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June 1, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Ln, Room 1061
Rockville, MD 20852

Re: Prescription Drug Importation: Requests for Public Comment [Docket No. 2004N-0115]

The purpose of this correspondence is to provide comments to the United States Department of Health and Human Services Task Force on Drug Importation as the Task Force studies the potential ramifications of legalized drug importation pursuant to Section 1121 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

The National Association of Boards of Pharmacy[®] (NABP[®]), founded in 1904, represents all of the pharmacy regulatory and licensing jurisdictions in the US, Guam, Puerto Rico, the Virgin Islands, eight provinces of Canada, two states in Australia, New Zealand, and South Africa. NABP's 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.

The importation of medications includes an important economic component that impacts the public health. NABP agrees with proponents of importation that American patients need, and deserve, access to affordable medications. NABP also acknowledges that the pricing of pharmaceuticals in the US differs from Canada and other parts of the world. NABP and the state boards of pharmacy, although aware of this factor, have no involvement or influence over the pricing of pharmaceuticals and no direct affiliation or ties to the pharmaceutical industry.

Although lower prices of foreign drugs, particularly Canadian drugs, have been the primary impetus for importation, it is unclear whether or not legalized importation will have a long-lasting and meaningful effect on the costs of medications for American consumers. One of NABP's paramount oppositions to importation has been the inability to assure the safety of the drugs imported.

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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 American patients within the US-regulated system is safe. Unfortunately, the same safeguards do not exist for patients purchasing and importing drugs from other countries. Although Health Canada prohibits the import of drugs for dispensing to Canadian patients, it does not prohibit or regulate the import of drugs for export to American patients. The regulatory void and breach of the safety net for American patients is significant and unknown to the overwhelming majority of patients ordering drugs from Canadian pharmacies.

Numerous factors must be considered before steps are undertaken to open the U.S. borders to the importation of drugs from outside the U.S. medication distribution system. The challenge to assure safe and effective medications for U.S. patients becomes almost insurmountable when the borders are opened and the sources of drugs exported into the U.S. are unknown or unregulated. Adulteration, counterfeiting, and misbranding are consequences of a careless importation policy and consequences that will increase dramatically given existing evidence provided by the FDA and states from seizures and investigations of drugs received from outside of the U.S. drug approval process.

In fact, there are no limitations as to where drugs will originate from for delivery to American patients. Shockingly, Internet operations in Canada are already providing American patients with drugs from other countries unapproved in Canada or the US. Although the scope and volume of unapproved drugs entering the US through mail shipments and border crossings cannot be precisely determined, FDA conducted investigations at mail facilities and at US borders have revealed numerous safety concerns. Foreign brand-name drugs, including Canadian drugs, are not necessarily the same as their US counterparts. Different dosages and dosage forms may exist and drugs often have different propriety names, further adding to the confusion. Allowing for the purchase and importation of drugs from other countries essentially abolishes FDA's drug approval process and circumvents state regulation.

NABP and its Canadian counterpart, the National Association of Pharmacy Regulatory Authorities (NAPRA), recognize that a solution resolving the conflict of affordable access versus safety must be developed to address the needs of American patients and prevent irreparable damage to, if not the elimination of, the regulatory systems in the US and Canada if importation is legalized. The first step of this process was the launching of the Verified Internet Pharmacy Practice Sites™ (VIPPS®) program in Canada in November 2003 by NABP and NAPRA. 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 and NAPRA are also in discussions to develop a regulatory framework that regulates the inter-border practice of pharmacy and dispensing of medications to patients in the US and Canada. The framework would provide protections similar to those afforded American patients who utilize pharmacies engaged in the interstate practice of pharmacy and dispensing of medications. The framework will coordinate the regulatory efforts and resources of Canadian

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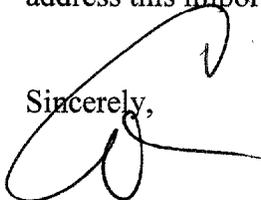
provinces and US state boards of pharmacy and seek to address the lack of resources at the state and federal levels to adequately enforce an importation policy.

In February 2004, NABP released the updated Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products, which was the result of a concerted effort to protect the public from the deleterious effects of counterfeit drugs and devices. These Model Rules were fully endorsed by FDA as the agency recognized the states' role in detecting and deterring drug counterfeiting. However, the impact of the Model Rules, when adopted by states, will not be fully realized if an appropriate regulatory framework has not been established to protect the integrity of a proposed international drug supply. As a result, American patients, although purchasing medications at reduced costs from Canadian sources, may become the victims of drugs that contain inactive ingredients, incorrect ingredients, sub-potent, or super-potent ingredients. NABP believes that any level of risk that results from the failure of FDA to assure the safety of imported drugs is unacceptable and poses greater costs that our society cannot afford.

In closing, NABP hopes that if the foreign importation of drugs is legalized, it is done within a safe and secure manner without sacrificing the safety, health, and well being of our public. However, this can only be achieved through cross-border governmental and regulatory relationships that share common goals.

If I can provide any additional information, please contact me. Thank you for the opportunity to address this important issue.

Sincerely,



Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

CAC/cj

cc: NABP Executive Committee