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The Honorable Kumar P. Barve
313 Lowe House Office Building
Annapolis, Maryland 21401-1991

Dear Delegate Barve:

You have asked for advice concerning the legal consequences of a program under which the State, or one of its political subdivisions, would facilitate the importation of prescription drugs from a foreign source, such as Canada. It is my view that importation of prescription drugs from foreign sources, and thus the facilitation of such importation, is currently illegal, whether performed by the State or a political subdivision thereof. It is also possible that some liability could accrue to the State or a political subdivision from this type of activity, depending on the level of involvement of the State and the facts of the individual case. However, putting the issue of illegality aside for a moment, the State could statutorily create immunity for such a program at either the State or local level.

You have not specified the type of governmental involvement that is anticipated with respect to the importation of drugs from foreign sources, that is, whether the governmental entity would undertake importation itself, contract with an entity that imports prescription drugs, offer pharmacies in Canada as participating pharmacies with respect to pharmacy programs funded by the governmental entity, or simply provide information about the existence of entities that import drugs to residents of the United States. Obviously, the level of participation would affect the likelihood of enforcement as well as the possibility of liability. However, it is worthy of note that the Wisconsin Governor has interpreted the law to prohibit him from even posting the names of Canadian internet pharmacies on his web site.[1]

FEDERAL LAW - CURRENT

It is the position of the federal Food and Drug Administration ("FDA") that virtually any

[1] At http://www.drugsavings.wi.gov/ Governor Jim Doyle states, "I would like to provide you with the names of those Web sites, but I can't. The Bush administration refuses to permit states to help people save money by purchasing medicine from Canada. Governor Doyle has also asked the FDA to approve the State's plan to facilitate the purchase of Canadian pharmaceuticals by providing direct links to "reputable, proven web-based companies in Canada." http://www.drugsavings.wi.gov/docview.asp?docid=29

importation of prescription drugs, from Canada or elsewhere, would violate federal law ("the FDA Act) because the drugs are generally unapproved, 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). Importation of unapproved or mislabeled drugs violates 21 U.S.C. § 331(a) or (b). Importation of drugs manufactured in a state then sent abroad is limited to the original manufacturer. 21 U.S.C. § 381(d)(1). Importation by any other person violates 21 U.S.C. § 331(t). All of these violations carry criminal penalties. 21 U.S.C. § 333.

Since the FDA is the agency charged with enforcement of the federal laws governing prescription drugs, their interpretation of the statute is entitled to significant weight. Indeed, a letter from me concluding that the FDA misinterprets its own law would be of little use in the event that the FDA were to decide to bring an enforcement action against the State or one of its political subdivisions for facilitating the importation of prescription drugs. Having reviewed the matter, however, I find that I agree with their conclusions. The only court that I am aware of to look at these issues, in the context of a company that had storefronts in the United States for Canadian pharmacies, has also upheld the position of the FDA. *United States v. Rx Depot, Inc.*, 290 F.Supp.2d 1238 (N.D.Okla.2003), *stay denied, United States v. Rx Depot, Inc.*, --- F.Supp.2d ----, 2003 WL 23120030 (N.D.Okla. Nov 12, 2003).

Federal law, at 21 U.S.C. § 355 (a) provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." The approval covers not just the active ingredient, or the combination of ingredients, but also such matters as the processes, equipment and controls used during manufacture and packaging. 21 C.F.R. § 314.50. Changes in these factors, including a change in the facility or establishment used in the manufacture, processing or packaging of the drug product, requires a supplement to the approved application. 21 C.F.R. § 314.70. Thus, the mere fact that a drug has been approved for use in the United States does not mean that a version of it that is manufactured and packaged elsewhere qualifies as "approved." While it is possible for foreign manufacturers to get approval, the FDA states that most of the prescription drugs imported into the country are not approved, and that statement is supported by analysis of drug recently seized on their way into the country.[2]

The FDA Act, at 21 U.S.C. § 352, place detailed labeling requirements on drugs, including the name and place of business of the manufacturer, packer or distributor, § 352(b), an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, § 352(b), the established name of the drug and of each active ingredient, § 352(e), adequate directions for use and warnings about use by persons with pathological conditions or by children if its use may be dangerous to health, and also as to unsafe dosages or methods or duration of administration, § 352(f), any applicable requirements of the U.S. Pharmacopoeia with respect to packaging, § 352(g), and the

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[2] *Sweep Shows Imported Drugs Risky, U.S. Says*, Washington Post, January 28, 2004 page A2.

medication guide if one is required, § 352(n), 21 C.F.R. § 208.20. It is apparently common that imported drugs fail to meet one or more of these requirements.

Finally, 21 U.S.C. § 381(d)(1) provides that a drug that is subject to the prescription requirement which is manufactured in a State and exported may not be brought back into the United States except by the manufacturer of the drug. Thus, re-importation of approved drugs that were manufactured in the United States under that approval and which bear all the required labeling would still be illegal for any person other than the manufacturer.

The penalty provision, 21 U.S.C. § 333(a) provides that "[a]ny person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both." The law defines the term "person" to include individuals, partnerships, corporations and associations. 21 U.S.C. § 321(e). The term does not expressly include a State or other governmental entity. Nor has any case been decided that interprets the law to apply to States or their political subdivisions. A State law written in this way would not be interpreted to apply to the State. *Nationwide v. USF&G*, 314 Md. 131, 141-142 (1988). However, it has been held that the term "person" when used in federal law is broad enough to include the states and that it is not necessary to expressly mention states for them to be subject to federal law. *Case v. Bowles*, 327 U.S. 92, 99-100 (1946). As a result, it is my view that the State and its political subdivisions are bound by the requirements of federal law with respect to the importation of prescription drugs.

A showing of intent is not ordinarily required for a violation of provisions of the federal food and drug laws. *United States v. Dotterweich*, 320 U.S. 277, 281 (1943). However, the Act does require some level of involvement in the acts that constitute a violation in order for criminal liability to attach. Thus, in the corporate context, criminal penalties are applicable only to those officers or employees who had a responsible share in the furtherance of the transaction, or were in a position to prevent the violation by the exercise of foresight and vigilance. *United States v. Park*, 421 U.S. 658, 667-674 (1975). Obviously, if the State or a political subdivision were to directly undertake to import prescription drugs it would come within the criminal prohibitions of the statute., as would involved officials and employees. Contracting with an entity that imports prescription drugs in violation of the Act could also place the State or a political subdivision in a position of possible criminal liability. Whether lesser acts, such as payment of claims for prescription drugs purchased from a Canadian online pharmacy, could also lead to criminal liability is not, in my view, clearly established by current law. However, a prosecution based on such actions is not impossible.

FEDERAL LAW - NEW

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. 108-173, which was signed by the President on December 8, 2003, enacted a new 21 U.S.C. § 384, directed at a possible loosening of the current prohibitions of the importation of prescription drugs. The new law would require the Secretary, "after consultation with the United States Trade

Representative and the Commissioner of Customs, [to] promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." The regulations must require that safeguards be in place to ensure that the drugs imported under the regulations comply with the various provisions of the FDA Act with respect to approval, labeling and other matters, require that the importer comply with recordkeeping and testing requirements established by the new law, and contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs. The new law would also require that any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment. It would also permit waiver for importation by individuals for personal use on the basis of regulations or on a case-by-case basis. However, all of the provisions of the new law are contingent on certification to Congress by the Secretary that implementation will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer, and effectiveness will end if the Secretary subsequently certifies that the benefits of the program do not outweigh the detriment.

At this point there are no regulations. If such regulations were promulgated the State or a political subdivision clearly could contract with importers approved under the regulations or recommend them to its citizens. Moreover, the State or a political subdivision could form an entity that could get a license and the necessary approvals to import from approved Canadian pharmacies itself. However, I do not anticipate the promulgation of these regulations in the near future.

TORT LIABILITY

You have supplied two memoranda that discuss the potential liability of a state or local subdivision that has some involvement in the importation of drugs. The first, *State that Import or Facilitate the Importation of Foreign Pharmaceuticals Risk Lawsuits*, concentrates on the limits of common law sovereign immunity and also lists some theories under which the State or a local subdivision could be sued. The second, prepared for the Pharmaceutical Research and Manufacturers of America by Covington & Burling, discusses possible bases of liability in more detail, and concludes that "States that provide Canadian drugs directly to patients or that facilitate the provision of these drugs, though a state-sponsored pharmacy benefit plan or by other means, thus face real risks of liability." Neither focuses on specific types of government involvement or specifies what would constitute facilitation.

Without writing my own treatise on tort law, I think that is safe to conclude that there are possible State or local programs, and possible fact situations, under which the State or a political subdivision could find itself liable for injuries caused by use of imported prescription drugs. This risk would obviously be higher if the State itself engaged in importation, and lower at lesser levels

of participation. However, the State has the authority to statutorily immunize itself or its political subdivisions against suits brought on this basis if it decides to establish a program or to allow its political subdivisions to do so. Thus, while tort liability is a matter of some concern, federal criminal prohibition, in my view, presents a much more significant hurdle for such a program.

Sincerely,

Kathryn M. Rowe
Assistant Attorney General

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