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H-5478

To: Senator Celona Fax: 222-4263

From: Jack Kramer Date: 5/22/03

Re: Attached Pages 4

CC:

Urgent For Review Please Comment Please Reply Please Recycle

Senator Celona -

Attached is talking points re-Importation Legislation. It should have been sufficient that "it (re-Importation from Canada) is illegal. If I can supply additional info, please call.

Best,
Jack



Re-importation Legislation

House bill H-5478 would require the Rhode Island Board of Pharmacy to license Canadian pharmacies. It would accomplish this by amending Rhode Island General law Section 5-19.1-11 Nonresident Pharmacies. A new sub-section (b) would be added that reads as follows:

"Any pharmacy located in a province of Canada which maintains a valid, unexpired license, permit or registration to operate the pharmacy in compliance with the laws of said province shall be license in this state upon payment of a license fee as determined by the Director in subsection (a) above. THE FEDERAL PROHIBITION ON THE IMPORTATION OF PHARMACEUTICALS SHALL NOT BE A BASIS FOR DENYING LICENSURE TO A CANADIAN PHARMACY....."

This legislation, which would require the Board of Pharmacy to license pharmacies engaged in an illegal activity, would set a VERY dangerous precedent. How can the Board of Pharmacy in good conscience enforce any of the Federal laws, including the prevention of controlled drug diversion, if they are prohibited by the Rhode Island General Assembly from enforcing other Federal laws.

Additionally the National Association of Boards of Pharmacy (NABP) has indicated that there is a definite possibility that passage of this legislation may preclude the Rhode Island Board from membership in NABP. This is a serious consequence as it would preclude the Rhode Island Board from administering the national pharmacist licensure examination (NABPLEX). Failure by the Rhode Island board to administer NABPLEX would prevent Rhode Island licensed pharmacist from reciprocating their Rhode Island license to other states. It would also prevent pharmacists licensed in other states from reciprocating their licenses into Rhode Island.

Some of the possible changes and their respective pros and cons:

- Amend H-5478 by changing Section 2 to read - This act shall take effect upon approval by the FDA that the re-importation of pharmaceuticals for personal use is legal and safe.
 - >Pro - This eliminates all questions of the legality of the proposed legislation. Supporters of this amendment would include PhRMA, Community Pharmacy, and Board of Pharmacy.

- >Con – It would delay the effective date of the legislation. Opponents would include the current proponents.
- Amend H-5478 to require the said licensed Canadian pharmacy to ship the finished prescription to a Rhode Island based pharmacy for dispensing to the ultimate consumer.
 - >Pro – It would allow an immediate effective date and provide the essential quality assurance for Rhode Island residents. Supporters would probably include the current proponents.
 - >Con – It is highly doubtful that any Rhode Island based pharmacy could LEGALLY participate in this program. Because every Rhode Island pharmacy must obtain a license from the Federal Drug Enforcement Administration (DEA), engaging in an illegal activity would jeopardize their continued operation. Opponents would include PhRMA, the Federal government, and most Rhode Island based pharmacies. A possible alternative solution would be to add the same amendment as mentioned in the above bullet to Section 2.
- Amend H-5478 to require pharmaceutical manufacturers to sell products to Rhode Island based pharmacies for the same price as in Canada.
 - >Pro – It would achieve all of the objectives of the proposed legislation and also provide the quality assurance (including a complete drug interaction check) that is missing in the proposed legislation. Supporters would include all of the current proponents AND community pharmacies.
 - >Con – PhRMA would strongly oppose and would probably file legal action to block implementation

Some important talking points with regard to this issue would include the following:

- Requiring the Board of Pharmacy to license pharmacies involved in illegal activities is an extremely dangerous precedent. What other Federal laws are going to be ignored just because it's convenient or of questionable benefit?
- Since consumers will only go to Canada for those prescriptions that are not covered by an insurance company (ie. after they exceed their insurance cap) and brand name prescriptions (because generic drugs are cheaper in the United States) no pharmacy will have a complete patient medication profile. In our highly fragmented health care delivery system this is extremely important. It is important to know ALL the

- medications a patient is utilizing in order to check for drug interactions and drug disease contraindications.
- While most people feel comfortable with drugs from Canada, where will the next wave of drugs come from. Some manufacturers are cutting off supplies to Canadian pharmacies. Will the General Assembly next require the Board of Pharmacy to license pharmacies in Mexico if their supplies are greater than Canadian pharmacies or if their prices are cheaper than Canada? The entire Canadian prescription drug market is less than \$9 Billion U.S. at retail. CVS alone sells over \$16 Billion worth of prescription drugs. There is no way that Canada can supply the U.S. market. Consumers availing themselves of Canadian drugs will soon have to turn to other countries.
 - The high cost of prescription drugs coupled with a shortage of supply serves as fertile breeding ground for counterfeit drugs (please see the USA today cover story of Thursday May 16th). The increasing shortage of certain drugs in Canada and the lack of close accountability of the pharmacies dispensing these drugs will exacerbate this situation.
 - While Canadian drugs are generally safe, their approval process is not as diligent as the FDA. For example even though the United States ban the sale of Thalidamide for general use, it was routinely available in Canada. The U.S. avoided the tragedy of thousands of Thalidamide babies because of the diligence of the FDA.

Please let me know if you have any questions.

See Celone 222-4243
See Moss 222-2947



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

ISSUE UPDATE

For Pharmacy, Government Affairs & Front End Executives

Friday, May 23, 2003

Confidential memo not for attribution or distribution outside your company

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John Covasa
Brew
Ivans

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Canada publicly disavows Washington Post reports that it guarantees the safety of medication imported to the U.S.

In case you missed it, *The Washington Post* ran a letter to the editor from Health Canada this week ([click here](#) for a copy), correcting its May 7 article entitled, *Canada to Guarantee Imported Medicine* ([click here](#) for a copy). The article erroneously reported that, "The Canadian government has officially said that it will be responsible for the safety and quality of the large and growing flow of prescription drugs across the border to American consumers..."

→ In its letter, Health Canada wrote that the story "gave the inaccurate impression that Health Canada agreed to take responsibility for the safety of drugs exported to the United States."

Unfortunately the original article was re-run in publications across the country, creating much confusion and misperception among seniors and others about the safety of illegal importation from Canada. Please take the opportunity to disseminate this correction as widely as possible.

New Jersey takes a shot against illegal importation... →

washingtonpost.com

FDA: Canadian Drug Position Misinterpreted

By Marc Kaufman
Washington Post Staff Writer
Monday, May 26, 2003; Page A11

Federal officials said last week they had misunderstood Canada's recent statement about how much authority and ability it has to ensure the safety of prescription drugs that American consumers buy from across the border.

Food and Drug Administration officials said the Canadian statement issued earlier this month did not expand Canadian oversight of the millions of prescriptions being re-imported into the United States, as the FDA at first believed.

Instead, Canada was trying to clarify its position that while it regulates all drugs imported into the country -- whether for internal consumption or export -- it cannot vouch for the safety of medications that are then exported back to the United States.

"There have been ongoing discussions between the Canadians and the United States, and we're glad that we more clearly understand their position," said Peter J. Pitts, the FDA's associate commissioner for external relations.

"The Canadian government is now on record saying they cannot guarantee the safety and effectiveness of drugs not legally exported into the U.S.," he said. "The Canadian position reinforces our position that bringing in any medical products from outside our borders that are not FDA-approved is inherently risky and dangerous."

The issue of re-importing drugs from Canada is a contentious and increasingly important one because of the large and growing number of Americans who are getting their medications through Canada.

Because of price controls, medications in Canada -- both those imported from the United States and elsewhere and those manufactured there -- cost considerably less than the same drugs in the United States. To take advantage of the lower prices, millions of Americans, especially the elderly, are buying drugs through American storefront drugstores supplied from Canada or through Internet sites that are, or claim to be, in Canada.

Re-importing medications from abroad is technically illegal in the United States, but the FDA and other law enforcement agencies have generally not interfered with individual efforts to buy drugs from Canada. But the agencies are becoming increasingly aggressive about targeting some groups and businesses that encourage or profit from the Canadian trade.

Congress has twice passed bills legalizing re-importing of drugs from Canada, but both times the secretary of Health and Human Services said the agency could not vouch for the drugs' safety, and so the bills died.

After Health Canada posted a new "guidance" on its Web site in early May, FDA Commissioner Mark B. McClellan said, "The fact that they are explicitly stating that they are trying to assure safety and effectiveness not only for Canadians, but for the millions of prescriptions sold to Americans through

Canada, is a potentially useful step."

After a story that included McClellan's comments ran in The Washington Post, Health Canada said that its position had been misunderstood. In a letter to The Post, Health Canada Assistant Deputy Minister Diane Gorman wrote that the story "gave the inaccurate impression that Health Canada agreed to take responsibility for the safety of drugs exported to the United States."

McClellan says his concerns about the safety of re-imported drugs are now as great as before the Canadian statement.

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