F I S C A L I M P A C T R E P O R T

SPONSOR Heaton **DATE TYPED** 2/25/05 **HB** 601

SHORT TITLE Allow Importation of Certain Drugs **SB**

ANALYST Medina

APPROPRIATION

Appropriation Contained		Estimated Additional Impact		Recurring or Non-Rec	Fund Affected
FY05	**FY06**	**FY05**	**FY06**		
	NFI				

(Parenthesis ( ) Indicate Expenditure Decreases)

Relates to SJM 8

SOURCES OF INFORMATION
LFC Files

Responses Received From
Attorney General (AGO)
Retiree Health Care Authority (RHCA)
Regulation and Licensing Department—Pharmacy Board (RLD)
Aging and Long-Term Services Department (ALTSD)

SUMMARY

Synopsis of Bill

House Bill 601 amends the New Mexico Drug, Device and Cosmetic Act to allow for the re-importation of prescription drugs from a wholesale distributor in Canada for retail sale, provided that certain conditions are met. These conditions are that the re-imported drug was originally manufactured in the United States and a continuous chain of custody of the drug can be demonstrated, and the drug has been approved by the federal Food and Drug Administration as a safe drug. The chain of custody is defined as written or electronic evidence of custody for a medication from the manufacturer in the U.S. to a manufacturer or distributor in Canada. Another condition is that any savings realized as a result of the prescription drug re-importation are to be passed on to the patient for whom the drug is prescribed.

Significant Issues

According to ALTSD, in some instances the same drug bought in Canada costs 40 to 70 percent less than if purchased in the United States.

The Attorney General notes that in *US v RXDEPOT*, the U.S. Supreme Court noted that the Food and Drug Administration does not enforce the federal Food, Drug, and Cosmetic Act against individuals who travel to Canada or use the Internet to purchase prescription drugs from Canada for personal use. It is reasonable to expect that the Food and Drug Administration would commit its limited resources against large-scale commercial operations, which this bill attempts to legitimize.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

Senate Joint Memorial 8 requests that that the Aging and Long-Term Services Department, in cooperation with the Attorney General and the Board of Pharmacy create a task force to study the feasibility, legality and safety of importing prescription drugs from Canada and Mexico. It also requests that that the findings and recommendations of this study be reported to the Legislative Health and Human Services Committee at its October 2005 meeting.

OTHER SUBSTANTIVE ISSUES

According to the Attorney General's staff analysis, there is numerous background legislation on this issue. AGO notes the following:

Congress passed the Medicine Equity and Drug Safety Act of 2000 ("MEDSA") that allowed pharmacists and wholesalers to re-import American-made, FDA-approved drugs into the United States by amending Chapter VIII of the Federal Food, Drug, and Cosmetic Act ("FDCA"). This act was signed into law but no regulations were promulgated to implement it.

In November of 2003 the Department of Justice prosecuted a chain of pharmacies incorporated under the laws of Nevada that assisted individuals in procuring prescription medications from pharmacies in Canada. In US v RX DEPOT, INC., 290 F. Supp. 2^{d} 1238, (N.D. Okla. November 6, 2003), the Court held that the re-importation of U.S. manufactured drugs, even those approved for use in the United States, violates the Federal Food Drug and Cosmetic Act (FDCA) because only the manufacturer of a drug can re-import that drug into the United States. 21 U.S.C. § 381 (d)(1). Id. at 1245.

The Court acknowledged that because of the high cost of prescription drugs in the United States, some citizens cannot afford their medications at U.S. prices. The Court, however, also found that there is a legitimate safety concern by the FDA regarding the unregulated commercial re-importation of U.S.-manufactured drugs by someone other than the manufacturer and importation of foreign-manufactured drugs not approved by the FDA. Thus, although the defendants claimed that American citizens who cannot afford to purchase prescription drugs in the United States... will be precluded from obtaining affordable prescription drugs, the Court stated that it must enforce the priorities of Congress, and RXDEPOT was enjoined from re-importing prescriptions.

In December 2003, the Medicare Prescription Drug, Improvement, and Modernization Act ("Medicare Act") was signed into law. This Act leaves the ultimate decision regarding re-importation in the hands of the Secretary of Health and Human Services by directing him to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States. The Medicare Act does lift the supposed ban on drug re-importation from Canada, however there is a requirement that the Secretary of Health and Human Services approve the product. To date, regulations detailing this process have not been promulgated. The Code of Federal regulations still contains restrictions on the re-importation of prescription medications. 21 CFR § 203.10 states that no prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be re-imported by anyone other that its manufacturer, except that the FDA may grant permission to a person other than the manufacturer to re-import a prescription drug or insulin-containing drug if it determines that such re-importation is required for emergency medical care.

Warnings from the FDA have kept states from re-importing prescription drugs themselves, but some states are finding ways to work around the law. For example, Minnesota has established a special office and a Web site to guide patients though the purchase of prescriptions from registered Canadian pharmacies. This Bill may give New Mexico state sanction to the same process.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 contains language that amended 21 USCA § 384, the Food Drug and Cosmetic Act by permitting the importation of prescription drugs from Canada. However, the Secretary of Health and Human Services has not promulgated rules to implement this amendment. Currently, the Code of Federal Regulations states that no prescription drug may be re-imported by anyone except the manufacturer unless the FDA expressly grants permission if the drug is required for emergency medical care. The FDA continues to “turn a blind eye” to individuals who re-import. There are currently bills before both the U.S. House and the Senate related to this issue.”

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