June 24, 2019

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Re: State Prescription Drug Importation Plans

Dear Secretary Azar:

On behalf of the American Pharmacists Association (APhA), the National Association of Chain Drug Stores (NACDS) and the National Alliance of State Pharmacy Associations (NASPA), we are writing today in response to state activities which are expected to result in drug importation plans submitted to the Secretary for approval.

APhA, NACDS and NASPA support efforts to provide Americans access to quality, safe, effective, and affordable prescription drugs, but do not believe that importation is a viable route to achieve this goal. Broad importation of non-FDA approved medications, likely from non-FDA inspected manufacturers, disregards the value of FDA’s regulatory authority and enforcement powers, posing unreasonable risks to patients and endangering public safety. Our organizations oppose approval of a state drug importation program that disrupts care or creates gaps in the pharmaceutical supply chain. An importation program that meets a lower standard than that set by the Drug Supply Chain Security Act (DSCSA) poses risks to consumers, creates loopholes and does not allow pharmacists to assure the quality of medicines dispensed to patients. Currently, we are limited in our ability to access information about state drug importation plans as well as information regarding the framework and process the Secretary will employ in reviewing such plans.

Despite the good intentions of policymakers who offer prescription drug importation as a solution to high drug costs, we are concerned that difficulty in quantifying the risks to patient safety, therapy
outcomes, security demands, patient expenditures and supply chain disruptions, among other issues, will result in severe underestimation of importation-related costs. As noted in past statements (see attached), we believe importation of non-FDA approved drugs or medications provided by questionable sources has the potential to harm patients, increase out-of-pocket costs for patients, and undermine key efforts underway to enhance the safety and quality of health care delivery for all Americans.

Therefore, we urge the Secretary to provide a clear and transparent process that allows for public input when HHS reviews state importation plans. Our organizations believe careful consideration of the perspectives of patients, pharmacists and pharmacies, regulatory bodies and other relevant stakeholders, including those from Canada, is needed for sound decision-making. Without an opportunity to respond to the framework the Secretary will consider when evaluating plans or the state-submitted importation plans, we are deeply concerned approval decisions will have far-reaching, negative implications for the U.S. supply chain and most importantly, patients.

We look forward to continuing to work with you on this very important issue. For additional information, please contact Jenna Ventresca, J.D., APhA Director of Health Policy, at jventresca@aphanet.org, Deepti A. Loharikar, J.D., NACDS Director, Federal and State Public Policy at DLoharikar@NACDS.org, or Krystalyn Weaver, PharmD, NASPA Vice President, Policy and Operations at kweaver@naspa.us

Sincerely,

The American Pharmacists Association
The National Association of Chain Drug Stores
The National Alliance of State Pharmacy Associations

Founded in 1852 as the American Pharmaceutical Association, APhA represents nearly 60,000 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’ over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3 million individuals, including 157,000 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 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

The National Alliance of State Pharmacy Associations (NASPA), founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA’s membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.