Drug Importation: The Realities of Safety and Security
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Executive Director
Testimony

Chairman Enzi and Members of the Committee:

I am honored to respond to the request of the Committee and present information concerning the National Association of Boards of pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) program. Hopefully this information can/will assist the Committee in determining if and how the VIPPS program could be utilized to help assure the safety of drugs purchased over the Internet if the US were to legalize drug importation.

The NABP 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, two 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.

In May, 2004, we appeared before the Health and Human Services' (HHS) Task Force on Importation chaired by Richard H. Carmona, M.D., M.P.H., F.A.C.S., United States Surgeon General. At that time we stated NABP's opposition to the illegal importation of drug products and presented information to document the compromise of our medication system and state regulation of the practice of pharmacy that is occurring because of the illegal importation of drug products. Our testimony also noted that the member states of NABP adopted a resolution which resolved:

That NABP continue to oppose the illegal importation of medications and express to the Food and Drug Administration (FDA) the concerns of its member boards and strongly urge the FDA or appropriate legal authority to pursue actions against state and local governments for endorsing, promoting, or engaging in the illegal importation of medications.

The illegal importation of drugs from Canada and other countries is one of the most complicated and frustrating issues confronting pharmacy regulators. It is an issue that has the potential of altering how drugs are approved, medications are dispensed in the United States, and the practice of pharmacy is regulated. In fact, if the illegal importation of drugs into the US is allowed to continue unabated, the impact on patient safety will be devastating. Patients illegally importing drugs are bypassing the drug approval process of the Food and Drug Administration (FDA) and the safety of US licensed pharmacists and

pharmacies and placing their health and well being in the hands of the country, territory, or back room with the seemingly, lowest prices for drugs.

Critics of the regulatory actions of the FDA and state boards of pharmacy against entities illegally distributing or assisting in the illegal distribution of drugs from countries outside of the US contend that there have been only a few reports of patient harm and injury. Although the number of reports may be low, the actual harm to patients could be significant. NABP maintains that the number of reported patient injuries is low and immeasurable because patients may not be able to discern whether the drugs received from other countries are authentic or appropriate and adverse reactions resulting from patients receiving wrong or counterfeit drugs may not manifest in the health care system until sometime later when the patient's condition worsens and requires emergency treatment or hospitalization. NABP also maintains that consumers purchasing drugs from other countries are reluctant to report any adverse consequences because of the fear of prosecution that could result for violating federal and state laws.

NABP's Verified Internet Pharmacy Practice Sites™ (VIPPS®) Program

The Verified Internet Pharmacy Practice Sites Program™ (VIPPS®) was introduced by NABP in 1999 and incorporates traditional regulation and consumer empowerment into a thorough and successful accreditation and certification system. 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 FDA and the Center for Medicare and Medicaid Services (CMS) also reference and recommend that consumers refer to the VIPPS program. Professional organizations such as the Federation of State Medical Boards (FSMB), American Pharmacists Association (APhA), and the American Medical Association (AMA) have also referenced and recommended consumers to the VIPPS program to consumers.

The VIPPS accreditation program is similar to the national accreditation of hospitals recognized by federal and state agencies and health care insurance companies. The VIPPS program addresses the Internet pharmacy's level of performance in key functional areas and focuses on an Internet pharmacy's ability to provide safe medications and quality care. The VIPPS program is unique to the practice of pharmacy and the Internet. There are no equal or equivalent accreditation or certification programs in the world. Other certification or accreditation programs which operate in the Internet arena lack NABP's extensive evaluation process, access to licensure and disciplinary information,

and intense onsite inspection procedures. The majority of programs representing themselves as accreditation or certification bodies for Internet pharmacies are simply promotional vehicles for Internet entrepreneurs and charlatans.

The VIPPS process ensures compliance with state and federal laws governing the practice of pharmacy and verifies directly with the state boards of pharmacy the licensure and disciplinary status of the Internet pharmacy seeking accreditation. VIPPS also certifies compliance with an 18-point criterion (Attachment A) through rigorous on-site inspections and the meticulous analysis of the site's operations and submitted written information. The VIPPS Criteria include criterion 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 Criteria also set forth performance expectations for activities that affect the integrity of the medications and quality of patient care. If an Internet pharmacy does the right things and does them well, there is a strong likelihood that its patients will experience good outcomes. NABP develops its criteria in consultation with health care experts, providers, measurement experts, regulators, and consumers. Achieving VIPPS accreditation is an indication that the Internet pharmacy is recognized for complying with national performance standards that promote safe medications and quality healthcare delivery.

In early 2003, NABP 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. Most recently, with the proliferation of Canadian Internet pharmacies exporting prescription medications to the US, NABP has discovered surreptitious Web sites designed to look like they are based in Canada, when in actuality they are operated in and/or ship medications from Latin America or overseas and have no ties to Canada other than their misappropriation of the Canadian flag.

In November of 2003, NABP and the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada 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 identifies for Canadian patients Internet pharmacies accredited through a credible process with standards focusing 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.

VIPPS: Whether and how this type of program could help assure the safety of drugs purchased over the Internet if the U.S. were to legalize drug importation

The importation of medications into the United States from Canadian and other non-US based pharmacies poses a public health concern and regulatory quagmire. The public health concern rests with the inability of foreign and US pharmacy regulators to ensure that medications illegally imported into the US are legitimate and safe because the importation activities fall outside of the existing regulatory safeguards. The regulatory position advocated by NABP emphasizes the importance of ensuring that the dispensing and distribution of medications in the United States are safe for American patients.

The only means of providing such assurances is the development of a sound regulatory framework that allows only drug products that are approved by the FDA and manufactured in FDA registered facilities to be imported in the US for dispensing to US patients from US licensed pharmacists and pharmacies. If the appropriate inter-border regulatory framework is not in place, then allowing for the purchase and import of drugs from pharmacies or foreign operations that do not comply with existing federal and state laws and regulations places US patients at significant risk. If the safeguards in place for the US drug approval system and state regulation of pharmacists and pharmacies and wholesale distributors are not in place or deliberately compromised, then US patients will be subject to the dangers of a “buyers beware” environment and left unprotected to gamble with their health and safety.

More importantly, each progression to extend the distribution source of drugs outside of the FDA drug approval process and US licensed pharmacists and pharmacies to unknown borders exacerbates an already dangerous situation. The importation of drugs without an effective regulatory framework to countries lacking valid drug approval processes, regulatory systems, or practice standards, provides for the almost certain erosion and destruction of the entire drug approval process and regulatory structure of the US. Allowing the illegal importation of drugs to continue will, in effect, turn back the hands of time to the days of the Elixir Sulfanilamide disaster (1937) when 105 people died after ingesting a preparation containing diethylene glycol, anti-freeze. It was a time before the FDA was charged to ensure the safety of drugs and the drug development strategy was to throw drugs together and if they didn’t explode, they were appropriate to sell.

The US system, based within the regulatory framework of state practice acts and the FDA drug approval and monitoring processes, has been exemplary in protecting the citizens of the various states and providing patients and health care practitioners with the assurances and confidence that the medications prescribed and dispensed are safe and effective products. The state based regulatory system successfully protects patients and is flexible enough to extend the regulatory framework and safety net across state borders and allow for the practices of telepharmacy and telemedicine.

A discussion of whether the VIPPS Program or a VIPPS model can be utilized to allow

for the importation of drugs is mute if the violation of federal laws and compromise of the FDA drug approval process are not addressed and corrected. Clearly the VIPPS program can be implemented to ensure that foreign pharmacies and wholesale distributors are dispensing and distributing medications, respectively, in accordance with state and federal laws. This can be accomplished through the following modifications of the VIPPS program:

1) NABP would define an International VIPPS Patient Care Pharmacy agreement to certify VIPPS accredited pharmacies outside of the United States. NABP would amend the VIPPS Criteria to require pharmacies dispensing medications across the border and seeking VIPPS accreditation to document and provide evidence on an on-going basis that the drug products being distributed were FDA approved and obtained from FDA registered facilities. The international pharmacy seeking VIPPS accreditation would also have to document and demonstrate compliance with the laws and the patient care standards of all jurisdictions in which the patient and the pharmacy resides.

2) NABP would work with US and foreign pharmacy authorities to develop mutual enforcement agreements with the pharmacy jurisdictions in other countries that would regulate international pharmacies by requiring the licensure/registration of these entities by the appropriate authority in the country where they are located and where the patient resides. The mutual enforcement agreements would also require continued monitoring of the distribution and dispensing of medications in order to ensure that the pharmacy maintains its compliance with all applicable laws/regulations. This requirement could also be managed through the International VIPPS Patient Care Pharmacy program.

However, and most importantly, absent action to resolve the violations of federal law, no modification of the VIPPS program is possible to create a legal and effective regulatory framework for the importation of medications to US patients. Legislation passed in Rhode Island requiring the Rhode Island Board of Pharmacy to license Canadian pharmacies despite the obvious and knowing violation of federal laws is a perilous and illogical action. The Rhode Island legislation is in effect requiring the agency mandated to uphold the pharmacy laws of the state to license pharmacies willfully engaged in violation of federal laws in complete defiance of the legislative mandate of the state board. It is inconceivable to place such a confounding burden on the state board of pharmacy or to implement an importation model that does not recognize the necessity of complying with federal law. Similarly, to implement a VIPPS like program for the importation of drugs in direct violation of federal law would not be feasible and defy the entire enforcement and legal system of the United States.

Verified-Accredited Wholesale Distributors™ (VAWD™) Program

On a final but very important note, if an importation model is advanced, provided federal law is not violated, then serious consideration must be given to the regulation and accreditation of foreign wholesale distributors. NABP's Verified-Accredited Wholesale Distributors™ (VAWD™) program, created in response to the FDA's Report on Counterfeit Drugs, provides a mechanism for the accreditation of prescription drug and

device distributors that helps to ensure the safety of the US drug distribution system and thwart counterfeit products. Similar to the VIPPS program, the VAWD program requires licensure verification, policy and procedure evaluation, and an on-site inspection to ensure compliance with comprehensive drug distribution laws and standards addressing such important issues as background checks, facility security, pedigrees, authentications, quarantine of suspect product, and verification of product sellers and purchasers. The VAWD program represents an additional regulatory model that can be utilized to oversee the safe cross-border distribution of prescription medications to US wholesale distributors and pharmacies.

Conclusions

NABP appreciates the opportunity to share its comments with the Committee. NABP respectfully requests that the Committee recognize that allowing and encouraging the illegal purchase and importation of medications from other countries without the appropriate regulatory safeguards is a serious threat to our regulatory foundation and patient safety. NABP requests further, the Committee's assistance in preserving the sanctity of current regulations so as to prevent any patient from being seriously injured by the illegal importation of drug products from countries where US laws and regulations are being ignored or the laws and standards for drug safety and effectiveness of that country or territory are not equivalent to US laws and standards. NABP also respectfully requests that if importation of medications to US patients is allowed then careful consideration be given to the importance of federal and state laws, maintaining the FDA drug approval and monitoring process, and the adoption of solutions that are focused on patient safety.

Thank you for the opportunity to address this important issue.