Drugs

Hawaii: Governor Linda Lingle

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Rockville MD 20857

August 14, 2008

The Honorable Linda Lingle
Governor, State of Hawaii
Executive Chambers
State Capitol
Honolulu, Hawaii 96813

Dear Governor Lingle:

Thank you for your May 22, 2008 letter informing FDA that the State of Hawaii recently passed Bill 7, which requires you to enter into an agreement allowing Hawaii residents to participate in the I-SaveRx prescription drug importation program. We understand Hawaii's desire to provide safe and effective prescription drugs at lower cost to Hawaii residents, but we are concerned that such an agreement would present a significant risk to your citizens. Furthermore, it is illegal to import drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

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 FDA-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 Report on Drug Importation (see http://www.hhs.gov/importtaskforce/Report1220.pdf) has found that the unregulated importation of prescription drugs poses serious health risks. Even though three years have passed since this Report issued, it is still the most comprehensive examination of the issue and we continue to find evidence to confirm its findings.

The agency cannot provide adequate assurance that the drug products delivered to consumers in the United States (U.S.) from any foreign country, including Canada, U.K., Australia, or others are the same as products that the FDA has approved through its rigorous safety and efficacy review process. In fact, many drugs that U.S. consumers purchase from Canada and believe were made in Canada actually are shipped from other countries, such as India and Costa Rica, and originate from dozens of countries around the world. (http://www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html).

Other recent announcements warning consumers of potentially dangerous drug products purchased over the Internet from Canadian or purportedly Canadian websites are included here:

FDA Warns Consumers Not to Buy or Use Prescription Drugs from Various Canadian Websites that Apparently Sell Counterfeit Products
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01441.html

FDA Alerts Consumers to Unsafe, Misrepresented Drugs Purchased Over the Internet

http://www.fda.gov/bbs/topics/NEWS/2007/NEW01564.html

FDA Says Consumers Continue to Buy Risky Drugs Online
Self-medication a concern; FDA-approved generics may be cheaper alternativehttp://www.fda.gov/bbs/topics/NEWS/2007/NEW01735.html

These safety concerns are also reflected in Congress' enactment of the drug and import provisions of 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 U.S. from Canada or other foreign countries 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 or causing the importation of 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), and may be enjoined or prosecuted. *See also* 21 U.S.C. §332(a), 333(a).

FDA approvals are specific to the manufacturer, product and manufacturing site, 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 U.S. 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 U.S. 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 U.S. 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-approve 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 U.S. 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).

I-Save Rx Program

With respect to the I-Save Rx program, which forms the basis of the importation program adopted under the Hawaii House Bill 7, the Illinois Auditor General issued a report in September 2006 concluding that not only is the I-Save Rx program in violation of federal law, but that it also may be in violation of Illinois' Pharmacy Practice Act. See http://www.auditor.illinois.gov/Audit-Reports/Performance-Special-Multi/Performance-Audits/FY06-Flu-Vaccine-ISaveRX-MGMT-digest.pdf[1] We recommend that Hawaii state officials examine whether the I-Save Rx program violates the Hawaii Pharmacy Practice Act or other applicable state laws.

In addition, the Illinois Auditor General found that 40% of inspection forms for pharmacies inspected for the I-Save Rx program were incomplete, and that the State did not monitor whether prescriptions were being filled only by approved pharmacies. Moreover, it found that the State had not adequately monitored the pharmacy benefits manager of the program regarding compliance with provisions of the contract.

Conclusion

Imported drug shipments under Hawaii's importation program would most likely violate Federal law as described above. As such, these packages would be subject to detention by U.S. Custom and Border Protection and FDA officials when offered for import. While FDA works to protect Americans from such potentially unsafe unapproved drugs, we do not have the ability and resources to assure the safety of unapproved imported drugs that claim to be "just as good" as FDA-approved drugs. Consequently, FDA cannot condone any program that encourages Americans to use unapproved and potentially unsafe drugs.

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. http://www.fda.gov/cder/info/consumer_generic.htm 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 ha become a hallmark of public health protection. I am confident we can work cooperatively towards solutions that will not be a disservice to the people of Hawaii.

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

[1] Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import otherwise illegal drugs. Under this policy, FDA permits 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. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. See FDA Regulatory Procedures Manual, http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-2.html. However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. Because the I-SaveRx program is "commercializing" personal importation of drug products, imports under that program would not be eligible for enforcement discretion under this policy.

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1. https://wayback.archive-it.org/7993/20170722175850/http://www.auditor.illinois.gov/Audit-Reports/Performance-Special-Multi/Performance-Audits/FY06-Flu-Vaccine-ISaveRX-MGMT-digest.pdf