DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

July 1, 2004

Governor Donald L. Carcieri
Office of the Governor
State House, Room 115
Providence, RI 02903

Dear Governor Carcieri:

It has come to our attention that you may soon be receiving legislation passed by the State of Rhode Island General Assembly that would allow for the licensing of Canadian pharmacies by the State of Rhode Island. We strongly believe such legislation would undermine one of our nation's key consumer protection statutes and place your constituents at unnecessary risk of harm from unregulated pharmaceuticals.

Secretary Thompson has made the provision of affordable prescription drugs for seniors one of the Department's highest priorities. With assistance from Congress last year we achieved successful passage of the Medicare Prescription Drug, Improvement, and Modernization Act, providing for a prescription drug benefit under Medicare. Pending the effective date of that benefit, the Secretary has published new rules under which immediate savings are available for seniors through a drug discount card program. Meanwhile, at FDA, we have made it a priority for the Agency's medical and scientific experts to establish programs that promote access to innovative treatments designed to help Americans live healthier lives and to assure that Americans have access to medications and treatments that they can afford.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. In recent years, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients. The Agency is doing its best to use its current authorities and resources to stop the increasing flow of violative drugs into this country, but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S. FDA is working to speed the availability of anti-counterfeiting technologies, but these technologies have not yet been proven.

As you may know, sixty-five years ago Congress enacted the Food, Drug, and Cosmetic Act (the Act) to create a strong drug regulatory system requiring that drugs be carefully tested before marketing, produced under exacting standards overseen by the Food and Drug Administration (FDA), and dispensed by state-licensed pharmacies and pharmacists. That regulatory system has enabled our citizens to have the safest, most advanced drug supply in the world, and every day millions of patients in the United States (U.S.) are successfully treated by safe and effective medications. Drugs made or distributed in other countries are not necessarily subject to FDA strict regulatory standards, and we have no way to assure that drugs imported from such places

are safe and effective. FDA has, therefore, been vigilant in protecting unknowing patients from those who would lure our citizens to buy unproven and unregulated drugs from foreign countries.

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws.

Virtually every shipment of prescription drugs from Canadian pharmacies to consumers in the U.S. violates the Act. Most such drugs violate the Act because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. § 352), and/or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). However, even if such a drug is approved in the U.S., if the drug was originally manufactured in the U.S., it is also a violation of the Act for anyone other than the U.S. manufacturer to import that drug into the U.S. (21 U.S.C. § 381(d)(1)).

The reason that Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. is that FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system and appearance. 21 C.F.R. § 314.50. Frequently, drugs sold outside of the U.S. are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and it is considered to be unapproved. 21 U.S.C. § 355.

Put differently, in order to ensure compliance with the Act when they are involved in shipping prescription drugs to consumers in the U.S., businesses and individuals must ensure, among other things, that they only sell FDA-approved drugs that are made outside of the U.S. and that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. They must also ensure that each drug meets all U.S. labeling requirements. The drug must also be dispensed by a pharmacist pursuant to a valid prescription. 21 U.S.C. § 353(b)(1).

Practically speaking, it is extremely unlikely that a Canadian pharmacy could ensure that all of the applicable legal requirements are met. Consequently, almost every time an individual or business ships a prescription drug from Canada or brings that drug into the U.S. to a U.S. consumer, the individual or business shipping the drug violates the Act. Moreover, individuals and businesses that cause those shipments also violate the Act. 21 U.S.C. § 331 (The following acts and the causing thereof are hereby prohibited...").

Under FDA's Personal Importation policy, as a matter of enforcement discretion in certain defined circumstances, FDA has allowed consumers to import otherwise illegal drugs. However, this policy is not intended to allow commercial importation of foreign versions of drugs of which

there is a FDA-approved version. Moreover, the policy simply describes the agency's enforcement priorities. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the U.S.

Accordingly, we are concerned that, if signed into law, the legislation passed by the State of Rhode Island General Assembly would result in state licensure of foreign pharmacies that would systematically send drugs into the United States in violation of the Act. We are particularly concerned that the state's endorsement of such pharmacies would give Rhode Island residents a false sense of safety in the drugs dispensed from abroad when, in fact, neither FDA nor the state would be able to assure their safety or effectiveness. To this end, we urge you to consider how the state licensure program contemplated by the Rhode Island legislation would ensure that the drugs dispensed into Rhode Island comply with applicable federal legal requirements. Otherwise, we note that the legislation may so frustrate the importation provisions of the Act that it is preempted under the Supremacy Clause of the United States Constitution. *See* U.S. Const. art. VI, cl. 2; *see also* Sprietsma v. Mercury Marine, 537 U.S. 51, 64 (2002) (implied conflict preemption exists when a state law stands as an obstacle to accomplishment and execution of the full purposes and objectives of Congress); Crosby v. National Foreign Trade Council, 530 U.S. 363, 366 (2000) (holding Massachusetts statute unconstitutional on implied conflict preemption grounds because it "frustrated federal statutory objectives"); Jones v. Rath Packing Co., 430 U.S. 519, 543 (1977), *reh'g denied*, 431 U.S. 925 (1977) (holding a California statute that set weight standards for commodities unconstitutional on implied conflict preemption grounds because it would prevent "the accomplishment and execution of the full purposes of Congress").

We are aware that the high cost of some prescription drugs is a serious public health issue and a pressing concern for you and the citizens you serve. We suggest there are many other ways that the state could pursue providing affordable, but safe, medications to your citizens, and we would welcome the opportunity to explain our thinking on that. We and others in the Federal government are ready to work with you to implement these approaches for the people of Rhode Island. These approaches include: promoting access to FDA-approved generic drugs, which are proven safe and effective, account for the majority of prescriptions filled in the U.S., and generally cost less than generic drugs sold in Canada; disease management programs to help educate patients and practitioners about low cost ways to meet medical needs; and implementation of the new Medicare Drug Discount Program, which became effective in June and will enable seniors who lack medical coverage to obtain medicines at reduced prices.

Meanwhile, you should also know that we are working diligently to respond to our mandate from Congress to assess whether and how foreign drugs could be imported while providing assurances of their safety and effectiveness. Surgeon General Richard Carmona is chairing a Task Force on Importation, which was created by the Secretary of Health and Human Services (HHS), to advise and assist HHS in determining how drug importation might be conducted safely and its potential impact, positive and negative, on the health of American patients, medical costs and the development of new medicines. The Task Force intends to consider the public health questions posed by Congress in a way that is fair, public, and evidence-based. The Surgeon General has begun a series of meetings with the various stakeholders in this important area, and we hope that you will provide your advice to the Task Force as it conducts its work.

FDA firmly believes that we can do even more to make safe and innovative drugs more affordable in the United States, but to succeed we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. FDA appreciates and supports your commitment to making drugs more affordable for seniors and other consumers and there are several safe and legal approaches that we would be happy to explore further with you. But we must be cautious and deliberate when considering proposals to accomplish this goal to ensure that any changes do not require American citizens to give up the "gold standard" in drug safety that has become a hallmark in this country. I am confident we can work cooperatively towards solutions that will not be a disservice to the American people.

Please contact me if you would like to discuss further, and we will be pleased to arrange a meeting.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy
and Planning