

Testimony of
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Written Statement of
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Introduction

Chairman Leahy, Ranking Member Specter, and distinguished Members of the Judiciary Committee, on behalf of the men and women of the Drug Enforcement Administration, I want to thank you for the opportunity to discuss the problem of prescription drug abuse, and in particular, the illegal distribution of controlled substance pharmaceuticals via the Internet.

Non-medical use of addictive prescription drugs has been increasing throughout the United States at alarming rates. In 2005, an estimated 6.4 million Americans age 12 and older reported past month use of prescription drugs for non-medical purposes.¹ Of these, 4.7 million used pain relievers non-medically. Nationally, the misuse of prescription drugs was second only to marijuana in CY 2005.

Part of this increase in abuse is fueled by the perception among many that prescription drugs are relatively safe when compared to what some might consider more conventional "street" drugs such as heroin or cocaine. There is relatively little stigma associated with prescription drugs. Because they are manufactured for a legitimate medical purpose, many take these drugs without the anxiety of thinking they will be ostracized for their habit.

Perhaps even more alarming is the false sense of security associated with the abuse of these substances. Many feel as though if a doctor can prescribe it, the drug can't be as harmful to your health. According to the 2005 Partnership Attitude Tracking Study, 40% believe that prescription medicines are "much safer" to use than illegal drugs.² Furthermore, the same study concluded that 31% believe there's "nothing wrong" with using prescription medicines without a prescription "once in awhile." The truth of the matter is, these controlled substances are not just highly dangerous, but they can prove lethal.

This study also found that teens believe a key reason for abusing prescription pain relievers is their widespread availability and easy access. This ease of access, which teens indicate is provided by parent's medicine cabinets, friend's prescriptions, and by the Internet, 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

drugs³ (e.g., anti-anxiety medications, hydrocodone combination products, and anabolic steroids), on the other hand, are increasingly accessible and often illegally purchased through the Internet. And unlike someone stealing a few pills out of the medicine cabinet from someone else's prescription, large, high-potency sales of 100 or more pills occur hundreds of times everyday over the Internet.

The Internet as a Method of Diversion

The Internet has become one of the fastest methods used today to divert huge quantities of controlled pharmaceuticals. Certainly there are benefits to allowing individuals with a valid prescription to get their prescriptions over the Internet, ranging from simple convenience to providing individuals in remote areas or with limited mobility with access to needed medications they may not otherwise obtain. As with many other products, the Internet affords businesses access to a customer base not possible for a traditional "brick and mortar" location. The convenience appeals to consumers as well. Legitimate pharmacies operate everyday providing services over the Internet and operate well within the bounds of both the law and sound medical practice. In support of these legitimate efforts, the National Association of Boards of Pharmacy (NABP) has established a registry of pharmacies that operate online and meet certain criteria, including compliance with licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.

Unfortunately, other so-called 'pharmacy' sites on the Internet today illegally sell controlled substance pharmaceuticals. These rogue Internet sites are not there to benefit the public, but to generate millions in illegal sales. To the uninformed individual these sites may seem convenient, cost-effective and safe, but to the investigator and the drug-seeking individual there are indicators on the rogue sites which should serve as a warning that the site is operating beyond the bounds of what's safe and legal.

A consumer will notice a level of authorization and accountability with legitimate sites that is very rare to find with a "rogue" site. Before you even access its main page, an illicit site will draw you in by advertising powerful prescription medicines. The drugs and their cost (often designed to convey the sense that the consumer is saving money, when in actuality, they're frequently spending far more via "rogue" sites) are the first pieces of information these sites typically publish in order to get the customer's attention. More often than not, a "rogue" site will also validate and process prescriptions based on the completion of a cursory questionnaire. This process is designed to elicit what drug the customer wants and what the method of payment will be, rather than diagnosing a health problem and establishing a sound course of medical treatment.

In contrast, a legitimate site will never authorize a prescription based merely on this criterion. There will be an expectation in working with a legitimate on-line pharmacy that a customer will have a prescription from a doctor before visiting the site--just as a customer would when visiting a brick and mortar drug store. While DEA does not certify websites or the legitimacy of Internet pharmaceutical sales, if an Internet pharmacy follows all rules applicable to their brick and mortar counterparts (including, but not limited to, ensuring a patient's right to privacy, authenticating and securing prescription orders, and adhering to a recognized quality assurance policy), then the Internet pharmacy is acting in compliance with existing law.

Rogue sites, on the other hand, may provide bogus pictures of individuals wearing white lab coats designed to imply a level of trustworthiness, but these sites have structured themselves to avoid accountability for the products they sell. DEA believes a majority of the rogue sites operating today are based in the United States and work in concert with unscrupulous doctors

and pharmacies. The fact that all of these individuals are complicit in this operation defeats the important checks and balances that have been established in the legitimate process of supplying controlled substance prescriptions to patients in need. While DEA has had some law enforcement successes against these organizations, the criminals promoting this activity are becoming more sophisticated. Their business model takes advantage of the anonymity of the Internet, the ease with which new web sites can be created, and the trust of the American people in the safety and efficacy of pharmaceutical products.

While this business model has evolved significantly over time (and we expect it to keep doing so), there are three primary players that facilitate these web sites: the doctor, the pharmacy, and the Internet facilitator. These three players collaborate in an almost seamless fashion. Illegal pharmaceutical sales are promoted by Internet facilitators who have no medical training and are not DEA registrants. These facilitators start by targeting doctors who may be carrying a significant debt, such as a young doctor fresh out of medical school, or those who have retired and are looking for some extra income. The facilitator convinces these doctors that it's OK to approve the prescriptions because they will be provided with some 'medical history' (submitted by the "patient" through a web site). Increasingly common is for the facilitator to provide an opportunity for the doctor to have a telephone conversation with the "patient" or for the "patient" to fax or email 'medical' information to the doctor. The doctor then approves a prescription for a schedule III or schedule IV substance with the mistaken belief or "justification" that these substances are not as "dangerous" as those in schedule II. (Note: The criminal penalties for violations involving schedule II substances can be significantly higher than for those involving a schedule III or IV substance.) This poorly constructed veil of medical evaluation is designed to provide added justification for the requested medicine. And for every prescription the doctor authorizes, the Internet facilitator will pay the doctor ten to twenty-five dollars. Law enforcement has discovered website-affiliated doctors who authorize hundreds of prescriptions a day. The Internet facilitators will also recruit pharmacies into their scheme. They often target small, independent pharmacies struggling to make ends meet. The Internet facilitator will tell the pharmacist that all they have to do is fill and ship these prescriptions to customers. The prescriptions have all been approved by a doctor, and they are only for schedule III or schedule IV substances. In addition to paying the pharmacy for the cost of the medicine, the Internet facilitator will also pay the pharmacy an agreed upon amount that may reach into the millions of dollars. DEA has seen pharmacies close their doors completely to walk-in customers and convert their entire business to filling these orders.

The Internet facilitator generates the web sites that draw customers into this scheme.

Web sites used by Internet facilitators often mislead the public by advertising themselves as pharmacies, but they do not operate in the same manner as brick-and-mortar pharmacies. These rogue sites offer only a few pharmaceutical products for sale, and are typically limited to only controlled substance and life-style drugs. Advertising typically emphasizes the ability to acquire controlled substances without a prescription or an appropriate examination, and none include a face-to-face medical examination from a licensed physician. They provide the customer with a wide-variety of quick and easy payment methods, ranging from cash-on-delivery to credit 'gift' cards. Various steps of the ordering process will link and shift the buyer to different web sites, making it difficult to connect payments, products, and web providers together. Rarely is there any identifying information on the web site about where the Internet pharmacy is located or who owns or operates the web site.

Frequently, and as mentioned in previous paragraphs, these web sites offer, at best, abbreviated

medical interaction. This brief interlude is not meant to elicit meaningful health information; and is generally done by way of a questionnaire filled out by the customer without meaningful interaction between the doctor and the "patient". All too often the questionnaire is a ruse constructed in a manner solely for the purpose of identifying exactly just what type of controlled substance the customer is looking to purchase. In some cases, we have seen web site questionnaires that will not allow the customer to continue unless the 'right' information is entered to "justify" the drugs being requested. For example, if someone wanted a weight-loss drug, but filled out the questionnaire saying they were five feet tall and weighed ninety pounds, the questionnaire would not allow the customer to advance until the provided height and weight were more conducive to someone needing a weight-loss drug.

The Effects of Rogue Internet Pharmacies

In calendar year 2006, thirty-four known or suspected rogue Internet pharmacies dispensed 98,566,711 dosage units of hydrocodone combination-products.⁴ To put this in perspective, controlled substances account for 11 percent of dosages at legitimate "brick and mortar" pharmacies in the United States versus 95 percent at these rogue Internet pharmacies. These thirty-four pharmacies alone dispensed enough hydrocodone combination-products to supply over 410,000 actual patients with a one-month supply at the maximum amount recommended per prescription.⁵

Controlled pharmaceuticals in the United States are legitimately prescribed and dispensed within a closed system of distribution. Importers and manufacturers of controlled substances as well as physicians who dispense or prescribe them and pharmacies that fill controlled substance prescriptions are all DEA registrants subject to the Controlled Substance Act and the Code of Federal Regulations. As a closed system there are built-in checks and balances. Each registrant has a corresponding liability to keep the integrity of the closed system intact. However, with rogue Internet pharmacies there is complicity amongst all of the participants, effectively eliminating all of the normal checks and balances. Even some major corporations may turn a blind eye to obvious warning signs when supplying these rogue pharmacies.

Common methods of drug diversion, by their nature, provide some constraints on the amount of controlled substances individuals can acquire over a given period of time. These methods place the "patient" at a greater risk of being caught by law enforcement because the DEA registrant is frequently not complicit in the scheme and will report the suspicious behavior. The sheer volume of controlled substances being dispensed anonymously over the Internet contributes significantly to other downstream methods of diversion, (e.g. children and young adults getting controlled substances from the medicine cabinet or family and friends). While studies such as National Survey on Drug Use and Health indicate that only a small percentage of youth get controlled pharmaceuticals via the

Internet (the majority obtaining them from family and friends), it's important to remember that when these individuals obtain these substances they generally acquire only a few pills at a time. In contrast, individuals ordering via the Internet frequently receive 100-120 pills at a time, making it a potentially much higher-volume source than friends or the family medicine cabinet. But the consequences to those individuals who seek controlled prescription drugs illegally over the Internet can be just as dangerous and deadly as the consequences of those abusing more traditional substances, such as cocaine or heroin. Many parents of young people who died from the misuse of prescription drugs have told us that they were unaware of the source of the pills which killed their sons and daughters. However, in some cases, parents such as Francine Haight and others discovered that their children were using the Internet as the source for

pharmaceuticals.

Linda Surks, mother of Jason Surks, testified before Congress last year about the tragedy which befell her family when they discovered that Jason had overdosed on prescription drugs at the age of 19. A pre-pharmacy major as an undergraduate, he had an academic curiosity about prescription drug formulas and combinations.

What they didn't know was that Jason had been drawn in by the Internet facilitators who made it far too easy to order dangerous controlled substance pharmaceuticals from illicit online sites. A search of his computer after he died revealed that he had visited multiple Internet pharmacies. One in particular had automatically renewed his order regardless of whether or not Jason had actually placed it himself, even after he died. The drugs just kept coming.

Enforcement Challenges

As this threat has grown, DEA has also increased its effort to go after these cyber drug dealers. There no longer needs to be a direct interaction between these modern criminals and the drug seeker, they have the ability to reach directly into every computer on the Internet. Whether temptation in the form of a cleverly worded "spam" email or someone actively seeking to acquire narcotics without seeing a doctor, the Internet has created a whole new delivery and sales system for drug traffickers.

While Internet investigations do offer the advantage of having an extensive paper trail, the amount of information generated by one web transaction is so voluminous it becomes difficult to separate the important investigative information from the routine.

The methods and structures of these online organizations continue to evolve, and we are watching some organizations adjust and shift operating methods in response to law enforcement initiatives.

In short, the Internet has provided drug trafficking organizations with the perfect medium. It connects individuals from anywhere in the globe at any time; it provides anonymity, and it can be deployed from almost anywhere with very little formal training. All of these features allow for a more rapid means of diverting larger and larger quantities of controlled substances. The proliferation of rogue Internet pharmacies has also brought new legal challenges as well.

DEA's Response

Despite these challenges, DEA has been successfully using the tools that we have to counter this growing threat. We are using all current regulatory tools possible to identify and shut down those that choose to operate outside of the Controlled Substance Act. DEA is using the Automation of Reports and Consolidated Orders System (ARCOS) to identify high or excessive volume purchases and determine which retail pharmacies and practitioners are likely to be involved in the illicit distribution of controlled substances via the Internet. Typically, a traditional independent brick and mortar pharmacy will sell about 180 prescriptions per day. Of these sales, only 11 percent will involve controlled substances.⁶ Conversely, the typical 'cyber' pharmacy will sell around 450 prescriptions each day--425 of these, or 95 percent, will involve controlled substances.

Both manufacturers and distributors are only required to provide information electronically to the ARCOS data base about any sale of narcotic substances. Although this data is limited to narcotics, DEA is able to develop leads and augment investigations from this information. In addition to trying to identify the retail pharmacies that are involved in the illegal sale of controlled substances over the Internet, DEA has also begun educating and, when appropriate, taking legal action against, the distributors who are providing these pharmacies with the huge quantities of pharmaceuticals being sold. In 2006, DEA began an Internet Distributor Initiative

designed to focus on the more than 800 DEA registered distributors of controlled substances. DEA has focused on these distributors because, for any transaction involving controlled substances, whether from the manufacturer to the distributor, from the distributor to the pharmacy, or from the pharmacist to the patient, the seller has a legal obligation to ensure the substances transferred are not destined for diversion. In other words, the seller may not facilitate, or otherwise contribute to, the diversion of the substances sold. DEA's educational presentation to these distributors provides wholesalers some examples of domestic Internet pharmacies, their purchase patterns, and methods of operation. The presentation is designed to emphasize to wholesalers their obligation not to sell where diversion appears to be occurring or face the loss of their DEA registration or judicial sanctions. While these educational efforts were successful in some situations, DEA has had to initiate appropriate administrative, civil, or criminal sanctions against some distributors.

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 providers⁷; express package delivery companies; and financial services companies, including major credit card companies and third party payment service providers. And in 2004, DEA became part of a federal interagency task force (with FDA, FBI, CBP, ICE) established to combat the increasing diversion of pharmaceuticals over the Internet.

In FY 2004, DEA established a specialized section within its Special Operations Division (SOD) to coordinate multi-jurisdictional Title III investigations involving the diversion of pharmaceuticals and chemicals over the Internet. During FY 2006, SOD has coordinated over 90 Internet investigations, resulting in the arrest of approximately 64 individuals and the seizure of approximately 14 million dosage units of controlled substances and approximately \$30.9 million in U.S. currency. In FY 2006, 14.7 percent of Diversion Control Program case work hours were dedicated to diversion cases involving the Internet. This was an increase of approximately 27 percent from FY 2005 when Internet cases represented 11.3 percent of the investigative work hours and an increase of 50 percent from FY 2004 when 8.8 percent of investigative work hours were for Internet cases.

Conclusion

Drug traffickers continue to exploit the Internet and threaten the health and safety of Americans. Nevertheless, the DEA has refined its methods by which we identify, pursue, and ultimately dismantle these groups and we remain committed to bringing to bear all of the resources at our disposal to fight this growing problem while simultaneously ensuring an uninterrupted supply of controlled pharmaceuticals for legitimate demands. DEA's core mission of disrupting and dismantling drug trafficking organizations, including those who seek to illegally distribute licit drugs, is an integral component to the 2006 Synthetic Drug Control Strategy and we will continue to implement this aspect of the Strategy with our inter-agency partners to combat controlled substance pharmaceutical diversion. Chairman Leahy, Ranking Member Specter, and members of the Committee, I thank you for the opportunity to discuss this vital issue and welcome any questions you may have.

1 U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration.

(2006). Results from the 2005 National Survey on Drug Use and Health.

2 Partnership for a Drug Free America, (2006) 2005 Partnership and Attitude Study (PATs), 18th Annual study of teen drug use and attitudes.

3 For a more complete listing of substances controlled under the Controlled Substances Act, please see

<http://www.dea.gov/pubs/scheduling.html>. A full list of all controlled substances can be found in chapter 21 of the

Code of Federal Regulations, section 1308.11 through section 1308.15.

4 Information gathered from information reported to DEA and recorded in the ARCOS database.

5 The 2006 Physicians Desk Reference recommends a maximum of 8 tablets per day of hydrocodone with acetaminophen.

6 2003 NCPA-Pfizer Digest New York, New York - June 26, 2003.

7 Including web hosting services, domain name registration companies, and search engines.