August 2, 2017

Re: Prescription Drug Importation Legislation

Dear Senator:

On behalf of the National Association of Chain Drug Stores (NACDS) and the American Pharmacists Association (APhA), we are writing today in opposition to any amendment that would allow for personal or commercial importation of non-Food and Drug Administration (FDA) approved prescription drugs. We support efforts to provide Americans access to safe, effective, and affordable prescription drugs, but allowing for broad importation undermines the integrity and security of the U.S. drug supply by posing an unreasonable risk to patient health and endangering public safety. We strongly oppose any expansion of importation of non-FDA approved drugs that could be offered as the Senate considers legislation to reauthorize FDA prescription drug user fees.

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.

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.

The Drug Supply Chain Security Act (DSCSA) is Undermined by Drug Importation

In 2013, Congress passed the DSCSA, which requires the track and trace of 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. Any expansion of importation, personal and commercial, will undermine the DSCSA's goal to protect consumers from exposure to dangerous counterfeit drugs. Proposals for importation fail to align with track and trace requirements of the DSCSA, as well as other DSCSA requirements involving licensure of supply chain participants, verification and validation of drug products, and the handling of suspect and illegitimate products. Attempts to create alignment are misguided, as United States enforcement of the DSCSA over foreign facilities and manufacturers that are not subject to FDA oversight, wholesalers, and dispensers is practically impossible to achieve. In the end, broad importation creates loopholes within the DSCSA regulatory framework, easily allowing counterfeit drugs to slip into the United States supply chain.

Historically Both FDA and the Canadian Government Have Raised Grave Concerns Regarding Importation of Non-FDA Approved Drugs into the United States

Both the FDA and Canada recognize the risk posed by drug importation of non-FDA approved drugs in terms of danger to individual patient health and general public safety. Throughout the past 15 years, through speeches, testimony, letters, and other consumer resources, FDA has repeatedly sounded the alarm on the risk to patient safety posed by importation of non-FDA approved drugs.[1] Moreover, the newly confirmed FDA commissioner, Dr. Scott Gottlieb, and four former FDA commissioners, have made statements opposing drug importation, noting that broad drug importation exposes the U.S. supply chain to foreign counterfeit drugs.[2,3] In a recent open letter to Congress, the former Commissioners stated:

> 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]

The Canadian government shares the FDA and FDA commissioners' concerns. Diane C. Gorman, Assistant Deputy Minister of Health Canada, has 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."[5] 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."[6]

We support continued strong FDA oversight over the drug supply chain. Only through such oversight can the public be assured that the drugs they receive are high quality, safe, and effective. To support broad importation is to compromise the integrity and security of the supply chain for prescription drugs.

Importation Increases the Risk of Counterfeit Drugs in the Supply Chain

Foreign importation from entities not subject to FDA oversight is rife with avenues for counterfeit drugs to enter the United States supply chain. In many countries, foreign internet pharmacies remain unregulated. This lack of regulation allows a foreign internet pharmacy to appear as if it is based in a country that regulates internet pharmacies, like Canada, while it is really located in a country without such regulations and with a high volume of drug counterfeiters. The lack of a strong regulatory framework for internet pharmacies in certain foreign countries has led to the large number of illegitimate foreign internet pharmacies and the proliferation of more and more such pharmacies as they become more sophisticated in their operations.

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[1] Food and Drug Administration, Importing Prescription Drugs, available at: https://www.fda.gov/Drugs/DrugSafety/ucm170594.htm, last accessed May 16, 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] 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.
[6] Letter to The Washington Post, Diane Gorman, Assistant Deputy Minister, Health Canada, May 9, 2003.

The growing population of illegitimate foreign internet pharmacies directly leads to more and more counterfeit drugs being mailed into the United States, particularly in a United States regulatory environment that more openly allows drug importation. 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."[7] The prevalence of counterfeit drugs is particularly high in Africa and parts of Asia and Latin America, where more than 30 percent of drugs may be counterfeit.[8] In fact, WHO estimates that when an internet pharmacy conceals its physical address, the drugs dispensed by such a pharmacy are counterfeit in over 50 percent of the cases.[9]

Counterfeit drugs in the United States supply chain have dire consequences. People get sick and die from counterfeit medications. In the past, some consumers have been poisoned by toxic substances in counterfeit medications. In other cases, cancer patients have died because their foreign counterfeit medications contained no active ingredient. Moreover, if a foreign non-FDA approved drug is subject to a recall or is withdrawn from the market, there is no way to inform patients. Importation removes safety mechanisms that protect patients from harm. Open importation would greatly increase the probability of patients getting sick and dying from counterfeit foreign drugs.

Importation Detracts from Value-Based Care

Broader importation laws will hinder the progress made to move U.S. health care delivery and payment towards value, as opposed to volume, and further fragment care. Because Canadian pharmacists may only fill prescriptions written by Canadian prescribers, expanded importation policies will encourage Americans to seek care from foreign prescribers and pharmacists, whose systems and standards are not integrated into, or consistent with, U.S. systems or care. Value-based care models and other efforts to produce savings and promote quality, such as outcomes-based reimbursement, will be more difficult to measure and optimize if patients are allowed to receive care outside the model's mechanisms to drive results. [10] Moreover, because of the implementation of outcomes-based payment, U.S. health care providers and facilities may be unjustly penalized due to the actions of foreign providers or patients' reactions to non-FDA approved medications.

Other negative events can result from broadened importation, such as increased adverse events and decreased medication adherence, as practitioners may make care decisions based on a patient's incomplete medical and medication profile. Pharmacist-provided services that help patients optimize medications, such as medication therapy management covered under Medicare Part D, may lose their value as medication reviews will likely not be comprehensive. The U.S. spends nearly $300 billion as a result of medication-related problems, we anticipate that importation will only increase this number.[11] Our organizations have consistently emphasized the value of pharmacist-provided care services, noting that pharmacists' roles extend well beyond the dispensing of a medication. Patients

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[7] 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
[8] WHO IMPACT, ibid.
[9] WHO IMPACT, ibid.
[10] Centers for Medicare & Medicaid Services, (May 2016). CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs), available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf, last accessed: May 23, 2017.
[11] New England Healthcare Institute. Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. August 2009. http://www.nehi.net/publications/17-thinking-outside-the-pillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view

benefit significantly when they have a relationship with a pharmacist.[12,13,14,15,16] The pharmacist-patient relationship will be seriously undermined if importation of non-FDA approved drugs is permitted.

Conclusion

Despite the good intentions of policymakers who offer prescription drug importation as a solution to high drug costs, we are concerned that any savings will only be short-term. Instead, importation will potentially lead to long-term costs for patients and the healthcare system overall. Therefore, we urge Congress to oppose measures that would legalize importation of non-FDA approved drugs. Alternatively, we support current efforts to improve patient access to affordable and safe medications, including FDA's ongoing implementation of the DSCSA. The risk of foreign counterfeit drugs is too high, and the consequences for United States consumers are too deadly. We look forward to continuing to work with you on this very important issue.

Sincerely,

American Pharmacists Association

National Association of Chain Drug Stores

[12] Phatak, A., Prusi, R., Ward, B., Hansen, L.O., Williams, M.V., Vetter, E., Chapman, N. & Postelnick, M. (2015). Impact of pharmacist involvement in the transitional care of high-risk patients through medication reconciliation, medication education and post-discharge call-backs (IPITCH Study), *Journal of Hospital Medicine*, 11(1), 39-44.

[13] McCullough, M.B., Petrakis, B.A., Gillespie, C., Solomon, J.L., Park, A.M. & Ourth, H. (2016). Knowing the patient: A qualitative study on care-taking and the clinical pharmacist-patient relationship, *Research in Social and Administrative Pharmacy*, 12(1), 78-90).

[14] Braaf, S., Rixon, S., Williams, A., Lieu, D. & Manias, E. (2014). Pharmacist-patient medication communication during admission and discharge in specialty hospital settings: implications for person centered healthcare, *The International Journal of Person Centered Medicine*

[15] Schuessler, T.J., Ruisinger, J.F., Hare, S.E., Prohaska, E.S. & Melton, B.L. (2015). Patient satisfaction with pharmacist-led chronic disease state management programs, *Journal of Pharmacy Practice*, 29(5), 2015.

[16] Mossialos, E., Courtin, E., Naci, H., Benrimoj, S., Bouvy, M., Farris, K., Noyce, P. & Sketris, I. (2016). From "retailers" to health care providers: Transforming the role of community pharmacists in chronic disease management, *Health Policy*, 119(5), 628-639.