



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

March 22, 2017

Re: Importation of Non-FDA Approved Prescription Drugs

Dear Member of Congress:

On behalf of the American Pharmacists Association (APhA), we are writing to thank you for your efforts to make prescription medications more affordable and accessible for Americans. 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.

APhA appreciates ongoing congressional efforts to gather input from stakeholders on issues related to drug importation for incorporation into existing or future legislation. Although, APhA supports efforts to increase patients' access to appropriate, safe, effective, and affordable prescription medications, we believe proposals to legalize importation of non-FDA approved drugs is in direct conflict with recent efforts by Congress and federal agencies to increase the integrity and security of the U.S. drug supply. Moreover, obtaining safe and effective medications is only one part of appropriate medication use. It also requires a health practitioner's knowledge of the patient's complete medication profile and an understanding by the patient of how to take the medication, side effects and/or potential interactions — all of which could be negatively affected by importation proposals. APhA believes such policy could hurt the very patients intended to benefit from importation proposals. Consequently, the risks to patient safety from harmful or ineffective products or avoidable medication errors due to fractured care outweighs any increase in access or cost-savings.

Despite the good intentions of policymakers who offer prescription drug importation as a mechanism to help patients reduce their medication costs, APhA is concerned savings, if any, will be short-term. We worry importation will instead result in long-term costs to patients and the health care system. Furthermore, APhA is skeptical whether the intended effect of importation proposals —lower cost medications for patients —will be realized broadly. Accordingly, APhA urges Congress to oppose bills that legalize importation of non-FDA approved drugs by pharmacies, wholesale distributors, and individuals.

I. Importation by pharmacies, wholesale distributors and individuals

Current importation proposals differ in regards to who is permitted to import non-FDA approved¹ products and from whom they may obtain such products. For example, some proposals permit importation by U.S. pharmacies, wholesale distributors and individuals purchasing from Canadian-licensed pharmacies, while others are limited to individual importation only or permit import when sent from certain pharmacies or wholesale distributors located in a variety of countries. APhA believes allowing pharmacies, wholesale distributors and individuals to import non-FDA approved products from foreign trading partners, which are not compliant with state and other federal laws and policies, such as the Drug Supply Chain and Security Act (DSCSA), will pose significant risks to patient safety and the safety and security of our nation's drug supply. Also, cost savings could be reduced by trade-related taxes and fees that may be imposed on these foreign products and entities.

APhA is concerned pharmacies will have little control over the medications they receive if wholesale distributors are permitted to import non-FDA approved products. For example, under some proposals, a wholesale distributor can legally distribute a medication from an upstream, foreign trading partner to a pharmacy. It will be burdensome and time consuming for pharmacists to identify which of its medications from their wholesale distributor were purchased directly or indirectly, from a foreign entity. Many pharmacists may be unable to make these kinds of distinctions. Therefore, under certain proposals, if a pharmacy or some of their patients only want FDA-approved medications obtained in compliance with FDA's regulations, they will likely have to find other wholesalers for certain medications and repeat the laborious process to identify the wholesaler's sources. Complicating this scenario further is the fact that the DSCSA and many state laws effectively encourage pharmacies to contract with fewer wholesalers because compliance with DSCSA requirements is complex and that burden increases with the number of trading partners. These unintended and unwanted consequences of importation could delay patient access to medications and have patients questioning the source and safety of each medication dispensed.

Permitting individual importation significantly shifts responsibility and risk onto patients. Patients are generally not aware of supply chain protections and would have difficulty distinguishing between reputable and un reputable sources. In addition, individual importation may shift the cost of medications onto patients when payers deny a claim or the foreign pharmacy and foreign providers do not meet payer requirements, even if the payer covers imported medications. Patients who pay cash or out-of-pocket for medications, may find that not all of their medications are cheaper from foreign sources. Moreover, importation can confuse patients who have long-standing expectations of a product's appearance and labeling. A product's color, size, shape, labeling and dosage, among other characteristics, may vary in other countries, making it difficult for patients to recognize and use their medications. Other unintended consequences and patient safety concerns related to importation by individuals, pharmacies and wholesale distributors is discussed in more detail below. Thus, APhA urges Congress to oppose bills that legalize importation of non-FDA approved drugs by pharmacies, wholesale distributors, and individuals as importation by any entity or individual poses significant risk to patient safety.

¹ A non-FDA approved product may be a drug that is approved by a foreign regulatory agency, such as Health Canada, but may also be a drug that is illicit, counterfeit or adulterated. Some products may have the same active ingredient or ingredients, route of administration, and strength as a prescription drug or biological product approved by the FDA, but since such product are not actually approved by the FDA, APhA regards these as non-FDA approved products.

II. Supply Chain Considerations

a. FDA's Role

APhA strongly believes 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. FDA has warned broader importation laws risk patient safety. 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 condition. These unknowns put patient's health at risk if they cannot be sure of the products identity, purity and source."² Additionally, Dr. Scott Gottlieb, President Trump's nomination for FDA commissioner, 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.^{3,4}

There have been efforts in the U.S. and abroad in recent years to implement mechanisms to improve patient safety, including adverse event reporting, medication recalls, and post-marketing surveillance. These mechanisms may not be applicable to imported, non-FDA approved medications, or are difficult to maintain across borders. Subsequently, it is unclear how supply chain stakeholders, such as pharmacists, wholesale distributors and individuals, will receive or report information related to these patient safety protections.

Importation laws also detract from recent efforts to secure the drug supply chain. 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 certain prescription drugs as they are distributed in the United States. APhA is 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. Since 2013, FDA, pharmacists and other members of the supply chain have been implementing DSCSA, which includes employing new technology systems and reporting processes, among other changes. APhA believes allowing importation would severely disrupt DSCSA compliance efforts and goals of protecting patient safety, as it would allow non-DSCSA compliant trading partners to enter and disrupt the supply chain.

In addition, APhA is concerned whether U.S. oversight of foreign entities, such as pharmacies and wholesale distributors, would be realistic. While FDA currently inspects some foreign manufacturing facilities and permits importation of FDA-approved products from those limited sources, quality issues at such facilities have been recently reported even after FDA's initial inspection.⁵ Thus, current oversight efforts demonstrate the difficulty in maintaining

² Food and Drug Administration, Importing Prescription Drugs, available at: <https://www.fda.gov/Drugs/DrugSafety/ucm170594.htm>, last accessed March 15, 2017.

³ 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.

⁴ 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.

⁵ See Regulatory Affairs Professional Society, (October 2016). *FDA Warns Four Foreign Drug Manufacturers*, available at: <http://www.raps.org/Regulatory-Focus/News/2016/10/11/25980/FDA-Warns-Four-Foreign-Drug-Manufacturers/>, last accessed: March 16, 2017.

quality from abroad from select manufacturers, which tend to be more highly regulated than entities like foreign pharmacies, which are greater in number. Expanding importation laws to allow for importation of non-FDA approved drugs from more and different kinds of entities will exacerbate FDA's current oversight limitations and risk patient safety.

Pharmacists consistently rely upon FDA-approval as confirmation of a drug's safety and effectiveness. Proposals to allow prescription drug importation, although well-intended, devalues FDA's rigorous approval standards by permitting non-FDA approved medications to enter the supply chain. Such activity sends the message to health care professionals and patients regarding the necessity of FDA-approval, detracting from a long-standing history of the agency's role in working to ensure the quality, safety and efficacy drugs and devices. Based on the impact to patients and the concerns raised by the agency responsible for evaluating the quality, safety and efficacy of U.S. medications, APhA urges Congress to oppose bills expanding opportunities to import non-FDA approved drugs.

b. Buying options

While APhA appreciates the efforts in proposals to mitigate risks associated with imported drugs, including limiting individuals' buying options to pharmacies that meet specific criteria and/or are certified, we believe risks associated with these proposals significantly outweigh any benefit. For example, only authorizing importation from approved pharmacies may be ineffective because patients may be unaware of an FDA-hosted webpage listing approved foreign pharmacies or are unable to identify an approved pharmacy from one trying to appear as "approved." In addition, the process the federal government will use to validate and monitor foreign pharmacies, including foreign online pharmacies, remains unclear, and calls into question whether effective oversight is feasible. Also, APhA is not aware of existing technology platforms with functionality to enable practitioners and payers to seamlessly verify valid foreign sources and approve coverage. Without such a system, patients may actually pay more if their medication is not covered by their insurance— a result that is in conflict with the goal of importation.

Additionally, as patients grow more comfortable buying medications from pre-selected or otherwise credentialed/certified by foreign or domestic entity(ies), they may be enticed to try alternative foreign pharmacies offering lower prices but are not appropriately credentialed/certified. Requiring foreign entities to pay extra fees for approval to export could have the unintended result of increasing costs to consumers and driving patients to lower-cost, unapproved foreign entities.

Even in the case of proposals mitigating risks by limiting importation from select Canadian pharmacies, oversight of these entities will remain an issue. For example, if the Secretary relies upon provincial licensure or certification, which varies from U.S. and states' standards, oversight of facility inspections, compliance checks, and addressing consumer complaints or concerns would rely heavily on cooperation from many foreign stakeholders. This point is highlighted by the fact that key stakeholders in Canada, such as the Canadian Pharmacists Association (CPhA), oppose the "cross-border prescription drug trade."⁶ CPhA encourages the Canadian federal government to work to ban exporting of drug from Canadian

⁶ Canadian Pharmacists Association, (2009). CPhA Position Statement: Cross-Border Prescription Drug Trade, available at: <https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Cross%20Border%20Prescription%20Drug%20Trade.pdf>, last accessed: February 22, 2016.

pharmacies to citizens of other countries until such time as governments can implement systems to ensure the effective regulation of these practices to protect public safety. While foreign entities cannot be mandated to cooperate, current proposals do not address the need to facilitate cooperation, especially prior to implementing importation. Such cooperation is essential to optimizing countries' systems and processes to protect patients and supply chain integrity. Accordingly, APhA urges Congress to oppose pharmaceutical importation bills, including those that restrict the entities from which individuals, pharmacies and wholesale distributors may import medications.

c. Foreign internet pharmacies

APhA believes legislation permitting importation from select countries' pharmacies will not effectively protect patients. U.S.-based internet pharmacies are mainly regulated by the state board of pharmacy in which a pharmacy is physically located.⁷ Additionally, most states also regulate "out-of-state pharmacies" shipping medication to patients in their jurisdictions. Alternatively, foreign internet pharmacies, depending on the country of "origin," may be wholly unregulated. Even if the foreign internet pharmacy was operating in a country with oversight, medications sent to patients abroad could be beyond that country's regulatory purview and patients receiving those medications would have limited options for recourse. Because drug importation policies effectively encourage patients to buy medications online from foreign sources, patients will be at an even greater risk of taking harmful or ineffective medications.

APhA's concerns regarding foreign internet pharmacies are compounded by the large number of illegitimate internet "pharmacies" which have increased and become more sophisticated in recent years, making them difficult to track and permanently stop. Some of the problems identified related to illegitimate pharmacies include: improper licensure; failure to meet regulatory standards; not domiciled in the country claimed; not selling medications approved by that country's regulatory authority; or concealment of a bifurcated supply chain that legally fills prescriptions for customers from their country while filling prescriptions for customers located abroad using unapproved, illicit, counterfeit or adulterated drugs. Such imported products may also be contaminated, sub-potent (not contain enough active ingredient), super-potent (contain too much active ingredient), or may not include any active ingredient. Consequently, it is difficult for patients to distinguish between both legitimate and illegitimate pharmacies and medications.

Limiting the foreign pharmacies from which an individual may purchase is unlikely to sufficiently constrain risks to patients. Foreign pharmacies are likely to be physically located a significant distance away from the patient. Therefore, many patients can be expected to purchase their imported medications online or by mail, rather than walking into a store. APhA is concerned that expanding importation laws will make U.S. patients an even greater target for fraudulent online pharmacies, especially those appearing legitimate. Accordingly, limiting patients' buying options may actually give rise to unauthorized pharmacies and inadvertently drive patients to lower-cost and riskier alternatives due to their ability to identify and target victims. In addition, as currently experienced, there is generally little to no recourse against online pharmacies operating illegally.⁸ For the aforementioned reasons, APhA continues to urge

⁷ See National Association of Boards of Pharmacy, VIPPS Frequently Asked Questions, available at: <https://nabp.pharmacy/programs/vipps/faqs/#regulatorygroups>, last accessed: March 17, 2017.

⁸ Mackey, T.K. & Liang, B.A. (2013). Pharmaceutical digital marketing and governance: illicit actors and challenges to global patient safety and public health, *Globalization and Health*, 9:45.

Congress to oppose importation bills that enable importation of non-FDA approved medications from foreign, online pharmacies.

III. Licensure

Another mechanism drug importation proposals use to mitigate risks is it to have the Department of Health and Human Services certify foreign entities, including recognizing foreign licensure. As noted above, pharmacists and pharmacies, including online pharmacies, are primarily regulated by state boards of pharmacy. APhA believes HHS certification will undermine state authority by authorizing foreign pharmacists and pharmacies to provide services to state residents without complying with state requirements

Each state requires graduates of foreign pharmacy schools to achieve Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification before being able to apply to a state board of pharmacy for a license.⁹ Each state has specific requirements that a pharmacist must satisfy to obtain and maintain a license to practice pharmacy. These requirements often include a degree (e.g., PharmD), minimum number of clinical hours, and passage of a knowledge-based competency exam and pharmacy law exam.¹⁰ Some states also require passage of a skills-based competency exam for pharmaceutical compounding.¹¹ In addition, a criminal background check is included as part of the licensing process, along with continuing education for license renewal. Generally, a state board of pharmacy also identifies licensure standards for U.S. pharmacists licensed by another state. In general, proposals permitting importation are essentially permitting the practice of pharmacy by health care practitioners and entities that may not meet state-specific requirements and therefore, run afoul of state licensure standards which are put into place by states to protect their residents. Consequently, APhA encourages members of Congress to oppose expanding importation laws as they may detract from state efforts to protect its residents and regulate pharmacy.

IV. Pharmacist-patient relationship

APhA has consistently emphasized the value of pharmacist-provided care services, noting that pharmacists' roles extend well beyond the dispensing of a medication. Patients benefit significantly when they have a relationship with a pharmacist.^{12,13,14,15,16} Laws aiming to

⁹ National Association of Board of Pharmacy, The FPGEC Certification Program, available at: <https://nabp.pharmacy/programs/fpgec/>, last accessed: February 24, 2017.

¹⁰ Connecticut Pharmacists Association, Licensing Reference Tool, available at: http://faopharmacy.unc.edu/files/2015/05/licensure-tool-kit-revised_Feb_2013-2.pdf, last accessed: February 24, 2017.

¹¹ New York State Education Department Office of the Profession, Pharmacy License Requirements, available at: <http://www.op.nysed.gov/prof/pharm/pharmlic.htm>, last accessed: March 21, 2017

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.

legalize personal importation overlook the value of an established pharmacist-patient relationship, as well as the relationships with other health care practitioners.

It is important for the entire patient care team (e.g., physician, pharmacist, specialist) to have a full awareness of the patient's medical and medication profile and history when providing care and recommending services. If importation is allowed, APhA fears no practitioner will have a comprehensive view of the patients medical and medication profile because patients may only get some of their medications through importation due to the fact that not all medications will be cheaper from foreign sources or covered by insurers. For example, Canadian pharmacists can only dispense prescriptions written by a Canadian prescriber and it is not clear that insurers will cover care and prescriptions provided abroad. Even if such coverage did exist, U.S. health care providers would face greater challenges overcoming obstacles, such as those related to technology and variable data-sharing laws between countries which will hinder effective communication. Rather, adding foreign providers to the mix will detract from advancements in communications between providers as foreign providers' systems are unlikely interoperable or able to seamlessly integrate health information into U.S. electronic health information systems and records. One thing we do know, is medication errors, adverse events and other harm to patients are more likely as communications between members of the patient's health care team decline. Consequently, APhA believes importation is in direct conflict with efforts to improve the delivery of coordinated team-based care and patient outcomes by further fragmenting health care services.

As discussed previously, 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. Patients are likely to be reluctant to make an international call to talk to a foreign pharmacist, especially one they have never met, and there may be a language barrier. APhA recognizes that many medications can be very costly, both to patients and to the health care system. However, there are also significant costs associated with failing to take the suitable medications or taking them inappropriately. The U.S. spends nearly \$300 billion annually on medication-related problems.¹⁷ APhA is concerned drug importation will only exacerbate those costs and negatively affect patients' health outcomes. Thus, APhA urges Congress, in the interest of patient safety, to oppose importation bills which disrupt the pharmacist-patient relationship conflict with team-based care models, and inhibit communications between payers, providers and patients.

Once again, we appreciate congressional efforts to improve patient access to affordable medications, but urge Congress to carefully consider the consequences of broader drug importation laws on patient safety and care and reject proposals to allow importation of non-approved FDA 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 202-429-7507.

Sincerely,



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¹⁷ Iuga, A.O. & McGuire, M.J. (2014). Adherence and health care costs, *Risk Management and Healthcare Policy*, 7, 35-44.

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