



**MAINE PHARMACY**  
ASSOCIATION  
PO Box 5257 | Augusta, ME | 04332

April 18, 2019

The Honorable Heather Sanborn, Chair  
The Honorable Denise Tepler, Chair  
The Joint Standing Committee on Health Coverage, Insurance and Financial  
Services

Dear Senators and Representatives,

My name is Amelia Arnold. I'm a resident of Winthrop, Maine. I'm president of Maine Pharmacy Association and I've been a licensed pharmacist for 10 years. On behalf of the Maine Pharmacy Association, I am writing in opposition of LD 1272, "An Act to Increase Access to Low-Cost Prescription Drugs: Wholesale Prescription Drug Importation Program."

Pharmacists support efforts to reduce prescription drug prices that do not compromise patient safety. In the 128<sup>th</sup> Maine Legislative Session, we successfully advocated for LD 6, Chapter 44 Public Law, which prohibits contracts from pharmacy benefit managers that ban pharmacists from disclosing to patients the most affordable payment option for their medications (ie, "gag clauses").<sup>1</sup> In the current legislative session, we advocated for LD 659 which allows the pharmacist to substitute more affordable interchangeable biosimilar medications when the patent of the brand product has expired.<sup>2</sup> LD 659 has been signed by Governor Mills and will now become law. The FDA Commissioner, Dr. Scott Gottlieb, announced on April 2, 2019, that insulin has been transitioned from the drug to the biologics pathway in order to open biosimilar competition and thereby reduce prices of insulins.<sup>3</sup>

The basic principles of LD 1272 are:

- 1) Brand prescription drugs cost too much in the US (we agree).
- 2) Canada has a better prescription drug pricing system.
- 3) Let's take from Canada's medication supply rather than fixing our own drug pricing problem.

To begin with, medicines we import from Canada will not come from the regulated Canadian drug supply. Canadian pharmacists are only legally allowed to fill prescriptions written by Canadian doctors, so no reputable pharmacy could sell Health Canada-approved medicines to patients in the U.S.<sup>4</sup> Furthermore, Canadian regulators already deal with systemic drug shortages.<sup>5</sup> A country with one-ninth the population of the United States cannot meet the additional needs of American patients.

We have years of evidence that third-party drug brokers are selling Americans unreliable and dangerous medicine. In 2014, during the brief time that drug importation was legal in Maine and before it was deemed unconstitutional in federal court, Maine Pharmacy Association collaborated with an investigative journalist at WGME news. We ordered and tested drugs (Viagra, Celebrex, Plavix and Nexium) from Canada Drug Center, an online "pharmacy" that had placed ads in local Maine papers. As it turns out, Canada Drug Center isn't even a licensed pharmacy in Canada. Canada Drug Center, which falsely marketed itself as Canadian, sent us medicines directly from Turkey, India and Mauritius. When we analytically tested them, three medicines were the wrong dose of ingredient and the fourth medication included a contaminant.<sup>6</sup> Patients who take substandard drugs like these can suffer long term health consequences—often without anyone knowing why.

Businesses which hold legitimate pharmacy licenses in Canada have also proven to be dangerous. For example, CanadaDrugs.com, a licensed Manitoba pharmacy founded in 2001, claimed to be selling Americans approved medicines from Canada, Australia and the United Kingdom. The company was shut down in July 2018 after its subsidiaries sold American doctors \$78 million in misbranded and

counterfeit cancer drugs.<sup>7</sup> The counterfeits were manufactured by an unauthorized distributor in Egypt, and evaded detection as they were shipped through Turkey, Switzerland and Denmark, landing with a British wholesaler who sold them to CanadaDrugs.com.<sup>8</sup>

Another foreign entity which has imported medications into Maine, CanaRx, received a warning letter from the FDA on February 26<sup>th</sup>, 2019.<sup>9</sup> The FDA is taking action against CanaRx, "...because of the risks posed by its conduct in facilitating the importation of unapproved new drugs and misbranded drugs to U.S. consumers." The FDA letter defines the magnitude of the problem by stating, "Substituting an unapproved drug for the FDA-approved drug prescribed by a patient's healthcare practitioner can negatively affect patient outcomes because the health care practitioner may unknowingly make subsequent treatment decisions based on the patient's response to the unapproved drug. This can also cause potentially dangerous drug interactions with the patient's other medications. In addition, sourcing drugs from uninspected, unregulated, and/or unknown supply chains can result in serious health consequences, especially in vulnerable patient populations, which may receive medications that are adulterated and are not shipped and/or stored properly."

Right now, the FDA and manufacturing industry are in the middle of a 10-year implementation of the Drug Supply Chain Security Act (DSCSA), which establishes systems to electronically track complicated chains of custody as companies licensed by American regulators manufacture and distribute pharmaceuticals. Introducing imported drugs to this system will undercut safety, creating a second class of prescription drugs produced by companies that the FDA and state regulators have not licensed and cannot control.

I am not alone in my assessment of these dangers. In March 2017, former FDA commissioners, Drs. Robert Califf, Margaret Hamburg, Mark McClellan and Andrew Von Eschenbach, wrote that drug importation "represents a complex and risky approach...that is likely to harm patients and consumers" and that such a program would be so resource intensive that any cost savings would be minimal.<sup>10</sup>

Importation sounds like an easy solution to this problem, but it endangers American patients. Congress is currently considering policy proposals such as fast-tracking the approval of generics and regulating the role of pharmacy benefit managers. These initiatives and others may lower the price of prescription drugs without compromising patient safety. Please protect American patients by pursuing public policies that do not undermine safety. I urge you to oppose drug importation legislation. For the reasons above, I ask for your opposition of LD 1272. Thank you for your time and consideration.

Most Sincerely,

Amelia Arnold, PharmD, RPh  
President | Maine Pharmacy Association

1. <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0010&item=5&snum=128>
2. <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP0480&item=3&snum=129>
3. FDA Statement: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm634999.htm>
4. Leona Aglukkaq, "Dear Bernie Sanders: Canada is Not the United States' Drugstore," *The Washington Post*, May 12, 2017, <https://wapo.st/2zO5IO5>.
5. Drug Shortages Canada, [www.drugshortagescanada.ca](http://www.drugshortagescanada.ca).
6. [https://www.slideshare.net/SafeMedicines/drug-importation-maines-experience-with-unreliable-foreign-pharmacies-20132014-congressional-briefing-march-78-2016?next\\_slideshow=1](https://www.slideshare.net/SafeMedicines/drug-importation-maines-experience-with-unreliable-foreign-pharmacies-20132014-congressional-briefing-march-78-2016?next_slideshow=1)
7. Matt Volz, "Canadian Pharmacy Fined \$34 Million for Illegal Imports," *US News & World Report*, April 13, 2018, <http://bit.ly/2zO5SoF>.
8. Aramen Keteyian, "How Fake Avastin From Overseas Ends Up in U.S.," CBS News, March 21, 2012, <https://cbsn.ws/2zKDMKX>.
9. <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm632061.htm>
10. Letter from Drs. Robert Califf, Margaret Hamburg, Mark McClellan and Andrew Von Eschenbach to Congress, March 16, 2017, <http://bit.ly/2JMdZVn>.