Biotechnology Innovation Organization
1201 New York Ave NW
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June 12, 2024

Chair Mathews and Members of the
House Health Policy Committee
Ohio House of Representatives
Room 121
Columbus, OH 43215

RE: Testimony in Opposition to HB 92: Enact Save Ohio Safe Rx Act

Chair Mathews and Members of the Committee:

The Biotechnology Innovation Organization (BIO) thanks the committee for the opportunity to comment in opposition to HB 92, proposed legislation to create a Canadian drug importation program for Ohio.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Our members are committed to advancing science and improving the health and well-being of our planet using biotechnology.

Position: BIO respectfully opposes wholesale drug importation from Canada and other countries because it would restrict patient access to innovative biopharmaceutical products and severely compromise the safety of the U.S. biopharmaceutical supply chain for minimal gains. Allowing for the wholesale importation of drugs from Canada and other countries would expose American patients to counterfeit, adulterated, or unapproved drugs. With the effective lack of oversight on any importation schemes, Americans have no guarantee of the safety of the pharmaceuticals that would be entering the country's biopharmaceutical supply chain and are therefore exposed to significantly more risk.

Drug importation will eviscerate existing protections for the drug supply chain, resulting in the erosion of the integrity and overall safety of the U.S. biopharmaceutical supply chain. Past Commissioners of the FDA—Republican and Democrat—wrote an open letter to the US Congress, urging them to reject proposals to import drugs from other countries.[1] One of the reasons cited by the commissioners for their opposition was that the FDA lacks the resources to

[1] Robert M. Califf, MD, Margaret Hamburg, MD, Mark B. McClellan, MD, and Andrew Von Eschenbach, MD, Open letter to Congress, March 16, 2017.

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effectively screen and verify the authenticity and integrity of every product headed for American consumers. Scholars have noted the importance of the satisfactory certification of sellers[2], and the past FDA commissioners warned that without such a system, there could be a "host of unintended consequences… including serious harm stemming from the use of adulterated, substandard, or counterfeit drugs." [3] Counterfeit drugs, including drugs that cover conditions such as cancer, and HIV/AIDS have been found in all 50 states and deaths have been recorded in 42. In addition, opioids are often laced with fentanyl and are found across the United States.[4]

In 2013, Congress passed the bipartisan *Drug Quality and Security Act* (DQSA)[5] to enhance the safety of the U.S. drug supply. Title II of DQSA (the Drug Supply Chain Security Act, DSCSA) created a national tracking system to secure the drug supply and protect patients from compromised or counterfeit drug products by tracking drugs from the manufacturer to the pharmacy. Prescription drug importation will disrupt, and undermine the ability to track drug products accurately, especially across borders, thus weakening the important protections put into place by the DSCSA. Moreover, the FDA requires certain drugs in the US to have Risk and Evaluation Mitigation Strategies (REMS). According to the FDA**, "REMS are designed to help reduce the occurrence and/or severity of certain serious risks, by informing and/or supporting the execution of the safe use conditions described in the medication's FDA-approved prescribing information." If these medications are imported to patients, they likely will not have the same monitoring and precautions that ensure safe and effective administration and use of the drug by patients, thereby jeopardizing their health.**

Officials from both the United States and Canada warn of the dangers of importation from Canada. Former Canadian Health Minister, Leona Aglukkaq, stated in the *Washington Post*,[6] ". . . if bulk Canada-U.S. drug shipments were to become a reality, Americans could receive uncertified, uninspected, third-party drugs. Canada inspects drugs for its own citizens; Canadian authorities wouldn't have the ability or resources to inspect medicines destined for the United States." While Canadian regulators rightfully oversee the safety of the supply of medicines that are intended for and used by Canadians, they do not apply those standards to drugs intended only for export. Importation would place US citizens at risk of receiving uninspected drugs.

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[2] Bate, Roger, Jin, Ginger Zhe and Mathur, Aparna. "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets" *The B.E. Journal of Economic Analysis & Policy*, vol. 14, no. 1, 2014, pp. 111-150. https://doi.org/10.1515/bejeap-2013-0085
[3] Robert M. Califf, MD, Margaret Hamburg, MD, Mark B. McClellan, MD, and Andrew Von Eschenbach, MD, Open letter to Congress, March 16, 2017.
[4] https://www.safemedicines.org/2020/10/deadly-counterfeit-pills-found-in-all-50-u-s-states.html
[5] H.R. 3204 Drug Quality and Security Act https://www.congress.gov/bill/113th-congress/house-bill/3204
[6] https://www.washingtonpost.com/news/global-opinions/wp/2017/05/12/dear-bernie-sanders-canada-is-not-americas-drug-store/

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Studies have found that any improved access or cost savings resulting from importation are likely to be minimal–with more savings winding up as profits for middlemen.[7] Independent studies by the Department of Health and Human Services (HHS) Task Force on Drug Importation and the U.S. Department of Commerce have concluded that importing prescription drugs from foreign countries poses safety risks to American consumers and does not result in overall net cost savings.

In addition, Vermont's Agency of Human Services (VAHS) released a report[8] in response to that state's importation law acknowledging that any savings from importation would be minimal and that a compliant drug importation program would require substantial upfront investment and appropriations as well as inspection and auditing activities[9] -- none of which would ultimately serve the well-being of patients. A 2020 academic study found that if the US tested imported drugs from Canada, the cost of testing exceeds the presumed cost savings from 2 times as much to more than 34,000 times as much.[10] Any public savings would be diminished and outright eradicated by the cost of the regulatory schemes necessary in trying to ensure the safety of the drugs imported. "[T]hese schemes can be cheap, or they can be safe, but not both." [11]

Importation would create serious drug supply shortages in Canada and pose greater safety concerns from foreign sources. A 2018 study found that the 2015 Canadian drug supply would be depleted in only 201 days if there is a 20% demand from the US.[12] Canada would need to increase its supply quickly, and this would likely include additional drugs from foreign sources.[13] This would impose greater safety risks to Canada and the US. Additionally, Canada would need to willingly allow prescription drugs to be exported under any US program to import drugs. However, because of the dangers of a drug supply shortage, Canada has always rejected the idea. When the US finalized the regulatory scheme to permit possible importation, the Canadian government imposed an order to ban the exporting of drugs to the US that would "cause or exacerbate" shortages in that country.[14]

Importation schemes would have a negative impact on biopharmaceutical innovation. The HHS Task Force on Importation found that importation would likely have a negative effect on investment research and development. Because the United States does not have price controls,

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[7] Report of the HHS Task Force on Drug Importation. 2005. Available at: https://www.surgeongeneral.gov/news/testimony/t01262005.html.
[8] https://legislature.vermont.gov/assets/Legislative-Reports/AHS-12-31-2018-Wholesale-Importation-of-Drugs.pdf
[9] Vermont Report Finds that the Costs of Prescription Drug Importation May Outweigh Savings http://www.fdalawblog.net/2019/01/vermont-report-finds-that-the-costs-of-prescription-drug-importation-may-outweigh-savings/
[10] Acri (nee Lybecker), Kristina, "State pharmaceutical importation programmes: an analysis of the cost-effectiveness," *Journal of Pharmaceutical Health Services Research*, Volume 11, Issue 2, June 2020, Pages 117–126, https://doi.org/10.1111/jphs.12349
[11] Ibid.
[12] Shepard, Marv, "U.S. Drug Importation: Impact on Canada's Prescription Drug Supply," *Health Economics and Outcome Research*: Open Access, University of Texas, 2018.
[13] Ibid.
[14] Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply), Government of Canada, November 27, 2020.

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and other countries including Canada do, these schemes would also be importing price controls. These importation schemes would make it difficult for companies to earn any return on their investments and limit their ability to reinvest in life-saving research. Implementing price controls of any kind can have a chilling effect on innovation. Economists have estimated that a 50% drop in drug prices in the United States could reduce the number of drugs in the development pipeline by 14-24 percent,[15] decreasing the hopes of patients seeking new cures and treatments.

Slowing the pace of innovation will not only impact patient access to innovative medicines but will undermine one of the most effective means of bringing drug prices down – competition. Fewer new drugs mean less competition for existing drugs for a longer period and slow migration to generic drugs. These reduced benefits may significantly offset savings from legalized importation.[16]

For these reasons, BIO and its members respectfully oppose HB 92, Canadian drug importation program for Ohio and urge you and your colleagues not to advance this piece of legislation.

Thank you for your consideration.

/S/

Lilly Melander
Director, State Government Affairs – Midwestern Region
The Biotechnology Innovation Organization (BIO)

[15] Economists Michael Maloney and Abdulkadir Civan, cited at https://www.drugcostfacts.org/drug-price-controls. Accessed: September 11, 2020.
[16] Ibid.