February 24, 2017

Dear Senator:

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. The importation of prescription medicines 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.

Recent draft legislation on importation includes a reference to a provision within the DSCSA that relates to transaction information, transaction history and a transaction statement. While the draft includes the passage of this information for a transaction between an importer and foreign seller, the requirement is voluntary and only made available upon request. In contrast, in the DSCSA statute, this transactional information is mandatory and passed with each transaction made within the supply chain. 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 this draft legislation does not incorporate critical provisions of the law that are necessary to ensure the integrity of the closed system of drug distribution.

Further, HDA has concerns that the draft legislation would permit products such as biologics, sterile injectables and infused drugs to be imported. Pharmaceutical distributors are accustomed to handling these complex products that routinely require a certain temperature during storage and transit. Distributors are equipped with specialized, temperature-controlled containment devices and refrigerated storage areas. There are no assurances that the quality of these products would be ensured through importation.
HDA firmly believes that allowing importation, even from a specific country, increases the likelihood of counterfeit or adulterated drugs entering the United States and will not ensure meaningful reductions in the cost of prescription drugs. Before considering importation of potentially dangerous products from other countries, whether through personal or commercial importation, or Internet purchasing, Congress should consider the implications of introducing such risk to the pharmaceutical supply chain – a supply chain Congress sought to protect through enactment of the DSCSA. We urge you to oppose any importation proposal.

Sincerely,

Elizabeth Gallenagh, Esq.
Senior Vice President, Government Affairs and General Healthcare Distribution Alliance