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## Drugs

### Oregon: Governor Theodore R. Kulongoski



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration  
Rockville MD 20857

October 14, 2005

The Honorable Theodore R. Kulongoski  
State of Oregon  
Office of the Governor  
160 State Capitol  
900 Court Street  
Salem, Oregon 97301-4047

Re: Requested Waiver for Certification of Oregon's Pioneer Prescription Drug Program

Dear Governor Kulongoski:

I have been asked to respond to your request for certification of a Canadian pharmaceutical importation program called the Oregon Pioneer Prescription Drug project. I understand you raised this issue in a letter submitted on August 12, 2004, to Secretary Tommy Thompson on behalf of the State of Oregon and that you have requested additional information to augment the reply from Secretary Thompson on December 22, 2004. Your letter described a proposed program to allow the Oregon Board of Pharmacy to license and inspect Canadian pharmaceutical wholesalers who would then sell a limited formulary of prescription medicines to Oregon pharmacies.

We have reviewed your proposal thoroughly and for the reasons stated below, we must deny your proposal.

#### **I. Background**

We are very concerned about the potential 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. In fact, the HHS Task Force on Drug Importation found that the unregulated importation of prescription drugs poses serious health risks. The agency cannot provide adequate assurance that the drug products delivered to consumers in the United States from foreign countries are the same as 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), 21 U.S.C. 301 *et. seq.*, 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 drugs. Virtually all prescription drugs imported into the United States from Canada for personal use violate the Act because they are unapproved new drugs (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 (21 U.S.C. 353(b))). Importing a drug into the United States that does not comply with the labeling and dispensing requirements in the Act and/or is an unapproved new drug is prohibited under section 301(a) and/or (d) of the Act (21 U.S.C. 331(a) and/or (d)). See also 21 U.S.C. 381(a).

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, packaging location, container/closure system, and appearance (21 CFR 314.50). Frequently, drugs sold outside of the United States are not manufactured or packaged 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 would be considered to be unapproved (section 505 of the Act (21 U.S.C. 355)).

Furthermore, if a prescription drug is 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) comply with an applicable FDA approval in all respects and (3) if manufactured in the United States, are imported back into the United States only by the manufacturer. The businesses and individuals must also ensure that each drug meets all U.S. labeling requirements (sections 502 and 503(b) 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 wholesaler or 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, that individual or business 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 August 20, 2004, a consent decree of permanent injunction was filed in the U.S. District Court for the Northern District of Oklahoma against Rx Depot, Inc. to prevent it from causing the importation of unapproved and misbranded drugs into the United States from Canada. This followed an evidentiary hearing and a preliminary injunction issued on November 6, 2003, by Federal District Court Judge Claire V. Eagan. See *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003).

Rx Depot was 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 U.S. 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.* The Court also observed that, "because 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.*

Another federal court reached a similar conclusion in *Vermont v. Leavitt*, 2005 U.S. Dist. LEXIS 20864 (D. Vt. 2005). The case arose from a petition that the Vermont Agency of Administration ("VAA") submitted to FDA in December 2003. The VAA requested that the Agency allow the Vermont State Employee Medical Benefit Plan to establish a program for the individual importation of prescription drugs from Canada. FDA denied the Petition, explaining, among other things, that drugs imported into Vermont per the proposed program would violate sections 505, 502, and/or 801(d) of the Act. The VAA and the State of Vermont subsequently filed a lawsuit in August 2004, challenging FDA's denial on several grounds.

On September 19, 2005, the federal district court ruled in favor of the government and dismissed the state's complaint. The court's opinion specifically addressed the legality of the state's proposed importation plan. Citing *Rx Depot*, the court concluded, "there is no question that Vermont's proposed program would violate the FDCA." *Id.* at 13. The court explained that, "as Vermont's proposed plan would be highly likely to include drugs manufactured in the United States, it would lead to violations of section [301(t)]." *Id.* In addition, the court explained that the plan would likely lead to violations of section 301(a) because "many Canadian drugs will have packaging and labeling that is not approved by FDA" and "many Canadian drugs may not have been manufactured according to GMP (even if these drugs are pharmacologically identical to drugs approved by FDA)." *Id.*

## **II. The Oregon Pioneer Prescription Drug Project Proposal**

You request that FDA promptly issue regulations as called for by section 1121 of The Medicare Modernization Act (MMA) to facilitate the importation of prescription drugs from Canada to allow the Oregon Pioneer Prescription Drug program to take advantage of lower prices for drugs in Canada.

The 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) first 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 former Secretary Thompson and Secretary Shalala concluded (separately) in the past that such products may pose additional risks to safety and therefore declined to make the certification necessary to authorize importation.

The certification requirement in the MMA does not authorize a partial certification or specific waiver for a discrete state pilot program. This was confirmed recently in *Vermont v. Leavitt*. As noted above, the state of Vermont sued FDA on several grounds when the agency denied the state's December 2003 petition. One of Vermont's allegations was that the certification requirement applied only to some of the importation provisions in the MMA. Thus, Vermont argued, its program was actually legal under the MMA despite the fact that there had been no certification from the Secretary of HHS. The court rejected this argument. "Overall," said the court, "the only sensible way to read the statute is to assume that Congress intended the certification provision to apply to the whole of section 384." *Id.* at 16.

FDA 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 the MMA, which provides a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs under Medicare.

### III. Conclusion

We understand your desire to provide safe and effective prescription drugs at lower cost to the citizens of Oregon 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, we must deny your proposal.

Sincerely yours,

Randall W. Lutter, Ph.D.  
Acting Associate Commissioner for  
Policy and Planning

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