The Partnership for
SAFEMEDICINES

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Dear Senator,

As a public health group whose outreach and operations extend to Brazil, China and India, and whose membership is comprised of more than 60 organizations committed to the safety of prescription drugs and protecting U.S. consumers against counterfeit, substandard or otherwise unsafe medicines, **we are deeply concerned that potential amendments to the Food and Drug Administration Safety and Innovation Act will undermine America's existing and proposed drug safety protocols by allowing drug importation.**

Drug importation advocates believe that drugs purchased from countries such as Canada and the United Kingdom are safe because of their strict health regulations. Unfortunately, this is simply not true. **There is no regulation for products trans-shipped through "safe" countries such as Canada and the United Kingdom and thus, Americans would be put at great risk.** In a letter issued in 2009, FDA Commissioner Margaret Hamburg outlined the agency's concerns with drug importation, arguing that the importation of FDA-approved drugs from countries like Canada could endanger the U.S. medicine supply because of the lack of FDA jurisdiction over foreign supply chains. "In establishing an infrastructure for the importation of prescription drugs, there are two critical challenges in addressing these risks. First, FDA does not have clear authority over foreign supply chains.... Second, FDA review of both the drugs and the facilities would be very costly."

In 2006 the European Commission conducted a study into the parallel trade of medicine. In response to the study, E.U. Commissioner Günter Verheugen said "parallel trade brings a considerable risk for the safety of the patients. The reasons for that are numerous - there are problems with the packaging and labeling of the products, as well as with product recalls, the complexity of distribution channels and the supply. And finally it is difficult to effectively enforce the law."

When individuals, or even medical experts, break the closed secure supply chain, they are victimized by criminals. Just last month the FDA sent warnings to doctors in thirteen more states that their attempts to acquire anti-cancer injectables outside the closed, secure drug supply chain from supposedly reliable sources were in fact criminal sellers of fake medication. Such incidents demonstrate conclusively that **if trained doctors cannot reliably source their medications, we will endanger all Americans by encouraging them to break the closed, secure drug supply chain.**

Amendments allowing importation would undermine nearly two decades of drug safety policy. Large volume importation of prescription drugs could be permitted under current law only if the Health and Human Services (HHS) Secretary was willing to certify that imported drugs "pose no additional risk to the public's health and safety, and result in a significant reduction in the cost of covered products to the American consumer." Recent HHS Secretaries have not been willing to make this certification of "no risk."

This means that throughout the past 18 years and under three Administrations, no HHS Secretary (Democrat or Republican) has certified a drug importation plan—a clear indication of the extreme

safety concerns associated with drug importation and the challenges with ensuring safety of the globalized drug supply.

We urge Congress to focus on creating substantive programs that protect the nation's drug supply to maintain access to safe medicines. The risks of policy failure fall upon this country's most vulnerable and traditionally underserved minorities.

With very best regards,

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