



## **State of the Internet: NABP Position Paper on the Continued Proliferation of Rogue Internet Drug Outlets**

**May 2009**

In March 2003, NABP identified a crisis, wherein the need for affordable medications was “driving patients outside of the [United States] regulatory system into unidentified and unregulated areas.” The NABP “Position Paper on the Importation of Foreign Prescription Drugs” further states, “[p]urchasing medications from unknown and illegal sources via the Internet and other means is compromising the US medication distribution system and making US citizens vulnerable to bioterrorism attacks.” In the six years since NABP called attention to this situation, little has changed.

### **Valid Prescription Needed**

The laws are fairly clear on this issue: To obtain prescription medication, a patient needs a valid prescription drug order. Professional consensus on what constitutes a valid prescription drug order is also clear: A prescription must be written by an authorized medical practitioner who has a pre-existing relationship with the patient that has included an in-person physical examination. Most state boards of pharmacy and boards of medicine, along with Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), Federation of State Medical Boards (FSMB), the American Medical Association (AMA), and NABP, agree that writing a prescription or dispensing a prescription medication without such a relationship is illegal or fails to meet the standard of care. So then why, out of 1,351 Internet drug outlets assessed by NABP as of January 2009, do 1,183 (88%) of them continue, unhindered, to offer prescription drugs without a valid prescription?

Finding an illegal seller of prescription drugs, controlled and otherwise, is as easy as typing in one of countless key words in an Internet browser window. The results will include not only pages upon pages of search results, but also several paid advertisements linking to Internet drug outlets selling prescription drugs without a valid prescription. Many of them accept several major credit cards, and banks process these transactions like any other sale. Further, Internet service providers, which sell domain names to registrants without verifying their information, provide easy access to an unlimited number of virtual storefronts.

To see why this “wild west” of an electronic marketplace is a problem, one need only follow the trail of dead and injured patients:

- Ryan Haight died on February 21, 2001, at the age of 18 from an overdose of Vicodin<sup>®</sup> he had purchased over the Internet without a doctor’s examination. He is, of course, the namesake of the Ryan Haight Online Pharmacy Consumer Protection Act, which, as of fall 2008, prohibits the dispensing of controlled substance medications over the Internet without a valid prescription that is based on a valid patient-prescriber relationship which included at least one face-to-face physical examination by the prescribing practitioner.
- Justin Pearson, 24, of St Cloud, MN, died on December 25, 2006, from an overdose of prescription drugs he had ordered from a rogue Internet pharmacy. He reportedly became addicted to Vicodin after injuring his back during a four-wheeling accident. When his doctor stopped prescribing the drug, he obtained it online without a prescription. In his memory, Minnesota adopted “Justin's Bill” in early 2008, according to which, a prescription is not considered valid unless documented proof of a face-to-face, patient-physician evaluation is provided.
- A deadly overdose from drugs purchased over the Internet without a prescription or a physical examination by a practitioner is spotlighted in a news story appearing May 22, 2008, on CNN.com/health, “Widow: My husband died from online drugs” ([www.cnn.com/2008/HEALTH/05/21/online.drugs/index.html](http://www.cnn.com/2008/HEALTH/05/21/online.drugs/index.html)).
- In July 2007 came news of a Canadian woman’s death from drugs that turned out to be counterfeit purchased over the Internet. These drugs were later determined to be contaminated with extremely high quantities of metal. The pharmacy claimed to be in Canada.
- In February 2007, FDA reported that several patients who thought they were purchasing a variety of different medications, including Ambien<sup>®</sup>, Xanax<sup>®</sup>, Lexapro<sup>®</sup>, and Ativan<sup>®</sup>, over the Internet, instead received the schizophrenia drug, haloperidol, sending some patients to the emergency room. FDA said the agency had received reports of several patients seeking emergency medical treatment for symptoms such as difficulty in

breathing, muscle spasms, and muscle stiffness after taking the pills. The patients reportedly ordered the drugs through a variety of commercial Web sites.

- NABP also has received several reports from patients who became ill after taking medications received from Internet drug outlets, received the wrong medications, or were defrauded by Internet drug outlets that charged their credit cards but never sent the ordered medications.

### **Seek and Ye Shall Find**

Despite obvious problems with the rampant availability of prescription medications, Internet search engines continue to post advertisements and search results linking to rogue sites. Several major search engines filter the drug outlets they allow to advertise on their Web sites through a verification program (not recognized by NABP). An alarming number of Internet drug outlets advertising on search engines flagrantly offer prescription medicine, including controlled substances, without a valid prescription. Some rogue sites may slip through the search engine's filters, for example, if the Web site operator obtains approval to advertise a site that does meet the company's verification standards the operator may go on to use that user name and password to display ads for other rogue sites.

Many of these sites violate the recently adopted Ryan Haight Online Pharmacy Consumer Protection Act, which prohibits the dispensing of controlled substance medications over the Internet without a valid prescription that is based on a valid patient-prescriber relationship which has included at least one face-to-face physical examination. The question often asked is why are these sites allowed to continue their advertising and presence on search engines. The answer may be advertising dollars.

### **Internet Filters Have Holes**

One of the problems with some Internet drug outlet screening services is the size of the holes in their filters. While federal law prohibits the importation of prescription medications from foreign sources, some screening services openly approve them, regardless of the fact that many of these sites may be rogue operations masquerading as legitimate pharmacies. Many sites purporting to be Canadian pharmacies, for instance, sell medications that are not approved under Canadian regulations, and many have no discernable ties to Canada whatsoever.

Additionally, many of the sites currently posing as Canadian pharmacies advertise adulterated concoctions of brand-name drugs. For instance, legitimate Viagra<sup>®</sup> is sold only as a 25 mg, 50 mg, and 100 mg tablet. So called Viagra Soft Tabs or quick-dissolving Viagra are not legitimate branded products and do not go through the same tests for safety and efficacy as the legitimate product, and are not approved for sale in the United States. Likewise, there is no legitimate soft tab or fast dissolving Cialis<sup>®</sup>. Such products have not have been evaluated by the FDA for safety and effectiveness and are not approved for sale in the US.

According to an FDA statement before the Nevada State Board of Pharmacy in 2006, “evidence shows there are weaknesses in the oversight of the drug distribution system by foreign governments for drugs that are imported into the U.S. We have found that although ‘Canadian pharmacies’ purport to dispense drugs that are FDA approved, generally the drugs, in fact, are not. Rather, the dispensed drugs are of unknown quality and country of origin.”

Cyveillance, an online risk monitoring and management firm in Arlington, VA, in 2005 discovered approximately 11,000 Web sites that were designed to appear as Canadian pharmacy sites. Of these sites, most redirected users to 1,009 sites that actually sell prescription drugs, and of those, only 214 were actually based in Canada. Cyveillance also found many of the online pharmacy sites claiming to be based in Canada were actually registered to individuals or companies in other countries, such as Australia, the Czech Republic, El Salvador, Germany, Mexico, and Vietnam, the *Washington Post* reported on June 14, 2005

Following the death of the Canadian woman who ingested counterfeit drugs she bought online, Canadian Pharmacists Association Executive Director Jeff Poston was quoted in a news release as saying, “[m]any internet pharmacies claim to be Canadian but in fact can be based anywhere in the world. A Canadian flag is no guarantee – nor can the origin and safety of drugs bought online be guaranteed.”

Counterfeit and substandard drugs are becoming more common in the global marketplace. The World Health Organization has estimated that more than 50% of drugs purchased over the Internet from sites that conceal their physical address are counterfeit.

“Many internet drug sites have been created to look like legitimate Canadian pharmacies but you might receive counterfeit drugs with no active ingredients, drugs with substandard or dangerous ingredients, or drugs past their expiry date,” Poston noted. “You might receive an incorrect dose

or no product at all. You also risk having your personal and credit card information stolen by organized crime. Even if these drugs do not harm you directly or immediately, your condition may get worse without effective treatment.”

### **WhoIs Data Is Anybody’s Guess**

Also contributing to the problem is the fact that domain name registration information is frequently falsified and never verified by the domain name registrars that sell the Web site names. When an individual wanting to post a Web site on the Internet buys a domain name, ie, Web site address (such as *NABP.net*), he or she must register online, providing contact and payment information to the registrar. This registration information, accessible online by means of a “WhoIs” search, can be listed either as public or, for a fee, private, but there is ample evidence that a significant number of public domain records are falsified, rendering this means of accountability less than trustworthy.

The US Government Accountability Office (GAO) undertook a study to determine just how accurate domain name records are. Citing the results of this study in its 2005 report to the US House of Representatives’ Subcommittee on Courts, the Internet, and Intellectual Property, GAO estimates that 2.31 million domain names (5.14%) were registered with data that appeared obviously and intentionally false in one or more of the required contact information fields. Examples of such entries included “(999) 999-9999” for a telephone number, “asdasdad” for a street address, and “XXXXXX” for a postal code. The GAO report, entitled *Internet Management: Prevalence of False Contact Information for Registered Domain Names*, also states that 1.64 million domain names (3.65%) were registered with incomplete data in one or more of the required fields. In total, GAO estimates that 3.89 million domain names (8.65%) had at least one instance of patently false or incomplete data in the required WhoIs contact information fields.

The report further notes that, “although registrants are required to provide accurate contact information during the domain name registration process, they may supply false or incomplete information in order to hide their identities or to shield themselves from being contacted by members of the public.”

More recently, in a June 24, 2008 statement before the US House Committee on the Judiciary Subcommittee on Crime, Terrorism, and Homeland Security, Christine N. Jones, general counsel and corporate secretary of the Go Daddy Group, Inc, corroborated this finding. The Go Daddy

Group consists of eight Internet Corporation for Assigned Names and Numbers (ICANN)-accredited registrars, including GoDaddy.com, and manages some 30 million domain names.

Jones says, “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.”

Jones also acknowledges that the registrar does not verify registration information for domain names; the process is conducted electronically, and the information is never viewed by a person. “The domain name registration system is entirely automated. There is no human intervention into the process,” she says.

Bob Parsons, CEO and founder of GoDaddy.com writes in a March 23, 2005 blog post, “often times the information within the [WhoIs] database is inaccurate. Inaccurate information happens mostly because some registrants who want to achieve anonymity – for a myriad of reasons, some of which are despicable – provide false information to begin with. . . . There’s often no way to track down a registrant who provided false information when registering their domain name.”

In September 2003, Benjamin Edelman, then a research fellow at the Berkman Center for Internet & Society at Harvard Law School, testified to similar findings before the US House of Representatives’ Subcommittee on Courts, the Internet, and Intellectual Property. “As the DNS [domain name system] is currently structured, registrants are under only an honor system to provide accurate WhoIs data. Meanwhile, it makes no economic sense for registrars to enforce WhoIs accuracy,” says Edelman, now an assistant professor at the Harvard Business School. “The result is that in terms of accuracy, when compared with other compilations of public data (such as driver’s licenses and trademark registrations), the WhoIs database is substantially fiction. Despite years of inquiry by this subcommittee, in addition to numerous ICANN working groups and other discussions, intentionally invalid WhoIs data remains widespread.”

### **Credit Where None is Due**

The majority of Internet drug outlets advise patients to pay by credit card. Some major credit card companies actively screen and refuse to conduct business with Internet drug outlets selling controlled substances. Many sites selling controlled substances illegally, however, still post the logos of major credit card companies, presumably to give themselves a veneer of credibility.

Credit card companies do not, however, screen for illegal transactions involving the sale of non-controlled substances without a prescription, or the sale of foreign or non-FDA-approved drugs to patients in the US. Through various sources, NABP has confirmed that a major credit card can be used in the purchase of prescription medications online without a prescription. NABP also has confirmed that a major credit card can be used in the purchase of controlled substances through an online auction site.

### **Community Pharmacies Solicited**

Several boards of pharmacy, including those in Iowa, Ohio, and Kansas, have reported that community pharmacies in their jurisdictions have been bombarded by faxed solicitations from Internet drug outlets to fill prescription drug orders for its operations, frequently written by physicians who have never examined or even met the patients.

The Iowa Board of Pharmacy reported in its November 2007 newsletter that the Board had received numerous complaints about faxes transmitted from an Internet company to private and business fax machines, including those of pharmacies and medical clinics, throughout Iowa. The Board reported that this company goes by various names, including: *MyPharmaNow.com*, *MyPharma1.net*, *MyPharmaCentral.com*, *MyPharmaCentral.net*, *MyPharmaUSA.biz*, *MyPharmaUSA.com*, *MyFirstPharma.com*, *MyPharmaStop.net*, *MyPharmacyWorld.net*, *MyRxUnited.com*, *MyDrugStore1.com*, *MyDrugStore1.net*, *AmericaPharmacyWorld.com*, and *DrugStoreTM.com*. The company offers a variety of prescription drugs to consumers without a valid prescription.

These sites, which are among a much longer list of subsidiaries of Alliance Health Group and/or Handy Healthcare Group, are posted on the NABP Web site as Not Recommended. NABP lists such sites that do not appear to comply with state and federal pharmacy laws or practice standards on its Web site as a means to educate patients and empower them to make informed choices regarding the use of Internet drug outlets. The sites in this network all list an address in the Mediterranean island of Cyprus, and their domain name registrants are listed with addresses in the Philippines, Portugal, and Singapore. Many of these sites appear to be operating from a server location in San Antonio, TX. They also display the Visa logo, although the only payment option appears to be cash on delivery.

The Board reported in a subsequent newsletter that one of the pharmacies that filled prescriptions for MyPharma.com was Hogan's Pharmacy of Lyons, KS. During 2007,

MyPharma.com sold prescription drugs to numerous Iowans via Hogan's Pharmacy, which was not licensed to conduct business in Iowa. On March 12, 2008, the Kansas State Board of Pharmacy issued an emergency order, which closed Hogan's Pharmacy and declared it an imminent danger to the public. The Kansas Board's order alleged that Hogan's operations were 95% Internet and that Hogan's did not obtain valid prescriptions before dispensing prescription drugs to Internet customers. Most of the Internet drug outlets named by the Board, however, remain active.

The Ohio State Board of Pharmacy warned pharmacists in its February 2007 and February 2008 newsletters about scams involving Internet drug outlets soliciting pharmacies to fill prescription drug orders without a prescription after answering questions on the Web site. The Board reported that pharmacists were being bombarded with offers from these Internet sites. The offers seem to primarily target independent pharmacies, "probably knowing that many of them are suffering financially due to the initial problems with Medicare Part D, Medicaid reimbursement cuts, insurance cuts, etc," the Board states. A few Ohio pharmacists have been subjected to disciplinary actions, including revocation of licensure, for doing business with illegally operating Internet drug outlets. These faxes appear to have originated from the same network of Internet drug outlets as those reported in Iowa.

In its December 2007 newsletter, the Kansas State Board of Pharmacy also reported that the Board has received numerous complaints from physicians and pharmacists in Kansas concerning faxes that are being transmitted from an Internet company to business fax machines, including those of medical clinics and pharmacies, in Kansas. The source of these faxes appears to be the same company referenced by the Iowa and Ohio boards.

### **State Laws . . . or Not**

State laws specifically prohibit the dispensing of prescription medications without a valid prescription that is based on a valid patient-prescriber relationship which has included at least one face-to-face physical examination, as DEA and the Ryan Haight Act now do for controlled substances. In the states, although regulatory language is broad, it is instead addressed and

defined through the compilation and interweaving of federal or state laws and regulations and recognized standards of practice.

“Illegal activities should not be allowed to continue due to inefficient regulatory systems and rules that were developed at a time when huge problems such as the one we are currently experiencing could not have been foreseen,” NABP stated in its 2003 position statement.

“Further, the lack of resources for enforcement must be addressed prior to a complete compromise of the US drug distribution system, and subsequent patient injury or death.” Six years later, as consumer use of Internet drug outlets has grown exponentially and shifted to purchasing controlled substances, this imperative is more urgent than ever. “As regulatory authorities in the US and other countries grapple with this important issue, educating the American public on the danger and illegality of purchasing prescription medications abroad is a necessary component of any solution to the problem” – as much now, as it was then.