NATIONAL PHARMACEUTICAL CONGRESS
INSTITUTE

WHITE PAPER
WINTER 2024 EDITION

Protecting patient interests: How U.S. politics affect medication cost and access in Canada

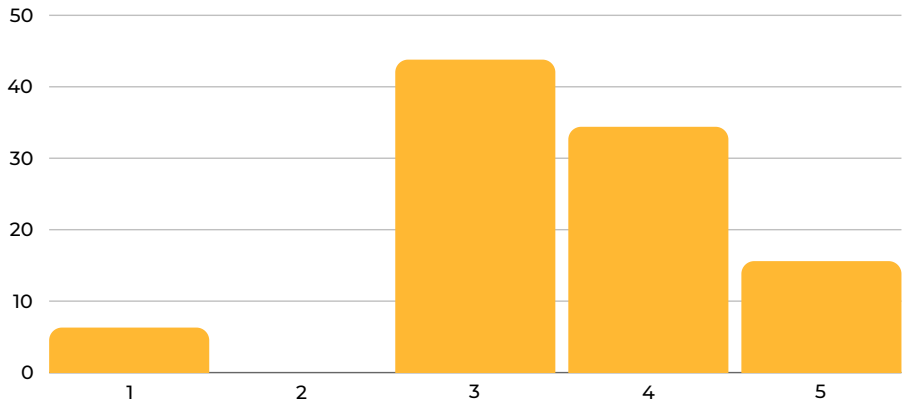
In light of recent moves by the FDA allowing Florida to begin purchasing prescription drugs from Canada, the NPC Institute analyses how politics south of the border have and continue to affect the affordability and accessibility of medication for Canadians. Key opinion leaders in the healthcare and pharmaceutical industry weigh in on how they anticipate this ruling will affect the Canadian market and patient wellbeing.

It's widely acknowledged that prescription drug prices in the U.S. are significantly higher than in other countries, causing financial strain for many Americans. A recent U.S. Food and Drug Administration (FDA) authorization permitting Florida to import select drugs from Canada could result in an estimated savings of $150 million USD in the first year of the program.[1,2] The Florida initiative has raised concerns about potential threats to drug supplies for Canadian patients.

In this White Paper, The National Pharmaceutical Congress Institute contacted experts about the challenges this policy presents, to be further discussed during the National Pharmaceutical Congress Winter Webinar on Wednesday, Feb. 28, 2024 at 11 a.m. (ET).

NPC Institute Thought Leaders Survey

How concerned are you about the affordability of medications in your markets? (1 - Not at all concerned; 5 - Highly concerned)



The NPC Institute surveyed Canadian pharmaceutical and healthcare executives to gather their thoughts on how U.S. politics will affect the affordability and accessibility of medication in Canada. The data in the chart represents their anonymized responses to the above question (n=33).

[1] https://www.nytimes.com/2024/01/05/health/drug-imports-canada-florida.html
[2] https://www.cbc.ca/news/politics/fda-florida-drug-import-canada-1.7075392

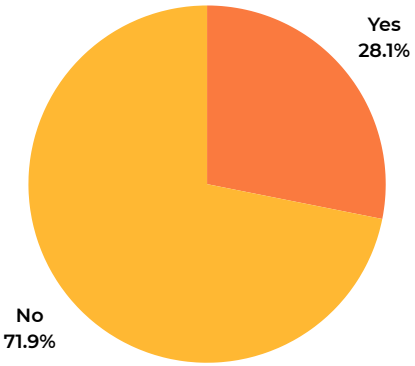
Not a new plan

“Governor [Ron] De Santis proposed this four years ago, but the FDA didn’t accept it until now,” said Dr. David Kreling, a former pharmacist and Professor of Pharmacy at the University of Wisconsin in Madison. “I’m not sure of their reasoning behind their acceptance now, but it could be that the FDA was concerned about supply chain integrity back then and may not view that as a problem anymore.”

“While U.S. interest in importing drugs from Canada has been around for a very long time, the recent FDA approval of Florida's plan could pose a significant threat to Canadian patients and our drug supply, especially when you consider that other states are working towards FDA approval for their importation initiatives," said David Renwick, Interim President of Innovative Medicines Canada in Ottawa.

NPC Institute Thought Leaders Survey

Should U.S. institutional buyers be able to enter purchasing contracts with medication suppliers outside of their nation of operation?



The majority of participants also believed that this kind of purchasing agreement would have **long-term effects**, improving affordability in the U.S. while **reducing affordability in Canada**.

The NPC Institute surveyed Canadian pharmaceutical and healthcare executives to gather their thoughts on how U.S. politics will affect the affordability and accessibility of medication in Canada. The data in the chart represents their anonymized responses to the above question (n=33).

Which drugs does Florida plan to import?

Drugs that treat HIV, AIDS, diabetes, Hep C, prostate cancer, and mental health conditions are some of the medications forecast for importation.[2] However, Dr. Kreling pointed out that 90% of the market in the U.S. is for low-cost generic drugs. "In contrast, specialty drugs for rarer conditions are super expensive, and that's what this issue is about," he said.

Impact on the Canadian drug supply

According to Danielle Peters, President of Magnet Strategy Group, Florida's importation program could cause a significant drug shortage in Canada.

"Canada already exports medicines to the U.S., but these are legitimate exports to meet the needs of the population outside Canada," she said. "The issue associated with Florida's plan is that it relies on Canada's drug supply intended for Canada's population. Given that the U.S. population is ten times the size of Canada's population, there's no upside for the Canadian industry."

Renwick echoed her concern by pointing out that Florida's population alone is more than 22 million people.

> **"Consequently, even occasional bulk importation could cause supply issues in Canada while being unlikely to result in any benefit to U.S. patients."**
>
> **DAVID RENWICK**
> INTERIM PRESIDENT, INNOVATIVE MEDICINES CANADA (IMC)

"There was a study done in 2010 which estimated that if 10 percent of U.S. prescriptions were filled from Canada, the drug supply would run out in 224 day," said Jaclyn Katelnikoff, pharmacist and founder of JKAT Health Solutions in Saskatoon. "I'm not sure how Florida thinks we are capable of supplying the volumes of medications that they require unless we are manufacturing for the sole purpose of export."

[2] https://www.cbc.ca/news/politics/fda-florida-drug-import-canada-1.7075392

Barriers to easy access

However, Florida still needs to clear significant hurdles before it can distribute Canadian drugs. These include sending the FDA details on those drugs it plans to import, verifying that they meet FDA's standards and relabelling them with FDA approved labels instead of those used in Canada.[1,3,4] In addition, the FDA will maintain oversight to ensure Florida's adherence to the program's regulations.[5]

Florida's approval to import lasts for two years from the date of the first drug treatment.[1] Will their approval encourage other states to make similar requests?

"Colorado and New Mexico have submitted SIPs [Section 804 Importation Programs] to the FDA, while 17 others have either passed legislation or have legislation pending to facilitate importation," Renwick said.

"There are currently no regulations in place that prevent putting Canadians on back order to favor other markets. Furthermore, the assumption is that the medications sold in Canada are manufactured here which is not always the case. Companies will not ship to Canada as a mechanism of preventing re-importation. As such the questions should not be only about affordability but also availbility."

ANONYMOUS INDUSTRY EXECUTIVE
VIA THE NPC INSTITUTE
2024 WINTER SURVEY

[1] https://www.nytimes.com/2024/01/05/health/drug-imports-canada-florida.html
[3] https://www.npr.org/sections/health-shots/2024/01/05/1223070066/fda-approves-floridas-plan-to-import-cheaper-drugs-from-canada
[4] https://www.kff.org/policy-watch/what-to-know-about-the-fdas-recent-decision-to-allow-florida-to-import-prescription-drugs-from-canada/
[5] https://www.pharmaceutical-technology.com/news/fda-florida-import-medicines/

What can Canada do?

Health Canada has already taken steps to block the export of prescription drugs that are in short supply.[1,3,6] The pharmaceutical industry in the U.S., represented by the Pharmaceutical Research and Manufacturers of America (PhRMA), has also opposed the decision, arguing that it poses a serious danger to patient safety by importing substandard or counterfeit therapies.[3,7,8,9]

Legally, there are various steps companies can take to try to prevent the importation of Canadian-labelled prescription drugs into the U.S., said Eileen McMahon, Partner and Chair of the Drug Regulatory/IP Groups at Torys LLP in Toronto.

"From a Canadian perspective, we can first ensure that the downstream contracts [wholesalers, distributors, retail pharmacies, etc.] prohibit the direct sale/re-sale of Canadian-labelled prescription drugs to the U.S. This would include audit rights, termination rights, and penalties if the contracts are breached."

"Second, we can press the Canadian government to implement stronger prohibitions on export of Canadian-labelled prescription drugs and take enforcement steps relating to violation of these prohibitions.

"Third, we can monitor supply chains to see where anomalies in purchase exist compared to forecasted Canadian purchases," she said. "We can investigate them, and if required, take enforcement steps including litigation [e.g., contract litigation, patent infringement or litigation if applicable]."

"Fourth, if required, we can limit supplies in Canada, to match forecasted Canadian demand, and subject with anti-trust laws."*

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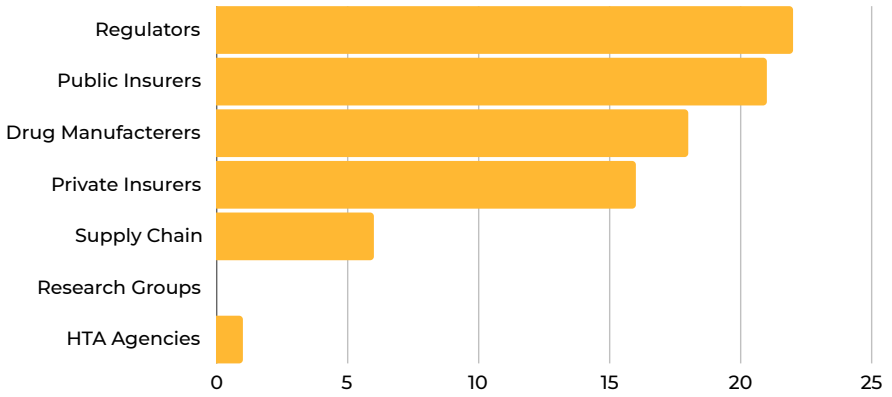
[1] https://www.nytimes.com/2024/01/05/health/drug-imports-canada-florida.html
[3]https://www.npr.org/sections/health-shots/2024/01/05/1223070066/fda-approves-floridas-plan-to-import-cheaper-drugs-from-canada
[6] https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/
[7] https://thehill.com/policy/healthcare/4390990-florida-drugs-canada-approval/
[8] https://phrma.org/Blog/Floridas-importation-plan-puts-patients-in-danger
[9] https://www.pharmacist.com/APhA-Press-Releases/fdas-decision-on-floridas-importation-program-jeopardizes-patient-safety
**These are high level comments in response to questions and are not legal advice.*

NPC Institute Thought Leaders Survey

Which stakeholders would you say have the greatest control over medication affordability?



The NPC Institute surveyed Canadian pharmaceutical and healthcare executives to gather their thoughts on how U.S. politics will affect the affordability and accessibility of medication in Canada. The data in the chart represents their anonymized responses to the above question (n=33).

Is Florida's plan feasible?

Despite the hype, many observers have doubts about Florida starting bulk imports any time soon. According to Dr. Kreling, the logistics of implementing this cross-border plan involves too many factors to allow for an easy transition.

"It's important to recognize that it's very rare in the U.S. for people to lack some form of health coverage. As a result, the whole supply chain, encompassing pricing and payment process, goes through coverage plans, which are based on standard lists for ex-factory pricing established by manufacturers. This affects what the consumer has to pay, and what pharmacists get paid for dispensing the drugs."

DR. DAVID KRELING
PROFESSOR OF PHARMACY
UNIVERSITY OF WINSCONSIN

Conclusion

While it may result in cost savings for some, bulk importation will not address the root cause of high drug prices in the U.S. Then there is the issue of getting all the players onboard with the plan.

“Florida’s plan requires a willing partner in Canada in order to be implemented. While a Canadian exporter has been listed in Florida’s application, it remains to be seen if Canadian medications can be accessed by the exporter to participate in the program.”

DANIELLE PETERS
PRESIDENT,
MAGNET STRATEGY GROUP

“You have to play in the sandbox,” Dr. Kreling added. “If you’re going to take all the other kid’s toys, they won’t let you play.”

NATIONAL PHARMACEUTICAL CONGRESS
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Since 2006, the National Pharmaceutical Congress (NPC) has provided a world-class stage for Canada's thought leaders in the pharmaceutical industry. The NPC Institute, a new initiative in 2024, seeks to facilitate open dialogue and collaboration among stakeholders such as industry representatives, government officials, and healthcare providers to identify and recommend potential solutions to address challenges and promote sustainable growth and innovation in the life sciences sector.

For more information on the NPC Institute, please get in touch with us at health@chronicle.org or visit pharmacongress.info.

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2024 WINTER WEBINAR
ADVANCE BRIEFING

NPC Institute 2024 Winter Webinar

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11:00 A.M. - 12:00 P.M. ET

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2024 Winter Webinar Faculty

JACLYN KATELNIKOFF
CLINICAL PHARMACIST,
SASKATOON FAMILY PHARMACY

Jaclyn Katelnikoff has been a pharmacist at Saskatoon Family Pharmacy since 2021. Prior to that, she was a manager at Glencairn Pharmasave in Regina. Jaclyn obtained her Pharmacology Degree in 2005 and her Pharmacy degree in 2009, both at the University of Alberta.

Jaclyn has long been an early adopter and advocate of Expanded Pharmacy Services since she was a pharmacist at Stafford Pharmacy in Lethbridge, Alta. She obtained her Advanced Prescribing Authority designation in 2013 and encouraged colleagues to utilize their clinical skills through public speaking. She relocated to Saskatchewan with her family in 2021 and has continued to advocate for a full scope of practice there.

With over 15 years of experience in the industry, Jaclyn has a passion for compounding and has managed labs to meet National Association of Pharmacy Regulatory Authorities (NAPRA) standards in both provinces. Jaclyn has been able to share her love of pharmacy by teaching students and sharing her experiences through precepting.

DAVID KRELING
PROFESSOR OF PHARMACY,
UNIVERSITY OF WISCONSIN

Dr. David Kreling earned a BS degree in pharmacy from Ferris State University, a MS in pharmacy administration from Purdue University and PhD in pharmacy administration from the University of Texas at Austin. He joined the faculty of the University of Wisconsin School of Pharmacy after completing his graduate work. He has been an administrative board member of the Sonderreger Research Center since its inception in 1986 and is Director of the SRC

Pharmacy Practice Enhancement and Action Research Link (PEARL Rx), a fledgling research network of pharmacist partners throughout Wisconsin. As a member of the Midwest Pharmacy Workforce Consortium, David has been a key researcher for national pharmacist workforce studies and has been involved in biennial state-wide salary and workforce studies throughout his tenure at UW. He is also a Fellow of the Academy of Pharmaceutical Research and Science in the American Pharmacists Association.

David practiced as a pharmacist in independent, chain, and institutional pharmacies before completing his PhD. His primary academic and research interests are in what often is referred to as traditional pharmacy administration, marketing, and economics. Much of his research has been in the area of pharmacy economics and policy, primarily finance and reimbursement issues in community pharmacy. Other research activities have spanned a variety of topics generally related to pharmacy, practice, and consumers. He has published on topics including formularies, drug coverage, prescription costs and pricing, pharmacy benefit managers, pharmacist salaries, and general trends related to prescription drugs, with funding for his research from a variety of sources including state and federal government agencies, private corporations, state and national organizations, and foundations.

DANIELLE PETERS
PRESIDENT,
MAGNET STRATEGY GROUP

Danielle Peters is President of Magnet Strategy Group, a consulting firm that manages public affairs strategies in Canada and the United States. Danielle serves as a Principal Advisor to the Alliance for Safe Online Pharmacies in Canada. Over the course of her 20-year career, Danielle has specialized in cross-border strategies between the U.S. and Canada, concentrating on fields that include innovation, health, and life sciences.

Danielle co-founded the Cross-Border Health Foundation, an organization that fostered dialogue between Canada and the United States around common health priorities. In addition to operating Magnet Strategy Group, Danielle serves on the Industry Advisory Board for Bloom Burton & Co., a healthcare investment advisory firm in Toronto. She is also a Health Leader-in-Residence for the World Health Innovation Network (WIN), within the University of Windsor's Odette School of Business and a Senior Advisor to the Canadian Antimicrobial Innovation Coalition (CAIC).

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DAVID RENWICK
INTERIM PRESIDENT, INNOVATIVE MEDICINES CANADA (IMC)

David Renwick is a pharmaceutical executive with over 25 years of experience, renowned for his strategic acumen, operational expertise, and commitment to advancing healthcare. Prior to joining Innovative Medicines Canada (IMC) as Interim President, he was the Vice President and General Manager, Canada, at Emergent BioSolutions. In that capacity, David played a pivotal role in spearheading the Canadian business for a groundbreaking opioid overdose reversal product, demonstrating his commitment to making a positive impact on the lives of Canadians.

His career includes noteworthy achievements at Oryx Pharmaceuticals and AstraZeneca Canada, where his strategic leadership contributed significantly to key product launches. In recognition of these outstanding contributions, David was inducted into The Canadian Healthcare Marketing Hall of Fame in 2019. Today at IMC, David leads with a desire to champion policies that facilitate the discovery, development, and delivery of innovative medicines for all Canadians. His commitment to community welfare extends beyond his professional endeavors, as evidenced by his role on the Board of Directors of BGC Canada Foundation (formerly Boys & Girls Clubs of Canada) since 2019.

David holds a Bachelor of Arts in Economics from the University of Western Ontario and resides in Mississauga with his wife Michelle and three sons. His passion for improving access to life-saving medicines underscores his dedication to positively impacting the lives of Canadians.

TED WITEK
PROFESSOR AND SENIOR FELLOW, INSTITUTE HEALTH POLICY MANAGEMENT & EVALUATION, UNIVERSITY OF TORONTO

Dr. Ted Witek is a distinguished healthcare leader, scholar, and executive with a multifaceted career spanning both academia and industry. Based in Toronto and Lisbon, he is a Senior Fellow at the Institute of Health Policy, Management, and Evaluation (IHPME) of the University of

Toronto and Adjunct Professor at the Dalla Lana School of Public Health (DLSPH) and Faculty of Pharmacy. In 2020, he was appointed Director of the DrPH program at the DLSPH, the first such program to be launched in Canada. Ted's expertise encompasses various domains, from directing innovative public health programs to spearheading strategic collaborations in pharmaceutical development.

With a rich background in executive roles at companies such as Boehringer Ingelheim and Innoviva, Ted has played pivotal roles in launching groundbreaking respiratory products and shaping global healthcare policies. He has a notable track record of leadership in professional organizations, serving on boards and committees focused on advancing healthcare technologies and public health initiatives. He is also a prolific author and respected authority in respiratory public health, with numerous publications to his credit.

Beyond his professional pursuits, Ted is an avid photographer and connoisseur of food and wine. He brings a diverse range of interests and experiences to his work, embodying a holistic approach to health and wellness. He holds advanced degrees from Columbia University and Yale University, reflecting his commitment to continuous learning and professional development.

Moderators

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2024 Winter Webinar Agenda

Wednesday, February 28, 2024

**all times noted are in ET*

11:00 AM	**WELCOME**	**BEN PARRY & MITCH SHANNON**
11:10 AM	**OPENING OVERVIEW**	**DAVID KRELING**
11:15 AM	**PANELIST INTRODUCTION**	**DAVID RENWICK, DANIELLE PETERS, TED WITEK, & JACLYN KATELNIKOFF**
11:20 AM	PANEL DISCUSSION: **DO US POLITICS THREATEN CANADIAN PATIENT INTERESTS?**	
11:55 AM	**CONCLUSION**	**BEN PARRY & MITCH SHANNON**

Join your colleagues virtually on **Wednesday, February 28, 2024 from 11 a.m. to 12 p.m. ET** where these Life Science industry leaders will discuss how priorities and politics south of the border might threaten Canadian patient interests.

Are there ways life sciences industry leaders can unite with policymakers on awareness-building and proactive measures to uphold access for all? Attend the Winter Webinar at no charge to learn more.

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