

Prepared Statement of the National Association of Boards of Pharmacy
Before the Federal Trade Commission
Internet Workshop Telemedicine/Pharmaceutical Panel
Regarding
The Impact of State Regulation on Competition on the Internet for the Dispensing of
Pharmaceuticals

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I thank the Commission on behalf of the member state boards and jurisdictions of the National Association of Boards of Pharmacy (NABP) for the opportunity to discuss the issue of state regulation of Internet pharmacies. I am Carmen Catizone, executive director/secretary of the NABP, founded in 1904 and representing all of the pharmacy regulatory and licensing jurisdictions in the United States, Puerto Rico, the Virgin Islands, eight provinces of Canada, four Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

HISTORY

Our involvement in the Internet and the delivery of pharmaceuticals began in the late 1990's with the startling observation that web sites were offering prescription medications in violation of state laws and regulations. It appeared at first that such activity was an aberration or the genesis of uninformed entrepreneurs who viewed the distribution of pharmaceuticals in the same light as books and compact discs. Subsequent research and interest in this emerging area of e-commerce indicated otherwise. As the number of sites increased, NABP detected a clear pattern of lawlessness and disregard for the safeguards in place for the practices of pharmacy and medicine.

In early 1999, working with federal and state regulators, consumers, and the Internet pharmacy industry NABP developed the Verified Internet Pharmacy Practice Sites (VIPPS) program. The VIPPS program merged traditional regulation and consumer empowerment into a voluntary certification program. The VIPPS program verifies licensure of the Internet pharmacy with all states where licensure or registration is required and certifies compliance with a 18-point criteria that focuses on Internet practice, confidentiality of patient data, and quality improvement systems. More information about the VIPPS program is provided in our complete statement.

As the VIPPS program was implemented and consumer awareness of the program increased, NABP was able to catalogue the various web sites involved in the delivery and dispensing of pharmaceuticals. The Internet sites offering prescription medications were enterprises using the exploding dot.com business model, far-sighted traditional brick and

mortar pharmacies utilizing the new medium to assist with the filling of prescription orders, and rogue sites operating outside of the law. The rogue sites were organized by some of the same entities that previously operated offshore of the United States and offered to provide to U.S. consumers through the mail, prescription medications without a valid prescription. When in operation during the late 1980's, these off shore mail order sites drew the immediate attention of U.S. regulators. Federal and state regulators effectively closed this source of illegal distribution primarily because of the highly visible nature of the off shore sites, their contact with customers through print advertisements, and the consumers' lack of interest in these sites.

The advent of the Internet provided an efficient and convenient vehicle for entities wishing to transplant the off shore mail order model to this electronic and anonymous environment. The same strengths of the Internet, which made e-commerce a new means for conducting business, allowed these rogue sites to operate outside of the traditional regulatory system. State and federal regulators were at first stymied in their efforts to regulate these sites or cease their activities. With the introduction of the VIPPS program, increased consumer awareness about the dangers of rogue or illegal sites, and enhanced state and federal regulatory efforts, the number of illegal and rogue sites diminished at the end of 1999 and beginning of 2000 after peaking in early 1999 (at one point in this period, estimates placed the number of sites operating at some 400).

The most prevalent rogue sites remaining today and based in the United States are sizeable operations well financed and organized to exploit the loopholes in federal and state regulations. These sites often create several web pages around their primary operations: medical questionnaire and cyberspace consultation areas, distribution centers, and credit card processing systems. The objective is to capture as many consumers as possible and mislead consumers into believing that the web pages are independent sites operating and offering to deliver pharmaceuticals. The appearance of a multitude of sites offering prescription medications helps to deceive a high percentage of consumers into believing that such activities are legal and acceptable practice.

The remaining rogue and illegal sites based in the U.S. represent a smattering of smaller scale models for procuring prescription medications. These sites often operate for a short time under one URL and then periodically change their URL location and slightly vary their name to avoid detection and pursuit by regulators.

An important point to note in regard to illegal or rogue sites based in the U.S. is that the physical presence of a building (pharmacy or wholesale operation) or person (pharmacist or prescriber) in a state provides regulators with the information and access needed to identify these entities and successfully prosecute them. 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 multimillion dollar fines.

A persistent concern and seemingly untouchable operations are those sites located outside of the U.S. These foreign-based sites hold little or no regard for U.S. laws and operate

brazenly on the Internet. Cyber letters issued by the FDA to foreign-based sites have impacted the operation of these sites. However, in order to achieve the desired regulatory effect of eliminating foreign rogue or illegal sites from the Internet, further efforts by the FDA and cooperation from foreign governments are needed.

In the past six months a new phenomenon has appeared on the Internet; operations to procure prescription medications from Canadian pharmacies. Consumers in the U.S. are readily accessing sites which offer medications from Canada and ordering such products sometimes fully aware that their actions violate U.S. state and federal laws. The primary motivation for this activity is the considerable disparity in prices between U.S. and Canadian pharmaceuticals. Complicating the matter further is the support of some federal and state legislators for this activity through public statements and the organization of busloads of senior citizens to travel to Canada to purchase their medications from Canadian pharmacies.

In this milieu of legal and illegal sites offering pharmaceuticals on the Internet, it is NABP's observation and position that state regulation has not restricted competition but provided the foundation to eliminate illegal and rogue sites from the Internet in the best interest of the public health. In order to understand this position it is beneficial to examine how state regulation applies to Internet pharmacies.

STATE REGULATION AND APPLICATION TO INTERNET PHARMACIES

All states have in place laws and regulations governing the practice of pharmacy set by the state legislatures. These laws and regulations ensure that the provision of pharmaceuticals and pharmacist care meet accepted standards of practice and protect the public from incompetent or dangerous practitioners and pharmacies. The state pharmacy practice acts and regulations have been in place since 1871 and have been proven effective in regulating the practice of pharmacy without creating an undue burden on interstate commerce or competition. The various practice acts and regulations 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 pharmacies and pharmacists. Internet pharmacies, although unique in their structure and environment, 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. Only five states have enacted additional regulations for Internet pharmacies. The additional regulations enacted in these states reinforce that Internet pharmacies are regulated by the states and establish some notification

requirements. The additional regulations are in accord with the regulatory framework for non-resident or out of state pharmacies and do not present any additional burden or restraint of competition. One additional state (WV) specifically prohibits “online or telephonic evaluation by questionnaire to establish an appropriate practitioner-patient relationship ...” without, in NABP’s opinion, creating an undue burden on Internet sites or restricting competition.

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 without hindering competition in this market segment. 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 do not seek to stifle competition in the marketplace but transfer existing and accepted standards for patient care from traditional activities to the new, non-traditional activities of the Internet. The standards and requirements have not been increased but adapted to the Internet environment.

Conclusions

NABP acknowledges that some people regard the dispensing of pharmaceuticals via the Internet as the same process in place for a commodity such as a book or compact disc and therefore should be regulated, or not regulated, in similar fashion. This is not and cannot be the conclusion drawn by this workshop. Prescription medications are inherently dangerous products that must be prescribed by a licensed and regulated prescriber and dispensed by a licensed and regulated pharmacist in a licensed and regulated pharmacy. To allow otherwise would compromise the safety of patients and the drug distribution system of the United States. The present regulations do not hinder competition among Internet pharmacies but in fact, establish a fair and safe standard for their operation.

The number of Internet sites presently operating legitimately indicates that this is true. Internet pharmacies forced to close or cease operations because it was not economically feasible to continue may attribute this result to the burden of state regulation. However, doing so is inaccurate and simply not true. The number of legal sites that are complying with state laws and regulations and operating successfully far outnumber the number of sites that have had to cease operations because of the burden of state regulation. Those sites that were not able to comply with state laws and regulations should cease operations because to allow them to continue to provide medications to patients without adhering to necessary standards and practice of pharmacy requirements would endanger the lives of patients.

Other Internet sites that have been unsuccessful may have engaged the wrong business model or failed to understand that the consumer's prescription medication use is different from their online purchases of other products. Successful Internet pharmacies realize that consumers require a traditional brick and mortar component and direct interaction with the pharmacist for their medication needs. The failure to realize and implement this feature into their Internet operations was a key component of their failure not compliance with state laws and regulations.

Thank you for the opportunity to participate in this workshop.