

**Testimony of
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**Testimony before Committee on Government Reform
United States House of Representatives
Internet Pharmacy Consumer Protection Act**

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Mr. Chairman and Members of the Committee:

I am honored to be here today and discuss with you how to curb the illegal sale of prescription drugs over the Internet, particularly those sales which result without a valid prescription.

The National Association of Boards of Pharmacy (NABP), which I represent, was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

The Internet and Its Impact on the Practice of Pharmacy

The Internet is a remarkable medium that offers seemingly limitless opportunities for improving how we live and how medications can be dispensed to patients. The legitimate Internet pharmacies serving patients in the US are providing valuable and innovative services to their patients. It is unfortunate that the benefits of these legitimate pharmacies are often overshadowed by the activities of rogue sites whose concerns do not rest with the best interest of the patient or compliance with state and federal laws.

NABP's involvement with the distribution and dispensing of medications from pharmacies utilizing the Internet began in 1997. At that time NABP began to develop the Verified Internet Pharmacy Practice Sites (VIPPS) program, an innovative initiative to inform consumers of legal and safe Internet pharmacies. From the first awarding of a VIPPS certificate in 1999 to the present time, NABP has monitored the activities of Internet sites distributing and dispensing medications. We have observed firsthand the birth, evolution, and revolution of an industry that holds promise for growing populations of patients but, if allowed to proceed along the present course, will remove the Food and Drug Administration's (FDA) drug approval system and the dispensing of medications for chronic diseases out from the US to the country, territory, or back room with the

lowest prescription drug prices, regardless of the standards or safeguards in place in those other countries or territories.

NABP works with the state boards of pharmacy, the FDA and state legislatures to develop regulatory strategies that manage this emerging practice area and provide consumers with the information needed to distinguish legitimate Internet pharmacies from rogue or illegal sites. Our efforts have helped millions of consumers and resulted in the closing of rogue and illegal sites and the prosecution of pharmacists and prescribers involved with those sites. The data we have compiled and collect daily concerning the rogue sites and their operations serves as a useful source of information for other Congressional Committees, federal and state agencies, and consumer outreach programs.

Scope of Internet Sites

In late 1997, NABP and state and federal regulators made the startling observation that Web sites were appearing on the Internet and offering prescription medications to consumers without a valid prescription in direct violation of state and federal laws and regulations. At first, it appeared that such activity was an aberration or the misguided actions of uninformed entrepreneurs who viewed the distribution of medications via the Internet in the same light of opportunity as books and compact discs. However, subsequent research into this emerging area of e-commerce indicated otherwise. NABP detected a clear pattern of lawlessness and disregard for the legal safeguards in place for the practices of pharmacy and medicine.

The numbers of Web sites grew steadily in 1998 and soon were present in all areas of the Web. Data compiled by NABP, the FDA and other state and federal agencies presented a growing area of concern and potential compromise of the US medication distribution system and public health protections. In 1999, a coordinated effort between state agencies (state boards of pharmacy and medicine) and the FDA, and the introduction of NABP's Verified Internet Pharmacy Practice Sites Program (VIPPS) increased consumer awareness about the dangers of rogue or illegal sites, and helped to close a number of rogue and illegal sites. Those efforts were making significant progress in ceasing the operations of the rogue sites when the September 11 attack occurred and provided an unfortunate opportunity for the rogue sites to re-emerge and play on the fears of a shocked nation by offering prescription drugs and products to counter bio-terrorism attacks. The number of sites on the Internet operating outside of the law increased dramatically at this time. Fortunately, the threat of an anthrax attack dissipated in the early months of 2003 and subsequently, the number of sites offering antidotes and prophylactic therapies began to diminish.

In early 2003, NABP again detected a major shift in activity on the Internet. At this time, there appeared to be an unprecedented increase in the number of Internet Web sites offering American consumers lower priced medications from Canada and other foreign sources. Sites involved in this illegal activity jammed the Internet, deluged consumers with advertisements and solicitations at every turn and click, and aggressively lobbied

senior citizen groups and other special interest groups for Congressional support to protect their activities. NABP spoke out at the time, and continues to speak out, against these sites and their illegal activities. NABP has commented extensively on the need to close these sites and end their illegal operations. Working with the states and the FDA, NABP has documented incidences of patient harm from Internet sites and pharmacies operating in Canada and other parts of the world. The illegal distribution of drugs from foreign-based Web sites must be a major concern of any effort to regulate Internet sites. Although not the primary focus of the proposed legislation before the Committee today, such rogue sites must not be ignored.

The VIPPS Program

In early 1999, working with federal and state regulators, consumers, and the legitimate Internet pharmacy industry, NABP developed the Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program fashioned traditional regulation and consumer empowerment into a thorough and successful verification and authentication system. The VIPPS process developed by NABP encompasses compliance with state and federal laws governing the practice of pharmacy and the direct verification of licensure of the Internet pharmacy with all states where licensure or registration is required. VIPPS certifies, through on-site inspections and the meticulous analysis of the site's operations and submitted written information, compliance with a 19-point criteria review. The VIPPS criteria include verification of valid licensure in all of the US states with additional criteria that concentrate on the distinctions of Internet practice such as the transmission of prescription information and patient data, confidentiality of patient records, and quality improvement and monitoring of prescription processing and patient interactions.

The VIPPS program was implemented with wide consumer acceptance and support. Information about the VIPPS program has appeared on national and local news media programs and consumer information specials. The exposure included programming on CNN, ABC World News Tonight, NPR Radio, NBC News, CBS News, and Fox Special Report. Articles, stories and consumer advice recommending the VIPPS program have also appeared throughout the print media in local newspapers across the country as well as in Time, Newsweek, the Ladies Home Journal, Consumer Reports, USA Today, Wall Street Journal, New York Times, Washington Post, and other national publications. NABP estimates that more than 10 million consumers have heard, watched, or read about the VIPPS program. Government agencies such as the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services also reference and recommend that consumers refer to the VIPPS program. Professional organizations such as the Federation of State Medical Boards (FSMB), American Pharmaceutical Association (APhA), and the American Medical Association (AMA) have also referenced and recommended consumers to the VIPPS program to consumers.

In November 2003, NABP and the National Association of Pharmacy Regulatory Authorities (NAPRA) expanded the VIPPS program to include legitimate, legal, and safe pharmacies duly registered in the various provinces. The VIPPS Canada program mirrors NABP's VIPPS program in the US and will identify for Canadian patients legal and safe Internet pharmacies accredited by a credible and valid system with standards that focus on the protection of the public health and patient safety. Presently, those Canadian pharmacies which ship prescription drugs into the US in direct violation of state and federal laws would not qualify for VIPPS certification.

NABP and NAPRA are also in discussions to develop a regulatory framework that regulates the inter-border practice of pharmacy and dispensing of medications to patients in the US and Canada. The framework would provide similar protections as those afforded US patients who utilize pharmacies engaged in the interstate practice of pharmacy and dispensing of medications. The framework will coordinate the regulatory efforts and resources of Canadian provinces and US state boards of pharmacy.

Regulatory Challenges by Practicing Pharmacy Across State Lines

The Internet changed pharmacy practice in a revolutionary manner by allowing for the electronic transmission of prescriptions and patient data, enhanced access to health care information and treatment, improved communications among health care practitioners, and distant care treatment occurring in real time. These advances have also brought new challenges to practitioners and regulators; challenges that question traditional enforcement provisions. For state boards of pharmacy the regulation of US-based sites, although exigent is not impossible. The physical presence of a building (pharmacy or wholesale operation) or person (pharmacist or prescriber) in a state or US territory provides state regulators with the information and access needed to identify these entities and successfully prosecute them. In fact, the combined regulatory actions of states and the FDA have resulted in the disciplining of practitioners, the closing of sites, the restriction of sites from operating in certain states, and multi-million dollar fines.

NABP believes and is on record noting that the state boards of pharmacy and other state regulatory agencies, working with the FDA and other federal agencies, can be effective in monitoring and regulating US-based sites offering prescription medications over the Internet. All states have in place laws and regulations governing the practice of pharmacy. These laws and regulations ensure that the provision of pharmaceuticals and pharmacist care meet accepted standards of practice and protect the public from harm. The various practice acts and regulations also establish the criteria for licensing pharmacists and pharmacies, operating a pharmacy to dispense medications to patients, and disciplining those pharmacists and pharmacies who violate state laws and regulations and endanger the health and safety of the citizens of the states.

The states have determined that Internet sites offering prescription medications are engaged in the practice of pharmacy and therefore must abide by the same laws and rules that presently apply to traditional brick and mortar pharmacies. Internet pharmacies, although unique in their structure and environment, essentially represent the operations of non-resident or mail order pharmacies. The basic construction of these systems involves the receipt of prescription orders from patients who do not physically deliver the prescription orders to the pharmacy and the delivery of prescription medications to patients who reside in locations different than where the pharmacy is located. All activities between these beginning and end points involve the practice of pharmacy and require adherence to present state laws and regulations. Additional regulations enacted in these states to specifically address Internet pharmacies have more specifically identified Internet practice and defined a valid patient-prescriber relationship.

All but a handful of states require that non-resident or out of state pharmacies license or register with them and comply with their applicable laws and statutes. These laws and regulations have been in place for almost 20 years, effectively protecting the citizens of the states and fostering cooperation among the states. What the various laws and regulations governing the practice of pharmacy and Internet sites have restricted is the operation of illegal sites seeking to bypass the regulatory system. State laws and regulations recognize the advantages of the Internet and allow for the practice of telemedicine and telepharmacy. Specific provisions of the majority of state laws and regulations allow for the electronic transmission of prescriptions, shared data bases, electronic patient profiles, and other advantages offered through the Internet and other electronic means. These laws and regulations transfer existing and accepted standards for patient care from traditional activities to the new, non-traditional activities of the Internet.

Review of H.R. 3880

Posting of Practice and Licensure Information

The required posting of information by Internet sites, outlined by H.R. 3880, is an important component of identifying and eliminating rogue and illegal sites from the Internet. NABP is concerned that simply mandating the posting of information, without independent and credible verification of the information, could provide an avenue for rogue site operators to exploit the law and mislead consumers under the guise of complying with the mandated posting requirements. NABP's VIPPS Program provides and validates directly with the appropriate state licensing jurisdiction all of the information H.R. 3880 proposes to require as well as the actual license number in the various states, contact information for the state agency holding the license, indication if the pharmacy has any disciplinary actions against the license, services offered by the Internet pharmacy, and corporate information. The VIPPS Program information is identified through the VIPPS Seal and security protected links to NABP's Web site. NABP's VIPPS program also provides consumers with the opportunity to report any problems encountered with the site or the operation of any suspicious site they may have encountered while utilizing the Internet through a consumer awareness and reporting service.

Our experience in determining the true origin of rogue and illegal Web sites indicates that such operations deliberately conceal identifying information or fabricate information to provide the appearance of legitimacy to the site and affiliated persons. It is NABP's position that without this verification and validation of information, rogue sites will post fraudulent information to mislead and confuse the public without any regard for the possible penalties or actions for engaging in such conduct.

Although H.R. 3880 affords the Secretary of Health and Human Services the option of recognizing programs such as the VIPPS to implement the proposed revisions of Section 503B of the Federal Food, Drug, and Cosmetic Act, absent the mandating of a valid and credible certification process, it is highly unlikely that this will occur. Again, if Internet sites are simply required to post information to assist consumers in distinguishing legal Internet sites from rogue and illegal sites without any independent verification of that information, rogue operators will post fraudulent information in complete disregard for the law.

Defining a Bonafide Medical Relationship

NABP applauds the sponsors of H.R. 3880 for addressing one of the most problematic areas of Internet practice, the patient-prescriber relationship. NABP is alarmed by the number of Internet sites that purport to establish a bonafide patient-prescriber relationship through the use of cyberspace consultations or medical questionnaires. In NABP's opinion, the use of a questionnaire or cyberspace consultation as the sole basis for establishing a patient-prescriber relationship does not meet the standards of medical practice and violates state and federal laws defining a bonafide patient-prescriber relationship. The proposed revisions of H.R. 3880 which define a "Qualifying Medical Relationship" will close a regulatory loophole exploited by rogue and illegal Internet sites. Requiring at least one in-person medical evaluation of the patient will help to eliminate the dangerous practices of rogue and illegal Internet sites by establishing a legitimate patient-prescriber relationship. Equally as important, the proposed requirement of an in-person medical evaluation will not adversely impact the practices of telemedicine and telepharmacy. Conversely, the proposed requirement will further qualify the practice parameters of telepharmacy and telemedicine and eliminate those Internet sites which are concerned with exploiting consumers and cannot provide an acceptable medical evaluation because doing so would reduce their profit margin and expose their activities as fraudulent and dangerous.

Nationwide Injunctive Relief

NABP also strongly supports the provisions of H.R. 3880 which allow states to bring civil action forth to enjoin the practices of illegal Internet sites and obtain nationwide injunctions against their operations. NABP's experiences indicate that the operators of illegal and rogue sites are extremely knowledgeable about existing state and federal laws and will relocate their operations to those states or areas where their activities are not specifically prohibited and may in fact fall within a regulatory "gray area." Within this "safety net" the rogue or illegal site will operate in defiance of state and federal law and

without any desire to comply with existing laws and regulations if there appears to be even a scintilla of ambiguity in the law. Nationwide injunctive relief will cease these practices and allow states to work together to close regulatory loopholes and eliminate safe havens within the US for illegal and rogue sites.

Interactive Computer Service Advertising

NABP and state boards of pharmacy believe that Internet Service Providers (ISPs), advertising services, and search engines play a direct and abetting role in the activities of illegal and rogue Internet sites. The inclusion of advertising from these sites on legitimate Internet sites misinforms consumers that such sites are legitimate and safe and have been qualified in some way by the ISP, search engine, or advertising service that accepts and transmits their advertisements or services. States are beginning to take action against such entities for aiding and abetting in the violation of state and federal laws.

NABP requests that the provisions of H.R. 3880, which hold harmless interactive computer services or advertising services be reconsidered, and that these entities be required to assume responsibility for their acceptance of funding and services from illegal and rogue sites which threaten the public health and safety.

Conclusions

NABP appreciates the opportunity to share its comments with the Committee. We are hopeful that the proposed bill can be revised to address the concerns noted by NABP. NABP is anxious to assist the sponsors and supporters of H.R. 3880 in achieving the stated objectives and ultimately in ensuring that consumers can safely use the Internet to obtain prescription medications. Thank you.