June 5, 2022

The Honorable Patty Murray Chair Senate Committee on Health, Education, Labor & Pensions 154 Russell Senate Office Building Washington, DC 20510 The Honorable Richard Burr Ranking Member Senate Committee on Health, Education, Labor and Pensions 217 Russell Senate Office Building Washington, DC 20510

Dear Chair Murray and Ranking Member Burr,

RE: Pharmacist Opposition to the inclusion of drug importation in Prescription Drug User Fee Act (PDUFA)

The American Pharmacists Association (APhA), the National Alliance of State Pharmacy Associations (NASPA) and the state pharmacy associations listed below urge you to reject any legislative proposals to break the closed, secure drug supply chain through foreign drug importation.

The signatories below represent America's pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. Collectively our members provide care in all practice settings, including community pharmacies, specialty pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

We support efforts to provide Americans access to safe, effective, and affordable prescription drugs. While we appreciate a dynamic and consumer driven approach to tackling rising drug costs in the United States, we do not agree that importation is an effective solution to systemic domestic drug pricing issues and must voice our opposition to expanding importation laws that, in effect, pose risks to patient health and public safety or bifurcate care. Instead, we urge lawmakers to focus their energies on developing policies that address the underlying cost drivers within the scope of our closed and safe supply chain.

Foreign importation schemes will have no meaningful impact on what patients pay at the pharmacy counter, while required onerous program operational and systematic measures will only add to drug costs.

Pharmacists are the gatekeeper between the pharmaceutical supply chain and the patient. It is the pharmacist's obligation to ensure that patients are provided safe, effective, high quality, and authentic drugs.

Pharmacists' confidence in the safety and integrity of the drugs they dispense stems from the protections afforded in the United States by the closed drug distribution system, combined with the Food and Drug Administration's (FDA) expertise and experience assuring that drugs meet the high U.S. approval standards. Pharmacists have been working with other supply chain trading partners implementing the Drug Supply Chain Security Act (DSCSA) to further ensure the integrity of the closed drug supply chain. Drug importation undermines these fundamental protections in the supply chain, nullifying the law and supply chain investments made to put in place systems and processes to comply with DSCSA.

We urge you to reject any such policy proposals that come before you, as foreign drug importation would significantly undermine pharmacists' confidence in the drugs they dispense, compromise patient confidence, and ultimately jeopardize patient safety, clinical outcomes, and medication adherence.

We believe the risks to patient safety, including those associated with segmented and disjointed care and the amount of funding that would be needed for cross-border oversight in an attempt to try to protect patient safety, would outweigh any benefits derived from potential cost-savings to patients or payers. We support continued, strong FDA oversight over the drug supply chain. As such, we maintain serious concern for how enforcement and oversight related to importation of prescription drugs will occur.

Despite the good intentions of importation proposals and those who believe prescription drug importation is a solution to high drug costs, we are concerned that the risks to patient safety and the overall security of the prescription drug supply chain outweigh any potential savings. We believe that allowing drug importation will harm patients, potentially increase out-of-pocket costs for patients, and undermine key efforts underway to enhance the safety and quality of healthcare delivery in the U.S. Therefore, we urge the HELP Committee to oppose any amendments to PDUFA or otherwise that would allow for the foreign importation of prescription drugs. We look forward to continuing to work with you on this very important issue.

Sincerely,

Alabama Pharmacy Association **Alaska Pharmacists Association Arkansas Pharmacists Association American Pharmacists Association** California Pharmacists Association Colorado Pharmacists Society **Delaware Pharmacists Society** Florida Pharmacy Association Georgia Pharmacy Association Hawai'i Pharmacists Association **Idaho State Pharmacy Association Illinois Pharmacists Association Indiana Pharmacists Association Kansas Pharmacists Association Kentucky Pharmacists Association** Maine Pharmacy Association **Maryland Pharmacists Association** Michigan Pharmacists Association Minnesota Pharmacists Association Missouri Pharmacy Association National Alliance of State Pharmacy Associations Nebraska Pharmacists Association Nevada Pharmacy Alliance **New Jersey Pharmacists Association** North Carolina Association of Pharmacists North Dakota Pharmacists Association **Ohio Pharmacists Association**

Oklahoma Pharmacists Association Oregon State Pharmacy Association Pennsylvania Pharmacists Association Pharmacy Society of Wisconsin Rhode Island Pharmacists Association Tennessee Pharmacists Association Texas Pharmacy Association Utah Pharmacy Association Virginia Pharmacists Association