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## Drugs

### Minnesota: Mayor Don Ness



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration  
Rockville MD 20857

February 6, 2008

The Honorable Don Ness  
Mayor of Duluth  
Office of the Mayor  
411 West First Street, Room 403  
Duluth, Minnesota 55802

Dear Mayor Ness:

The Food and Drug Administration (FDA) has learned that the City of Duluth intends "develop an international prescription supply program" for city employees, retirees and their dependents working with CanaRx Services, Inc. ("CanaRx"). (*City of Duluth Communications Office, Press release. January 3, 2008*). We understand your desire to provide safe and effective prescription drugs at lower cost to City employees, retirees and their dependents, but we are concerned that your actions also present a significant risk to them.

#### **Patient Safety Concerns**

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 are represented as U.S. approved prescription drugs are of unknown origin and quality. In examining imported drugs sent through the mail, FDA has identified counterfeit drugs, so-called "foreign versions" of FDA-approved drugs, improperly labeled drugs, drugs that failed to meet special storage conditions, and drugs requiring physician monitoring. Such findings illustrate the types of risks posed by the illegal importation of prescription drugs. The December 2004 HHS Task Force on Drug Importation (see <http://www.hhs.gov/importtaskforce/Report1220.pdf>) has 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 any foreign country, including Canada, U.K., Australia, or others are the same as products we have approved. In fact, many drugs that U.S. consumers purchase from Canada and believe were made in Canada in fact originate from other countries, such as India and Costa Rica.

These safety concerns are reflected in Congress' enactment of the drug and 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 sold within and imported into the United States and who may import them. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective.

#### **General Legal Framework**

Virtually all prescription drugs imported for personal use into the United States from Canada violate the Act because they are unapproved new drugs (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353)), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements and dispensing

requirements in the Act is a prohibited act under 21 U.S.C. §§ 331(a), and/or (d) may be enjoined or prosecuted. See *also* 21 U.S.C. §332(a), 333(a).

FDA approvals are manufacturer-specific, product-specific, manufacturing site-specific, and include many requirements relating to the product, such as formulation, source and specifications of active ingredients, processing methods, manufacturing controls, packaging location, container/closure system and appearance. (21 C.F.R. § 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 and shipped to Canada or other foreign countries may not meet all of the specific requirements of the FDA approval, and thus it is unapproved (21 U.S.C. § 355). The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 353(b) but is not required in the foreign country, or it may be labeled in a language other than English (21 C.F.R. § 201.15(c)).

Furthermore, if a prescription drug is originally manufactured in this country and exported, only the United States manufacturer may import the drug back into the United States (21 U.S.C. §381(d)(1)). This is true even if the drug complies in all other respects with the Act. Importing a drug into the United States in violation of section 381(d)(1) is a prohibited act under Section 331(t) of the Act.

In light of the above, it is virtually certain that a foreign wholesaler or pharmacy would fail to comply with all of these applicable requirements, and therefore virtually every importation of prescription drugs for personal use would violate federal law. Consistent with this analysis, on November 6, 2003, following an evidentiary hearing, U.S. District Court Judge Claire V. Eagan entered an order of preliminary injunction to prevent RxDepot, Inc. from causing the importation of unapproved and misbranded drugs into the United States from Canada. See *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003). On August 20, 2004, Judge Eagan entered a consent decree of permanent injunction in which Rx Depot, Inc. agreed to obey permanently the import prohibitions ordered earlier by Judge Eagan.

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 prescriptions from U.S. customers and then transmit these prescriptions and the customers' credit card numbers to a cooperating pharmacy in Canada. The Canadian pharmacy would then fill the prescriptions, bill the customers' credit cards, and mail the prescription drugs directly to the U.S. citizens.

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 sections 505 and 801(d)(1) of the Act (21 USC §§ 355 and 381(d)(1)). 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 FDA." *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.*

The facts in the Rx Depot case are also instructive. FDA investigators made two undercover purchases of drugs from Rx Depot. Judge Eagan found that in one case the investigator had ordered FDA-approved Serzone (to treat depression) but received instead an unapproved version of that product (APO-Nefazodone). The investigator was allowed to purchase 100 pills (but received only 99 pills), even though his prescription called for dispensing of only 60 pills; the labeling accompanying his order did not, as did his prescription, limit the duration of treatment to 30 days (a potential safety concern); nor did the labeling warn the purchaser of all side effects that were listed in US-approved labeling. The second undercover purchase resulted in shipment of a drug illegally reimported into the US. See *Rx Depot, supra*, at 1242-43 (findings 22-31).

Another federal court reached a similar conclusion in *Vermont v. Leavitt*, 405 F.Supp.2d 466 (D. Vt. 2005). The case arose from a Citizen 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 under the proposed program would violate 21 USC §§ 355 and 381(d). 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, "[t]here 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 331(a) because "[m]any Canadian drugs will have packaging and labeling that is not approved by FDA" and "many Canadian drugs have not been manufactured according to GMP (even if these drugs are pharmacologically identical to drugs approved by FDA)." *Id.*

On March 31, 2005, in yet another case, a couple from Chicago claimed that the provisions of the Act that restrict the importation and reimportation of prescription drugs violated their Constitutional substantive due process rights. The United States District Court for the District of Columbia found: "The FDA's interest in ensuring the safety of prescription medications is a legitimate governmental interest. The statutory scheme of which plaintiffs complain reasonably furthers this legitimate interest by shielding the public from reimported drugs that may be adulterated or otherwise unsafe." *Andrews v. HHS*, No. 04-0307, 2005 U.S. Dist. LEXIS 5710, at \*8-\*9 (D.D.C. Mar. 31, 2005).

### Conclusion

FDA has expressed concerns in the past regarding CanaRx (see *FDA News, November 6, 2003*. <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00973.html>) and our position regarding this company has not changed.

Imported drug shipments under Duluth's plan would most likely violate Federal law as described above. It is therefore likely that such packages will be detained by U.S. Custom and Border Protection and FDA officials when offered for import.

It is obvious that you are seeking answers to a vexing societal problem: providing affordable drugs to your constituents. FDA shares with public officials and others the great concern for the high cost of prescription drugs and we understand the need to find solutions to this problem so that all American citizens will have affordable access to safe, effective, FDA-approved medications. Please understand that we recognize the depth of that concern and are doing whatever we can here at the FDA to provide affordable medications, principally by assuring that less expensive generic versions of brand name drugs get on the market as rapidly as possible. But we must be cautious and deliberate when considering proposals to address this problem 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 people of Duluth.

I would be happy to meet with you or your advisers to discuss these matters further at your convenience.

Sincerely,

Randall W. Lutter, Ph.D.  
Deputy Commissioner for  
Policy

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