costly trips to doctors in other counties. According to the CDC, the shortage of physicians in

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[8] *See id. Health, United States, 2007, supra* note 3
[9] *Id.*
[10] *See id. Health, United States, 2007, supra* note 3
[11] *See id. Health, United States, 2007, supra* note 3
[12] *See id. Health, United States, 2007, supra* note 3
[13] Jillian Claire Cohen, *Public Policy Implications of Cross-Boarder Internet Pharmacies*, Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).
[14] Paul Saatsoglou, *Pharmaceutical Reimporation: Magnitude, Trends, and Consumer*, Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).
[15] *See* Cohen, *supra* note 13.

nonmetropolitan areas is a deterrent to timely and appropriate healthcare.[16] 50 million Americans (17% of the U.S. population) live in nonmetropolitan counties. Additionally, 4% of counties in the U.S. have no physicians and an additional 7% classified as health profession shortage areas ("HPSA").[17]

The Proposed Bill would increase the deterrent of Americans in nonmetropolitan areas seeking any medical care or prescription drugs at all. "Online pharmacies" that do not need "valid prescriptions" enable these individuals the ability to interact with doctor's and healthcare providers online to receive prescription medicine at a reasonable cost. The "online pharmacy" is a new innovation that would avail individuals in nonmetropolitan areas access to healthcare and reduce the deterrent factor to seeking healthcare. The Proposed Bill would increase the overall cost to the 50 million lower- income Americans by having to get transportation to other counties. These, individuals should not receive substandard care because of the proportionately smaller risk of the use of prescription medicine for nonmedical use.

2. Americans Without Insurance

"Online Pharmacies" that do not require a "valid prescription" decrease the cost for uninsured Americans to receive medical care and prescription medicines. Americans with low incomes do not have consistent insurance coverage throughout the year. As recent as 2005, 20% of people under 65 have been uninsured for at least 12 months prior to the CDC study.[18]

Uninsured Americans are more likely to forego the use of medical care and prescription drugs.[19] These individuals are three times as likely not to have had a doctor's visit in the past three-years. The Proposed Bill would foreclose any chance for the uninsured population to receive medical care and prescription medicines. The ability for the uninsured to purchase cheaper medications from U.S. "online pharmacies" without a "valid prescription" is a valid option for the uninsured to obtain prescription medicine. If the uninsured were forced to go to doctors to get a "valid prescription," the uninsured would not go at all because these individuals can clearly not afford medical care. Thus, "online pharmacies" give uninsured Americans a unique benefit not offered elsewhere.

3. Lack of Sufficient Insurance Coverage

An estimated 62% of U.S. population that purchase prescriptions outside of the U.S., even though these individuals had prescription drug coverage.[20] Studies suggest that Americans need to buy medical prescriptions through "online pharmacies" because of high copayments, annual deductibles, and the rising cost of prescription medication.[21] Individuals in the range of 65-74 age group are 22% more likely to purchase prescription medicine outside of the U.S. All

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[16] *See, Health, United States, 2007, supra* note 3
[17] *See, Health, United States, 2007, supra* note 3
[18] *See, Health, United States, 2007, supra* note 3
[19] *See, Health, United States, 2007, supra* note 3
[20] *See* Saatsoglou, *Pharmaceutical Reimporation: Magnitude, Trends, and Consumer, supra* note 14.
[21] *Id.*

of these factors contribute to the estimated $650 million dollars spent a year in Canadian "online pharmacies."[22]

4. Individuals That Have Forgone Medical Care Due To Cost

Individuals with and without insurance tend to forego needed medical care because of cost. The cost of health insurance, deductibles, copayments, and prescription medicine financially prevents an estimates 2%-10% of Americans from receiving any medical care.[23] The following represents the percentage of people and age demographic that did not receive health-related services because of cost;

	Americans That Have Forgone Medical Care Due To Cost			
		Age Demographic		
		18-44 years	45-64 years	65 years and over
Service	Medical Care	8.10%	7.70%	2.50%
	Prescription Medicine	9.80%	8.70%	5.10%

The Proposed Bill would potentially increase the already substantial number of Americans that do not receive any medical care and prescription medicine. More Americans could succumb to this category if prevented from purchasing prescription medicine from "online pharmacies" without a "valid prescription." If the concern is overall health of Americans, the Proposed Bill would potentially work to the detriment of the whole, for the illusory benefit of requiring a prescription to purchase pain medication and other controlled substances online.

B. Safe Delivery of Controlled Substances

Although the FDA could potentially have greater control over the delivery of controlled substances to Americans, the effect of the Proposed Bill would force more Americans to purchase prescription medicines offshore, where the risk for counterfeit medications is higher. U.S. pharmacies and wholesalers are subject to rigorous prescription drug access and control.[24] A counterfeit drug is "deliberately and fraudulently mislabeled with respect to identity and or

[22] *Id.*
[23] *See, Health, United States, 2007, supra* note 3.
[24] Michael Dickson, *International Pharmaceutical Expenditure Differentials: Why?*, Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).

source."[25] Marv Shepard, PhD, the Director of the Center for Pharma-economic Studies at the College of Pharmacy at the University of Texas, states that this is a global problem, with the leading countries China, India, Russia, Brazil, Pakistan and Mexico.[26] Dr. Shepard continues to state that Americans are continually searching for cheaper and cheaper prescription drug access in these leading countries and exposing themselves to risk.

The proposed bill would further exacerbate the problem. Americans cannot presently afford the price of prescription medication provided through traditional sales channels available in the U.S. The requirement to receive a "valid prescription" would increase the overall out-of-pocket expenses for medical care and prescription medication. Therefore, if the Proposed Bill is passed, the increase cost of prescription drugs to Americans could actually force them to purchase greater numbers of prescription medication offshore. The countries listed above have significantly higher rates of counterfeit drugs. This could, according to Dr. Shepard, "result in more deaths, disabilities, and continued destabilization of our safe drug-distribution system."[27]

In conclusion, the Proposed Bill would have the cumulative effect of increasing the cost of controlled substances to U.S. patients. Additionally, the Proposed Bill would force Americans to pursue unsafe international channels of prescription drug trade and cause more deaths and disabilities.

II. The Benefits and Risks of Controlled Substances Sold Through "Online Pharmacies" without a "Valid Prescription"

Acting under the assumption that controlled substances used for medical purposes improve the lives of the patient, the benefits of prescription medicine sold by "online pharmacies" without the need for a "valid prescription" significantly outweigh the risks of abuse for nonmedical purposes, especially in teens. According to the U.S. Senate Resolution of the 109th Congress, 2D session, an estimated 26,000 citizens die from the effects of drug abuse each year.[28] In 2006, 17.4% of the seventeen-year old population had used pain relievers for non-medical use.[29] However, a majority of the pain medication used for nonmedical use are mild pain relievers, i.e. Vicodin rather than "Dilaudid."[30] In addition to pain medication, diet pills are commonly purchased through "online pharmacies." Although a percentage of youths have tried pain relievers and diet pills for nonmedical purposes, the majority of these drugs are obtained from friends and relatives, not online pharmacies. The benefit to low-income Americans, obese Americans, and elderly Americans to have the ability to purchase prescription medicine from "online pharmacies" without the need for a "valid prescription" grossly outweighs the risk to adults and teens purchasing pain medication from "online pharmacies."

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[25] Marv Shepard, *Vulnerable Points In the U.S. Drug-Distribution System,* Supplement to Managed Care, Vol. 13, No. 3 (2004) (*citing* World Health Organization, (1999)).
[26] *Id.*
[27] Marv Shepard, *Vulnerable Points In the U.S. Drug-Distribution System,* Supplement to Managed Care, Vol. 13, No. 3 (2004) (Internal Citations Omitted).
[28] National Vigil for Lost Promise, 109th Cong. § (2006).
[29] *Nonmedical Use of Pain Relievers in Lifetime, Past Year, and Past Month, by Detailed Age Category: Percentages*, (2008) http://www.drugabusestatistics.samhsa.gov/NSDUH/2k6NSDUH/tab
[30] *Id.*

Testimony of Patrick J. Egan, Esquire
"Online Pharmacies and the Problem of Internet Drug Abuse"
June 24, 2008

A. The Risk To Teens

Implementing the Proposed Bill would not change the drug seeking behavior of teens or the supply of prescription medication for nonmedical purposes. Youths receive a majority of prescription medication by theft from friends or relatives that have a prescription, "doctor shopping," prescription fraud, and irresponsible doctors.[31]

The Office of National Drug Control Policy reports that seventy-percent (70%) of teens get the products from friends and relatives.. Furthermore, sixty-four-percent take the prescription pain relievers without the knowledge of the friends or relatives. More than three in five teens say they got prescription pain relievers from parents' medicine cabinets. Lastly, users 12 and older received prescription pain relievers and used them for nonmedical purposes from their doctors.[32]

The National Drug Control Strategy comments upon the Ohio Prescription Monitoring Program that attributes "doctor shopping" as a predominant factor and means of getting prescription medication for nonmedical use.[33] Additionally, the Attorney General of Maryland cites prescription fraud, i.e. pharmacy intern stealing pills from the pharmacy, as a means of obtaining prescription meds.[34] Lastly, doctors individually contribute to the distribution of pain medication for nonmedical purpose. Recently a New Jersey doctor was found guilty of conspiracy to distribute oxcycodone.[35]

Therefore, the minor impact of requiring "online pharmacies" to only distribute controlled substances with a "valid prescription" would not be attacking the true and majority source of nonmedical use of pain relievers. The most efficient means of attack are through parenting, education and supervision. Moreover, those adolescents who are inclined to purchase controlled substances through "online pharmacies" will continue to do so. Only now the drugs they are purchasing will be from off-shore pharmacies and will be more likely to be adulterated or counterfeit.

B. The Benefits to Patients

1. Chronic Pain Management

Conversely, with a new record high in 2006 of life expectancy at birth 78.1 years and a 22,117 decrease in preliminary number of deaths from the 2005 total, individuals are living longer with the need of prescription medicines.[36] In 2005, Stanford University Medical Center in

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[31] Office of National Drug Control Policy, *Prescription for Danger*, http://www.whitehousedrugpolicy.gov/drugfact/prescrptn_drgs/index.html (internal citations omitted).
[32] *Id.*
[33] *Id.*
[34] Joseph Curran, *Prescription For Disaster*, State Office of Attorney General (September 2005) (internal citations omitted).
[35] Office of National Drug Control Policy, *Prescription for Danger*,
[36] *U.S. Mortality Drops Sharply in 2006, Latest Data Show*, U.S. Department of Health and Human Services (2008), http://www.cdc.gov/nchs/pressroom/08newsreleases/mortality2006.htm.

conjunction with ABC News, released a study that states, "[n]ineteen percent (19%) of all Americans suffer from chronic pain lasting three months or more, and 34% endure recurrent pain. Roughly 70% of the 10 million cancer patients in the U.S. suffer from moderate to severe chronic pain.[37] In 2006, the CDC estimated the average annual arthritis prevalence in the civilian "21.6% (41.4 million) adults reported arthritis (50% of persons aged > 65 have arthritis).[38] Adults over 65 account for 80% of the use of at least one prescription drug in the past month. In total, $15.6 billion dollars have been spent on prescription medicine to treat arthritis, and $100 billion annually on chronic pain management, including direct medical expenses, lost income and lost productivity.[39]

The need for more cost effective means for Americans living with chronic pain to have access to pain medication is substantial. Referencing the cost factors listed above, millions of American forego doctors visits and prescription drugs because of the prohibitive costs. The increasing population of elderly Americans on a limited income that suffer from disabling arthritis and chronic pain can more aptly afford "online pharmacies" in the because of the lower prices. A significant amount of the elderly are living below the poverty line because of unexpected out-of-pocket costs and rising healthcare costs. Visiting a physician is not an option for most, and the elderly are in the greatest need for prescription medication. The Proposed Bill would greatly inhibit the financially challenged from obtaining essential medication without solving the problem of teen prescription drug abuse in the U.S.

2. Obesity

Obesity is an epidemic that causes "more than 300,000 premature death each year in the U.S. second only to tobacco-related deaths."[40] Obesity medical expenses account for 9.1 percent of total U.S. medical expenditures in 1998 costing an estimated $92.6 billion dollars in 2002. Obesity is directly related to socioeconomic status, i.e the people that can afford diet pills the least.[41] If anything, the benefit of "online pharmacies" that do not require a "valid prescription" would help curb the increasing trend of obesity in America. Therefore, the Proposed Bill would contribute to the obesity trend in America, the second leading killer of the U.S. population.

In conclusion, although 26,000 citizens die from total drug use, pain medication included, this number pales in comparison to the 300,000 Americans dying from obesity each year, and the 49.2 millions suffering from arthritis. The combined effect of the Proposed Bill would be to force elderly and socio-economically disadvantaged citizens to purchase the cheapest available medication offshore, increasing concerns about counterfeit medicine.

IV. Criminalization of Drugs

[37] *See* Curran
[38] *NHIS Arthritis Surveillance*, http://www.cdc.gov/arthritis/data_statistics/natioanl_data_nhis.htm
[39] *Cost Statistics*, http://www.cdc.gov/arthritis/data_statistics/natioanl_data_nhis.htm
[40] *Id. Health, United States, 2007*
[41] Contributing Factors, *Department of Health and Human Service*, http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors

The Ronald Reagan administration, launched the "war on drugs" policy in 1982. [42] The 1970's left America with high rates of drug abuse, and the Reagan Administration responded with stringent punishment policies rather than drug abuse treatment. By 2004, the number of drug arrests has risen to a record level of 1,846,351, with four of five (81.7%) arrests for possession and only one in five (18.3%) for sales.[43]

A. Increased Sentences

The Anti-Drug Abuse Act of 1986 and the Anti-Drug Abuse Act of 1988 have created a host of severe mandatory minimum sentencing laws for drug offenses. The original legislative intent for the mandatory sentences were to go after "major traffickers" and "serious traffickers." Contrary to the legislative intent, only 1/13 cocaine defendants were classified as "high-level suppliers" and the rest were low-level assistants and purchasers. Between 1988 and 2004, a disproportionally exists between the increases in the average prison sentence for all offenses (8%) and the average prison sentence for drug offense (18%).[44] In 1980, roughly 19,000 (6%) drug offenders in state prisons and 4,900 (25%) in federal prison represented the inmate population. The mandatory minimum sentencing and the abolition of parole has resulted in drug offenders serving much longer sentences.

In 1986, the average drug offender served an average of 22 months in prison. Since the adoption of the mandatory sentences and sentencing guidelines, the average period in 2004 increased to 62 months in prison. As a result of the punitive movement and lengthier sentences since 1980, a twelve-fold increase in drug offenders are doing time in state prison representing 20% of the total inmate population. In federal system, drug offenders represent 55% of all inmates. In total, between state, federal, and local jails, the number of drug offenders in jail has increased by 1100%(493,800).

The Proposed Bill reflects the failed policy position that longer sentences and further criminalization is an effective policy for combating the social problem of drug abuse. The oft-stated definition for insanity is to continue taking the same actions and expecting different results. 25 years of data indicates that legislation of this nature will not solve the problem of prescription drug abuse.

B. Solving The Problem

Currently, more than half the persons in state prison suffer from substance abuse and/or dependence. However in 2004, only one in seven (14.1%) of persons that suffer from substance abuse have received treatment, compared to one in three (36.5%) in 1991. In federal prisons in 2004, 15.2% of persons in with substance abuse have received treatment compared to 33.7% in 1991. Thus, persons in prison that actually need treatment are not receiving it.

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[43] *Quagmire 25 Year Report*
[44] Bureau of Justice Statistics, *Compendium of Federal Justice Statistics, 2004*, December 2006 NCJ 213476

Although the shift in incarceration to treatment is reflected by Congress in 1994 when it adopted the "safety valve" provision that permits judges to sentence offenders below the applicable minimum penalty period if conditions are met, there is still a lack of treatment options in prison. This proposition is reflected by the increase in probation and parole violations as the result of drug use from 1980 (17.6%) to 2004 (34%). It is clear that punitive measures and prison sentences are not fixing the problem.

The Proposed Bill would not solve the problem of prescription medication for nonmedical use in the United States, especially among the young teens demographic. In 2006, the National Survey on Drug Use and Health estimated 12% of 17 year olds have used pain relievers for nonmedical use. However, amending Section 309 of the Controlled Substance Act (21 U.S.C. 829) would not change this. Pain medication abusers have multiple sources for the prescription medicine.

Although stories of teenage prescription medication abuse are well-known in our society, the American public is much less aware of the numbers of Americans that are able to afford prescription medicine through "online pharmacies." Additionally, the American public is not aware of the stringent incarceration rate on minor drug offenders that have no treatment options while in incarceration.

The solution to these problems is not the Proposed Bill. In fact, the Proposed Bill would contribute more to the problems the country is facing, while only solving a small fraction of them. The answer to drug abuse is education, rehabilitation and opportunity for advancement, not stigmatization of offenders and incarceration. By creating a model where a licensed physician reviews an on-line questionnaire and a valid prescription is filled by a licensed pharmacist, some control is maintained over the delivery process. The Proposed Bill would send that system overseas and underground thus exacerbating the problem.

I would like to recognize the assistance of Jason Manfrey, Summer Law Clerk, Villanova Law School Class of 09, in the preparation of this testimony.

Mr. SCOTT. Thank you very much.

We have a vote pending, and we will recess——

Mr. CONYERS. Mr. Chairman?

Mr. SCOTT. The gentleman from Michigan.

Mr. CONYERS. Could I get two cents in before we go?

Mr. SCOTT. The gentleman is recognized for 5 minutes for the purpose of questioning.

Mr. CONYERS. We have been doing a little talking and thinking here. The problem that we have got the hearing on is 1 percent of the total drug problem. The picture that, globally, trafficking globally in drugs is $300 billion; the U.S., it is $65 billion. We spend about $45 billion—I think that includes DEA, as well—in the U.S. fighting it.

And we incarcerate—this year, incarcerated for drug law offenses is 5,233 people so far. About 25 percent of our inmates are serving sentences for drug law violations.

Now, here is why we have a legislative branch: for you to keep doing the same thing over and over and wondering why we are going to get about that many, even if we did it correctly.

Why is this problem so intractable?

These are annual figures, by the way, these billions that I am talking about.

What is it about fighting drugs at the Federal level and at the State level and at the global level? What is happening here? Does Big Daddy know yet? Or does Little Daddy even know? What is going on, folks?

Because the first thing we know, we have got to write a new bill. I am not buying—you know, I was so happy when I came here this morning, Chairman Scott. I said, "Finally, the Senate got ahead of us on something." Well, they did, and they got it wrong. And now we have got to—unanimously wrong. I mean, it wasn't a close question.

So what is happening? You are the experts. We brought you here to tell us.

All right, I am going to pick somebody if you don't volunteer.

Mr. RANNAZZISI. I will jump in.

Where can I begin? The fact is that the drugs that are—I don't know your figures, I don't know where the 1 percent came from. So I am really in the dark as far as where the figures are and how you got them.

However, what I can tell you is that the drugs that are illegally distributed through Internet pharmacies are just as dangerous as any of the other drugs that are distributed on the street. Hydrocodone is a very potent narcotic. It will hurt you just as much as heroin will if taken unsupervised——

Mr. CONYERS. No, I am not questioning the potency of these illegal drugs and legal drugs being pursued commercially illegally. I mean, what is it about the nature of drugs in our culture that make this—I mean, we are spending hundreds of billions of dollars locking up people. We come here with a dozen mandatory sentences to lock up people more and longer. We are already incarcerating more people than anybody on Earth, including China, Russia and anybody else.

That is the problem I want—I don't want an explanation about how potent the drug is.

Mr. RANNAZZISI. I——

Mr. CONYERS. All right, I am calling on somebody else.

Mr. RANNAZZISI. Well, I just, if I could respond——

Mr. CONYERS. That is a good try.

Mr. RANNAZZISI. I——

Mr. CONYERS. All right, Daddy, Big Daddy, what have you got to say? Go Daddy.

Ms. JONES. Thank you.

I don't know why people like to do drugs. It has never been my thing.

I do think that if you are spending $300 billion a year to fight the problem, we are not educating people enough about the dangers of it. Right? So if you give me a tool—all I need is a database that says either you are authorized or you are not authorized to sell drugs online. That is all I need.

I will have to defer to my distinguished colleagues on drug sentencing and whether or not 5 years or 10 years is appropriate for a guy who sells oxycodone to a 12-year-old, okay, but——

Mr. CONYERS. Well, look, I know about your law enforcement background. You are an ex-prosecutor yourself. So don't blame the gentleman to your right.

Ms. JONES. Well, I can tell you when I was a prosecutor, a vast, vast majority of the cases that I tried, drug cases, right? I tried cases in Compton. You may have heard of it before. It is outside Los Angeles. Lots of drug users. You know what? We always had a theory that if we didn't get the guy the first time, that was okay because he was going to be back. So it is a big problem——

Mr. CONYERS. Well, that should have reflected—you got awards for that, I presume.

Ms. JONES. I didn't get any awards. And neither did we seek any awards. That is not why we did it.

But I do think if you are going to take $300 billion a year and spend on this problem, you might take a little bit of it and try educating people about the dangers of using drugs.

Mr. CONYERS. Well, how about prosecuting effectively, as opposed to getting longer and longer sentences? And I agree with you, education is part of it.

Okay, I will give you another chance.

Mr. RANNAZZISI. If we could go back to S. 980 a second, I am kind of confused you suggested that there were minimum mandatories in S. 980. The way I understand S. 980 to be is that they are raising the caps for Schedule 3, 4 and 5 drugs, just raising the cap.

If you look at the guidelines for these drugs, if you are looking at a Schedule 3 drug, if I am not mistaken, I think a level 20 in the guideline runs about 40,000 tablets that you have to be connected to, the distribution of 40,000 tablets——

Mr. CONYERS. So you don't think doubling the sentences is mandatory?

Mr. RANNAZZISI. I think that doubling the sentences is a deterrent, yeah, because right now under the current guidelines——

Mr. CONYERS. I am sure those guys out there look up the statutory sentencing——

Mr. RANNAZZISI. I beg to differ, but I think they do. These are white-collar criminals. These are people who are doing this knowingly and intentionally, using their licenses, their medical licenses——

Mr. CONYERS. Yeah, right, that is who she was locking up out in Compton.

Mr. RANNAZZISI. It is a facade for a medical process that doesn't exist. They are exploiting——

Mr. CONYERS. Okay. And I am sure the white-collar criminals here are very worried about whether there is a mandatory or not.

Mr. RANNAZZISI. I think they—I believe they do.

Mr. CONYERS. So that is why the drug problem is getting worse and worse.

Mr. SCOTT. If you could hold your point, we have got 2½ minutes to get to the floor, and you will be the first—you will get to answer as soon as we get back.

The Committee is in recess.

[Recess.]

Mr. SCOTT. The Committee will come to order.

Mr. Winsley, you were about to say something when I cut you off.

Mr. WINSLEY. Thank you, Mr. Chairman. I just was going to comment on the purpose of the bill in dealing with the drug problem.

The drug problem in the United States is made up primarily of two factors: One is the people that are abusing the drugs, and one is the people that are providing the drugs to them.

The purpose of this bill is to deal with the people that are providing the drugs to them. That is the job of DEA, that is my job, to enforce the laws. We certainly are not opposed to the treatment programs, but we are not part of the treatment programs.

This bill, the criminal penalties that are in it, unless I misread the Federal law, they deal with the trafficking section, not with the abusing section. This bill does nothing to the users. This bill only addresses those that are trafficking. That section of law that is referred to in this bill deals with those who manufacture, distribute, dispense or possess for purposes of manufacturing.

And so I just would point out that this bill will deal with a small part of the problem, but it will deal effectively with the part of the problem that is caused by those people who are trafficking in these controlled substances. And that is a big issue and becoming even bigger.

Thank you, sir.

Mr. SCOTT. Thank you.

The gentleman from California.

Mr. LUNGREN. Thank you very much, Mr. Chairman.

I am sorry that the Chairman of the full Committee is not here because we have had discussions over the years on our approach to drug problems, and one of the complaints that he and others have registered is that we don't go after all drug dealers alike, that it is easy for us to go after drug dealers on the street corner in the inner-city but we don't go after them elsewhere.

It seems to me this bill is an approach to try and deal with another part of the problem, which seems to me we ought to be concerned about, the abuse of prescription drugs, illegally dispensing them, illegally making them available outside the construct of the law that we have set up over the years.

Mr. Egan, I am a little confused about your testimony, and that is this. If I were to take the arguments that you have made against this bill, they would be arguments against the current set of laws that we have with respect to drugs. Is that correct?

Mr. EGAN. I don't think it is necessarily correct, but I do think you could certainly extrapolate that my view is that the war on drugs is a failure and that increased sentences and further criminalization of what is essentially a societal problem has been taking place for over 25 years. And I think the evidence is fairly clear that it is not working and that we, as a society, need to rethink that.

And, frankly, I am hoping that this body will look at that a whole lot more closely and have the courage to maybe try something new.

Mr. LUNGREN. What would you say about the fact that most recent reports suggest that drug use among young people is down?

Mr. EGAN. I would say that it has a lot more to do with education.

For instance, if you take what has been going on in the western states with regard to the use of methamphetamines and the advertising program that has been taking place out there, which has been largely funded by private dollars, which has indicated that the use of methamphetamine has been cut by a great amount through that type of education, and if you look at parenting and education of young people on these issues, those are successful means for attacking the problem.

The problem with criminalization is——

Mr. LUNGREN. So let me ask you this, since you brought up methamphetamine. You would not suggest the decriminalization of methamphetamine, would you?

Mr. EGAN. Well, frankly, I think it is off-point, but——

Mr. LUNGREN. No, no, but you brought it up. So I am asking you a question. Would you think about seriously decriminalizing methamphetamine use and distribution?

Mr. EGAN. I brought it up as an example of how education and advertising and information of that nature is more successful than criminalization.

I don't know necessarily that I would think that it would be wise to decriminalize methamphetamines. I think that we have to make intelligent choices and draw certain lines in certain places.

What I see, however, is a trend for ever-increasing length of sentences, ever-increasing mandatory minimums, ever-increasing "we are going to get tough on this issue" and a lot of money spent. And, frankly, it has become quite an industry, the prosecution of——

Mr. LUNGREN. Okay. I appreciate that. I would take issue with you that it has become an industry, as if those involved in the drug war from the law enforcement side somehow view it as an industry, in the sense that this somehow gives them a means of living and so forth.

Mr. EGAN. I didn't mean to suggest that——

Mr. LUNGREN. Well, we ought to be more careful with what we say about that, because there are a lot of good men and women working in a dedicated way to try and get rid of the scourge of drugs because they have seen what the abuse of drugs does to people in this country, particularly young people. Just about every family has had an experience with someone not too far from them who has been ruined by drugs. And I doubt that anybody is exempt from that.

When you see the devastation that it does to lives, it seems to me that we ought to attempt to try and fight it as best we can. We can have arguments on the margins, but it just seems to me the effort we are making is worth it.

Mr. Rannazzisi, there has been some criticism of the bill before us with respect to the penalties involved. Let me cite a couple of sections to you specifically.

Penalties, section 3(e) imposes mandatory minimum sentences to crimes that did not previously have mandatory minimums, or at least that is the argument. Specifically, the section changes existing law so that small amounts of flunitrazepam are now subject to the same statutory penalties as large amounts.

First of all, is that correct? And what is the reason for this? And how would that be related to the uniqueness of Internet pharmacies?

Mr. RANNAZZISI. Let me preface this by saying I am not an expert on sentencing.

From what I understand of the vision of the bill, the mandatory minimum would only trigger when there is death or serious bodily harm that results from distribution, known distribution of that drug, Rohypnol.

I am not very comfortable answering that question because that is just not my area of expertise, as far as Rohypnol.

Mr. LUNGREN. Okay. Well, the reason I ask that is it is my understanding that this section that it refers to, 21 USC 841(b)(1)(C), as currently written, and with reference through this bill, would impose the mandatory minimum where the prosecution has proven that "death or serious bodily injury resulted from the use of the substance that was unlawfully manufactured or distributed."

So, as I understand it—and I just wanted to know if this was your understanding—if death or serious bodily injury does not result from the unlawful manufacture or distribution of this specific substance, the effect of the bill would not be to have a mandatory minimum. Is that your understanding too?

Mr. RANNAZZISI. That is my understanding, that the mandatory minimum is not triggered. That is——

Mr. LUNGREN. So all I am saying is that we can talk about and argue about mandatory minimums—and I have said that on other statutes I would be willing to look at mandatory minimums, see whether they are appropriate, those that are already in law. But I just wanted to make clear that, in this instance, as I understand this bill, the mandatory minimum only comes into effect where you have death or serious bodily injury resulting from the illegal substance referred to.

Mr. RANNAZZISI. Yes, sir.

Mr. LUNGREN. Some would ask that if pharmacies and physicians are already subject to DEA registration and State licensure, why is this bill needed?

Mr. RANNAZZISI. Because what this bill does is it forces them—the first thing it does is creates a definition for what a valid prescription is. It basically sets out guidelines for what a doctor is responsible for.

The second thing it does—and this is very important to us—is it makes these pharmacies identify themselves on the Web site, so we know exactly who is in the pool. If you asked me right now how many pharmacies, and who are they, distributing by the Internet, I couldn't tell you. I just don't know——

Mr. LUNGREN. If I were to ask you that question about brick-and-mortar pharmacies in a particular State, could you tell me that?

Mr. RANNAZZISI. I could tell you exactly how many brick-and-mortar pharmacies in each State there are. There are about 66,000 retail pharmacies across the country, and I could tell you every one of them if they are DEA-registered.

Mr. LUNGREN. Is that true for you, Mr. Winsley, in your State?

Mr. WINSLEY. Yes, sir. There are a little over 2,000 retail pharmacies——

Mr. LUNGREN. So what we have here is, because of the newness of technology and its application, we have an ability to create distribution centers which are not regulated in any real sense, compared with the regulation we have developed over years with respect to dispensing authorities—that is, pharmacies. Is that correct?

Mr. RANNAZZISI. That is correct.

Mr. LUNGREN. Ms. Jones, you have talked about the number of online pharmacies that you basically, I guess I would say, closed down, but you have done your best to make sure that they are no longer operating with the benefit of Go Daddy.

You had given us some numbers, that, last year, I think it was 1,300, something like that, that you had closed down. And, this year, the first two quarters it has been 6,000?

Ms. JONES. Six thousand.

Mr. LUNGREN. Is that because you are more attentive to it, or is it because you see an explosion in the numbers, number one?

And, number two, do you find that there are individuals that set up multiple such online pharmacies?

Ms. JONES. To answer your first question, it is not that we are more attentive, because we have had an active, 24-by-7 network abuse department that has been responding to these issues for a long time now. What we do see is more third parties reporting instances of online pharmacies to us.

And, by the way, the 6,000 domain names that we disabled in the first 6 months of 2008 came to us by way of spam complaints. Okay? And that is really our only tool right now, is if we know that they are sending out pill spam, the kind of spam that all of us get in our e-mail boxes every day that advertises—well, you know what they advertise.

Mr. LUNGREN. So I should report it to you when I get these, is that right? [Laughter.]

Ms. JONES. Yes, absolutely.

And to answer your second question, we do see——

Mr. LUNGREN. I am afraid to even respond to them, afraid they will get my name. I just get rid of them right away.

Ms. JONES. Just a bit of unsolicited advice: Do not respond. Do not respond and say, "Please take my name off your list." It just proves to them that you actually are a good, valid e-mail address.

But to answer your second question, we do see a core of users who run multiple, multiple, multiple Web sites. So one violator may have 100 Web sites of all varying names and types. They may have some that are devoted to Viagra, some that are devoted to Propecia, some that are devoted to OxyContin, Vicodin, ecstasy. Whatever the name is, they register a domain name that is specifically associated with that particular drug. So we do see repeat, repeat, repeat offenders.

But today there is nothing that makes the content per se illegal. So, like, for example, with child pornography, the National Center for Missing and Exploited Children or the FBI or ICE or another agency can come to us and say, "We know that there is a child pornography site operating on your network; could you please take it down?", and we say, "Absolutely." No questions, no notice, "You go away, because what you are doing is illegal."

That is the kind of tool that we are looking for with the online pharmacy sites, not to disable the valid 2,000 sites in Ohio, but to disable the invalid, counterfeit, no-prescription-needed Web sites.

If we had that tool, then we could just say, "Are you on the list? If you are not on the list, you have to go away until you get your name on the list. It doesn't matter to me where you are. You can be overseas, you can be in any State, could be on the moon, I don't care. Get your name on the list, or you have to go away."

Mr. LUNGREN. Thank you, Mr. Chairman.

Mr. SCOTT. Thank you.

Let me follow up on that. There is no list right now?

Ms. JONES. There is no database that we can hit against to say, "Are you on the DEA's list? Are you on the FDA's list?" We don't have that tool.

Mr. SCOTT. And if there were such a list, you could check it and eliminate them from your site?

Ms. JONES. Correct.

Mr. SCOTT. What power would the Department of Justice have over sites operated in foreign countries?

Ms. JONES. I don't know what power they would have, other than to say, "If you are in another country and you want to sell drugs via a Web site that is available to U.S. users, you have to get your name on this list."

Mr. SCOTT. Well, and if they don't, what enforcement power would Department of Justice have for someone operating a site physically located in, say, Iran?

Ms. JONES. Only that they could call up the domain-name registrar or the hosting provider and say, "They are on the list. Could you please disable this Web site?" Would they have jurisdiction to go pursue the offense? Maybe, maybe not.

Mr. SCOTT. Are there hosting sites outside of the United States?

Ms. JONES. Absolutely.

Mr. SCOTT. And so they would have no jurisdiction over a hosting site physically located outside of the United States?

Ms. JONES. Presumably. I mean, I understand that law enforcement does work with cross-jurisdictional agencies from time to time. We——

Mr. SCOTT. And if it is a country with whom we do not have good diplomatic relations—I think Mr. Egan's point was you would get rid of all the domestic sites and you would force people offshore.

Ms. JONES. Potentially. And we have seen that.

Although, the availability and the ease of access of, for example, not to overuse this, but of child pornography has been effective. It is much more difficult for just your everyday, average user to find a child porn site, because what we have done here is said that content, itself, is per se illegal. And so it forces the users to have user-to-user access, makes it much more difficult for a child, for example, to go find that content.

Mr. SCOTT. Mr. Winsley, we want to allow the legitimate organizations to flourish and not the illegitimate ones. One of the issues is whether or not a face-to-face visit with a prescribing physician is necessary. We have heard that some people live in rural areas where this may not be feasible.

Is a face-to-face visit with a licensed physician necessary?

Mr. WINSLEY. Mr. Chairman, on every occasion, no. However, initially, yes.

Our point is and our State medical board's point—I have included their rule in my written testimony, which has been in existence since the 1990's—our opinion is that there must be an established doctor-patient relationship. That means that the doctor and the patient have come together.

For example, Mr. Chairman, your personal physician, if you are out travelling and you come down with a sinus infection, there is no problem with you calling your personal physician on the phone, saying, "Here is what my symptoms are," lo and behold, he calls in a prescription across State lines to where you are, deals with it. But he knows you. He has already done all the indignities to you that our doctors do to us. [Laughter.]

He has evaluated you. And so there is an established relationship.

Mr. SCOTT. So a requirement that there be at least one face-to-face visit and a valid doctor-patient relationship would be not be a problem even in rural areas?

Mr. WINSLEY. It should not be.

The other issue, Mr. Chairman, is that, in Ohio, we legally define prescription drugs—we call them "dangerous drugs." That is the legal term. The reason for that is that they are well-proven—I think Mr. Rannazzisi pointed this out too—but these drugs are dangerous if they are used inappropriately.

What I point to you in my written testimony is the drugs that the two Internet pharmacies that we most recently dealt with dispensed. And if you look at those hydrocodone products, you will notice that the overwhelming majority of them were the highest strength available.

And yet, I don't know if anybody on the Committee has had recent surgery; I am not asking because of the HIPAA privacy rules.

But I will tell you that I did, and I know a lot of people who have. And when we came out of surgery, the drug that we were prescribed was Vicodin, five milligrams. And that was perfectly adequate.

But every drug-trafficking site that we have been involved with and, in fact, some of the face-to-face drug-trafficking physicians that we have dealt with, the drugs that they have prescribed have always been the hydrocodone, 10 milligrams; the OxyContin, higher level milligram doses, not the doses that normal patients use.

So not only is there not an established doctor-patient relationship, but in many of these cases the patients are using this just to access the highest-strength drugs available.

Mr. SCOTT. If the Internet sites were required to be registered, it would be a State board of pharmacy with jurisdiction over each one that is registered; is that right?

Mr. WINSLEY. There would be.

Mr. SCOTT. And you would be able to have some quality control over what is going on. Which is unlike what is going on now.

Mr. WINSLEY. Mr. Chairman, if we know where they are at, we can reach them.

Mr. SCOTT. So if they are in your State, you would be able to oversee for quality control, so consumers would have some confidence in what they are dealing with. We have heard that some of these out-of-country sites mail in—you wonder why they even bother to mail the drugs. Why don't they just take the money and run? I mean, they close up after 4 months.

But you would be able to provide quality controls so that the consumer has some confidence that they are getting what was prescribed?

Mr. WINSLEY. If they were in my State and we knew about them, yes, sir.

Mr. SCOTT. And, Mr. Rannazzisi, if they are registered, the DEA could do occasional periodic testing to make sure that they are complying with the laws?

Mr. RANNAZZISI. Yes. And they would be identified, and it would help us out in the long run.

Mr. SCOTT. But the consumer could check the list to ascertain whether or not the pharmacy they are dealing with online is actually a legitimate pharmacy and not some fly-by-night something from who knows where?

Mr. RANNAZZISI. But when the consumer hits the Web site, he is going to see exactly who he is dealing with. All that information will be on the Web site. So he could check the list, but it is going to be on a Web site.

Mr. SCOTT. Yes, but the Web site is also on the list so he knows it is not a fraudulent Web site with counterfeit information.

Mr. RANNAZZISI. I think the consumer, if he was worried about that Web site, could cross-check the Web site with the State board of pharmacy, which has that information available. So he would basically be able to know that where he is ordering from is a legitimate pharmacy.

And that really knocks out a lot of the foreign pharmacies then, because if you are hitting a Web site that you know has a DEA reg-

istration number and is licensed by the State board of Ohio, he could check the board, check with DEA, and then order his drugs.

Mr. SCOTT. Thank you.

The gentleman from California.

Mr. LUNGREN. Mr. Rannazzisi, my question is this. I want to make sure we crack down on the illicit distribution of drugs. I want to make sure that people in rural areas are not denied access because of additional impediments.

What is the standard use now for doctors in their prescribing of drugs, the relationship with the patient? What does DEA look at, if they were to look at whether a doctor was prescribing appropriately or not?

Mr. RANNAZZISI. Well, to issue a valid prescription, the doctor has to issue that prescription for a legitimate medical purpose and in the usual course of that individual practitioner's practice. That is the standard, that is the standard that was set by the court, standard that is set in the regs.

And there are a lot of ways to look at that. But if you look at what the AMA guidelines and the Federation of State Medical Boards' guidelines, they discuss Internet prescribing and particularly what a valid prescription is. They say that, you know, you have to do a complete medical history. You should have at least one face-to-face, in-person examination. Those are the guidelines from the Federation of State Medical Boards and the American Medical Association.

Bill, if you want to jump in, I think that is what Ohio has too, doesn't it?

Mr. WINSLEY. Well, in my written testimony, at the very end there are copies of our medical board's rule and pharmacy board's rule dealing with this issue. Those rules came into effect after our first Internet case back in 1998. And if you read those, they pretty much are the basis for what FSMB and AMA have come out with.

Mr. LUNGREN. Well, see, my point is, I want to make sure, and I don't think the bill does, that this prospective law does not go beyond what the common practice would be in a relationship of a doctor-patient.

It is not required, as mentioned by Mr. Winsley, to have a face-to-face every time you get a prescription. You have to have an established relationship with the doctor. And that could be your physical, and then after that the doctors establish things. It could be that you have a physical every year. It could be that you don't see the doctor for 5 years, but he has your record, he talks with you, those sorts of things.

I don't want us to be interfering beyond that. But what I would want us to do is to make sure that if you are getting a prescription from an online pharmacy, you basically are following the same regime, the same custom and practice that you are with a physician when you get it from a brick-and-mortar pharmacy.

Mr. RANNAZZISI. Yes, sir. And that is outlined in the AMA and FSMB, the Federation of State Medical Boards, guidelines.

Additionally, what the federation says is, treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

Mr. LUNGREN. Let me ask this. Some might say, "Hey, look, all this is is the brick-and-mortar pharmacies trying to make it difficult for the online pharmacies." You know, that is what their axe to grind is in this whole thing.

And these doctors, including the medical societies, they want to make sure that you are not spinning off patients to doctors who have embraced the new technology, so that you don't have to have face-to-face, you can actually converse with your doctor over the phone or even through the Internet in some sort of way.

What would you say to that?

Mr. RANNAZZISI. I believe we are talking about now S. 980, the bill has——

Mr. LUNGREN. Correct.

Mr. RANNAZZISI [continuing]. Provisions that deal with that. They have telemedicine provisions. They have provisions that deal with certain situations where a doctor may not be able to do a face-to-face. But it is built into the law.

That bill went through the interagency, and everybody who looked at it, you know, looked at it from their point of view. How is it going to affect patient care? That is how HHS looked at it, and FDA. The Veterans Administration looked at it. When that bill was drafted, it had the input of every agency that evenly remotely had some kind of contact with patient care.

The provisions that were put in that bill protect a lot of the people that, for some reason, can't go to see a doctor. There are provisions built into that bill that will allow for exceptions; and also telemedicine, which is an emerging trend.

Mr. LUNGREN. It is my understanding that the bill has these penalties attached to people who are in the process of distributing the drugs, as opposed to the person using. Is that correct?

Mr. RANNAZZISI. That is right. The bill addresses, again, distributors of the drug, not ultimate drug users.

Mr. LUNGREN. Thank you very much.

Thank you, Mr. Chairman.

Mr. SCOTT. Thank you.

Mr. Rannazzisi, how does the distributor or the owner of the Web site get the drugs, get access to the drugs to begin with? Does the manufacturer ship them to a warehouse?

Mr. RANNAZZISI. The owner of the Web site generally does not touch the drugs. He is a facilitator. He employs or he recruits doctors and pharmacists. And those doctors and pharmacists run the transaction. The facilitator, the Web site facilitator is a generally a layman. All he does is bring the doctor and the pharmacy and the patient together for one transaction.

Mr. SCOTT. So they have to get—wherever the drugs land, wherever the warehouse is that the drugs—are they registered?

Mr. RANNAZZISI. The pharmacy that dispenses the ultimate prescription is generally a DEA-registered pharmacy.

Now, obviously, the question was asked about overseas pharmacies; DEA has no regulatory control over an overseas pharmacy or distributor. However, here in the United States, we do.

And, generally, our pharmacies that dispense the drugs are DEA registrants. Doctors that prescribe the medication are also DEA registrants.

Mr. SCOTT. So you already have a list of all of the domestic sources for the drugs?

Mr. RANNAZZISI. I have a list of all domestic pharmacies that are DEA-registered and all doctors that are DEA-registered as well. But that list only tells us that they are pharmacies. It doesn't tell us if they are involved in Internet dispensing. It doesn't say if the doctor is involved in Internet prescribing.

Mr. SCOTT. Is this bill limited to Internet drug sales? Or do the penalties relate to general sales in addition to Internet sales?

Mr. RANNAZZISI. I believe that the provisions increasing the caps relate to all Schedule 3, 4 and 5 drugs, and not just limited to Internet sales of Schedule 3, 4 and 5 drugs.

Mr. SCOTT. Now, you have acknowledged that there are mandatory minimums in the bill?

Mr. RANNAZZISI. No. The Rohypnol provision, which is—by the way, Rohypnol is not a pharmaceutical controlled substance in the United States. It is not a legitimate medication in the U.S. It is only used outside of the borders of the United States.

Mr. SCOTT. And that is the only mandatory minimum that is in the bill?

Mr. RANNAZZISI. That I am aware of, yes. And that is, again, if there is——

Mr. SCOTT. Is that the "roofie"?

Mr. RANNAZZISI. Yes, Rohypnol, yes.

Mr. SCOTT. But there are mandatory minimums for that drug?

Mr. RANNAZZISI. The way I understand it, again, is that that mandatory minimum is triggered if there is death and bodily harm attached to the distribution.

Mr. SCOTT. Okay. Are you aware of any studies that show racial bias in the application of mandatory minimums?

Mr. RANNAZZISI. Am I aware of any studies? I am aware that that subject has been debated in Congress and the Sentencing Commission, but, no, I am not aware of any studies, no, sir.

Mr. SCOTT. So if someone were to say that mandatory minimums are generally imposed in a racially discriminatory manner, you wouldn't have any evidence to contradict that?

Mr. RANNAZZISI. I don't believe I would be the best person to ask, sir. Again, I am not an expert on sentencing for the——

Mr. SCOTT. Well, you are here—well, so, if we drop the mandatory minimums out of the bill, would you object to that?

Mr. RANNAZZISI. That would be up to the Administration to make that decision.

Mr. SCOTT. Are you aware that the Judicial Conference has described mandatory minimums as often violating common sense?

Mr. RANNAZZISI. I am sorry, sir. Could you repeat that question?

Mr. SCOTT. Are you aware that the Judicial Conference has frequently communicated with this Committee describing mandatory minimums as frequently violating common sense?

Mr. RANNAZZISI. Again, sir, no, I am not aware of that. But, again, I don't follow sentencing——

Mr. SCOTT. So you don't have any evidence on behalf of the Administration to contradict the fact that mandatory minimums often violate common sense?

Mr. RANNAZZISI. I would rather not respond to that question, sir.

Mr. SCOTT. Okay. The RAND Corporation has studied mandatory minimums in drug offenses and concluded that mandatory minimums waste the taxpayers' money. Do you have any evidence to contradict the fact that the imposition of mandatory minimums in the bill will waste the taxpayers' money?

Mr. RANNAZZISI. No, sir, I don't have any information to give this Committee on that topic.

Mr. SCOTT. Can you explain to us whether or not you have found any studies that show that mandatory minimums work?

Mr. RANNAZZISI. Again, sir, I don't know of any studies and I wasn't prepared to come here to discuss the mandatory minimum sentences.

Mr. SCOTT. Well, they are in the bill, and, you know——

Mr. RANNAZZISI. Again, there is no mandatory minimum sentence, other than the imposition of the——

Mr. SCOTT. So if you are not here to defend the mandatory minimum, you wouldn't—or at least it is not your call to support or oppose whether they are removed from the bill.

Mr. RANNAZZISI. Again, that would be an Administration decision.

Mr. SCOTT. Who exactly would we hear from to ascertain whether or not you have given up on a provision that has racially discriminatory qualities to it, violates common sense and wastes the taxpayers' money?

Mr. RANNAZZISI. You could, I am sure, contact the department. And I will go back and relay that message to the department.

Mr. SCOTT. Now, you don't need increased penalties to enhance enforcement. I mean, even without the enhanced penalties, if you prosecuted someone and got a conviction, you would pretty much put them out of business with the present penalties, would you not?

Mr. RANNAZZISI. Obviously, yes, they would be incarcerated and we would remove their registration and, if appropriate, seize their assets, yes.

Mr. SCOTT. Now, what do you need to do to enhance enforcement?

Mr. RANNAZZISI. Again, the bill helps us by creating a pool of Internet pharmacies that are operating. It is a ready pool that we could look at and determine who is operating on the Internet and who is not. It helps us in our investigations to identify who the players are operating on the Internet.

Mr. SCOTT. And so, once you have that list, you have the tools that you need to prosecute those that are operating outside of the——

Mr. RANNAZZISI. Well, no, there are other things: the establishment of what a valid doctor-patient relationship is, what a valid prescription is. That is very important; puts everybody on notice that this is what is expected.

Mr. SCOTT. Okay, so you make a list. You have, what, the definition of valid prescriptions?

Mr. RANNAZZISI. Yes.

Mr. SCOTT. Okay, what else do you need to enhance enforcement?

Mr. RANNAZZISI. If you would excuse me 1 second.

Obviously, definition of what the Internet is, what Internet delivery is; all of the registration requirements that we have asked for, which we cannot do by regulation; reporting requirements—that is, if you are operating as an Internet pharmacy, you have to make certain reports to the attorney general on the quantity of drugs you are selling via the Internet.

Mr. SCOTT. Do you necessarily have to be under a State board of pharmacy?

Mr. RANNAZZISI. Any pharmacy that operates in the United States is governed by a State board of pharmacy.

Mr. SCOTT. Is that right, Mr. Winsley?

Mr. WINSLEY. Yes, sir. If it is a legitimate pharmacy, it is licensed with the State in which it is located and usually, if it transports drugs across State lines, with the rest of us for shipping. You know, in Ohio, for example, anyone who ships drugs into Ohio is licensed with us. So we have pharmacies licensed from all over the country.

Mr. SCOTT. So anyone that ships drugs in response to an Internet order, if they ship into Ohio, they should be registered in Ohio?

Mr. WINSLEY. The law is that they be licensed with us, yes, sir.

Mr. SCOTT. And so, if you have some of these well-known pharmacy Web sites—I have ordered stuff over the Web, not prescriptive drugs. If I were to order a prescriptive drug over the Internet, they would have to be licensed in Virginia?

Mr. WINSLEY. If they were operating legally, which is our concern here.

The ones we are talking about don't bother to get licensed. We have no ability to get to them. We know that Ohio people got drugs, and we know that they had a problem. So when they tell us where they got them, the site is not anybody that we have jurisdiction or control over.

And that is the advantage to this bill: It does give the Federal agencies, DEA in particular, the advantage to deal with those that are located outside of my State.

Mr. SCOTT. Okay. So we get a list, we create the pool, we have reporting to the attorney general, we define the Internet, we define valid prescriptions. What else is in the bill that helps you?

Mr. RANNAZZISI. The advertising provision. With the bill, this prohibits people advertising to sell a pharmaceutical controlled substance illegally.

Mr. SCOTT. Is spam advertising?

Mr. RANNAZZISI. I would have to go back and look at the spam, but I am—well, yes, I have seen some of those spam messages, absolutely, "Hydrocodone without a prescription, no doctor visit required," yes.

Mr. SCOTT. Ms. Jones, is there any question that spam would be advertising?

Ms. JONES. Absolutely not. It is absolutely—unsolicited commercial e-mail is an advertisement.

Mr. SCOTT. Is?

Ms. JONES. Is.

Mr. SCOTT. Okay.

Ms. JONES. And I would add another thing, is that the bill, I think, calls for a display of the compliance with the DEA list. That

would be very helpful, at least from our perspective, and, I think, noncontroversial.

Mr. SCOTT. So if someone received an advertisement without the DEA designation, you would know it was illegal. And if it came with the DEA logo, you would know where to go to check them out.

Ms. JONES. I wasn't even thinking of that, but that would be helpful as well. I don't think the current version of the Senate bill calls for that. But it would be an interesting idea, to actually require it in the advertising as well.

Mr. SCOTT. The gentleman from California?

Mr. LUNGREN. I am glad to hear that the Chairman is trying to beef up the bill. Very good. Parts of it.

We keep talking about the mandatory minimums. I just want to make it clear that, with Rohypnol, what the bill does is drop the one-gram requirement that currently is in the law, but it does not change the requirement that, for mandatory minimum, one must be prosecuted successfully for having death or serious bodily injury resulting from the use of the substance that was unlawfully manufactured or distributed.

And the cross-reference to serious bodily injury is "an injury which involves substantial risk of death, extreme physical pain, protracted, obvious disfigurement, protracted loss or impairment of the function of a bodily member, organ or mental faculty." That is pretty serious stuff.

So we are not really creating a new mandatory minimum. What we are saying is the one-gram requirement is not there with respect to the trafficker, so long as you can show that death or serious bodily injury resulted in that.

Mr. Rannazzisi, are you aware of any studies that suggest that Rohypnol is particularly utilized by one ethnic group or another or one racial group or another in the United States?

Mr. RANNAZZISI. No, sir.

Mr. LUNGREN. It is what is commonly known as the date-rape drug, is that correct?

Mr. RANNAZZISI. Yes, it is used in facilitation of sexual assault.

Mr. LUNGREN. And it was in the 1990's that Congress passed laws specifically dealing with this drug for the first time?

Mr. RANNAZZISI. Yes, I believe it was in the late 1990's. The drug is not a pharmaceutical in the U.S.

Mr. LUNGREN. Right. And in 2006, Congress amended the law to add a new specific offense prohibiting the use of the Internet to distribute the date-rape drug.

Mr. RANNAZZISI. Yes, sir.

Mr. LUNGREN. So this is beyond controlled substances or dangerous drugs. This isn't on any schedule whatsoever for use, correct, for an FDA-approved use?

Mr. RANNAZZISI. It is not approved to be marketed or dispensed in the United States. FDA has not approved it to be marketed or dispensed in the United States.

Mr. LUNGREN. And there has been question about Internet sites that are offshore. That is referred to in the bill when it talks about making this bill compatible with the already-existing provisions of law making it illegal to import controlled substances into the United States from foreign countries or territories, correct?

Mr. RANNAZZISI. Yes, sir.

Mr. LUNGREN. In fact, the law says specifically, on the books, "It shall be unlawful to import into the customs territory of the United States from any place outside thereof any controlled substances of Schedule 1 or Schedule 2, any narcotic drug in Schedule 3, 4 of 5 of this chapter."

So it is illegal to import the drugs into the United States, correct?

Mr. RANNAZZISI. As far as controlled substances, I could tell you that any quantity of controlled substances that are coming in via carrier or mail, unless it is going to a DEA-registered importer, it is illegal and it is subject to seizure.

Mr. LUNGREN. So this law would help you with respect to that, in that we would be setting up a schematic in which there would be information to the consuming public as to whether or not the site was registered with the DEA.

Mr. RANNAZZISI. Yes, sir.

Mr. LUNGREN. There would be the ability for them to check that against whatever approved list that you have.

Mr. RANNAZZISI. Yes, sir.

Mr. LUNGREN. There would be an ability for people then to check with the State involved, either the reported sending State or the receiving State, as to whether they were registered.

Mr. RANNAZZISI. Yes, sir.

Mr. LUNGREN. If, in fact, it failed those tests and it appeared that it was coming from outside the United States, that would at least give you some indication to start an investigation as to where it was coming from, and the act itself would be illegal under the terms of current law, correct?

Mr. RANNAZZISI. That is absolutely correct, sir.

Mr. LUNGREN. So even though we have the problem with those that are overseas, this would at least give us more databases and more information from which to launch an investigation into what may be an illegal site.

Mr. RANNAZZISI. That is correct, sir, yes.

Mr. LUNGREN. Thank you very much, Mr. Chairman.

Mr. SCOTT. Thank you.

I just had a couple of points.

One, distributing the date-rape drug over the Internet is already illegal. What this would do would be to expand that mandatory minimum to other sales not over the Internet. Is that right?

Mr. RANNAZZISI. I am sorry, sir. I don't follow you there.

Mr. SCOTT. In 2006, the Controlled Substances Act was amended prohibiting the use of the Internet to distribute a date-rape drug, which the Congress defined, included a maximum sentence of 20 years.

Mr. RANNAZZISI. Yes, sir.

Mr. SCOTT. And another question: One of the problems with the mandatory minimums is that you not only get the main perpetrator but everybody who is part of the conspiracy. Is that right?

You know, you bust a warehouse. Everybody is subject to the same mandatory minimum sentence, not just the ringleader, but the people off on a tangent would also be looking at the same man-

datory minimums, even if it made no sense to impose the penalty on someone who is just out there on a tangent.

Mr. RANNAZZISI. I believe that would be up to the United States attorney where the district is.

Mr. SCOTT. Wait a minute. But if they were prosecuted and found guilty, the judge would have no discretion but to impose the draconian mandatory minimum on someone who was just out there on a tangent.

Mr. RANNAZZISI. Again, sir——

Mr. SCOTT. So we will leave it to the discretion of the prosecutor to decide——

Mr. RANNAZZISI. Discretion of the judge.

Mr. SCOTT. Well, unfortunately, with a mandatory minimum, that is the problem. If it makes no sense, the judge has to impose the mandatory minimum anyway.

Mr. Egan, did you have something to say about that?

Mr. EGAN. Yes, sir. What I wanted to speak to was the fact that what this does is it takes the discretion to not apply that sentence to those individuals who maybe are not the main perpetrator away from the court and places it in the hands of the United States attorney, who makes that decision based upon whatever they feel is appropriate under the circumstances of the case.

So that the application is now vested in the executive branch and taken away from the judicial branch, where it properly resides.

Mr. SCOTT. And if someone has just a distant connection with the conspiracy and they are brought in and convicted with everybody else, how much discretion does the judge have in imposing a mandatory minimum sentence?

Mr. EGAN. None.

Mr. RANNAZZISI. Again, sir, for this particular drug, though, that only triggers if there is death or serious bodily harm.

Mr. SCOTT. And if you were not the ringleader but, say, a lookout, you get the same—what is the mandatory minimum? Twenty years or whatever it is? You get 20 years for being the lookout? You shouldn't have been a lookout.

And if you are the lookout's assistant, so if you took a message—this is where the girlfriends get involved—you took a message for somebody, you are part of the conspiracy, you get roped in, you get the same mandatory minimum with everybody else?

Mr. RANNAZZISI. Sir, again, that is a question that I am more than happy to take for the record and respond in writing.

Mr. SCOTT. Mr. Egan, if somebody takes a message and is part of the conspiracy and gets roped in, do they get the same mandatory minimum like everybody else?

Mr. EGAN. As long as what the mandatory minimum requires to have taken place is met by that person's actions, then they get the mandatory minimum, unless the prosecution decides not to pursue it. It is totally within their discretion.

Mr. SCOTT. Thank you.

The gentleman from California?

Mr. LUNGREN. Just for the record, to make it clear, what we are talking about is Rohypnol, a date-rape drug—date-rape drug—approved for no purpose in the United States, no medical purpose whatsoever—a date-rape drug. And in the distribution of this date-

rape drug, someone is killed or some victim receives serious bodily injury. And under those circumstances, the people who conspired together to create that situation will be subject to a mandatory minimum.

Is that correct, Mr. Rannazzisi?

Mr. RANNAZZISI. Yes, sir, that is correct.

Mr. LUNGREN. Okay.

Thank you, Mr. Chairman.

Mr. SCOTT. If there are no further questions, we want to thank the witnesses for their testimony.

Without objection, the hearing record will remain open for 1 week for the submission of additional materials.

And, again, I thank the witnesses.

And, without objection, the Committee stands adjourned.

[Whereupon, at 1:40 p.m., the Subcommittee was adjourned.]

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