May 9, 2017

Re: Importation of Non-FDA Approved Prescription Drugs

Dear Member of Congress:

On behalf of the American Pharmacists Association (APhA) and the National Association of Chain Drug Stores (NACDS), we are writing to express our strong concerns with potential legislation that would allow for importation of prescription drugs. Although we support efforts to increase patients' access to appropriate, safe, effective, and affordable prescription medications, we believe proposals to legalize importation of prescription drugs are in direct conflict with recent efforts by Congress and federal agencies to increase the integrity and security of the U.S. drug supply. We do not believe that consumer safety can be ensured in any system that allows for the personal or commercial importation of non-FDA approved prescription medications.

Founded in 1852 as the American Pharmaceutical Association, APhA represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 178,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 21 countries.

Importation Undermines the Drug Supply Chain Security Act (DSCSA)

The DSCSA was signed into law in 2013 and represents a ten-year, multi-stakeholder effort to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. We are extremely concerned that importation, both personal and commercial, will undermine the DSCSA's goal to protect consumers from exposure to counterfeit, stolen, contaminated, or otherwise harmful drugs. For example, under current legislative importation proposals, foreign entities providing personal importation would not be subject to the DSCSA. Moreover, in the commercial importation context, the federal government would be unable to enforce the DSCSA requirements on foreign manufacturers, foreign wholesalers, or foreign dispensers of products that are not verified to meet FDA standards. Personal and commercial importation of non-FDA approved drugs creates loopholes within the DSCSA regulatory framework, undermining the teeth of enforcement of the DSCSA as to counterfeit drugs.

FDA and the Canadian Government Recognize the Risk and Lack of Cost Savings from Importation

FDA has warned against the risk to patient safety posed by importation laws. Specifically, they note, "FDA cannot ensure the safety and effectiveness of products that are not FDA-approved and come

from unknown sources and foreign locations, or that may not have been manufactured under proper conditions. These unknowns put patient's health at risk if they cannot be sure of the products identity, purity, and source."[1]

Additionally, the proposed FDA commissioner, Dr. Scott Gottlieb, and four former FDA commissioners, recently made statements opposing drug importation as a means to control cost and have noted the negative effect a drug importation scheme will have on keeping counterfeit drugs out of the U.S. supply chain.[2,3] In a recent open letter to Congress, the former Commissioners detailed their concerns, including the following statement:

> We believe that such importation represents a complex and risky approach—one that the evidence shows will not achieve the aim, and that is likely to harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products.[4]

Dr. Gottlieb, in March 2016, commented that having studied the issue, safe regulation of foreign drugs "would have added so much cost to the imported drugs, they wouldn't be much cheaper than drugs sold inside our closed American system."[5]

The Canadian government has also weighed in on this issue. Diane C. Gorman, Assistant Deputy Minister of Health Canada, stated that "Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future."[6] Further, according to Gorman, "The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter."[7]

We strongly believe FDA oversight is needed to help maintain the integrity and security of the supply chain for prescription drugs. Without it, the federal government, pharmacists, and the public cannot ascertain the quality, safety, and efficacy of the medications being used by our nation's citizens.

Importation Poses a High Risk of Counterfeit Drugs

Foreign internet pharmacies, depending on the country of origin, may be wholly unregulated. Often a foreign internet pharmacy will appear as if to originate in a country with online pharmacy regulations, such as Canada, but actually originate from a country that has no such regulations. Therefore, it is no surprise that a large number of foreign internet pharmacies are illegitimate and this number is increasing as they become more sophisticated in their operations. Given the lack of regulation and risk

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[1] Food and Drug Administration, Importing Prescription Drugs, available at: https://www.fda.gov/Drugs/DrugSafety/ucm170594.htm, last accessed March 15, 2017.
[2] Gottlieb, S. (2016). What Trump Should Have Said on Drug Prices, *Forbes*, available at: https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#540c85a92e74, last accessed: March 15, 2017.
[3] Califf, R.M., Hamburg, M.B., McClellan, M. & Von Eschenbach, A. (March 2017). Open letter to members of Congress. Available at: /https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final.pdf.
[4] https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf (accessed April 3, 2017)
[5] https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#79721f022e74 (accessed April 3, 2017)
[6] 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.
[7] Letter to The Washington Post, Diane Gorman, Assistant Deputy Minister, Health Canada, May 9, 2003.

of illegitimacy, the potential for counterfeit drugs being mailed into the U.S. from foreign internet sites offering prescription drugs is very high. According to the World Health Organization (WHO), "the prevalence of counterfeit medicines ranges from less than 1 percent of sales in developed countries, to over 10 percent in developing countries, depending on the geographical area."[8] Many countries in Africa and parts of Asia and Latin America have areas where more than 30 percent of medicines on sale can be counterfeit.[9] Medicines purchased over the internet from sites that conceal their physical address are counterfeit in over 50 percent of the cases.[10]

Worldwide and in the U.S., consumers are harmed and die from counterfeit medications. Consumers have been poisoned by toxic substances in counterfeit medications and patients with chronic health conditions such as cancer have died from counterfeit medications that contain no active ingredient. Further, if a foreign dispensed drug is subject to a recall or is withdrawn from the market, there is no way to inform patients and protect them from harm.

Pharmacist-patient relationship

Legislation directed toward legalizing personal importation also overlooks the value of an established pharmacist-patient relationship. Importation proposals will likely encourage patients to receive imported medications through online mechanisms, adding an extra barrier to obtaining the necessary counseling patients need to optimize the impact of medications. Individuals who obtain prescription medications through personal importation schemes may not have an appropriately-licensed pharmacist available to consult with them about using the medications safely and effectively. Every day, U.S. pharmacists assist customers with obtaining the most cost effective, therapeutically-appropriate drug therapies. In the end, importation bills disrupt the pharmacist-patient relationship and inhibit communications between providers and patients.

Conclusion

Once again, we appreciate congressional efforts to improve patient access to affordable medications, but urge Congress to carefully consider the consequences of drug importation laws on patient safety and care and reject proposals to allow importation of prescription drugs. We look forward to continuing to work with Members of Congress and their staff as the legislative process continues. For additional information, please contact Alicia Kerry Mica, APhA's Senior Lobbyist, at amica@aphanet.org or Amber Manko, NACDS's Director of Federal Affairs, at amanko@nacds.org.

Sincerely,

The American Pharmacists Association (APhA)
The National Association of Chain Drug Stores (NACDS)

[8] WHO, International Medical Products Anti-Counterfeiting Taskforce (IMPACT), "Counterfeit Medicines: an update on estimates," November 15, 2006. http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf
[9] WHO IMPACT, ibid.
[10] WHO IMPACT, ibid.