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Statement on Importation in Senate PDUFA

(Washington, D.C.) — The following statement regarding the drug importation provision in the Senate HELP Committee's prescription drug user fee legislation may be attributed to James Edwards, Executive Director, <u>Conservatives for Property Rights</u>:

"The Senate HELP Committee's PDUFA bill, which includes a pharmaceutical importation provision, tosses substantive concerns for a political plum. The patient safety consequences alone will be serious under this misguided measure. It's comparatively less irresponsible than the importation language of Sen. Sanders's tabled amendment. But that won't be much consolation to American homes stricken by unnecessary illness or death from fake medicines.

"S. 4348's importation scheme will fail to protect American lives and health because importation is inherently high-risk. No HHS secretary, Republican or Democratic, from 1987 until 2020 dared to deem importation as safe for patients or significantly cost-saving for U.S. consumers. Nothing's changed in those regards. Drug importation risks serious harm from adulterated or counterfeit pharmaceuticals.

"Former Trump <u>FDA Commissioner Scott Gottlieb</u> reminded us in 2019 'the reason that we have the closed [pharmaceutical control] system in this country . . . [is] because of counterfeit drug problems that were originating in Florida. . . . We had concerns that the drugs weren't coming from brick-and-mortar places in Canada.'

"Before he capitulated in 2020, <u>HHS Sec. Alex Azar</u> — joining his bipartisan predecessors — warned against drug importation. He called 'Canadian' drug importation a dangerous 'gimmick.' The imported medicines are often 'routed from, say, a counterfeit factory in China or another country.' Sec. Azar said 'the last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved.' This remains an accurate assessment of importation, including of the HELP Committee's latest version.

"U.S. senators should remember: Drug importation puts American <u>patients' lives at risk</u>, gratuitously <u>agitates our Canadian neighbors</u>, does little to reduce consumer drug costs and attacks the property rights of pharmaceutical innovators. Property rights conservatives are cautioning and watching our senators."

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