

## **National Pharmaceutical Congress Institute Webinar**

Executive Summary

February 28, 2024, 11:00 A.M. - 12:00 P.M. ET

NATIONAL PHARMACEUTICAL CONGRESS  
WINTER 2024 WEBINAR

### **PHARMA RESPONDS TO U.S. FDA'S APPROVAL TO IMPORT DRUGS FROM CANADA**

A THREAT? OR AN OPPORTUNITY FOR CANADIANS TO  
SAFEGUARD THEIR DRUG SUPPLY?

FROM THE PERSPECTIVE OF PHARMA INSIDERS

This report has been prepared for the exclusive use of registrants to the 2024 Winter Webinar, and provides a summary of meeting highlights.



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## **Diverting drugs south at what cost?**

When the news emerged that the U.S. FDA was poised to permit Florida's plan to import lower cost pharmaceuticals from Canada, many healthcare leaders voiced their concerns that bulk importation might threaten Canadian patient interests. The panelists at the National Pharmaceutical Congress 2024 Winter Webinar on Feb. [date to be inserted] discussed the feasibility of the importation plan and how the life science industry could protect the affordability and accessibility of medications for Canadians.

The opening speaker, Dr. David Kreling, Professor of Pharmacy at the University of Wisconsin, Madison, questioned whether Florida's plan was really going to move forward.

"This is just kind of a reiteration of a plan that hasn't been successful in the past," he said. "So, I'm not really sure if this will have legs."

One reason is that the majority of Americans are covered by health insurance. "As a result, drug supply, pricing and payment goes through coverage plans," Kreling said. "Manufacturers in the U.S. set factory pricing for their products, which subsequently affects what consumers have to pay and influences the compensation pharmacists receive for dispensing these medications. Moreover, post-market adjustments in rebates, governed by contractual agreements between manufacturers and pharmacy benefit managers and plants further complicate the issue."

Introducing a different kind of cost structure through drug importation affect could drastically affect pharmacies, he explained.

"It would be difficult for pharmacists to know how to make necessary adjustments. How will they know when and where to make those adjustments? The same goes for consumers," he said. "Figuring out how this is potentially going to work involves so many details and it's likely to generate all kinds of craziness, given the manipulations and machinations that occur outside the standard chain of custody and pricing phenomena in the U.S."

According to Kreling, importing Canadian drugs won't necessarily mean lower drug costs for Americans. "We already have lower cost drugs in the U.S. This plan could, however, benefit those individuals who have expensive medications which are not covered."

Ted Witek, a Professor and Senior Fellow of the Institute of Health Policy, Management and Evaluation at the University of Toronto, echoed Kreling's sentiment regarding the potential lack of immediate impact on drug prices for U.S. patients.

"The original intention of the importation plan was to supply lower cost drugs in scenarios where people lack access to private insurance such as prison populations or Medicaid. So are Americans really getting a reduction on drug prices? Or is the government saving money in those patient populations that don't have access to private insurance?"



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## Sizeable population differences could affect supply

For David Renwick, Interim President of Innovative Medicines Canada, the substantial population gap between Canada and the U.S. is a major issue. "Florida alone has 23 million people. The prospect of 17 other states enacting laws that would facilitate bulk importation raises serious concerns for all of us. Given this scale difference, Canada would struggle to offer a substantial supply to meet U.S. demand, potentially leading to drug shortages for Canadians."

Small, independent Canadian pharmacies could be particularly affected by these drug shortages, said Jacelyn Katelnikoff, pharmacist and founder of JKAT Health Solutions in Saskatoon. "We try to maintain the lowest inventory possible for many reasons," she explained. "And in Saskatchewan we generally only hold enough supply for one month. That affects how wholesalers and manufacturers do their forecasting as well down the line. So even a small increase in demand can result in a shortage situation which can get stressful when we're talking about the U.S. asking for bulk export."

As an example, she pointed out a situation in post-pandemic 2022, when cough and cold season started early in Saskatchewan. "This led to shortages of Tylenol, Advil, and amoxicillin for children. Even with manufacturers increasing their production of these drugs, we didn't see a resolution or stability of these products until March 2023. And this could really happen at any given time for multiple medications, especially if patients start to panic and stockpile their meds."

**"Florida alone has 23 million people. The prospect of 17 other states enacting laws that would facilitate bulk importation raises serious concerns for all of us. Given this scale difference, Canada would struggle to offer a substantial supply to meet U.S. demand, potentially leading to drug shortages for Canadians."**

**DAVID RENWICK**  
INTERIM PRESIDENT, INNOVATIVE  
MEDICINES CANADA (IMC)





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## Long term feasibility?

The panelists highlighted the importance of honouring the strong relationship between Canada and the U.S., emphasizing the need to continually recognize Canada's role as a vital trading partner with the U.S.

"I think panic arises when the word 'bulk' is mentioned," Katelnikoff said. "Supply chain issues are a constant source of anxiety for pharmacists. Sometimes we place an order only to find out that 40 per cent of what we requested isn't available. However, I think we can help Americans with one specific medication in shortage situations. That may present a large opportunity."

Panelists also discussed the need to educate American patients about the distinction between legitimate and unauthorized drug purchases. "Many Americans don't realize that ordering drugs online from Canada is not actually approved by the FDA," Dani Peters, President of Magnet Strategy Group explained. "Furthermore, there's a lack of enforcement on both sides of the border, which means that what's being imported or exported isn't closely monitored. So, if Florida does end up importing drugs from Canada, people may think they can order online, potentially falling victim to an illegitimate online operation that isn't under provincial oversight. Addressing these oversight gaps is one of the challenges we have in Canada."

"Putting these policies in place could ensure the safety, purity, and supply of Canadian drugs," Witek agreed.

Reflecting on some of the changes that have already taken place on a federal level, Renwick felt positive. "There are a number of steps that have been taken to ensure that protection mechanisms are in place, with pharmaceutical manufacturers obligated to report and be mindful of the potential risks of shortages."

In summary, Kreling sought to allay concerns about Florida's importation plan pointing out the sheer logistical factors involved in its implementation. "Canadian pharma and healthcare professionals should express their concerns about the FDA's decision because they're legitimate. But I wouldn't get in too much of a tizzy over it because it's liable to go away on its own. To be honest, I'd really be surprised if this plan takes off and has an impact."



# Financial assistance solutions for patient support programs



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- Improved adherence tracking (patient level)

**For more information, contact Cameron Stewart LifeScience at [questions@cslifescience.com](mailto:questions@cslifescience.com).  
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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 (IHPE) of the University of

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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



**BEN PARRY**  
DIRECTOR,  
THE PANGAEA GROUP



**MITCH SHANNON**  
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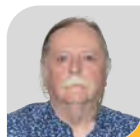


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For more information on the NPC Institute, please get in touch with us at [health@chronicle.org](mailto:health@chronicle.org) or visit [pharmacongress.info](http://pharmacongress.info).



**MITCH SHANNON**  
CEO AND PUBLISHER  
[SHANNON@CHRONICLE.ORG](mailto:SHANNON@CHRONICLE.ORG)



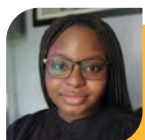
**R. ALLAN RYAN**  
VP AND EDITORIAL DIRECTOR  
[ALLAN@CHRONICLE.EMAIL](mailto:ALLAN@CHRONICLE.EMAIL)



**JOYCE PITTERS-HINDS**  
ASSISTANT PUBLISHER  
[JOYCE@CHRONICLE.EMAIL](mailto:JOYCE@CHRONICLE.EMAIL)



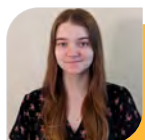
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CLIENT ENGAGEMENT &  
PARTNERSHIPS COORDINATOR  
[CRISTELA@CHRONICLE.EMAIL](mailto:CRISTELA@CHRONICLE.EMAIL)



**SYDNEY JOHN-BAPTISTE**  
CONFERENCE MANAGER  
[SYDNEY@CHRONICLE.EMAIL](mailto:SYDNEY@CHRONICLE.EMAIL)



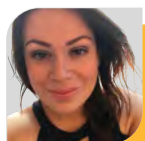
**JOHN EVANS**  
SENIOR EDITOR  
[JOHN@CHRONICLE.EMAIL](mailto:JOHN@CHRONICLE.EMAIL)



**AMY ELDER**  
ADMINISTRATIVE ASSISTANT  
[ADMIN@CHRONICLE.EMAIL](mailto:ADMIN@CHRONICLE.EMAIL)



**JEREMY VISSER**  
CO-ORDINATOR, DIGITAL  
CONTENT & ENGAGEMENT  
[JEREMY@CHRONICLE.EMAIL](mailto:JEREMY@CHRONICLE.EMAIL)



**KYLIE REBERNIK**  
CONSULTANT  
[KYLIE@CHRONICLE.EMAIL](mailto:KYLIE@CHRONICLE.EMAIL)

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As debate rages over Canada's proposed national pharmacare program, this webinar will cut through the noise to shed light on the myths and facts surrounding Bill C-64. The NPC panel will explore concerns raised about drug shortages, lost workplace benefits, and effects on industry, while examining how pharmacare could potentially reduce costs and improve medication affordability and access. With much still uncertain, get insights from existing universal drug plans as the panel tries to separate fact from fiction on this major healthcare reform.



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1460 The Queensway, Suite 212  
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