

National Association of Boards of Pharmacy
Position Paper on the Importation of Foreign Prescription Drugs
March 2003

Patients in the United States are facing a crisis. Access to affordable medications is driving patients outside of the US regulatory system into unidentified and unregulated areas. Purchasing medications from unknown and illegal sources via the Internet and other means is compromising the US medication distribution system and making US citizens vulnerable to bioterrorism attacks. Data collected by NABP indicates that the importation of drugs from foreign countries is fast becoming a concern for state and federal regulators. The US Food and Drug Administration (FDA) estimates that approximately two million parcels containing FDA-regulated products for personal use enter this country annually through international mail facilities.¹ Other sources estimate that nearly 70 pharmacies in Canada (40 in Manitoba) shipped almost \$500 million dollars worth of prescriptions into the US in 2002.² Fueling this mass exodus from US pharmacies to foreign outlets, particularly Canadian pharmacies, are US prescription drug prices and weak foreign currencies. These two factors allow for substantial savings by US patients on their prescription medications.

As an organization whose primary concern is assisting its member state boards of pharmacy in protecting the public health, the National Association of Boards of Pharmacy (NABP)³ is concerned that, while some Americans are choosing between purchasing their prescription medications and purchasing other staple necessities, others are ignoring the possible dangers associated with the unregulated importation or reimportation of prescription medications. The distribution by unregulated drug outlets of expired, contaminated, subpotent, superpotent and counterfeit drugs is a significant potential danger linked to foreign medications. Foreign dispensers may provide patients with incorrect or contraindicated medications, incorrect strengths, or medications without adequate directions for use. Absent regulation from the state boards of pharmacy, foreign drug outlets may not have implemented the appropriate standards and safeguards to prevent such occurrences. The “rewriting” of American prescriptions by foreign prescribers introduces another whole host of problems. Foreign prescribers often lack information regarding the patient’s medical and medication history and “unauthorized” therapeutic substitutions and transcription errors have been reported.

Most importantly, in all such instances, patients may never know there is a problem. Even if a problem is discovered by a patient, there is little or no recourse, since the actual dispenser or prescriber may not be known, there may be no legal authority to which a complaint may be submitted and action taken, and, oftentimes, patients have waived their right to sue⁴.

¹ *Drug Importation: Hearing before the House Subcommittee on Health*, 107th Cong., 2d Sess. (July 25, 2002) (statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning, and Legislation, FDA).

² Joel Baglole, Getting the Gray Out, *Wall Street Journal*, February 13, 2003.

³ NABP is the professional organization that represents state boards of pharmacy in all regions of the United States, the Virgin Islands, Puerto Rico, eight provinces of Canada, four states in Australia, South Africa, and New Zealand. NABP was established in 1904 to develop uniform standards and procedures for pharmaceutical licensure and for the transfer of licensure. Since its inception, NABP has been repeatedly called upon to develop programs and services to assist the state boards in their charge to protect the public health, safety, and welfare.

⁴ In fact, NABP has discovered that most if not all Canadian Internet pharmacies require US, but not Canadian, patients to waive their right to sue if a medication error occurs.

The potential for harm exists even with medications obtained from Canada. Canadian drugs, like all foreign drugs, are outside the realm of the US Food and Drug Administration (FDA) approval process and oversight systems, including those manufactured here in the US and exported. FDA officials maintain that once these products leave the US and control of the manufacturer, there is no way to verify where they have been, the conditions under which they have been stored, and whether or not they have been tampered with or contaminated. In light of threatened terrorist attacks, the risk of tampering seems to be one of great significance.

An added concern is that foreign brand-name drugs, including Canadian drugs, are not necessarily the same as their US counterparts. Different dosages and dosage forms exist and drugs often have different proprietary names, further adding to the confusion. Many generic drugs sold in Canada are even not available here in the US, are not manufactured in FDA-approved facilities, and have completely bypassed the FDA approval process.

Of utmost concern is the lack of ability to determine the actual country of origin. An order for what is purported to be a Canadian drug may never be filled by a legitimate Canadian pharmacy with a Canadian drug or even be filled in Canada. The well-known risks that all consumers take when purchasing over the Internet, where, for example, an anonymous company may be “here today and gone tomorrow” or an illicit business is disguised as a legitimate organization, are heightened when purchasing foreign drugs.

The newest twist to Canadian drug importation involves prescription “facilitators,” services that take prescription drug orders from patients then transmit them to Canadian pharmacies for dispensing. Although these operations, which range from Internet sites to store fronts, do not stock or dispense drugs, it is the position of NABP that they are conducting the practice of pharmacy and must be appropriately licensed by the state board of pharmacy.

Scope of the Problem - Study Results/Statistics

FDA/US Customs Service Studies

In an effort to more definitively identify the risks to the public from the drug products being shipped into the US, as well as the level of effort and resources required to handle drug importations at a mail facility, in early 2001, the FDA and US Customs Service conducted a survey of imported drug products entering the US through the Carson City, California mail facility.⁵ Over a period of five weeks, it was estimated that approximately 16,500 packages (650/day) could have been set aside for FDA review. Actually reviewed were 1,908 packages (72/day), with 721 packages containing 197 different drug products from 19 foreign countries detained. Addressees were notified that the package contents appeared to be unapproved for use in the US, misbranded, and/or a drug requiring a prescription.

Eight percent of the packages contained drugs that could not be identified due to the lack of labeling or labeling in a foreign language. Most of the drugs were packaged in plastic bags and one shipment contained drugs taped between magazine pages. Several samples did not appear to correspond with any FDA-approved drugs. One package contained a drug denied FDA approval due to lack of efficacy data and cardiac risks. Several shipments contained three drugs

⁵ *Drug Importation, supra* note 1.

withdrawn from the market due to safety concerns. Several controlled substances were identified, including lorazepam, codeine sulfate, chlordiazepoxide, chloral hydrate, and diphenoxylate.

Many of the drugs found were intended to treat conditions that only a physician can properly diagnose, and have potentially serious side effects, contraindications, and drug/food interactions. These drugs included antibiotics (nearly 10 percent) and steroids. The great majority of products were suspected of being issued without a prescription because less than four percent of addressees responded to detention notices by providing evidence of prescription or practitioner oversight. Overall, the FDA concluded the primary risks to patients were those associated with 1) taking drugs of unknown origin or quality, and 2) taking prescription drugs without prescriber supervision.

Similar border surveys conducted by the FDA at points of entry from Mexico and Canada revealed comparable results.⁶ A survey at the Mexican border, conducted at eight border points in California, Arizona, and Texas over four hours on August 12, 2000, found the following:

- Over 600 persons, mostly older Caucasian males, were found carrying prescription drugs across the border.
- Sixty-three percent of the persons interviewed had prescriptions for the medications they were bringing into the country (59 percent US prescriptions and 41 percent Mexican prescriptions).
- The most common drugs were amoxicillin, Glucophage (metformin), Premarin (conjugated estrogens), Vioxx (rofecoxib), Retin-A (tretinoin), Tafil (alprazolam), Celebrex (celecoxib), penicillin, Viagra (sildenafil), carisoprodol, and Dolo Neurobion (a vitamin supplement not available in the US that contains metamizole, a substance that is banned in the US due to potentially fatal agranulocytosis).

A second survey at the Mexican border, conducted at seven ports of entry over four hours on April 11, 2001, again found analogous results:

- 586 persons brought 1,120 prescription drug products into the US.
- Fifty-six percent had a prescription for the medications (61 percent US prescriptions and 39 percent Mexican prescriptions).
- The most common drugs imported were amoxicillin, Premarin, Claritine (loratidine), Terramicina (oxytetracycline), ampicillin, ibuprofen, penicillin, Vioxx, Tafil, Dolo Neurobion, Glucophage, Celebrex, naproxen, Retin-A, Ventolin (albuterol), and Valium (diazepam).

On January 6, 2001, the US Customs Services detained for the FDA 33 passenger vehicles (of a total of 10,374 passenger vehicles and 58 buses) crossing the Canadian border over eight hours at three ports of entry in New York, Michigan, and Washington. Interviews of the passengers found:

- Thirty-five persons carrying 47 containers of medications.
- The most common reasons given for import was that the products were available without a prescription and cost less than in the US.

⁶ *Drug Importation, supra* note 1.

- Most of the drugs were pain medications, primarily A-222 (acetaminophen, caffeine, and codeine).
- The next largest group of products found was herbal products not available in the US.
- Other products included Tobradex (tobramycin/dexamethasone), Claritin, Allegra (fexofenadine), and Sibelium (flunarizine HCl, a calcium channel blocker).

Researchers at the University of Texas conducted a survey of declaration forms submitted to Customs over 84 days, between July 1994 and June 1995, to assess the prevalence of patients purchasing medications from Mexico. Again, it revealed great concern regarding the importation of controlled substances.⁷ The most common drugs declared were Valium, Rohypnol (flunitrazepam, commonly known as the “date rape drug”), Tafil, Tenuate Dospan (diethylpropion), Neopercodan (propoxyphene), Diminex (mazindol), Asenlix (clobenzorex, an anorexiant), Tylox (oxycodone/acetaminophen), Nubain (nalbuphine), Qual (diazepam, propoxyphene, acetaminophen), Halcion (triazolam), Ritalin (methylphenidate), Ativan (lorazepam), and Somalgesic(naproxen/carisoprodol), with all except Somalgesic being controlled substances.

NABP Information

Between October 2002 and February 2003, NABP received seven complaints from consumers regarding contacts with what appeared to be foreign pharmacies. Three patients indicated they had been defrauded in that they paid for an order and never received it.⁸ Two patients reported having received what appeared to be counterfeit drugs.⁹ Another person, apparently testing the integrity of the Canadian-US system, complained that she was able to receive prescription medications without a prescription.¹⁰ Yet another patient from Great Britain reported receiving Meridia from Thailand loose in a baggie.¹¹

A February 2003 survey of state boards of pharmacy by NABP found that at least six boards have received complaints regarding foreign pharmacies. The Nevada Board of Pharmacy reported complaints about delayed deliveries, the receipt of incorrect product, and a Sri Lankan “bait and switch” scheme.¹² The New York Board of Pharmacy received a complaint about drugs

⁷ McKeithan EK, Shepherd MD, *Pharmaceutical products declared by US residents on returning to the United States from Mexico*, 18 Clin Ther, 1242 (1996).

⁸ www.1medsource.com, which sells foreign versions of a variety of prescription medications, including controlled substances, and sells online prescriptions to those who need them, is registered to an address in Mexico; www.pharma-international.com, which sells both controlled and non-controlled substances seemingly without a prescription, appears to be based in Pakistan; www.overseas-prescription.com, which focuses on selling lifestyle medications and controlled substances, no prescription required, appears to be based in the US but links consumers to foreign medications supplied by unknown sources.

⁹ www.Rx-Phy.com, which sells lifestyle drugs, is registered to an address in Namibia; www.ltmc.net, which appears to sell only Viagra (with no Pfizer markings, according to the complainant), posts an address in Florida, but is registered to an address in Israel.

¹⁰ This person, an employee of a US prescription drug manufacturer, received drugs without a prescription from www.canadapharmacy.com, which sells lifestyle drugs but no controlled substances, and is apparently based in Washington and Vancouver. The drugs were reportedly shipped from Canada.

¹¹ www.1drugstore-online.com, www.1onlinepharmacy.com sells a variety of prescription drugs, including Meridia.

¹² This involved a scenario where the “pharmacy” advertised Canadian drugs but contacted the patient to encourage the acceptance of a drug manufactured in Sri Lanka. The Sri Lankan drugs were much less expensive than the Canadian drugs and the business apparently made more money on the Sri Lankan transaction.

labeled in a foreign language, and the South Dakota State Board of Pharmacy reported complaints about drug “switching” (Zoloft v. Paxil). The Minnesota Board received a complaint about not receiving \$300 worth of drugs that had been charged to the patient’s credit card. The Oregon Board of Pharmacy received a complaint about a medication error where a breast cancer patient received lisinopril instead of tamoxifen and took the lisinopril for three months before the error was discovered. The Board is currently consulting with that state’s attorney general on action that may be taken. The North Dakota Board of Pharmacy reported incidents of duplicate therapy, one due to slightly different names of Canadian and US drugs and the other due to the filling of two different drugs in the same therapeutic category for the same condition, one at a US pharmacy and the other at a Canadian pharmacy.

Legal Assessment

New drugs marketed in the US must be approved by the FDA based upon demonstrated safety and efficacy and must be produced in manufacturing plants inspected and operated in conformance with FDA’s current Good Manufacturing Practices. In addition, their shipment and storage must be appropriately documented and subject to inspection. This “closed” system has been successful in preventing unapproved, adulterated or misbranded drugs from entering interstate commerce. With this in mind, the importation or reimportation of prescription drugs from foreign countries generally violates one or more of the following sections of the Federal Food, Drug, and Cosmetic Act (the Act):¹³

- 21 USC § 355, which makes it illegal to introduce or deliver into interstate commerce unapproved drugs. Foreign versions of US approved drugs are considered unapproved because FDA approvals are manufacturer-specific, product-specific, and include such factors as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance (21 CFR § 314.50). Even if the drug is originally manufactured in the US, foreign versions of US approved drugs are usually classified as unapproved because the versions produced for foreign markets usually do not meet all the requirements listed above.
- 21 USC § 353(b)(2), which makes it illegal to dispense a drug without proper labeling.
- 21 USC § 353(b)(1), which requires a valid prescription for dispensing prescription drugs.
- 21 USC § 331(a), (d), (i), which prohibit the introduction or delivery into interstate commerce of misbranded, adulterated, or counterfeit drugs.
- 21 USC § 381(d)(1), which makes it illegal for anyone other than the manufacturer to reimport a drug.

The liabilities associated with violations of the Act can be found in the following sections of the US Code¹⁴:

- 21 USC § 332, which allows a court to enjoin violations of the Act.

¹³ Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA to Robert P. Lombardi, Esq., The Kullman Firm (February 12, 2003)(on file at NABP).

¹⁴ *Id.*

- 21 USC § 333, which states a person can be held criminally liable for violations of the Act.
- 21 USC § 333(a)(1), which states a misdemeanor violation of the Act is a strict liability offense [see also *United States v. Dotterweich*, 320 US 277, 284 (1943)].
- 21 USC § 333(a)(2), which says a violation that is committed with intent to defraud or mislead or after a prior conviction for violating the act is a felony.
- 21 USC §§ 333(b)(1)(A), 381(d)(1), which states it is a felony to knowingly import a drug in violation of the reimport prohibition.
- 21 USC § 331, which says those who can be found civilly and criminally liable include all who cause a prohibited act.
- 18 USC § 2371, which says those who aid and abet a criminal violation of the Act, or conspire to violate the Act, can also be found criminally liable.

Personal Use Exemption

According to the FDA, under certain defined circumstances, the agency allows patients and physicians to import small quantities of unapproved drugs for the treatment of a serious condition. This policy has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to patients in the US. It is not intended to allow the importation of foreign versions of US approved drugs. This policy outlines the FDA's enforcement priority and guides the FDA in their enforcement discretion with respect to imports by individuals of drugs for their personal use. It does not change the law and does not give license to individuals to import or export foreign medications into the US.

State Law

Currently, 43 states require non-resident pharmacies to register with state boards of pharmacy if they are shipping prescription drug products to citizens of that state.¹⁵ These requirements allow state boards of pharmacy to order non-resident pharmacies to stop shipping product into the state. Within the US, such orders can be enforced by the board of pharmacy where the violation took place, or by mutual action by the board of pharmacy in the state where the pharmacy is located.

An August 2002 survey of the state boards of pharmacy conducted by NABP indicated that nine jurisdictions found their state laws and regulations to be broad enough to allow them to register foreign pharmacies;¹⁶ however, the dichotomy of providing legal recognition to an entity violating federal law is one that has prevented any state from registering foreign pharmacies¹⁷. Additionally, the enforcement of a state action or the initiation of a mutual action by a foreign licensing body is virtually unheard of, making it difficult, if not impossible, for state actions to have any effect on foreign pharmacies.

Drug Importation Legislation

¹⁵ National Association of Boards of Pharmacy. Survey of Pharmacy Law 45-47 (2002-2003).

¹⁶ National Association of Boards of Pharmacy, *Canadian Drug Imports to the United States*, 31NABP Newsletter, 97 (2002).

¹⁷ Although reports received by NABP on March 12, 2003, indicate that the Rhode Island legislature is considering such action, a move opposed by the Rhode Island Board of Pharmacy.

NABP believes that recent efforts by Congress to placate the swelling numbers of constituents seeking prescription drug price relief will cause more harm than good. One proposal would allow pharmacists and wholesalers to import drugs from Canada¹⁸. It is our position that such activities would put at risk the “closed” system currently guarded by federal, and to some extent, state authorities. Without jurisdiction over foreign sellers, it is and will continue to be impossible to ensure the products being sent to the US are approved, safe, effective, and not adulterated, contaminated or counterfeit.

Another proposal seeks to fine drug manufacturers for refusing to ship medications to Canadian pharmacies that dispense to US patients¹⁹. We cannot support legislation that penalizes anyone for complying with the laws and regulations of the US. Our members believe that existing laws and regulations prohibiting the importation of unapproved drugs must be obeyed and enforced or changed to incorporate these products and pharmacies into the federal and state regulatory system. Access to medication through illegal means does not resolve the problem of access but only increases the chances of US patients being harmed by unregulated entities.

A third proposal would disallow certain tax deductions and credits for pharmaceutical manufacturers that “discriminate” against Canadian pharmacies that sell prescription drugs to US patients.²⁰

Canadian Regulators

Several provincial authorities have advised federal and state regulatory agencies and NABP of their support on this issue and have identified or issued various laws, regulations, or standards of practice in keeping with this position.

Manitoba Pharmaceutical Association

The Standards of Practice of the Manitoba Pharmaceutical Association prohibit a pharmacy from breaking a law in the jurisdiction where the patient resides.²¹ Upon documentation of violation of state law, Manitoba advises its pharmacies to comply with that state’s law.²²

Ontario College of Pharmacists

The Ontario College of Pharmacists has stated that US prescriptions are not legal per Ontario and Canadian law, and the filling of prescriptions for US patients in Canada does not correspond with a safe standard of practice, because pharmacies are not providing counseling and other patient care services. In early 2003, the Council of the Ontario College of Pharmacists adopted a policy that prohibits the participation in agreements with physicians to co-sign or rewrite prescriptions for foreign patients, and prohibits waivers of patient care standards.²³

¹⁸ S. 7, 108th Cong., 1st Sess. (2003).

¹⁹ H.R. 847, 108th Cong., 1st Sess. (2003).

²⁰ S. 477, 108th Cong., 1st Sess. (2003).

²¹ The Manitoba Pharmaceutical Association, *Internet Pharmacy Standards* (July 2001).

²² Letter from Ronald F. Guse, Associate Registrar, Manitoba Pharmaceutical Association to James T. Carder, Executive Director, Wyoming Board of Pharmacy (June 4, 2002)(on file at NABP).

²³ Ontario College of Pharmacists, *New Policy Respecting Out of Country Prescriptions Approved*, Pharmacy Connection (Jan/Feb 2003). The full text of the policy reads: “Pharmacists shall not facilitate or enter into agreements with physicians for the purposes of co-signing or rewriting prescriptions for out-of-country patients. If a prescription is filled in Ontario, the Standards of Practice for pharmacists and pharmacies for Ontario must be met,

Newfoundland Pharmaceutical Association

The Newfoundland Pharmaceutical Association recently adopted Internet standards of practice that say a pharmacist shall not knowingly fill prescriptions that are issued in a manner contrary to normal practice standards, and uses as an example the countersigning of prescriptions written by a physician in another country if the physician has not seen and examined the patient.²⁴

College of Physicians and Surgeons of British Columbia

In June 2002, the College of Physicians and Surgeons of British Columbia issued a policy that declares Internet prescribing based on a mailed, faxed, or electronically transmitted questionnaire, and the countersigning of prescriptions issued by other physicians without direct patient contact to be activities that fall outside acceptable medical practice standards.²⁵

NAPRA

In 2002, the National Association of Pharmacy Regulatory Authorities (NAPRA) in Canada partnered with NABP to launch the Verified Internet Pharmacy Practice Sites (VIPPS)²⁶ program in Canada. This program will certify validly licensed, legitimately operating online Canadian

regardless of where the patient resides and these Standards cannot be waived through any agreements or contracts. The Council considers that pharmacists who knowingly facilitate the practice by any Ontario prescriber to co-sign/authorize prescriptions where no established physician/patient relationship exists are acting unethically and fall below a standard of practice of our profession.”

²⁴ Newfoundland Pharmaceutical Association, *Standards of Pharmacy Practice, The Provision of Pharmacy Services via the Internet* (April 12, 2002).

²⁵ College of Physicians & Surgeons of British Columbia, *Policy Manual, Prescribing Practice/ Countersigning, Prescriptions/Internet Prescribing* (June 2002). The full text of the policy reads: “Prescribing for a patient solely on the basis of mailed or faxed information, or an electronic questionnaire, or countersigning a prescription issued by another physician, without direct patient contact, is not an acceptable standard of medical practice. The provision of a prescription to a patient is a medical act. It is the result of a clinical decision made by a physician subsequent to a comprehensive evaluation of the patient by that same physician. This evaluation should be based on a face-to-face encounter with the patient which includes the usual elements of clinical assessment such as the taking of a history, conducting a physical examination and any necessary investigations, and reaching a provisional diagnosis. Patient records should clearly reflect that the pertinent elements of the patient evaluation have been completed and documented. In situations where the patient is known to the physician, and where he or she has current knowledge of the patient’s clinical status from previous encounters, a prescription may be provided on the basis of a more focused clinical evaluation. If the physician is part of a group practice or a call group, he or she may choose to accept a previous patient evaluation by an associate as the basis for further prescribing. However, under such circumstances, the prescribing physician would retain the professional responsibility for the prescription that he or she has written. If a medication is prescribed, physicians have a responsibility to advise the patient about such matters as, drug effects and interactions, side effects, contraindications, precautions, and any other information pertinent to their use of the medication. There is an obligation for the prescribing physician to arrange appropriate follow-up, either personally or with the most responsible physician.”

²⁶ NABP’s VIPPS program and its accompanying VIPPS seal of approval identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. VIPPS pharmacy sites are identified by the VIPPS hyperlink seal displayed on their Web site. By clicking on the seal, a visitor is linked to the NABP VIPPS site where verified information about the pharmacy is maintained by NABP. Accessing the VIPPS site at www.nabp.net allows visitors to search for a VIPPS Internet pharmacy.

pharmacies that meet the program's criteria. The Canadian VIPPS program will assist Canadian consumers in identifying legitimate Canadian pharmacies serving Canadian residents, and will aid the boards of pharmacy and patients by excluding those Canadian pharmacies that ship prescription medications to US patients.

In February 2003 NAPRA convened a forum to discuss the international sale of prescription drugs from Canada, focusing on issues related to professional regulation, public protection, and compliance with professional standards of practice. Participating in the forum were approximately 50 representatives from Canadian and US government and pharmacy organizations, including NABP.²⁷

NABP/Boards of Pharmacy

On February 26, 2003, NABP, in a letter to the US Department of Health and Human Services and the FDA, urged the FDA to enforce US laws addressing the importation of drugs from outside the US.²⁸ In addition to declaring its opposition to efforts to allow a system of drug importation that cannot guarantee the quality and safety of the products imported, NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program stands as the only information and

²⁷ Alberta College of Pharmacists, *NAPRA hosts forum on international sale of prescription drugs from Canada*, <http://www.altapharm.org/college/Home/DetailsPage.cfm?ID=3787> (March 5, 2003).

²⁸ Letter from Carmen A. Catizone, Executive Director/Secretary, NABP, to Tommy G. Thompson, Secretary, US Department of Health and Human Services, and Mark B. McClellan, Commissioner, FDA (February 26, 2003) (on file at NABP). The letter reads:

I am writing to you today on behalf of the National Association of Boards of Pharmacy (NABP) to urge you to enforce the law(s) of United States with regard to the importation of drugs from outside the U.S. Allowing unlicensed practitioners to dispense non-FDA approved medicines without regard for patient health and safety sets a dangerous precedent that puts Americans at risk. We should ensure that Americans have appropriate access to affordable medicines from within the protections of the health care system in the United States - not by sending them to purchase medicines from across the border. I would further urge you, therefore, to also call for passage of a Medicare prescription drug benefit in Congress.

The National Association of Boards of Pharmacy (NABP), whose membership includes all of the state boards of pharmacy in the United States, provincial authorities in Canada, state boards of pharmacy in Australia, New Zealand and South Africa believes as the FDA has said in Congressional testimony, "...Consumers are exposed to a number of risks when they purchase drugs from Internet sites that are not licensed and operating within [U.S.] state pharmacy laws or [from] sites that dispense foreign drugs."

The state boards of pharmacy and NABP have partnered with the FDA to formalize cooperative efforts to enforce applicable acts and statutes in regard to the Internet and strongly maintain that federal-state cooperation is essential to policing these activities. NABP also supports the information on the FDA's own website (<http://www.fda.gov/oc/buyonline/faqs.html#faqs1>) which advises consumers:

Patients who buy prescription drugs from Websites operating outside the law are at increased risk of suffering life-threatening adverse events, such as side effects from inappropriately prescribed medications, dangerous drug interactions, contaminated drugs, and impure or unknown ingredients found in unapproved drugs.

While recognizing that access to affordable medications is an important concern for U.S. citizens, NABP believes that existing laws and regulations prohibiting this activity need to be obeyed and enforced to allow for the safe and regulated supply of drugs and medications. Allowing the practice of cross-border Internet trade of medicines to continue and expand opens up the U.S. population to those who would take full advantage of the lack of regulatory enforcement to increasingly prey on American patients.

Access to medications through illegal means does not resolve the problem of access, but only increases the opportunity that U.S. citizens will be harmed by unregulated entities. I urge you to do what is necessary and right to protect the American public. We should not wait until increasing numbers of Americans are injured or die before our government acts on their behalf.

enforcement aid to regulatory authorities and consumers. Implemented in 1999, the VIPPS Program identifies legal and safe pharmacies and, through information and empowerment, creates a partnership between state and federal regulators and the public. Through the VIPPS web site, NABP also operates a “Report-A-Site” feature for consumers to use to file complaints about on-line pharmacies. NABP shares the reported information with state and federal regulatory authorities.

Attempts by states to take action against foreign pharmacies have been minimal, primarily due to the lack of jurisdiction the boards have over such entities. Information obtained by NABP indicates that at least four boards have attempted to contact Canadian pharmacies by mail and/or phone to advise them of the illegality of their actions.²⁹

At least six boards have taken some action against local businesses that facilitate the transmission of prescriptions to Canada.³⁰ The most recent action involved a collaborative effort between the Arkansas State Board of Pharmacy and the FDA, with the Board issuing a “Cease and Desist” letter and the FDA issuing a warning letter to Rx Depot, Inc., charging them with various violations of state and federal laws and regulations³¹. In its warning letter, The Arkansas Board lists the violations, including practicing pharmacy without a license³² and using pharmacy related wording in its advertising and signage³³. The FDA states in its letter that Rx Depot violates federal law by causing shipments of prescription drugs from Canada into the US³⁴ and that it makes misleading statements about the legality of drug importation and drug safety.

²⁹ Dennis Jones, executive secretary of the South Dakota Board, reported personally calling Canadian pharmacies to request a visit but received no response, and he reports notifying them that it is illegal to ship prescription medications to South Dakota from a foreign country. He has also contacted local newspapers that publish advertisements for these pharmacies explaining their potential liability for encouraging persons to participate in an illegal activity. Don Williams, executive director of the Washington State Board of Pharmacy, reported having sent several letters to Canadian pharmacies advising them not to ship prescriptions into the state. Kendall Lynch, executive director of the Tennessee Board of Pharmacy, has sent a “Cease and Desist” letter to CanadaDiscountRx, which has run full-page ads for Canadian prescription drugs in *The Tennessean*. Howard Anderson, executive director of the North Dakota Board of Pharmacy, has sent “Cease and Desist” letters to Canadian pharmacies, with copies to the provincial authority, the FDA, and the US Customs Service. Rebecca Deschamps, executive director of the Montana Board of Pharmacy, reports having sent “Cease and Desist” letters to five foreign pharmacies advertising in Montana.

³⁰ The Pennsylvania Board, the South Dakota Board, and the Washington State Board of Pharmacy all report having met with and/or taken some sort of action against prescription facilitators. The North Dakota Board reports contacting the facilitators and asking them to stop their activities on the basis they are operating without a valid license and aiding and abetting an illegal activity. They have also asked local newspapers and radio and television stations not to run their advertisements, since the businesses are operating illegally. The Montana Board sent a “Cease and Desist” letter to Gary Moffitt and Club MedzRx, saying that by “implementing prescriber orders and assisting patients in procuring drugs from RealFast Drugstore, a Canadian mail order pharmacy,” Mr Moffitt and Club MedzRx are practicing pharmacy without a license and aiding and abetting a pharmacy not licensed in Montana, unlawfully using the “Rx” symbol, acting as unlicensed pharmacy technicians, among other violations. Letter from Rebecca H. Deschamps, Executive Director, Montana Board of Pharmacy to Gary Moffitt, ClubMedzRx (March 10, 2003) (on file at NABP).

³¹ Letter from David J. Horowitz, Director, Office of Compliance, CDER, FDA to Harry Lee Jones, Store Manager, Rx Depot, Inc. (March 21, 2003) (on file at NABP); Letter from Charlie S. Campbell, Executive Director, Arkansas State Board of Pharmacy to Harry Lee Jones, Store Manager, Rx Depot, Inc. (March 21, 2003) (on file at NABP).

³² Ark. Code Ann. § 17-92-401 et seq.

³³ Ark. Code Ann. § 17-92-404(b).

³⁴ 21 USC § 331.

The Oregon Board of Pharmacy sent a letter to the College of Pharmacists of British Columbia notifying them that pharmacies in that province are dispensing prescriptions to citizens of Oregon in violation of state and federal laws, and urged the College to instruct its licensees to “refrain from providing drugs and other professional services into Oregon in violation of US and Oregon law.”³⁵ The College responded saying their understanding of the situation was that US laws were violated when US citizens import the drugs, not when their licensees export the drugs. The College has taken a provisionally-focused position stating “it is the responsibility of the individual US jurisdictions to monitor for the shipment of drugs from foreign countries and for compliance by foreign pharmacies with the laws of their jurisdictions” and that they “did not support the notion that it is our College’s responsibility to enforce other jurisdictions’ legislated requirements.” The College did state that the pharmacies that they know of that ship drugs to the US have been determined to be in full compliance with all provincial laws and standards of practice, and that they have advised such pharmacies that many states require non-resident pharmacy registration.³⁶

FDA

In addition to the warning letter mentioned above, the FDA has issued warning letters to a number of foreign pharmacies requesting that they stop shipping prescription medications to US residents.³⁷ Although it has been reported that certain foreign pharmacies have heeded these warnings, many have not. The FDA has also published several documents for consumers aimed at educating them on the dangers of importation.³⁸ Additionally, FDA has responded to numerous inquiries clarifying the illegal status of drug importation, including those from active and associate NABP member boards of pharmacy.³⁹

³⁵ Letter from Gary A. Schnabel, Executive Director, Oregon Board of Pharmacy to Linda Lytle, Registrar, College of Pharmacists of British Columbia (August 22, 2002) (on file at NABP).

³⁶ Letter from Linda Lytle, Registrar, College of Pharmacists of British Columbia to Gary A. Schnabel, Executive Director, Oregon Board of Pharmacy (September 19, 2002) (on file at NABP).

³⁷ <http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html>

³⁸ FDA Drug Importation Web sites:

- Testimony: July 25, 2002, Statement of William K. Hubbard before the House Subcommittee on Health: <http://www.fda.gov/ola/2002/drugimportation0725.html>
- FDA Consumer Magazine: Imported Drugs Raise Safety Concerns: http://www.fda.gov/fdac/features/2002/502_import.html
- Looks Can Be Deceiving (brochure): <http://www.fda.gov/cder/consumerinfo/border.pdf>
- Buying Prescription Medicine Online: A Consumer Safety Guide: <http://www.fda.gov/cder/drug/consumer/buyonline/guide.htm>
- Consumer Information: <http://www.fda.gov/cder/consumerinfo/DPAdefault.htm>
- Buying Medicines and Medical Products Online: <http://www.fda.gov/oc/buyonline/default.htm>
- “FDA Strengthens Controls, Issues Consumer Alert on Importing Certain Prescription Drugs (press release), December 9, 2002

³⁹ *E.g.*, Letter from David J. Horowitz, Acting Director, Office of Compliance, CDER, FDA to Ronald F. Guse, Registrar, The Manitoba Pharmaceutical Association (April 12, 2002)(on file at NABP); Letter from David J. Horowitz, Acting Director, Office of Compliance, CDER, FDA to DJ Eriksen, Assistant Registrar, Saskatchewan Pharmaceutical Association (April 3, 2002)(on file at NABP); Letter from John M. Taylor, Senior Associate Commissioner for Regulatory Affairs, FDA to Howard C. Anderson, Jr., Executive Director, North Dakota Board of Pharmacy (September 10, 2002)(on file at NABP).

Efforts to seize parcels containing imported prescription drugs are hampered by current regulations that require the FDA to issue notice to an addressee that his parcel has been detained and provide an opportunity to respond with reasons why the parcel should be allowed entry. If an inadequate or no response is received, the FDA must return the parcel to the sender. These detention, notice, and return requirements are time consuming and require significant resources unavailable to the FDA.⁴⁰ With this in mind, either the regulations governing the seizure of packages at the border must be simplified, or the FDA must be provided with additional resources to search and seize foreign drugs at US mail facilities. Illegal activities should not be allowed to continue due to inefficient regulatory systems and rules that were developed at a time when huge problems such as the one we are currently experiencing could not have been foreseen. Further, the lack of resources for enforcement must be addressed prior to a complete compromise of the US drug distribution system, and subsequent patient injury or death.

Conclusion

Regardless of the obvious illegality of these activities, particularly distressing is the blatant disregard for the law by those in positions of authority: politicians sponsoring bus trips to Canada and Mexico for constituents to purchase foreign medications and introducing legislation to penalize anyone for taking action that support current federal laws and regulations, as well as US insurance companies or pharmacy benefit managers offering or even mandating the use of foreign pharmacies by patients. These activities are particularly distressing to state and federal regulators charged with enforcing the law and protecting patients. It is this dichotomy of messages that is being sent to the American public, the support for illegal activities by entities of authority, which is making this a difficult situation.

While the price of prescription drugs obviously is of concern to US patients, it should not be the driving force behind their importation. The practice of importing drugs from foreign jurisdictions is illegal and has been made so to support the overriding purpose of the law, namely the protection of the public health and welfare. Until there is equity in the pricing of prescription medications, it may be impossible to completely stop US patients from obtaining medications from Canada, Mexico, and other countries. Notwithstanding the illegalities associated with importing unapproved medications, we are deeply concerned that illegitimate pharmacy Web sites could be a front for criminals seeking to introduce adulterated medications, counterfeit drugs, or worse, to the American public. Considering current world events, we believe it is dangerous to purchase medications from abroad. As regulatory authorities in the US and other countries grapple with this important issue, educating the American public on the danger and illegality of purchasing prescription medications abroad is a necessary component of any solution to the problem. If the laws need to be changed to recognize the globalization of pharmacy practice, then licensure of legitimate foreign pharmacies by US state boards of pharmacy may help to ensure that US patients receive appropriate medications and care.

⁴⁰ *Drug Importation, supra* note 1.