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APhA Alarmed by HHS/FDA Drug Importation Plans

In response to today's announcement of Trump administration proposals to allow importation of certain prescription drugs, the American Pharmacists Association (APhA) today expressed its overwhelming concerns for patient safety. The Food and Drug Administration's proposed scheme would allow the introduction of risky product into our secure U.S. drug supply chain while evading details regarding any beneficial cost savings.

Pharmacists are the gatekeeper of safe medications between the supply chain and their patients. APhA supports efforts to increase patient access to affordable, appropriate, safe and effective prescription medication. But the safeguards to protect Americans that are in place to ensure that prescription drugs are manufactured, stored, shipped and dispensed in a safe manner would be undermined if this proposal is finalized as written. This would have a negative effect on patient confidence in the safety of their medications.

Pharmacists and other drug supply chain stakeholders have been working for years to implement the Drug Supply Chain Security Act (DSCSA), which adds new protections to further secure our nation's drugs. DSCSA creates a closed supply chain to track and trace prescription drugs as they move from manufacturer to distributor to pharmacist. These same safeguards do not exist in Canada. FDA's proposed rule creates a patchwork of interim supply chain measures that introduce gaps and loopholes in the supply chain as drugs are distributed from Canada into the U.S.

Today's proposal undermines the DSCSA's protections by introducing unsecure foreign prescription drug packages into our drug supply and commingling them with secure FDA-approved products. The lack of clarity around unknown, unproven cost savings does not justify jeopardizing U.S. supply chain integrity and patient safety.