



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 4 2004

2003 08 04 10:00 AM

Michael K. Smith
Secretary of Administration
State of Vermont
109 State Street
Montpelier, VT 05609

Re: Docket No. 2003P-0479/CP2

Dear Mr. Smith:

This responds to the citizen petition you submitted on December 12, 2003 (Petition), on behalf of the State of Vermont. Your petition requests that the Food and Drug Administration (FDA) issue regulations or otherwise commit to exercise its enforcement discretion to allow the Vermont State Employee Medical Benefit Plan (VTSEMBP) to establish a program for the individual importation of prescription drugs from Canada. You also request that FDA establish regulations to provide for importation of prescription drugs from Canada in accordance with section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

For the reasons stated below, your petition is denied.

I. BACKGROUND

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. In examining imported drugs sent through the mail, FDA has identified so-called "foreign versions" of FDA-approved drugs, improperly labeled drugs, drugs that failed to meet special storage conditions, drugs requiring close physician monitoring, and drugs containing addictive controlled substances. Such findings show the serious risks posed by the illegal importation of prescription drugs. The Agency cannot provide adequate assurance that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA, or that they are safe and effective for their intended uses.

These concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (the Act), which strictly limit the types of drugs that may be imported into the United States. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. The Act provides the legal framework applicable to imports of prescription

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drugs. Virtually all drugs imported to the United States from Canada violate the Act because they are unapproved (section 505 of the Act (21 U.S.C. 355)), labeled incorrectly (sections 502 and 503 of the Act (21 U.S.C. 352 and 353)), or dispensed without a valid prescription (section 503(b)(1) of the Act). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the Act is prohibited under section 301(a) and/or (d) of the Act (21 U.S.C. 331(a) and/or (d)).

FDA drug approvals are manufacturer- and 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 CFR 314.50). Frequently, drugs sold outside of the United States 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 may not meet all of the specific requirements of the U.S. approval, and thus it is considered to be unapproved (section 505 of the Act).

Furthermore, if a prescription drug is also originally manufactured in this country and exported, only the U.S. manufacturer may import the drug back into the United States (section 801(d)(1) of the Act (21 U.S.C. 381(d)(1))). This is true even if the drug complies with the Act in all other respects. Importing a drug into the United States in violation of section 801(d)(1) is prohibited under section 301(t) of the Act.

Thus, to comply with the Act when shipping prescription drugs to consumers in the United States, businesses and individuals must ensure, among other things, that the drugs sold (1) are FDA-approved; (2) if manufactured in the United States, are imported back into the United States only by the manufacturer; and (3) comply with an applicable FDA approval in all respects. The businesses and individuals must also ensure that each drug meets all U.S. labeling requirements (section 502 of the Act). In addition, the drug must be dispensed by a pharmacist pursuant to a valid prescription (section 503(b)(1) of the Act).

Practically speaking, it is extremely unlikely that a foreign pharmacy could ensure that all of the applicable legal requirements for importation are met. Consequently, almost every time an individual or business ships a prescription drug from Canada or brings that drug into the United States for overnight shipment to a U.S. consumer, the individual or business shipping the drug violates the Act. Moreover, individuals, businesses, and their responsible personnel that *cause* those shipments also violate the Act (section 301 of the Act).

Consistent with this analysis, on November 6, 2003, Federal District Court Judge Claire V. Eagan issued a preliminary injunction against Rx Depot, Inc. to prevent it from causing the importation of unapproved and misbranded drugs into the United States from Canada. See *United States v. Rx Depot, Inc. and Rx of Canada LLC*, 2003 WL 22519473 (N.D. Okla.)

Rx Depot is a domestic "storefront pharmacy" that was engaged in the business of helping individuals procure prescription medications from pharmacies in Canada. Rx Depot would accept a prescription from a U.S. customer and then transmit that prescription and the customer's credit card number to a cooperating pharmacy in Canada. The Canadian pharmacy would then fill the prescription, bill the customer's credit card, and mail the prescription drugs directly to the U.S. citizen. Rx Depot typically received a 10-12 percent commission for each sale it facilitated.

Judge Eagan held that, although Rx Depot never took possession of the imported drugs, its facilitation of the transactions caused the importation of unapproved new drugs into the United States in violation of section 505 of the Act and also caused the importation of U.S.-manufactured drugs into the United States by someone other than their original manufacturer in violation of section 801(d)(1) of the Act. The Court explained that "unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer do not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration." *Id.* at 4. The Court also observed that, "[b]ecause the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States." *Id.*

II. DISCUSSION

A. The VTSEMBP Proposal

You ask that FDA issue regulations or otherwise commit to exercise its enforcement discretion to allow the VTSEMBP to establish a program for the orderly importation of prescription drugs (Petition at 1). You request that VTSEMBP be given the authority to create a system under which its members have the option of forwarding a prescription to a Canadian firm where the prescription would be reviewed by a physician familiar with the member's medical history and rewritten as a Canadian prescription, which would be forwarded to a licensed Canadian pharmacy to be filled and sent by mail to the member in the United States (*id.* at 2). You state that FDA, in its Personal Importation Policy,¹ has declared that the Agency will not commit its resources to controlling importation of prescription drugs from outside the United States by individuals for their own use (*id.* at 2). You state that the combination of FDA's policy, the fact that many prescription drugs cost less in Canada than in the United States, and the proximity of VTSEMBP members to Canada creates a situation in which members are likely to import prescription drugs on an ad hoc, personal level, which does not provide VTSEMBP the opportunity to intervene to minimize the risks associated with obtaining drugs from outside the United States (*id.* at 2-3). You maintain that by granting the petition, FDA will promote the health of VTSEMBP members by allowing the plan to manage and minimize potential health risks.

¹ FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importation.

We understand your desire to establish a system under which VTSEMBP members could more safely obtain lower-priced drugs from Canada. However, your proposal would not be consistent with FDA's Personal Importation Policy or the Agency's statutory responsibility to protect the nation's drug supply. Under the Personal Importation Policy, as a matter of enforcement discretion, FDA may allow consumers to import otherwise illegal drugs under certain defined circumstances. Under this policy, FDA may permit individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. FDA has generally followed this approach with products that do not present an unreasonable risk and for which there is no known commercialization and promotion to U.S. residents. A patient seeking to import such a product should also provide the name of the licensed physician in the United States responsible for his or her treatment with the unapproved drug product.

Although the Personal Importation Policy describes the Agency's enforcement priorities, it does not change the law. The policy does not legalize importation of unapproved foreign versions of FDA-approved drugs that have been manufactured, shipped, and held outside of this country's comprehensive system for assuring a drug's safety from the point of manufacture, through distribution, and on to the pharmacy and patients.

Your proposal goes beyond the Personal Importation Policy by allowing State officials to actively assist State employees in obtaining foreign drugs, which could significantly increase the volume of drugs imported from Canada. Despite your proposed plan's system of prescription review, it would be extremely unlikely that the State of Vermont could ensure that all the Canadian drugs that VTSEMBP helped its members obtain were in full compliance with all laws and regulations applicable to FDA-approved drug products and were safe and effective. Therefore, FDA does not believe that it would be appropriate to permit the kind of importation program you propose. The question of FDA issuance of regulations to permit this or any other proposed importation plan is addressed below.

B. MMA

You request that FDA promptly issue regulations as called for by section 1121 of MMA to facilitate the wholesale importation of prescription drugs from Canada to allow VTSEMBP and its members to take advantage of lower prices for drugs in Canada (Petition at 2). Although we deny your request that we immediately issue such regulations, we are studying the matter of drug importation in accordance with MMA.

MMA retains the requirement, originally included in the Medicine Equity and Drug Safety Act of 2000, that FDA may make effective a program for the importation of drugs by pharmacists and wholesalers only if the Secretary of Health and Human Services (HHS) (Secretary) certifies that implementing the program would (1) pose no additional risk to the public health and safety and (2) result in a significant reduction in the cost of drugs to the American consumer. Both Secretary Thompson and former Secretary

Shalala have concluded (separately) in the past that such products may pose additional risks to safety and therefore should not be imported.

The Agency is well aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs without subjecting U.S. citizens to potentially dangerous unapproved drugs. These steps include (1) establishing new initiatives to accelerate approval of innovative medical procedures and drug therapies, (2) changing our regulations to reduce litigation that has been shown to delay access to more affordable generic drugs, and (3) proposing a plan to increase Agency resources for the review and approval of generic drugs – products that are often far less expensive than brand-name products and may in fact be less expensive in the United States than generic drugs sold abroad. The Administration also worked with Congress on MMA, which provides a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs under Medicare.

Section 1122 of MMA directs the Secretary to submit a comprehensive study to Congress on the importation of drugs within one year of enactment. Completion of this study is critical to making an informed decision as to whether the drug importation program in MMA can be implemented safely. The Department is working expeditiously on the study and has created an intergovernmental Task Force on Drug Importation (Task Force) to steer the effort to completion. FDA is participating on this Task Force, which will advise and assist HHS in determining how drug importation might be conducted safely and its potential impact, both positive and negative, on the health of American patients, medical costs, and the development of new medicines.

FDA is working diligently to respond to this mandate from Congress under MMA, and we will consider the public health questions posed by Congress in a way that is fair, public, and evidence-based. The Task Force has opened a public docket and conducted a series of meetings with the various stakeholders in this important area so that it can advise Congress on how and whether to proceed in its deliberations on drug importation.

III. CONCLUSION

FDA understands your desire to provide safe and effective prescription drugs at lower cost to Vermont state employees by obtaining drugs from Canada. We are doing all we can to lower the price of drugs in the United States without opening our borders to unapproved pharmaceuticals. However, for the reasons stated above, your petition is denied.

Sincerely yours,



William K. Hubbard
Associate Commissioner
for Policy and Planning