## Proposed HHS regulations on Canadian drug importation are unworkable and dangerous to American patients. File your own comments at https://safedr.ug/takeaction/

**PSM strongly opposes the proposed HHS regulations to import medicine from Canada.** We don't see how Canada can provide us enough medicine to make a difference because they don't manufacture 70%+ of their own medicines, and already struggle with shortages.

Concern	Explanation
Canada is too small a market to supply America with medicine.	Canada is 1/9th the population of the U.S. and possesses very little manufacturing capabilities of its own. <sup>1</sup> They are currently experiencing crippling shortages of medicine in their own country. <sup>2</sup>
Canadian stakeholders and the Canadian government have told the U.S. they do not wish to cooperate with this plan.	Canadian drug distributors, <sup>3</sup> the Canadian federal government, <sup>4</sup> and Canadian patient and healthcare advocates <sup>5</sup> oppose exporting their drugs to U.S. residents.
Past importation efforts could not meet their own safety standards.	Investigators found that Minnesota RxConnect's Canadian pharmacies had safety violations that would have shut down a Minnesota pharmacy, <sup>6</sup> and a state audit of Illinois' ISaveRx showed that 40% of its foreign pharmacies did not have complete inspections, and that unapproved pharmacies were filling patient prescriptions in violation of state law. <sup>7</sup>
The costs of importation programs are prohibitively expensive.	Recent analysis reconfirms the opinion of previous FDA Commissioners that the cost to meet testing requirements for imported medications far exceeds any cost benefits from importing foreign medicines. <sup>8, 9</sup>
Regulators do not have the resources to assess imported medicines for their legitimacy.	No funding is earmarked for stepped up regulation, testing or inspection and the existing system is already under strain, so importation would make the U.S. prescription drug supply vulnerable to black market medications. <sup>10</sup>
Importation walks back progress we have made to strengthen our drug supply chain.	U.S. supply chain security relies on a track-and-trace system that documents where a medicine has been from the manufacturer to the patient. <sup>11</sup> Canada has no analogous system, which reopens a path for counterfeit drugs to make their way into the U.S. <sup>12</sup>
Even licensed Canadian drug sellers have sold Americans counterfeit medicines.	Canadian authorities do not take responsibility for the safety of drugs Canadians may sell to U.S. patients, <sup>13</sup> and this shows in the cases of RxNorth and CanadaDrugs.com, who sold fake medicines that made their way to U.S. patients. <sup>14</sup>
Imported counterfeit drugs are dangerous and will worsen the opioid crisis.	Counterfeit drugs are more deadly as a result of fentanyl-laced counterfeit opioids. A recent nation-wide sampling of pills the DEA seized found that that 27% were counterfeits laced with fentanyl, That is with the borders closed to importation. <sup>15</sup>
Importation will overwhelm law enforcement and creates public safety concerns.	National law enforcement experts and a wide range of law enforcement groups are concerned that importation would transfer the risks and costs of illegal trade to state and local law enforcement agencies, requiring them to do additional work without additional funding. <sup>16</sup>



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