Testimony of

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Executive Director/Secretary
National Association of Boards of Pharmacy Boards
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Examining the Implications of Drug Importation,

Mr. Chairman and Members of the Committee:

I am honored to submit information on the implications of the illegal importation of drugs into the United States on the public safety and state regulation of the practice of pharmacy.

The National Association of Boards of Pharmacy (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.

NABP does not oppose importation if it can be implemented within the safe and secure regulatory framework of the Food and Drug Administration (FDA) and state boards of pharmacy. NABP does oppose the illegal importation of medications which is presently occurring and compromising the integrity of our medication system and state regulation of the practice of pharmacy. At our recently concluded Annual Meeting, which marked the 100th Anniversary of the founding of NABP, the member boards passed 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.

Illegal Importation is a Real Threat to the Public Health and Safety

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 medications are dispensed in the United States and how the practice of pharmacy is regulated. In fact, if the illegal importation of drugs into the US is allowed to continue, the impact on patient safety, pharmacy practice, and the regulation of pharmacy practice will be devastating. Patients illegally importing drugs are bypassing the drug approval process of the Food and Drug Administration (FDA) and the safety of licensed US pharmacies thus placing their health and well being in the hands of the country, territory, or back room with the seemingly lowest prices for pharmaceuticals.

At its worst, the illegal importation of drugs creates the opportunity for unknowing and unsuspecting patients to suffer harm, counterfeit and dangerous drugs to contaminate the US medication distribution system, and a thalidomide-like disaster to reoccur.

When the patient safety concerns of state boards of pharmacy, the FDA, and other regulatory agencies are ignored by patients, governors, mayors, and legislators with a chilling, "If the illegal importation of drugs is unsafe, then show us the bodies!" the situation becomes even more compelling. NABP cannot accept the premise that people must die from the illegal importation of drugs before the existing laws ensuring the safety of patients are complied with and enforced. The "show us the bodies" strategy proposed by some legislators, governors, mayors, and other public officials is irresponsible.

Critics of the regulatory actions of the FDA and state boards of pharmacy against entities distributing or assisting in the distribution of medications from other countries 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 is immeasurable and 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, injuries 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, and consumers purchasing drugs from other countries are reluctant to report any adverse consequences because of the fear of prosecution for violating federal and state laws.

NABP's response to critics of the actions of the state boards of pharmacy to enforce existing state and federal laws protecting the public and prohibiting illegal importation is the presentation of reports from consumers describing real problems which are occurring with illegal importation. Some of the incidents reported to NABP include:

? A Wisconsin patient who ordered medications from a Canadian web site and suffered unexplained reactions after taking the medications received.
? Consumer complaints, totaling thousands of dollars, reporting that payment was made (credit

cards charged) and no product received.
? Consumer complaints of counterfeit or inactive products:
o Ordered Acyclovir 400MG from this site received some other medication. Verified using imprint codes.
o Product has no effect. Seems counterfeit.
o The pills have no obvious effect.
o I have taken pain medication before (prescribed by a local doctor). The effects of such meds are obvious. For one thing, the taste is bitter, bordering on awful. In contrast, the pills from MedPrescribe have no taste (I split one in half and tasted it). More importantly, the MedPrescibe pills have no effect (no benefit). In short, they do nothing to alleviate my pain. Nothing.
o The item I received was very close to the shape and size of genuine Viagra. However, they bore no marking, logo, or insignia. Also the surface of the tablet was not as smooth and polished as real Viagra. The tablets were received sealed inside of a foil pouch with no indication of origin.
o Order arrived with pills in a zip lock bag with drug name and dose on an adhesive label stuck on the bag. No return address on the mailing envelope and no receipt in the envelope.
o I ordered "Tramadol" from this site, but what I received was not Tramadol. I contacted the poison control center, and they stated that they did not know what this medication was, nor did any local pharmacy know. I called [the site's] customer service number but they would not let me speak to the pharmacist that filled the script.
? Consumer complaints regarding illegal and life-threatening access to addicting drugs,
o My wife is ordering drugs such as phendimetrazine and clonopin over the internet. They arrive by FedEx. Her charge card is charged because she gave the pharmacies her info. The pharmacies have some unknown drugs.
o The header read, Vicodin, 24 Hour Sale Online - looks to be aimed at drug addicts. My son is a prescription drug addict (currently non-using), so the potential is very high.

One of the most startling examples of the atrocities of illegal importation drugs is the receipt of drugs wrapped in tin foil void of any labeling, product identification, directions for use, warning labels, or protective container.

NABP has also learned that the purchase and import of drugs from other countries is gravely compromising state laws and regulations by granting the authority to practice medicine and prescribe medications to unqualified, unlicensed individuals and fueling the proliferation of solicitations for controlled substances:

? A US entity affiliated with a Canadian pharmacy operation is paying paramedics in the US to conduct the physical examination and diagnosis of patients. The paramedics' examinations and diagnosis are then forwarded to a Canadian pharmacy where prescriptions are issued by a Canadian doctor and drugs shipped to US patients. This activity contravenes US laws by allowing paramedics to practice medicine without appropriate education, training, and licensure.
? A certification/purchasing program is providing the means for psychologists to illegally order psychotropic drugs (e.g. barbiturates, Clozapine, haloperidol, etc.) for their patients through a Canadian pharmacy. Again, the opportunity to obtain prescription medications through foreign sources is directly abrogating the US regulatory system and allowing individuals to practice

medicine without the appropriate education, training, and licensure.
? NABP continues to identify a staggering number of web sites brazenly offering controlled substances without a valid prescription (as required by federal and state laws) and a never before witnessed preponderance of spam emails offering unrestricted and illegal access to controlled substances.

The General Assembly of the State of Rhode Island passed legislation that will require the Rhode Island Department of Health to issue licenses to Canadian pharmacies. The legislation became law without the governor's signature in early July and distinguishes Rhode Island the first state to allow foreign pharmacies to obtain U.S. pharmacy licenses. The law's disregard of the existing state regulations and safeguards is particularly troubling to NABP in its mandate that "any pharmacy located in a province of Canada which maintains a valid, unexpired license, permit, or registration, to operate the pharmacy in compliance with the laws of said province shall be licensed in this state upon payment of a license fee ..."

The Food and Drug Administration directed a letter to Rhode Island Governor Carcieri warning him that federal law supersedes the new law and thus deems the state law unconstitutional. The FDA further noted to Governor Carcieri that the Rhode Island law will undermine the FDA's efforts to control drug quality.

The entire regulatory process for the practice of pharmacy could be decimated if other states follow the actions of Rhode Island and mandate the licensure of Canadian pharmacies with laws that are unconstitutional and completely compromise federal and state public protection safeguards. Comparable actions by other states could extend the distribution of drugs to US patients from outside of the US and Canada to countries or territories with laws and standards that differ markedly from the US. In doing so, such actions would eliminate the drug approval process of the FDA and replace state regulation with unknown and disparate regulatory processes and standards. No individual state would have control over the medications provided to its patients because the entire distribution system would be compromised by the state that allows for the purchase of drugs from the country with the lowest prices, regardless of what standards may exist in that country.

Importation Places Patients Outside of Regulatory Safeguards

NABP acknowledges that appropriate safeguards exist within Canada's federal and provincial regulatory systems to ensure that the dispensing of medications in Canada to Canadian patients is safe. Similarly, NABP attests that the dispensing of medications to US patients within the US regulated system is safe.

Unfortunately, the same safeguards do not exist for US patients purchasing and importing drugs from Canada and other countries. Information received by NABP indicates that although Health Canada prohibits the import of drugs outside of the Canadian approval system for dispensing to Canadian patients, it does not prohibit or regulate the import of such drugs for export to US patients. The regulatory void and breach of the safety net for US patients is significant and unknown to the overwhelming majority of patients ordering drugs from Canadian, or believed to be Canadian, pharmacies. NABP learned first-hand from the president of an Internet pharmacy

corporation based in Canada that drugs shipped to US patients may not be approved by the Canadian drug approval process and may originate in New Zealand, Vietnam, Pakistan or any country in the world where prescription drug prices are lower than those in the US or Canada.

In fact, there are no limitations as to where drugs will originate from for delivery to US patients. Although NABP has information regarding the drug approval process and provincial regulatory system in Canada, related information from countries in Europe and other parts of the world is extremely limited. Each progression to extend the distribution source to unknown borders further away from the FDA drug approval process and state regulation of pharmacy practice makes the situation more dangerous. The extension of importation to countries lacking effective drug approval processes, regulatory systems, or practice standards, the further the erosion and destruction of the entire regulatory structure for the practice of pharmacy. The US system, based within the states and the FDA, 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 to become realities.

The keys to this interstate regulatory framework have been uniform practice standards, state licensure of pharmacists and pharmacies, and licensure or registration of non-resident pharmacies. In fact, 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 in some states for almost 20 years, effectively protecting the citizens of the states and fostering cooperation among the states. The nonresident pharmacy laws and regulations protect the practices of pharmacy and medicine across state lines without unduly burdening interstate commerce and rightfully restricting the operation of illegal operations seeking to bypass the regulatory system of the states. State laws and regulations also allow for Internet pharmacies, the electronic transmission of prescriptions, shared data bases, electronic patient profiles, and other means for patients to receive pharmacist care and appropriately prescribed medications across state lines, through the Internet, or by the use of the mail. These laws and regulations transfer existing and accepted standards for patient care from traditional brick and mortar pharmacies to new, non-traditional Internet pharmacies and interstate practices. In order for importation to occur safely and appropriately, the same regulatory framework and safeguards must be in place across the borders of the US.

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 risk. If the safeguards in place for the US drug approval system and state regulation of pharmacies and wholesale distributors are deliberately compromised, US patients will be subject to the dangers of a "buyers beware" environment and left unprotected to gamble with their health and safety.

NABP is not willing to accept a "buyers beware" environment for US patients and finds itself in the middle of a policy and political quagmire concerning access to medications and preservation of state regulation and patient safety standards. Until importation is legalized, NABP must stay the course of assisting its members in enforcing existing laws and regulations and prosecuting those entities involved in the illegal importation of drugs.

On June 21 and 22, representatives of the state boards of pharmacy and state attorney general offices participated in a special workshop to discuss the public health dangers of illegal importation and the successful prosecution of physicians, pharmacists, and pharmacies involved in this illegal activity. The workshop identified the legal basis and strategies for pursuing action against those entities involved in the illegal importation of drugs and allowed states to share their experiences in dealing with this complex and sometimes irresolvable problem.

As a result of the workshop, an enforcement template to guide state boards of pharmacy and the offices of the attorneys general in assembling the information needed to prosecute entities involved in the illegal importation of drugs will be distributed to all states. A strategic planning process was also initiated at the workshop and will be continued at an upcoming Fall Conference to help states manage a regulatory environment significantly impacted by efforts to bypass state laws and regulations and the ongoing globalization of the practices of pharmacy and medicine.

Legalized Importation Requires an Inter-border Regulatory Framework
NABP recognizes that a solution resolving the conflict of affordable access to medications versus safety concerns must be developed to address the needs of US patients and prevent irreparable damage to, if not the elimination of, the regulatory systems in the US. The first step of this process was the launching of the VIPPS program in Canada in November 2003 by NABP and the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada. 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.

NABP is also in discussions with a variety of regulatory agencies and affected stakeholders to develop the necessary regulatory framework to regulate the inter-border practice of pharmacy and dispensing of medications to patients in the US and Canada if legislation legalizing importation is enacted. The framework would provide similar protections as those afforded US patients who utilize pharmacies engaged in the interstate practice of pharmacy and would focus on identifying and monitoring the source of medications. The framework will coordinate the regulatory efforts and resources of the Canadian provinces and US state boards of pharmacy.

In closing, NABP respectfully requests that the Committee recognize that allowing and encouraging the 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 medications from other countries where US laws and regulations are being ignored or the laws of

that country or territory do not equate to US laws and regulations. NABP does not believe that even one patient should suffer or be harmed as a consequence of disregarding federal and state laws that ensure the dispensing of safe and effective medications to US patients.

Thank you for the opportunity to address this important issue.