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SB 310



NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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SENATE PUBLIC HEALTH, WELFARE & SAFETY

EXHIBIT NO. ~~6~~ 6

Issue Brief

DATE: 2-4-5

BILL NO. SB 310

Commercial Importation of Pharmaceuticals

Several bills have been introduced that would authorize a program of commercial reimportation of pharmaceuticals from foreign countries (e.g., Canada), or require the Secretary to issue regulations that would implement the program enacted in 2000 (MEDS Act of 2000). Neither former HHS Secretary Shalala nor current HHS Secretary Thompson issued regulations authorizing the implementation of that program because they could not certify that the program would assure quality or reduce pharmaceutical costs.

The National Association of Chain Drug Stores (NACDS) agrees with the position of these HHS Secretaries in not implementing this program. There are multiple reasons relating to cost, quality, and efficiency why NACDS cannot support a program of commercial reimportation of pharmaceuticals.

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Liability for Injury Caused by Commercially Imported Prescription Drugs: There are serious questions regarding who will bear the liability if imported drugs result in harm to American patients. For example, manufacturers currently bear the potential liability resulting from harm for a properly dispensed prescription drug sold to an American pharmacy through established, licensed domestic distribution channels. It is unclear how pharmacy liability would be affected if a drug that caused injury was made for a foreign country but was imported by and dispensed in a domestic pharmacy. This is an even greater concern for pharmacies due to the likelihood that any possible recourse against the foreign supplier of a harmful drug may be lost due to a waiver or subject to foreign courts and foreign law.

Adequate, Consistent, and Integrity of Supply Issues: There are questions of whether international sources of pharmaceutical supply will be adequate and consistently reliable. Pharmacies may be able to obtain sufficient international drug products at one time, but inadequate product supply at another. This might lead to a higher price for consumers – or a different quality of drug – when consumers come back for their medication if the source of supply is unavailable. Pharmacies must have access to consistent, reliable, quality sources of medication supply.

Also, pharmacies must be assured that products are not counterfeit or diverted. According to the World Health Organization, 5-8% of drugs world wide are counterfeit. The best way to prevent the infiltration of counterfeit drugs into the drug supply is to restrict and regulate access to the drug supply as much as possible, such as is done in the United States. To apply this system on a global scale is operationally and financially cost prohibitive. Consequently, permitting importation under the current proposals favors counterfeiters. Relatedly, even if products are thought to be from a particular country that has high manufacturing or quality standards, the products may in fact be diverted from a country that does not. Commercial reimportation will clearly generate “black markets” for pharmaceuticals, raising serious questions about the quality of these drugs.

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Problems with Dual Inventories: Pharmacies will likely have to maintain dual inventories of pharmaceutical products to assure those products that have not been imported, and those that have been imported, are tracked and billed appropriately. However, space limitations in pharmacies, carrying costs, and other considerations make it virtually impossible to maintain separate pharmaceutical inventories. Yet, if American pharmacies do possess dual inventories, no one has answered the question of who decides which patients get domestic versus imported drugs. Also, there has nothing to address the potential impact of a dual inventory on pharmacies under the third party payor programs that they service, both government (*e.g.*, Medicaid) and private, must be addressed. For example, all domestic-source prescription drugs have an NDC (national drug control) number to allow the third party payor to track the drugs dispensed by a pharmacy for reimbursement purposes. Imported drugs under the current proposals do not have NDC numbers. Without this number to track, pharmacies cannot be reimbursed for dispensing imported drugs under third party payor plans.

Quality and Safety Reasons: Many pharmaceutical products sold in other countries – albeit containing the same active pharmaceutical ingredients as those sold here – may have different shapes, sizes, colors, and even trade names. Some are made with different inactive ingredients, while some are sold in different doses because the patients in other countries have different dose-response relationships. Introducing different-looking foreign pharmaceutical products into the U.S. system will only confuse patients and health professionals. Additionally, there is no mechanism in place to notify Americans of a foreign-sourced drug recall. There is no way at present that an American pharmacist would know if a drug in Canada was recalled such that he or she could properly inform the patient to protect patient safety. Consequently, patient safety is at risk.

This will lead to an increase in medication-related events, which already lead to deaths and injury for thousands of individuals each year, and already results in \$177 billion in related health care costs.

Burdensome Testing Requirements: The testing requirements that may be required to assure the quality of imported products are costly and complex. Pharmacists cannot be expected to perform these functions or bear these costs.

Cost of Establishing System: Establishing the infrastructure necessary to effectively and efficiently operate a reimportation program – coupled with potential testing and other regulatory requirements – could result in significant start-up and operational costs. Given the unstable political environment surrounding reimportation, pharmacies would not be guaranteed the ability to recover their costs.

Potential Price Controls on Pharmacies: Because seniors and others will likely be disappointed by the savings from prescription drugs imported through a commercial reimportation system, NACDS is concerned that policymakers will turn to controlling the sales prices of these drugs to assure savings to consumers.

Conclusion

In light of the potential dangers relating to quality and consistency of pharmaceutical supply, potential disruptions to the existing efficient pharmaceutical distribution system, and the likelihood that the distributive and testing functions would add significant costs to the process, NACDS cannot support programs of commercial pharmaceutical reimportation.