NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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Submitted via email: Aryan.showers@state.nm.us

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To New Mexico Department of Health:

On behalf of our members operating pharmacies in the state of New Mexico, the National Association of Chain Drug Stores (NACDS) opposes New Mexico's proposed Wholesale Prescription Drug Importation Program ("Importation Program"). We strongly urge the Department of Health ("Department") to reject the Importation Program.

Although the federal Food and Drug Administration (FDA) has adopted regulations that would authorize programs of commercial importation of pharmaceuticals from Canada, we believe that commercial importation programs cannot successfully be implemented. Indeed, any program would likely violate federal laws against drug importation, undermine federally mandated security protections of the drug supply chain, and would increase the risk of counterfeit drugs in a state's drug supply chain. Moreover, historically, both FDA Commissioners and the Canadian government have raised serious concerns regarding the danger to public safety posed by allowing commercial importation.

Commercial Importation Weakens the Drug Supply Chain Security Act (DSCSA)

In 2013, Congress passed the DSCSA to track and trace prescription drugs from manufacturer to receipt by the dispenser. Through tracking prescription drugs, the law aims to prevent counterfeit drugs from entering the United States supply chain. If New Mexico were to allow commercial importation from Canada, such a proposal would undermine the safety and security protections of the DSCSA. It is impossible to fully enforce the DSCSA over foreign facilities, manufacturers, wholesalers, and dispensers. The New Mexico Importation Program would create loopholes within the DSCSA regulatory framework, easily allowing counterfeit drugs to reach New Mexicans.

FDA and Canadian Safety Concerns Regarding Commercial Importation

Throughout the past 15 years, through speeches, testimony, letters, and other consumer resources, FDA has repeatedly sounded the alarm as to the risk to patient safety posed by importation. Moreover, five former FDA commissioners have made previous statements opposing drug importation, noting that broad drug importation exposes the U.S. supply

chain to foreign counterfeit drugs.[1,2] The Canadian government also shares the FDA's concerns.[3] The New Mexico Importation Program would ignore the serious safety concerns repeatedly raised by Canada and the federal government.

Drug Supply Chain Integrity Issues

A state importation scheme must assure that imported drug products are not counterfeit or diverted. Otherwise, with counterfeit drugs, people will get sick and potentially die. According to the World Health Organization, 10% of drugs worldwide are counterfeit, so the risk of illness and death is very real.[4] 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, through Canada, from a country that does not. The New Mexico Importation Program will generate "black markets" for pharmaceuticals, raising serious questions about the quality of these drugs.

The Lack of an Adequate, Consistent, and Safe Supply of Foreign Drugs

There are questions of whether international sources of pharmaceutical supply will be adequate and consistently reliable, as well as safe. The New Mexico Importation Program could provide only a sporadic supply of international drug products. Moreover, imported drugs from Canada and elsewhere would pose safety concerns as drug products sold abroad – albeit containing the same active pharmaceutical ingredients as those sold here – often have different shapes, sizes, colors, and even trade names. They can be 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 confuse patients and health professionals. The lack of stability and clarity places patient safety at risk.

Since New Mexico would contract with entities in a foreign country, the State would have no authority or ability to ensure that a particular entity is a legitimate business and is not dealing in counterfeit drugs. Moreover, patients would have no legal recourse if harm does occur.

Publicly Shaming Non-participating Pharmacies

Particularly troubling is the proposal for state and health plans to inform enrollees and residents about which pharmacies were not dispensing imported medications so patients

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[1] Gottlieb, Scott; "What Trump Should Have Said on Drug Prices;" *Forbes*; March 04, 2016. https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#540c85a92e74.

[2] Califf, R.M., Hamburg, M.B., McClellan, M. & Von Eschenbach, A. (March 2017); Open letter to members of Congress.

[3] HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004.

[4] World Health Organization (WHO); "Counterfeit medicines: an update on estimates"; *Geneva: WHO International Medical Products Anti-Counterfeiting Task Force* (2006).

could avoid those pharmacies. The state of New Mexico has not proven that it can import drugs safely while delivering significant savings. Until you can do so, you should not be threatening pharmacies and pharmacists that continue to put patient safety first.

Pharmacy-Specific Concerns

The Department would also have to address pharmacy-specific concerns in the Importation Program. First, the proposed requirement for pharmacies to report adverse events within 15 or 90 days, depending on the type of event, is not workable. This proposal would be cumbersome and duplicative of the FDA established process for reporting adverse events. The Department should follow the FDA established processes for adverse event reporting.

Second, pharmacies would be reluctant to participate in the Importation Program because they could not be assured adequate reimbursement. The reimbursement must be sufficient such that it is financially sustainable for a pharmacy to participate. Although the Department indicates that you will work with the health plans to reimburse the actual acquisition cost plus a dispensing fee, considering the inherent risks in the Importation Program, pharmacies may not be able to participate without a guarantee.

Conclusion

Considering the numerous concerns and challenges inherent to the Importation Program, NACDS strongly urges the Department to reject the proposal. We appreciate the opportunity to present the concerns of our members in New Mexico on this very important issue.

Sincerely,

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President and Chief Executive Officer