April 24, 2017

Senator Lamar Alexander  
Chairman, Senate Health, Education, Labor and Pensions Committee  
428 Dirksen Senate Office Building  
Washington, DC 20510  

Senator Patty Murray  
Ranking Member, Senate Health, Education, Labor and Pensions Committee  
428 Dirksen Senate Office Building  
Washington, DC 20510  

Dear Chairman Alexander and Senator Murray:

On behalf of the Healthcare Distribution Alliance (HDA), I am writing to you to express our firm opposition to legislation that would allow for the importation of pharmaceuticals. As the Senate Health, Education, Labor and Pensions Committee considers important legislation reauthorizing the Prescription Drug User Fee Act, HDA is concerned that an amendment to allow for importation would endanger the safety of the domestic pharmaceutical supply chain and would be counter to the work Congress has done to secure our nation’s drug supply and protect patients.

HDA is the national association representing primary healthcare distributors, the vital link between the nation’s pharmaceutical manufacturers and healthcare providers. Each business day, HDA member companies ensure that over 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide.

The U.S. pharmaceutical supply chain is a sophisticated, efficient, and highly secure system, and was further strengthened in 2013 by the passage of the Drug Supply Chain Security Act (DSCSA, or Title II of the Drug Quality and Security Act). The Act provides for a federal traceability solution for prescription medicines, which by 2023, will lead to the establishment of FDA-regulated, electronic, unit-level traceability requirements across the entire supply chain for prescription drug products. Given the action Congress has taken to enhance supply chain safety and security, allowing for importation of prescription drug products runs counter to the efforts of the industry and regulators to further protect the supply chain and will expose the domestic supply and patients to unnecessary risk.

The DSCSA statute includes important mandatory requirements for the passage of transaction information, transaction history and a transaction statement. Further, the DSCSA also contains numerous requirements on trading partners to utilize the transaction information for verification and record keeping purposes, all working towards the goal of further securing the supply chain. The DSCSA is an extremely complex law and we are concerned that if importation is allowed, it would not incorporate critical provisions of the law that are necessary to ensure the integrity of the closed system of drug distribution.
HDA stands with former FDA Commissioners Robert Califf, Margaret Hamburg, Mark McClellan and Andrew Von Eschenbach in urging Congress not to allow importation due to concerns about the potential for substandard, unsafe medicines entering the US supply chain and the serious risk posed to patients.

With all the effort Congress and the FDA have put into protecting the US supply chain, the concerns and risks posed by importation far outweigh any potential benefit. On behalf of all the members of HDA, we strongly urge you to oppose any importation proposal.

Sincerely,

John M. Gray
President and CEO

CC: Members of the Senate Health, Education, Labor and Pensions Committee