



# newsletter

National Association of Boards of Pharmacy®

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aid to government  
the profession  
the public  
1904 to 2008

## State, Federal Regulatory Authorities Combat Rogue Internet Drug Distributors

### Upcoming Events

**May 17-20, 2008**  
NABP 104<sup>th</sup> Annual Meeting  
Baltimore Marriott Waterfront  
Baltimore, MD

**June 5-6, 2008**  
MPJE Item-writing Workshop  
NABP Headquarters  
Mount Prospect, IL

**June 28, 2008**  
FPGEE Administration  
New York City, NY  
Northlake, IL  
San Mateo, CA

**July 30-31, 2008**  
NABP Program Review and Training Session  
NABP Headquarters  
Mount Prospect, IL

The public health risk posed by Internet drug distributors that operate in unapproved, unsafe, and illegal manners has continued to grow over the last couple of years. (See “Internet Drug Distributors Posing New Concerns” in the March 2008 issue of the *NABP Newsletter*.) Combating this epidemic has been a challenge for the state boards of pharmacy and law enforcement agencies as well as federal regulatory agencies. The fluidity and anonymity offered by the Internet and the prevalence of foreign-operated sites that lie outside the United States regulatory jurisdiction provide a barrier behind which these rogue operations hide.

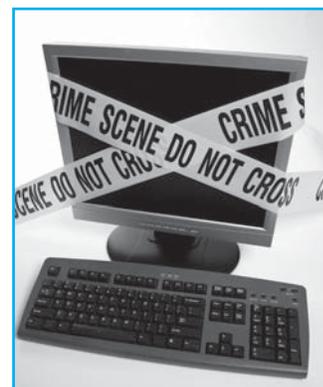
Nonetheless, those in charge of safeguarding the public health and enforcing compliance with state

and federal laws continue the fight. The most effective approaches generally have been multi-pronged and have involved communication and collaboration between various entities.

### State Actions

While some states have taken legislative action specifically targeting illicit drug distributors operating on the Internet, others apply existing laws to address the issue. States generally have taken one of three approaches to regulating Internet drug distributors: out-of-state pharmacy licensing requirements, valid patient-practitioner relationships, and state controlled substance laws.

Not every state specifically addresses Internet drug distributors in its regulations. But the vast majority require out-of-



state drug distributors that dispense medications to state residents to be registered or licensed in that state – a requirement that encompasses Internet pharmacies.

The Wisconsin Pharmacy Examining Board’s description of its requirements for out-of-state drug distributors is fairly standard: “No pharmacy that is in another state may ship, mail, or otherwise deliver a prescribed drug or device to

(continued on page 58)

## In This Issue. . . .

**Association News:**  
NABP Launches PCOA to Assist Schools, Colleges of Pharmacy in Curriculum Assessment

59

**Association News:**  
FPGEC Certification Process Streamlined; US Educational Standards Maintained

63

**104<sup>th</sup> Annual Meeting:**  
Opportunity to Earn Nine Hours of Continuing Education Credit

65

**104<sup>th</sup> Annual Meeting:**  
2008 NABP Award Recipients to be Honored at the 104<sup>th</sup> Annual Meeting

66

**Professional Affairs Update:**  
Medicare Pilot Project Nears End

70

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## Rogue Internet Drug Distributors

(continued from page 57)

persons in Wisconsin unless the pharmacy is licensed in Wisconsin.” While the requirements for this license are not identical to those for in-state drug distributors (“An out-of-state pharmacy . . . is not required to comply with Wisconsin law relating to the professional service area of a pharmacy or the minimum equipment requirements . . .”), the requirement allows the state to weed out rogue drug distributors and provides a mechanism to sanction drug distributors that dispense without a license.

Other states find it useful to cite Internet drug distributors in their regulations. Kentucky and North Carolina, for example, specifically require Internet drug distributors dispensing in those states to hold the NABP Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation.

Meanwhile, out-of-state pharmacy regulations are supplemented with state requirements concerning the patient-practitioner relationship for a prescription to be considered legitimate by the pharmacist. (See “States Begin to Define What Constitutes Legitimate Patient-Practitioner Relationships” in the September 2007 issue of the *NABP Newsletter*.) In general, that relationship includes at least the following elements: a medical history; a physical examination; and some logical connection between the patient’s medi-

cal complaint, the medical history, the physical examination, and the drug prescribed. State boards of pharmacy in Arkansas, North Carolina, West Virginia, and Colorado, for example, emphasize the need for a legitimate patient-practitioner relationship in determining the validity of a prescription that may be dispensed. California, in another example, specifies the need for such a relationship particularly in relation to controlled substances available via the Internet (“No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices . . . on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination.”) The many rogue Internet drug distributors that sell prescription medications based solely on an online questionnaire do not meet these legitimacy requirements.

Last, many rogue Internet drug distribution sites offer would-be patients easy access to controlled substances and, in doing so, run afoul of numerous state and federal laws and regulations. In his May 2007 testimony during a US Senate Judiciary Committee hearing, Joseph T. Rannaz-

zisi, JD, deputy assistant administrator at the Drug Enforcement Administration’s Office of Diversion Control, stated that, in particular, Schedule III and IV drugs, such as anti-anxiety medications, hydrocodone combination products, and anabolic steroids, “are increasingly accessible and often illegally purchased through the Internet.” The process violates both federal and state laws addressing controlled substances.

Doubtless, states will continue to draft legislation that ever more specifically addresses the problem of rogue Internet drug distributors. The difficulty in combating the rogue operations, however, often seems to be one more of enforcement than of having the appropriate regulations on the books. Often, determining if a site has violated the law is glaringly obvious, while information for shutting down or prosecuting the operation is not. The Internet often yields few clues as to the identity of the site’s operators, or even the country in which they live. Fortunately, drugs are tangible products that have to be purchased from manufacturers and shipped to customers. It is attacking these physical steps where law enforcement has had its greatest impact.

Laws and regulations calling for a legitimate patient-practitioner relationship and limiting access to controlled substances often give state regulators another potent tool in combating rogue Internet

(continued on page 74)

## Rogue Internet Drug Distributors

(continued from page 58)

drug distributors – by making it easier to tackle those in-state, brick-and-mortar drug distributors with which those amorphous, ever-changing, often untraceable Web sites may contract to dispense the actual drugs.

A number of state boards of pharmacy, including in North Carolina, Oklahoma, and Texas, have reminded their licensees of the illegality of agreeing to dispense medications for such Web sites, and to alert them to the issue. “The Board is aware that some Internet-based operations are actively soliciting pharmacists – particularly independent pharmacists – to act as a dispensing clearinghouse for Internet-based prescriptions,” warns the North Carolina Board of Pharmacy on its Web site. “Internet-based prescriptions generated without a physical examination or a prior prescriber-patient relationship . . . are not valid, and filling them violates state law. Filling such prescriptions for controlled substances also violates federal law.”

Boards are asking pharmacists to advise them and/or Food and Drug Administration (FDA) about such solicitations. While some solicitations appear to come from foreign sites (“[Texas State Board of Pharmacy] has obtained information that these domains appear to be linked to Internet

Protocol (IP) address[es] located outside the United States,” reports the Texas Board on its Web site), others appear to be generated domestically. The North Carolina Board has issued cease-and-desist letters to a number of Internet drug distribution sites.

Cooperation outside the pharmacy regulation arena also helps. In Kentucky, then-Attorney General Greg Stumbo highlighted the role of shipping facilities in a 2006 seizure of illegal prescription drug shipments. “Shipping hubs across the state are to be commended for their vigilance in recognizing when packages arriving at their hubs are not from a registered Internet pharmacy,” Stumbo stated in a press release. “We urge commercial carriers to be alert to what is passing through their hubs and call upon them to alert the KBI [Kentucky Bureau of Investigation] of suspicious packages from unlicensed pharmacies,” he said.

He also emphasized collaboration among different law enforcement entities and across states. “KBI agents are working in cooperation with Kentucky State Police, Drug Enforcement Administration, Kentucky National Guard, Florida Office of the Attorney General and the Florida Department of Law Enforcement in its efforts to crack down on rogue Internet Pharmacies shipping drugs into Kentucky,” the release stated.

Reminders and warnings are not limited to board

of pharmacy licensees. Many boards of pharmacy (and state governments in general) have endeavored to reach out to consumers as well, to inform them of the hazards of ordering drugs from unlicensed Internet pharmacies.

## Federal Efforts

Because of the Internet’s role in consumers’ illegal acquisition of controlled substances, DEA has necessarily been active in the effort to combat rogue online pharmacies. As on the state level, the nature of the Internet has made enforcement efforts difficult. “[T]he Internet has provided drug trafficking organizations with the perfect medium,” stated DEA’s Rannazzisi in his congressional testimony. “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.”

Again similar to the states, the DEA’s successes have involved those tangible, real-world aspects of drug distribution. “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,” said Rannazzisi. While the ARCOS information is limited to narcotics, he noted, it is useful in developing leads and assisting investigations in general.

Collaboration figures in here, too. “DEA has also developed a productive relationship with other businesses that are affected or inadvertently used to facilitate these Internet pharmacies,” Rannazzisi stated. “DEA’s Internet Industry Initiative was established to exploit the weaknesses inherent to the schemes used by Internet traffickers who rely extensively on the commercial services of three principal legitimate business sectors: Internet service providers; express package delivery companies; and financial services companies, including major credit card companies and third-party payment service providers.”

Both DEA and FDA have embarked on public education efforts, advising consumers about the legalities and dangers associated with purchasing drugs from unlicensed Internet drug distributors. To assist patients with identifying licensed facilities, FDA directs them to the NABP VIPPS program.

Despite occasional efforts by Congress to transfer regulation of Internet drug distributors to the federal government – a recent attempt was Senator Judd Gregg’s 2007 bill, which specified regulatory requirements for Internet drug distributors and

would have allowed the Secretary of Health and Human Services to suspend or terminate the license of an Internet pharmacy – these powers have remained with the states.

A slightly different approach was taken by Senator Dianne Feinstein and Representative Jeff Sessions, who jointly submitted legislation titled “The Ryan Haight Online Pharmacy Consumer Protection Act of 2007” in an effort to combat those Web sites that sell controlled substances without a valid prescription. Their bill, which was approved by the Senate Judiciary Committee and subsequently incorporated into an omnibus crime bill (the “Crime Control and Prevention Act of 2007,” introduced by Senator Joseph Biden in late 2007), would, among other provisions:

- prohibit online drug distributors from selling controlled substances without a valid prescription, including a practitioner’s in-person examination;
- require online drug distributors to comply with the requirements of each state in which they operate;
- require an online drug distributor to post

ownership and licensing information on its home page;

- increase criminal penalties for certain controlled substance offenses, and clarify that Internet distributors, like other drug dealers, could be prosecuted in federal courts; and
- allow a state attorney general, after giving the US Department of Justice notice and opportunity to intervene, to shut down a rogue Internet drug distribution site across the country, not just in his or her state.

### NABP Contributions

NABP was early to recognize the potential public health implications of unregulated Internet drug distributors and, in 1999, launched the VIPPS program, which remains the cornerstone of the Association’s efforts and is an excellent countermeasure for fraudulent sites. The VIPPS accreditation seal tells patients (and state boards of pharmacy) that a particular Web site has complied with licensing and inspection requirements in each state in which it dispenses prescription medications, and, further, that it has demonstrated compli-

ance with such criteria as patient rights to privacy, authentication and security of prescription orders (including the presence of a valid patient-practitioner relationship), and the availability of meaningful consultation between patients and pharmacists. In consumer education efforts by both state and federal authorities, VIPPS accreditation is held up as the easiest – and often the most effective – way to ascertain that a Web site is legitimate.

NABP has continued in efforts to assist the state boards of pharmacy in protecting the public from rogue Internet drug distributors in other ways, from public education efforts to congressional testimony. At the Association’s 103<sup>rd</sup> Annual Meeting in May 2007, members passed Resolution 103-3-07, “Internet Pharmacy Public Safety Awareness,” which resolved “that NABP continue to collaborate with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources.”

As a result of this resolution, and with a grant from Pfizer Inc, NABP is launch-

ing a new initiative to assist patients in purchasing medications safely online. (See “NABP Developing Program to Monitor Online Drug Distributors” in the March 2008 issue of the *NABP Newsletter*.) The goal of this initiative, dubbed the Internet Drug Distributor Identification (IDDI) program, is to establish a comprehensive database of Internet sites involved in the distribution and dispensing of prescription medications. The project will identify illegitimate drug distributors that are not properly licensed in the states where they are doing business. Information on noncompliant Internet drug distributors will be provided to the state boards of pharmacy and law enforcement authorities.

Unfortunately, the only thing that seems to evolve as fast as the Internet is Internet-enabled fraud and crime. Meanwhile, regulatory and law enforcement authorities continue to make inroads in their efforts to protect the public from rogue Internet drug distributors: by working together to adapt existing tools, focusing on consumer education, and cooperating across jurisdictional boundaries. Ⓢ

For the full issue of the April 2008 *NABP Newsletter* visit [www.nabp.net](http://www.nabp.net).