

## **Importation Would Threaten Public Health and the Integrity of the U.S. Prescription Drug Supply with No Guarantee of Any Cost Savings**

Opening our closed distribution system to importation would gravely compromise the integrity and safety of the U.S. prescription drug supply. Importation presents a huge opportunity for unscrupulous suppliers and/or criminal organizations to increase the flow of substandard, adulterated or counterfeit drugs – including pills laced with deadly fentanyl – into the U.S.

FDA is the gold standard in ensuring the safety and effectiveness of medicines for the U.S. market. Importation would have the same effect as repealing current FDA and consumer protections.

- No Secretary of HHS, of either party, has been able to certify that importation is safe, nor have they been able to certify that it would provide significant cost savings to Americans. Even in 2020, despite claims to the contrary, the Secretary was no more able to certify than his predecessors and questionably circumvented the statute by punting the responsibility to state governments.
- FDA Commissioner Stephen Hahn stated in 2020 that “Consumers and physicians purchasing medicines cannot be assured the products they are receiving are legitimate, safe, or effective if they are obtained from outside of the FDA-regulated pharmaceutical supply chain.”<sup>1</sup>
- Four former FDA Commissioners from both Republican and Democratic administrations wrote a letter to Congress stating that importation “could lead to a host of unintended consequences and undesirable effects, including serious harm stemming from the use of adulterated, substandard or counterfeit drugs.”<sup>2</sup>
- Former FBI Director Louis Freeh reported that importation would overburden law enforcement and create new avenues for criminal organizations to smuggle fentanyl-laced drugs disguised as prescription medicines into the U.S.<sup>3</sup>
- Nearly 170 groups representing patients and the pharmaceutical supply chain, including pharmacists, wholesalers and others, wrote to Congress stating their opposition to importation, “Whether offered broadly or for a narrow set of medications, there’s never a good time to sacrifice safety.”<sup>4</sup>

Counterfeiting medicines is a high-profit criminal enterprise, and since imported drugs can look different (e.g., tablet color, shape, and size) and be offered in different strengths or dosage forms, it would be challenging to assess whether the import is counterfeit, the same, or similar to the FDA-approved drug.

- The World Health Organization estimates that 10 percent of medicines in low- and middle-income countries are substandard or falsified.<sup>5</sup>
- The National Association of Boards of Pharmacy found that 95 percent of internet drug outlets purporting to sell safe and legitimate medicines are operating illegally.<sup>6</sup>

There is also no way to ensure that any medicines imported satisfy FDA safety and efficacy standards, and there are concerns that unsafe, adulterated and counterfeit medicines may be introduced into the U.S. secure drug supply chain as a result of importation, even from developed countries.

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<sup>1</sup> FDA Press Release, FDA Takes Action with Indian Government to Protect Consumers from Illicit Medical Products, February 18, 2020.

<sup>2</sup> Letter to Members of Congress from former FDA Commissioners Robert Califf, MD, Mark McClellan, MD, Margaret Hamburg, MD, Andrew Von Eschenbach, MD, March 16, 2017.

<sup>3</sup> Freeh, Sporkin, and Sullivan LLC and Freeh Group International Solutions, LLC, “Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement,” June 2017.

<sup>4</sup> Partnership for Safe Medicines. “Nearly 170 Organizations Urge Congress To Protect Patients From Hazards Of Drug Importation.” February 2017.

<sup>5</sup> World Health Organization. “1 in 10 medical products in developing countries is substandard or falsified.” November 2017.

<sup>6</sup> NABP, Internet Drug Outlet Identification Program Progress Report: September 2018, <https://nabp.pharmacy/wp-content/uploads/2018/09/Internet-Drug-Outlet-Report-September-2018.pdf>.

- Canadian law does not prohibit the transshipment of drugs from any country—including those in the third world—into Canada and then into the United States, heightening concerns about the safety and reliability of these medicines.
- The FDA determined that 85 percent of the drugs sold by supposedly Canadian pharmacies come from 27 countries other than Canada.<sup>7</sup> Some online pharmacies that advertise as being Canadian in fact are not, and there's no real way for consumers to know.
- The Canadian government is not in a position to monitor and regulate medicines that are intended for the U.S. market. Canada's former Health Minister Leona Aglukkaq said, "Canada inspects drugs for its own citizens; Canadian authorities wouldn't have the ability or resources to inspect medicines destined for the United States."<sup>8</sup> Therefore, the financial and practical burden would fall to U.S. authorities and local law enforcement.
- Kirsten Hillman, acting Ambassador to the United States, stated that "the Canadian market is too small to have a real impact on U.S. drug prices. The U.S. consumes 44% of the global prescription drug supply, compared to Canada's 2%," and that "Canada's priority is to ensure a steady and solid supply of medications at affordable prices for Canadians."<sup>9</sup>
- In November 2020, Health Canada announced that the distribution of certain medicines intended for the Canadian market outside of Canada is prohibited if the distribution would cause or exacerbate a shortage of the medicines in Canada.<sup>10</sup> Various state importation efforts and a federal rule seek to allow importation into the U.S. of some prescription medicines intended for the Canadian market.

Importation could exacerbate the opioid crisis and lead to more deadly fentanyl and its analogues being smuggled into the U.S.

- The Drug Enforcement Agency testified that "The illicit market for prescription drugs is considerable in size, which significantly increases the risk that fentanyl or fentanyl derivative-laced counterfeit pills will cause more overdoses across the nation as they are more readily produced by drug trafficking organizations."<sup>11</sup>
- DEA stated that "criminals are putting fentanyl into fake pills and passing them off as legitimate prescription medications."<sup>12</sup> Authorities have found counterfeit examples of pain relievers and anti-anxiety medicines laced with fentanyl.<sup>13</sup>
- Tragically, these concerns are all too real. Jake Beddoe of Connecticut died from a fentanyl-laced counterfeit prescription drug.<sup>14</sup> The victim's source received similar counterfeit prescription drugs from Canada.<sup>15</sup>

Finally, there is no guarantee that any potential cost savings from importation will be passed onto consumers.

- Former FDA Commissioner Scott Gottlieb noted that a previously proposed importation scheme "would have added so much cost to the imported drugs; they wouldn't be much cheaper than drugs sold inside our closed American system."<sup>16</sup>
- The four former Commissioners of FDA also wrote in their letter that importation would result in small savings not likely to be passed on to consumers.<sup>17</sup>

<sup>7</sup> FDA, "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries." December 2005.

<sup>8</sup> Letter to the Washington Post, Leona Aglukkaq, Former Minister (2008-2013), Health Canada, May 12, 2017.

<sup>9</sup> Statement from Canada's Acting Ambassador to the United States on U.S. Importation of Pharmaceutical Drugs from Canada, December 18, 2019.

<sup>10</sup> Health Canada news release, "Canada announces new measures to prevent drug shortages," November 28, 2020, <https://www.canada.ca/en/health-canada/news/2020/11/canada-announces-new-measures-to-prevent-drug-shortages.html>.

<sup>11</sup> Rosenberg, C. Statement of the Acting Administrator Drug Enforcement Administration before the Committee on the Judiciary, U.S. Senate Hearing "Deadly Synthetic Drugs: The Need to Stay Ahead of the Poison Peddlers," June 7, 2016 (<https://www.Dea.Gov/Pr/Speeches-Testimony/2016t/060716t.pdf>).

<sup>12</sup> David Hernandez, "Fentanyl disguised as other drugs alarms authorities," *The San Diego Union-Tribune*, April 16, 2016

<sup>13</sup> Pat Anson, "Fake Oxycodone Seized at US-Mexican Border," Pain News Network, April 16, 2016, available at <https://www.painnewsnetwork.org/stories/2016/4/16/fake-oxycodone-seized-at-us-mexican-border>.

<sup>14</sup> <https://www.safemedicines.org/2020/11/jake-beddoe.html>

<sup>15</sup> <https://www.safemedicines.org/2018/11/man-admits-to-selling-counterfeit-xanax-pill-that-killed-a-connecticut-resident.html>

<sup>16</sup> Gottlieb S. "What Trump Should Have Said on Drug Prices." *Forbes*, March 2016.

<sup>17</sup> Letter from former FDA Commissioners, op cit.

- Experience from European “parallel trade” shows that middlemen profit most from drug price arbitrage between different markets, not patients.<sup>18</sup>
- The Congressional Budget Office (CBO) estimated that importation would reduce prescription drug expenditures in the U.S. by just 1 percent.<sup>19</sup>

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<sup>18</sup> London School of Economics and Political Science. “The Economic Impact of Parallel Trade.” November 2003.

<sup>19</sup> Congressional Budget Office. “Cost Estimate: S.1392 FTC Reauthorization Act of 2005.” September 2005.