Volume 1 Issue 2 Summer 2024

Hypothesis

PERSPECTIVES INSIGHTS & THOUGHT LEADERSHIP IN THE LIFE SCIENCES

The Trends Shaping Health Care Investing

A Conversation With Brian Bloom, Chairman and CEO of Bloom Burton & Co.

INSIDE THIS ISSUE

Medical minds gather here.

As the largest independent medical publisher in Canada, our peer-reviewed open access scientific journals are a practical resource for Canadian healthcare practitioners. We currently publish specialty journals in the areas of allergy & immunology, dermatology, hematology, ophthalmology, diabetes & endocrinology, gastroenterology, primary care, women's health, rheumatology, oncology and our press is constantly growing with new titles planned for 2025.

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Letter From Our Editor-in-Chief

Welcome back to *Hypothesis*!

We're delighted to provide you with Issue 2 of our magazine for the Canadian Life Sciences Industry. A big thank you to all our readers who have amplified the launch of the journal and who continue to provide such meaningful feedback! A reminder to all our readers that we need your input--please send us your content for the "People on the Move" and "Product Newswire" sections!

In this issue, we speak with Brian Bloom, CEO of Bloom Burton & Co., about the trends that are shaping healthcare investing. We also have the pleasure of hearing from Christine Lennon, the General Manager of Incyte Biosciences Canada, about her career and views on important subjects both personal and professional. We also had the chance to sit down with Chris Bunter from Edmonton, AB and speak with him about his journey with inflammatory bowel disease. Finally, Allan Slomovic, MD joined us from University Health Network and shared his views on all things ophthalmological---a fascinating discussion.

Our distribution continues to grow! We are reaching close to 1,500 life-sciences professionals across the country and we mail printed copies of the magazine to over 200 life-sciences companies in Canada. Please share our content with your network and encourage them to sign up for future issues for free @https://www.hypothesismag.com/subscribe/

As we head into the back quarter of the year, we wish everyone a safe end-of-summer and look forward to our Winter Issue, which will be out in November 2024!

Happy reading!

Lea

Lea Prevel Katsanis, PhD
is a Professor in the Department of Marketing at the John Molson School of Business at Concordia University. Katsanis who spent many years working around the world for major global pharmaceutical brands, is the author of Global Issues in Pharmaceutical Marketing.

Fool Me Once.

But just once. After that, you're on your own.

By Rohit Khanna, MBA, MSc, MPH

I recently read an article in which the authors advocated for the FDA and FTC to work together to crackdown on TikTok and Instagram influencers who are advertising and promoting drugs.

The goal here is, of course, to provide some sort of guardrail for innocent social media users around the promotion of prescription drugs which may contain misleading information and lack fair balance. The article states that "Influencers with no medical or pharmaceutical training regularly use these platforms to promote prescription drugs. Khloe Kardashian, for example, has posted ads on Instagram to promote a prescription migraine medication. So have Lady Gaga and gold-medalist Olympic athlete Aly Raisman, who recently endorsed a competing migraine medicine in an ad that began with her talking about Women's Mental Health Month."[1]

But are these social media users really innocent? With the demographic of some of these social media platforms skewing on the younger side, I can certainly see the rationale for protecting children and young teens from the potentially harmful misinformation about drugs and medicines that might understate harms and overemphasize benefits. But nobody under 18 is getting a prescription medicine without a referral to a specialist and/or without being accompanied by a parent or a guardian. Hence, some very important guardrails are actually already in place.

That leaves us with the rest of the population. The people older than eighteen years of age. Now, again,

these people also need a referral to a specialist who will undoubtedly perform a clinical workup and obtain the patient's relevant medical history before haphazardly prescribing a medication for a particular illness. No? Sure, a patient can ask for a drug by name and cite its use by someone famous. This doesn't mean he/she is getting it. In fact, I would submit that while the FDA and FTC might be behind the times, physicians are not. I spend time interacting with thousands of physicians per year and, with the exception of a very small minority, they are all aware of what is out there on social media. They are all (informally) trained and alert to asking the right questions and are not about to get hoodwinked into writing inappropriate prescriptions.

I'm not naïve, but why all the handwringing?

Maybe because we've just come through a bruising 3+ years in which science, epidemiology and public health was brought to its knees by a tsunami of misinformation and mistrust brought on by COVID-19. Maybe because we feel the need to protect the dissemination of drug information very closely. Maybe because vulnerable populations are involved.

All of these are fair points.

At some point, though, people need to remember that a guy sitting in his basement in Tuscaloosa, Alabama who works at the local 7-Eleven is not a doctor and it is highly likely that he does not have the requisite medical experience to render medical opinions. People need to remember that these posts are opinions, not facts.

Does this sound harsh? Maybe. But this comes from a place of realizing that it is impossible to remove all the illegal posts and moderate all the content out there on the internet. Facebook and TikTok and YouTube (aka Google) have tried to moderate content. They have hired veritable armies of people to moderate content.

It simply can't be done. And we need to stop pretending like we can do something about it.

We cannot find every instance where some individual has posted a thought on the benefit or harm of a medicine and scrub it from the internet. And this has nothing to do with First Amendment concerns or the right to free speech. It has to do with the sheer size and scope of the internet.

So, in this situation, what do we do? Some regulation doesn't hurt. But it is not the solution.

We can spend a few hundred million dollars on public service announcements reminding people of the dangers of taking medical advice over social media from individuals who are not clinicians. Maybe we can introduce social media training and education into grade schools so that in a generation we have smarter and better-informed young adults. We can certainly start formal training of medical students and other allied healthcare practitioners about how to deal with this issue. And there's probably a few other great ideas out there that we can implement.

But fundamentally, people need to take ownership of the content they consume. Full stop.

As Abraham Lincoln famously said, "You can fool some of the people all of the time, and all of the people some of the time, but you cannot fool all of the people all of the time."

Rohit Khanna, MBA, MSc, MPH
is the Managing Director of Catalytic Health, a leading life-sciences communication, publishing, and strategy firm. He holds a B.A. from McGill University, an M.B.A. from Queen's School of Business, an MSc. from the London School of Economics & Political Science and a Master of Public Health in Epidemiology from Harvard School of Public Health. His first book entitled *Misunderstanding Health: Making Sense of America's Broken Health Care System* was published in October 2021 by Johns Hopkins University Press. His second book is due for release in 2025. He can be reached at: **rohit@catalytichealth.com** or you can learn more about him at **rohitkhanna.com**

References

1. *https://www.statnews.com/2024/01/22/fda-ftc-tiktok-instagram-influencers-advertising-prescription-drugs/*

We are searching for the best of the best.

The Canadian Life Sciences Top 20 Under 40 Awards puts a spotlight on the young movers and shakers in the life sciences industry. Nominations for this award are currently open. Anyone affiliated with the life sciences industry can nominate a life sciences professional who is under the age of 40.

Go to **top20under40lifesciences.com** to nominate.

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The Trends Shaping Health Care Investing

A Conversation With Brian Bloom, Chairman and CEO of Bloom Burton & Co.

Brian Bloom is the chairman and chief executive officer of Bloom Burton & Co., the only Canadian investment banking firm focussed solely on health care companies. He spoke with Rohit Khanna, Hypothesis publisher and managing director of Catalytic Health, about the current, hot areas for health sector investment, how young health care companies can attract funding, and more.

Let's start with your background, and how you got into the business.

I was born and raised in Toronto. I initially thought that I would be a doctor, but after my undergrad in biochemistry, I wasn't sure if that was my path. I moved to New York City to pursue a PhD program, which I decided wasn't for me after a few years. I then launched my career on Wall Street. I moved back to Toronto, started my family, and worked for a bank before deciding to start my own investment banking firm with my cofounder Jolyon Burton. That was 15 years ago. To this day, we're the only investment banking firm in Canada that is 100% dedicated to the medical and healthcare sector.

What made you and your cofounder decide to go out on your own?

There were times when we were both working at a large investment bank and we wanted to seed and incubate new companies or be principal investors who would have a hand in the operations of a company. Our bosses at the time said, "We don't do that here." Jolyon and I had a bigger vision for what we could accomplish. We both had the risk tolerance and the personalities that made us think we would do well as partners.

What advice do you give to early- and late-stage companies about raising capital at this current juncture?

We've had this horrible bear market over the past few years, following the very frothy years of 2020 and 2021, when there were insane amounts of money flowing into the silliest things like non-fungible tokens (NFTs) and Metaverse real estate. Then, all of a sudden, there was capital scarcity. Now we're in a more balanced, rational market where many companies are neither flush nor starving.

For the pre-commercial companies, whether you're a medical device or a biotech company, you really have to be globally competitive. This is no longer a market where products that aren't fully thought through can get funding. Your idea must be able to hold up to the scrutiny of highly discerning investors. The bar is high. If investors see a risk that can't be overcome with data, with time, or with better execution, they will move on to something else. So, your science and your market research needs to be as airtight as possible. You need to show that there is wide acceptance of whatever you're trying to sell in the marketplace, using evidence such as sales information, key opinion leader interviews, and pharmacoeconomic analyses conducted by buyers.

> ***"We're in a balanced, rational market now. Your idea must be able to hold up to the scrutiny of highly discerning investors. The bar is high."***

When we hear about deals and mergers in the biopharmaceutical space, many zeros are thrown around. What are the major milestones that need to be met for an M&A deal to be successful?

That's a great question. While about half of our business at Bloom Burton & Co. is focused on raising capital for companies, through initial public offerings (IPOs), and venture capital, the other half of our business is mergers and acquisitions. We're the leading merger and acquisition advisor for healthcare companies in Canada. From that vantage point, I would say that great companies are bought, they're not sold. Usually what happens is a company has an extraordinary idea with impeccable execution. They raise capital and move quickly. This success is not only tracked by global investors, but also by competitors,

Photo by Ibrahim Boran on Unsplash

> ***The therapeutic area that was once the hardest area to attract venture capital investment is now the hottest space.***

including the larger multinationals. Representatives of those companies have initial partnership discussions or casual meetings with founders at medical conferences. When the multinational company approaches the younger, smaller company, that company will often hire an advisor like us. We walk them through the options including running an auction process and exclusive negotiations. We help them to extract the best outcome for shareholders and close a transaction, both legally and otherwise.

While I say that extraordinary companies are bought, other companies need to be sold. Those are companies that have less differentiation and they've hit a roadblock. Perhaps they can't raise their next round of financing. But they know there's value there. The next hurdle is too large or doesn't make sense for them to do as an independent company, but it makes sense on the balance sheet of a much larger company. So they approach companies like Bloom Burton & Co. to help with the selling process.

Are public and private reimbursement questions more central to your investment decisions in health care, compared to 15 years ago?

Market access is a huge part of diligence, even for venture capitalists that invest in drug programs at the preclinical stage. Of course, it's difficult to predict what will happen in 5 or 10 years, when a company may be approaching the market. But we try to take the temperature of insurers, government payers, regulatory bodies, and legislators. For example, we consider what's happening with the Biosecure Act and the Inflation Reduction Act, as well as Trudeau's statements about the need to reform the Patented Medicine Prices Review Board. Legislative moves can have huge implications for early-stage inventors and venture

capital investors, because they signal how much value will be ascribed to a product if it does come to market.

What are some therapeutic areas investors are especially interested in these days?

Surprisingly, the hardest space to raise venture capital dollars just 10 years ago – large population primary care indications like pain and obesity – is now the hottest space. I would never have predicted 10 years ago, before Ozempic and Wegovy, that obesity medications could one day be an $80-100 billion annual opportunity. Meanwhile, Vertex Pharmaceuticals is developing an ion-channel therapy at a time when there hasn't been a novel mechanism for pain for around 20 years.

Another big area right now is the molecular medicine approach for central nervous system (CNS) diseases, like Alzheimer's, Parkinson's, neurodegenerative disorders, and movement disorders like epilepsy. Many recent mergers and acquisitions have been in the CNS space, thanks to recent scientific breakthroughs in our understanding of these diseases.

What about psychedelics? Are you seeing activity in this space?

Burton Bloom & Co. just raised $150 million USD for Cybin, which we believe is the best-in-class psilocybin analog that's going into phase 3 trials. Psychedelics are often compared to cannabis. To me, though, psychedelics and cannabis are like night and day. CBD and THC have a few very specific therapeutic applications, such as epilepsy, and generally have shown very little promise outside of their approved orphan indications. Psychedelics, on the other hand, are showing promise in treating depression, addiction, post-traumatic stress disorder (PTSD), and anxiety. I think the clinical data that we already have, both academic- and industry-sponsored, is profound. I expect we will see a wave of acquisitions for companies like Compass Pathways, Cybin, MindMed, and others that are in late-stage development and on the path to FDA approval. For example, a ketamine analog called esketamine, marketed under the name Spravato by Johnson & Johnson, has demonstrated a game-changing impact in depression, and is expected to reach $1.5 billion in sales in the United States this year.

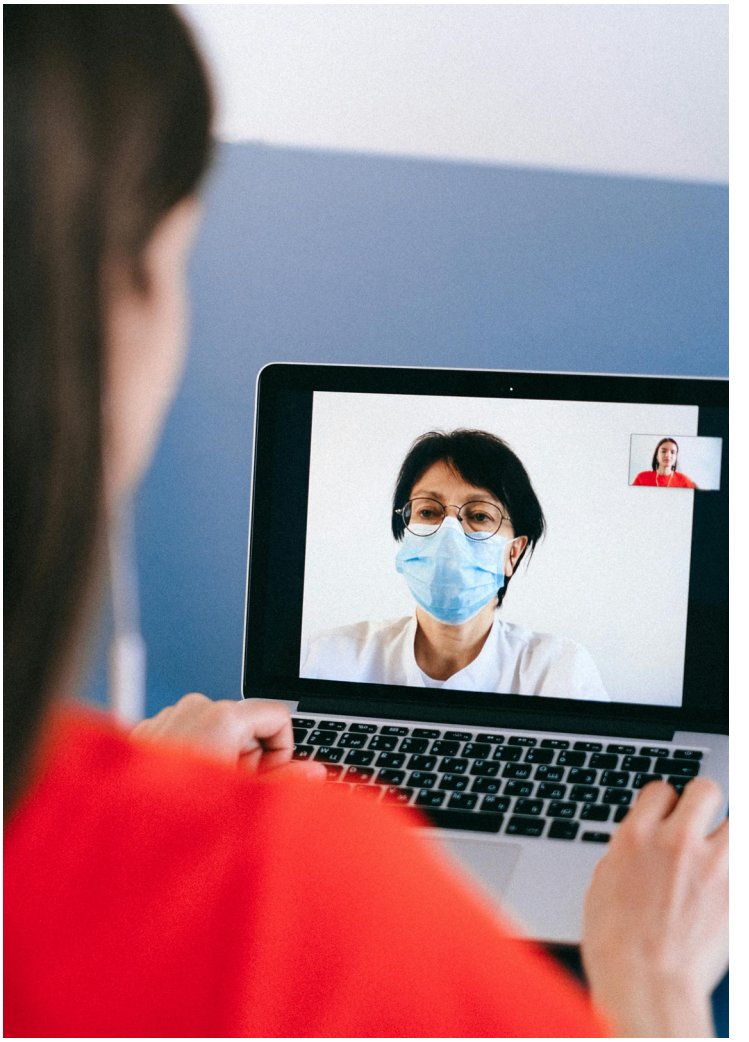

Photo by Anna Shvets on Pexels

Let's move on to some other cutting-edge technologies. Wearables, robotics and telemedicine. Do you recommend investing in any of these areas?

Wearables are a 'no' for me. Both public and private insurers aren't willing to reimburse wearables, for the most part. That may be because the process of collecting data through wearables hasn't yet been strongly shown to advanced important health outcomes.

Robotics are a 'yes' for me. Robotics have a bright present and very bright future in surgical intervention.

Telemedicine is one of the answers to much of what strains healthcare systems that are trying to equitably provide health care. The problem is there are many vested interests from those that deliver care in person, and I don't think the reimbursement incentive has caught up to the promise of telemedicine.

What advice would you give someone who wants to pursue a career in health care investment banking?

The opportunities are currently scarce in investment banking, both in Canada and the United States. So, any kind of foot in the door is worth exploring, and on-the-job would probably be a better experience and accelerator for one's career than any than any degree would be. My advice would be to start small and start imperfect. You could start in the investment world, even if the opportunity isn't in health care and then later pivot to health care. Or you could start at a health care consulting firm, and then later pivot into the investment world.

I'd also recommended reading equity research reports from banks about how stocks are valued and analyzed, the Canadian Securities Course, or the Chartered Financial Analyst certification, which are self-study programs. Even if you don't get the certification, these courses will give you the vocabulary and skills that you need if you're coming in as a scientist but lack the investment know-how.

I'm interested in hearing different perspectives on AI in health care, so this is a question I've been asking everyone. Is there an AI application for a health care investor like you?

So far, I haven't seen anything on the horizon. That may sound self-serving because I don't want to be replaced by a bot, and I don't want my junior analysts to be replaced by bots. But I would say that, as investors, we do need to know quite a bit about AI. A lot of companies are using AI in their drug discovery process, as well as in pharmacovigilance, real-world evidence generation, and patient support. It's hard to make investments in health care companies if you don't know how powerful AI is and how it's being used.

My last question is a fun one. If I gave you a budget to go out to dinner and you can invite three people, dead or alive, who are you inviting?

First would be Ronald Reagan. I think that he personified freedom and individual choice. At its core, entrepreneurialism is the ability to run with an idea, and to develop something for the market and for society, without too much government interference. On the artistic side, I would invite my hero, Stephen Sondheim, who was considered the Picasso of musical theater, and one of the most brilliant composers. He was also a great lyricist and observer of the human condition. I shook his hand once when he was alive, and I've seen many of his shows. The third person would be my wife. It would be great if we could do this together. She's always delightful to be with.

Brian Bloom, Chairman and CEO of Bloom Burton & Co.

Brian Bloom is a co-founder of Bloom Burton & Co. and serves as the firm's Chairman and Chief Executive Officer. By forging unique relationships with international healthcare-specialized investors, Brian raises capital for healthcare companies while helping investors realize returns. Brian serves on the Board of Directors of Satellos Bioscience and Appili Therapeutics. Brian was formerly the Chairman of the Board of Grey Wolf Animal Health and Triumvira Immunologics, a member of the Life Sciences Advisory Board at the National Research Council of Canada, the Dean's Advisory Board at McMaster University and on the Board of Directors of BIOTECanada, the Baycrest Foundation and Qing Bile Therapeutics. Before co-founding Bloom Burton in 2008, Brian spent six years at an independent investment dealer in the healthcare and biotechnology institutional sales and equity research groups. Brian started his career at New York-based investment banking firms SCO Financial Group and Molecular Securities. Brian received an Honours Bachelor of Science in Biochemistry from McMaster University and subsequently studied at the Mount Sinai Graduate School for Biological Sciences of New York University, with a focus in molecular endocrinology and biophysics. Brian is the proud recipient of the McMaster University 2017 Distinguished Alumni Award in Science and the co-recipient of the 2023 Life Sciences Ontario Community Service Award. In 2023, Bloom Burton celebrated its 15-year anniversary with an Ecosystem Builder Award from BIOTECanada.

At a Crossroads: The Incredible Innovations and Severe Accessibility Challenges in Ophthalmology

Ophthalmology is at the forefront of jaw-dropping surgical and medical breakthroughs, but also facing a severe human resources crunch. This is also happening at a time when Canada's aging population is increasingly in need of ophthalmological care. Dr. Allan Slomovic spoke with Rohit Khanna of Hypothesis about the great opportunities and challenges in ophthalmology, and the rewards of shaping the next generation.

What led you to pursue ophthalmology?

I've asked myself this so many times. In my position as Vice Chair of Education, many medical students ask me what specialty I would choose if I could go back in time, and I would still choose ophthalmology.

It's very suited to my personality. It's a wonderful combination of intellectual talent, manual dexterity, and surgery. I love the "toys." They're so precise and contribute to truly excellent outcomes. I've had patients present with 20-20 or 20-25 vision the day after cataract surgery. The technology has also improved so much with corneal transplantation. When I started, we were using 24 stitches. Now we're doing corneal transplantation with only one stitch, or even no stitches at all. The rehabilitation is much faster.

What are some of the biggest accomplishments, as well as challenges, you've faced as an educator, previously as Program Director and now as Vice-President of Education at the University of Toronto's Department of Opthalmology?

Education has been a theme running through my career for the past 40 years. It's so rewarding to encourage that next generation to follow their passions, including in research and teaching. My philosophy has been to teach people how to fish, rather than to give them a fish. It's been a joy to some of our former residents and fellows taking on leadership positions around the world. I have a special bond with the students I've had the pleasure to teach. Even those I taught 20 years ago still call me "Prof". I tell them, "Call me Allan" but they struggle with that. I love how that bond always remains between teacher and trainee.

The biggest challenge is preventing burnout among residents. People only have so much capacity and there's a tremendous clinical load that residents need to take on. I've always felt that we need to put family first and help residents to save a bit of time for themselves.

I think even more than the safeguards, however, it's the interpersonal relationships that prevent burnout. I think it's so important we recognize that our residents are also human beings. They're not robots.

How do you help physicians avoid burnout?

There are safeguards in place that weren't there in the past. For example, if a resident has been working past midnight, they don't have to show up for the clinic the next day. There was a bit of pushback about these safeguards, with senior opthalmologists saying they had to work extremely long hours when they were a resident. But just because that's the way it was, doesn't mean that this is the way it should be.

I think even more than the safeguards, however, it's the interpersonal relationships that prevent burnout. I think it's so important we recognize that our residents are also human beings. They're not robots. I'll say to a resident, "How are you doing? What's up? How's the family?" We plan social events. We have the residents

or fellows over for dinner or take them out for dinner periodically. It's not easy to find the time, but it's important to make the time to ask them how they're doing and giving them an opportunity to talk.

> ***I think we need to play both offense and defense better. We need to have more ophthalmologists.***

In the spring of 2024, the Canadian Ophthalmological Society released the results of a national survey on Canadians' eye health. Was there anything in the survey that surprised you?

I was not surprised by the findings. The public is not aware of many of the diseases in ophthalmology. To be honest, many doctors aren't aware of ophthalmological diseases. Part of the role of the Canadian Ophthalmological society, for which I am a past president, is educating the public. We raise awareness of Dry Eye Month in July, for example. We produce brochures with information about ocular disease.

It's especially important that we point out the dangers of glaucoma. You can lose your vision from glaucoma, and not even know that it's happening until it's too late to reverse it. Everyone should have an ocular exam with intraocular pressure testing, especially if there's a family history of glaucoma.

I appreciate your advocacy for the very simple screening test to detect glaucoma. Could primary care doctors help to increase the availability of this test?

The problem is that 2.4 million Ontarians don't have a family doctor and a large percentage of them live far from their family doctor. However, primary care ophthalmologists and optometrists are very capable of providing glaucoma screening tests.

Another report I want to get your feedback on is a report about the state of the ophthalmological workforce from the Canadian Ophthalmological Society, which was submitted to the House of Commons in 2022. The report demonstrated that we don't have enough ophthalmologists to meet the increasing demand for services. Concerningly, around 50% of ophthalmologists are above age 55. How do we reverse these trends?

I think we need to play both offense and defense better. We need to have more ophthalmologists. We also need to increase the operating time availability. Many ophthalmology operating rooms are open between 8:00 and 3:30. If we increase the number of ophthalmologists and don't increase the operating time, we'll still have long waits, because the operating room time will still be a limiting factor. It's like adding more cars onto the Don Valley Parkway on a long weekend on Friday afternoon. You've got to also add more lanes.

Regarding those 'other lanes', what are your thoughts on taking some, not all, ophthalmology services outside of the hospital setting into a private ambulatory surgical centre?

I'm against that, to be perfectly honest with you. Many private centres emphasize the bottom dollar. There isn't any time for teaching and they don't host residents. To my knowledge, there isn't a lot of research coming out of these centres. Teaching and research are vital parts of the profession.

A better route would be to extend the operating room hours from 3:30 to 7:30. We can also increase the funding for not-for-profit centres, like Kensington Eye Institute, which operates in an extremely efficient manner.

What are the top 3 innovations coming down the pipeline in ophthalmology, in your view?

I could give you a hundred. I'll start with my area of corneal transplants. Corneal transplants have gone from large incisions to micro incisions, with very quick visual rehabilitation and excellent outcomes. Another area is anti-vascular endothelial growth factor (anti-VEGF) injections to treat wet macular degeneration, which is when blood vessels grow beneath the retina and damage vision. Wet macular degeneration used to be very difficult to treat. Now, with anti-VEGF injections,

people diagnosed with this condition can continue driving. Finally, we've been experimenting with using human blood products to treat dry eye disease, with excellent results. We hope to present a paper in Venice in October on this therapy. On top of these innovations, AI will be a broad driving force that helps us to work smarter.

It's amazing to see these changes. In my view, the field of ophthalmology has always been at the forefront of innovation, both with drug development and medical devices. I want to ask about GLP-1 receptor agonists. There have been some media reports of potential ophthalmic side effects. What is your experience in treating patients who are on this category of drugs?

GLP-1 agonists have hit the mainstream, big time. These drugs may cause diabetic macular edema and anterior ischemic optic neuropathy as well as exacerbate diabetic retinopathy. The data on these side effects is not robust, but there is smoke, and I've learned that where there's smoke, there's often fire. I think we're in the early phases of defining the risks of using these drugs. There are strong benefits to these drugs as well, of course. It's worth discussing the risks versus benefits with one's doctor, and to work with one's family doctor and ophthalmologist to monitor their eye health and prevent untoward side effects.

My last question for you. What are you reading these days?

I like historical fiction. I just finished *Mrs. Van Gogh* by Caroline Cauchi. I'm going to be in Amsterdam at a meeting soon, so I'm looking forward to revisiting the Van Gogh museum with the rich details from this novel in mind. I've also just started *The Women* by Kristin Hannah. It's about a nurse who goes to Vietnam during the war. It's a little graphic and can be difficult to read at times. But the character development is excellent, and I'm really enjoying it.

Allan Slomovic, MD

Dr. Slomovic is the Vice Chair of Education and Continuing Education Director for the Department of Ophthalmology and Vision Sciences at the University of Toronto. He is also the Clinical Director of the Cornea/External Disease Service at the Toronto Western Hospital, University Health Network. He is the past President of the Canadian Ophthalmologic Society and previous Chair of the Canadian Cornea and External Disease Society for the Canadian Ophthalmological Society. Dr. Slomovic is a Professor of Ophthalmology at the University of Toronto and the Marta and Owen Boris Endowed Chair in Cornea and Stem Cell Research at the University Health Network. Prior to starting medical school, Dr. Slomovic completed a master's degree in clinical psychology at the University of Montreal. He then went on to do his Medical School training at Memorial University in St John's Newfoundland, followed by an internship in Internal Medicine at The Montreal General Hospital. Dr. Slomovic then went on to complete a 3-year residency training program at the New York University School of Medicine in Manhattan, New York. This was followed by 2 separate Fellowship programs at the Bascom Palmer Eye Institute in Miami, Florida. The first fellowship was in Cornea/External Ocular Diseases and the second was in Laser Microsurgery. Dr. Slomovic has been involved with teaching residents and fellows, research and clinical practice over the past 35 years at the University Health Network. He was the program Director for Ophthalmology for the University of Toronto for 10 years (1991–2001) and has led the program through 2 successful Royal College reviews. He has also trained 47 fellows in Cornea/External Ocular Diseases of the Eye from all over the world, including Canada, United States, Israel, Australia, Singapore, Malaysia, Thailand, the Philippines, and Great Britain. In 2001, Dr. Slomovic was awarded the Mentor of the Year Award by the Royal College of Physicians of Canada. Dr. Slomovic is the inaugural winner of this award in the province of Ontario. Dr. Slomovic has published numerous articles in the area of Cornea/External Diseases of the Eye and Refractive Surgery and has also lectured on these topics locally, nationally and internationally.

SEPTEMBER 2024

15 SEPT

Terry Fox Run

On September 15th, people around the world take part in a charity marathon for cancer research in honour of Canadian activist Terry Fox. Photo by Tong Su via unsplash.com.

Acne Awareness Month
Arthritis Awareness Month
Childhood Cancer Awareness Month
Duchenne Awareness Month
Fetal Alcohol Spectrum Disorder (FASD) Awareness Month
Inherited Retinal Disease Awareness Month
International Pain Awareness Month
Ovarian Cancer Awareness Month
Prostate Cancer Awareness Month
Pulmonary Fibrosis Awareness Month
Sickle Cell Awareness Month
World Alzheimer's Month
National Fibromyalgia Awareness Week – September 1 to 8
National Polycystic Kidney Disease (PKD) Awareness Day – September 4*
Living Donation Week – September 8 to 14
World First Aid Day – September 9*
World Suicide Prevention Day – September 10*
World Sepsis Day – September 13*
Myotonic Dystrophy Awareness Day – September 15
Terry Fox Run – September 15

OCTOBER 2024

All OCT

Breast Cancer Awareness Month

For the month of October, people take the time to raise awareness and funds for breast cancer research and treatment. Photo by Olyako Bruseva via unsplash.com.

10 OCT

World Sight Day

October 10th is World Sight Day where we acknowledge the importance of eye care and ways to make treatments more accessible and affordable. Photo by Antoni Shkraba via pexels.com.

ADHD Awareness Month
Breast Cancer Awareness Month
Children's Vision Month
Lupus Awareness Month

Source: www.canada.ca/en/health-canada/services/calendar-health-promotion-days.html
Events marked with an asterisk (*) take place on the same day every year.

NOVEMBER 2024

16 OCT

World Spine Day

World Spine Day is an international campaign to promote good spine health in people of all ages and bring awareness to those living with spinal issues; photo courtesy of CHUTTERSNAP via unsplash.com.

All NOV

Eczema Awareness Month

November is Eczema Awareness Month in Canada. Canadians will take the time to reflect on how this condition impacts individuals and how to improve eczema care and treatments. Photo by Alexander Grey via unsplash.com.

Occupational Therapy Month
Rett Syndrome Awareness Month
Sudden Infant Death Syndrome (SIDS) Awareness Month*
World Cerebral Palsy Day - October 6*
World PANS/PANDAS Awareness Day - October 9
National Children's Hospice Palliative Care Day - October 10
World Mental Health Day - October 10*
World Sight Day - October 10*
World Arthritis Day - October 12*
World Hospice and Palliative Care Day – October 12
World Thrombosis Day - October 13*
National Metastatic Breast Cancer Day - October 13*
RSV Awareness Week - October 13 to 19
Pregnancy and Infant Loss Remembrance Day - October 15*
World Spine Day - October 16*
National Psoriatic Arthritis Day - October 19*
Respiratory Therapy Week - October 20 to 26
Brain Cancer Awareness Day - October 24*
World Amyloidosis Day - October 26
World Psoriasis Day - October 29*

Crohn's and Colitis Awareness Month
Eczema Awareness Month
Fall Prevention Month
Indigenous Disability Awareness Month
Lung Cancer Awareness Month
Movember
Osteoporosis Month
Pulmonary Hypertension Awareness Month
National Pain Awareness Week - November 3 to 9
World Neuroendocrine Cancer (NET) Day - November 10*
National Nurse Practitioner Week - November 10 to 16
World Pneumonia Day - November 12*
World Diabetes Day - November 14*
World Antimicrobial Resistance Awareness Week - November 18 to 24*
National Enteropathic Arthritis Awareness Day - November 19*
National Addictions Awareness Week - November 24 to 30
International Day for the Elimination of Violence Against Women - November 25*
Stomach Cancer Awareness Day - November 30*

The Impact of Proposed Price Regulations on New Patented Medicine Launches in Canada

A Retrospective Cohort Study

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Background: The Patented Medicine Prices Review Board (PMPRB), the agency that regulates the prices of patented medicines in Canada, published proposed amendments to the regulatory framework in December 2017. Because of a series of changes and delays, the revised policy has not yet been finalized. We sought to evaluate the potential early impact of the uncertainty about the PMPRB policy on patented-medicine launches.

Methods: We developed a retrospective cohort of patented medicines (molecules) sold in Canada and the 13 countries that the PMPRB currently uses or has proposed to use as price comparators, from sales data from the IQVIA MIDAS database for 2012–2021. The outcome was whether a molecule was launched (i.e., sold) in a specific country within 2 years of its global first launch (2-yr launch). We compared the change of 2-year launch before (2012–2017) and after the proposed amendments were published ("uncertain period," 2018–2021) in Canada with the change in the United States and the other 12 countries as a group ("other-countries group"), using interrupted time series and logistic regressions, respectively. We further conducted analyses for each individual country and subgroups by molecule characteristics, such as therapeutic benefit, separately.

Results: We included 242 and 107 new molecules launched before publication of the proposed amendments and during the uncertain period, respectively. The corresponding 2-year launch proportions were 45.0% and 30.8% in Canada, 81.4% and 82.2% in the US, and 83.9% and 70.1% in the other-countries group. All analyses showed changes in 2-year launch during the uncertain period in the US and in the other-countries group that were similar to the changes in Canada. Greater decreases were observed in Norway and Sweden than in Canada. The 2-year launch proportion for molecules with major therapeutic benefit decreased from 45.8% to 31.3% in Canada during the uncertain period and from 87.5% to 62.5% in the other-countries group, but increased from 91.7% to 100% in the US.

Interpretation: No negative impact of the PMPRB-policy uncertainty on molecule launches was observed when comparing Canada with price-comparator countries, except for molecules with major therapeutic benefit. The reduction in launches of medicines with major therapeutic benefit in Canada requires continuing investigation.

Since 1987, Canada has regulated the prices of patented medicines to ensure they are not excessive through the Patented Medicine Prices Review Board (PMPRB). Whether the price of a patented medicine sold in Canada is considered excessive depends primarily on the list prices of the same medicine in other comparator countries (external reference pricing) or the list prices of medicines in the same therapeutic class in Canada (internal reference pricing). This regulatory regime has been controversial because of the relatively high costs of patented drugs in Canada.[1,2] Despite the relatively high drug prices, new drug launches in Canada are often delayed, and in many cases, drugs are never submitted for regulatory authorization in Canada.[3–6] Concerns have been expressed that delayed access to drugs with therapeutic benefit could result in inferior patient outcomes.[7–9] Designing the regulatory system to balance cost and access to new drugs is therefore of great importance.

In December 2015, the PMPRB announced its intention to change Canada's price regulatory framework (***Figure 1*** and ***Appendix 1***, available here).[10,11] The proposed amendments were published in the *Canada Gazette*, the official newspaper of the Government of Canada, in December 2017.[12] The amendments would, first, change the price comparator countries from the PMPRB7 (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States) to the PMPRB12 by removing 2 countries with list prices higher than in Canada (the US and Switzerland) and adding 7 countries with prices lower than in Canada (Australia, Belgium, Japan, the Netherlands, Norway, South Korea, and Spain).[2] Second, the amendments would require patentees to report actual transaction prices; these are list prices net of all confidential rebates and discounts that manufacturers pay to drug plans. Finally, the amendments would use new price regulatory factors including pharmacoeconomic value, market size, and gross domestic product per capita in Canada.[12]

By Aug. 21, 2019, following some revisions, the regulatory amendments were approved by the federal minister of health and scheduled to come into force July 1, 2020.[13] The key changes were similar to those proposed in December 2017 except that the newer list of reference countries were the "PMPRB11" countries (South Korea was removed).[13,14]

The implementation date of the amendments was postponed 4 times because of the COVID-19 pandemic, feedback from consultations, and a successful court challenge to the requirement that patentees disclose prices net of all adjustments.[10,15–18] In April 2022, the federal minister of health decided to implement the change in reference countries (PMPRB11) but not the second and third amendments described above.[18,19] The regulatory amendments came into force on July 1, 2022.[18,19] However, the updated guidelines that explain the PMPRB's approach to the price review process and investigations under the amended regulations have not yet been finalized.[19,20]

Tighter price regulations and lower expected drug prices have been shown to hinder access to new medicines through nonavailability and delayed time to launch.[21–27] However, few studies have investigated the impact of price changes or expected price changes within a single country.[28–31] The PMPRB's own assessment in 2020 found "no early signs that patented medicine price reforms are resulting in fewer new medicines being launched in Canada."[32] In contrast, assessments conducted or commissioned by industry groups found or projected reductions in the number of drug launches and delays in drug launches in Canada as a result of the proposed amendments.[33–35] However, these assessments were not peer reviewed and did not evaluate the therapeutic importance of the drugs that were not launched.

Gaudette and colleagues found only 1 medicine with added therapeutic benefit among new patented medicines approved in the US and Europe in 2016–2020 but not submitted for Health Canada review by February 2023.[5] In a cross-sectional study, Lexchin concluded that the "number of therapeutically important medicines not being introduced into Canada is increasing but that is not related to the proposed price reforms."[36] These analyses were descriptive only, lacked comparisons of the change of launch proportion in Canada with other countries, or did not test the sensitivity of their results by using differing effective dates for the period of policy uncertainty. To address these limitations and provide additional evidence on the issue, we sought to examine empirically whether there was an early impact of the uncertainty around the implementation of drug price regulations or the expected price reduction on new medicine launches in Canada.

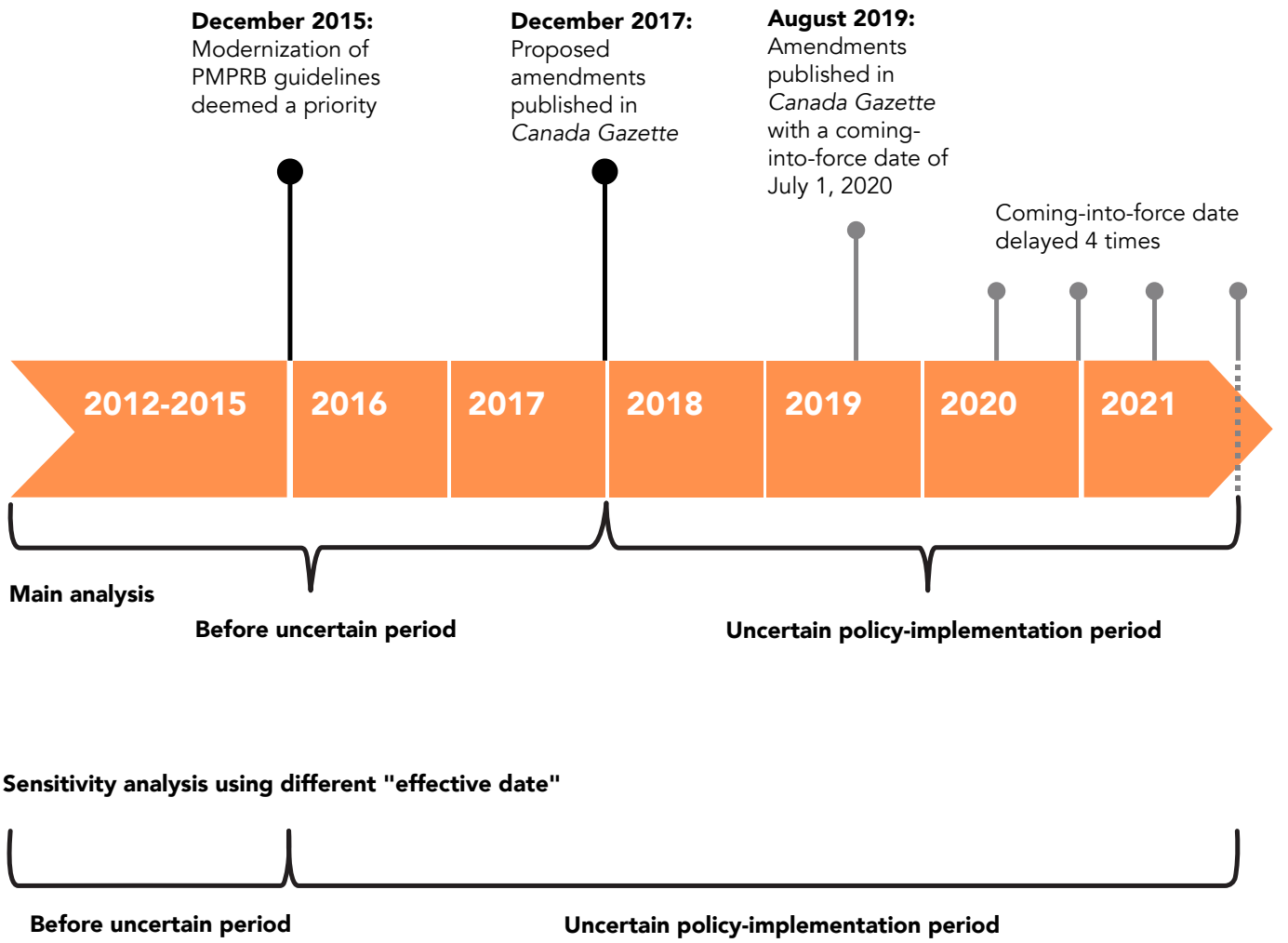

Figure 1. *The timeline of the Patented Medicine Prices Review Board (PMPRB) regulatory amendments. December 2017 is the "effective date" for the period of uncertain policy implementation in the main analyses; December 2015 is the "effective date" in sensitivity analyses.*

Methods

We conducted a retrospective cohort study of new patented medicines launched (i.e., sold) in 2012–2021 in 14 countries, that is, the combination of PMPRB7 and PMPRB11 (Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, Switzerland, the UK, and the US) and Canada. We reported the study according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.[37]

Although the PMPRB announced its intention of changing the regulatory framework in December 2015,[11] it is unclear when pharmaceutical companies decided to act or whether they did at all. With the detailed changes published in December 2017,[12] pharmaceutical companies could better estimate the expected price changes for new medicines and take corresponding actions (***Figure 1***). We therefore selected December 2017 as the "effective" date that pharmaceutical companies were initially exposed to the policy implementation uncertainty ("uncertain period," 2018–2021). We considered December 2015 as an alternative effective date in sensitivity analyses.

Data source

Sales data from the IQVIA MIDAS database (formerly IMS) provide sales values and volumes of pharmaceutical products based on detailed audits of the pharmaceutical market through retail and nonretail channels in a corresponding country.[38–40] The core data elements include product name, manufacturer, pack form, strength, and size. MIDAS sales data have been

widely used to investigate sales, prices, and launches across countries[5,22–26,28,41,42] and by PMPRB in their annual reports,[2] Meds Entry Watch reports,[43,44] existing guidelines,[45] and research webinars related to their proposed guidelines.[32,46,47] ***Appendix 2*** (available here) provides more description on IQVIA MIDAS sales data.

Study sample

Our study sample comprised all molecules that were "new active substances" and "innovative branded products" categorized in IQVIA MIDAS sales data in the 14 countries in 2012–2021. Innovative branded products included original branded products (manufactured or marketed by the originator), licensed branded products (manufactured or marketed by an official licensee), or other branded products with a known patent protection expiry date.

Outcomes

The launch date for each molecule in a specific country was determined by its first sale date, as recorded in the IQVIA MIDAS quarterly sales data. The global first launch date was the first sale date in the 14 countries. The main outcome was whether a new molecule was launched in a specific country within 2 years of its global first launch (2-yr launch). We chose a 2-year period because previous studies and our own data have suggested a median time to launch longer than 1 year and a low proportion of domestic launches within 1 year after global launch, in most of our study countries including Canada.[24,43,44,48] Our rationale is outlined in ***Appendix 3***, available here.

Variables

We considered variables found to be associated with drug launches in the literature[22–26] as covariates and effect modifiers. Variables comprised the following:

- The first level of the World Health Organization Anatomical Therapeutic Chemical (ATC) classification system, which has 14 main anatomical or pharmacologic groups[49] (each group was considered as a separate category; any groups including ≤ 5 molecules in any policy period were combined into the "other ATC" category);
- The number of comparators in Canada (the number of molecules within the same ATC fourth-level chemical, pharmacologic, or therapeutic subgroup that were sold in Canada in the quarter of the global first launch) to indicate the availability of drugs for therapeutic class comparison test conducted by PMPRB and the potential therapeutic advance in Canada (0, 1–4, and > 4);[45,50]
- High price defined as whether the average price per standard unit of the first globally launched molecule within the first year was in the top 10% among all existing innovative branded molecules in the corresponding launching country and time; and
- The first-year sales in the US (defined as 0 if the molecule was not launched in the US) inflated to 2021 US dollars using the Consumer Price Index (> $20 million v. ≤ $20 million, a cutoff value close to the overall median).[51]

Detailed definitions and rationales for these variables are presented in ***Appendix 4***, available here.

We rated each molecule's therapeutic benefit, using the evaluations, if available, by the PMPRB,[2,45] the Institute for Quality and Efficiency in Health Care (IQWiG),[52] and the independent French medicine bulletin *Prescrire International*.[53,54] As Lexchin did in previous assessments,[36,55] we grouped the ratings of therapeutic benefit into 3 categories: major, moderate, and little to no benefit. If more than 1 of these organizations rated a molecule, we used the highest rating.[36,55] The molecules without ratings from the 3 organizations were rated as major if they were designated as breakthrough therapies by the US Food and Drug Administration (FDA).[56] More details are presented in ***Appendix 5***, available here.

Statistical analysis

Our main analyses focused on the comparisons of Canada versus the US, and Canada versus the "other-countries" group that excluded the US.

We conducted interrupted time series analyses with a control (US or other countries) to compare the outcome in the 2 periods: uncertain period after publication of the proposed amendments (2018–2021) versus before the uncertain period (2012–2017). We used an autoregressive model with maximum likelihood estimation method for the analyses. We then used a bootstrapping approach with 5000 iterations to estimate the confidence interval (CI) of the expected absolute change (predicted – counterfactual) in 2-year launch proportion in Canada and the control, and the difference between the expected absolute changes in Canada and the control.[57] ***Appendix 6*** (available here) includes model specification and more details on the analyses.

We further applied a logistic regression by including periods, countries (v. Canada), interaction between countries and periods, and the covariates listed above except for the therapeutic benefit rating because of missing data. We used generalized estimating equation logistic regressions to account for the possible correlation between outcomes from the same molecule. Subgroup analyses were conducted to examine the modifying impact of those covariates.

Sensitivity analyses

As a sensitivity analysis, we used the proxy measures of first-inclass status and priority review status of FDA approvals[58] to impute the molecules with missing therapeutic benefit ratings. We also reanalyzed our data using December 2015 as the effective date (uncertain period 2016–2021). Additionally, we conducted the comparisons of Canada versus each country and examined the impact on 1-year launch among all study samples.

All of our analyses were performed using SAS version 9.4 (TS1M6) (SAS Institute). We interpreted our results at a p value of less than 0.05 and emphasized practical importance for molecules with major benefit.

Ethics approval

Ethics approval was not required for this study.

Results

Our cohort included 349 new molecules launched in the 14 countries (242 first launched globally before the uncertain period and 107 during the uncertain period). Correspondingly, 45.0% and 30.8% of these molecules were launched in Canada, 81.4% and 82.2% in the US, and 83.9% and 70.1% in the other-countries group. The characteristics of these molecules are presented in ***Table 1***. The number of launches by country, launch window (1 yr v. 2 yr), and policy period are presented in ***Appendix 3, Table S1***.

Figure 2 presents the observed quarterly 2-year launch proportion and the predicted proportion from the interrupted time series analysis models (***Appendix 6***, ***Table S2***). The difference between the expected absolute changes in Canada and the US was estimated to be –0.066 (95% CI –0.30 to 0.15) and the difference between Canada and the other-countries group was –0.028 (95% CI –0.25 to 0.21) (***Appendix Table S3***).

The coefficient of the interaction term of comparison country and the uncertain period variables in the logistic regressions indicates the difference between the changes of log odds of launching during the uncertain period (v. before) in the comparison country and in Canada (***Table 2*** and ***Appendix 6, Table S4***). The interaction term when comparing the US to Canada (coefficient 0.75, standard error [SE] 0.42; p = 0.08) and when comparing the other-countries group to Canada (coefficient –0.28, SE 0.36; p = 0.4) suggested no difference in the change of log odds of launching in the 2 periods in Canada compared with the US or other-countries group. Similar findings were observed among all the subgroups (***Appendix 6, Tables S5–S7***).

A total of 244 molecules were rated for their therapeutic value. The 2-year launch proportion for molecules with major benefit decreased from 45.8% to 31.3% in Canada during the uncertain period compared with before the uncertain period, and from 87.5% to 62.5% in the other-countries group but increased from 91.7% to 100% in the US (***Table 3***). Among molecules with moderate benefit, the launch proportion decreased in all countries: before and during the uncertain period, 93.3% and 83.3% were launched in the US, 97.8% and 91.7% in the other-countries group, and 75.6% and 66.7% in Canada, respectively. The proportion for molecules with little to no benefit decreased in Canada and other countries but increased in the US. The logistic regressions could not be estimated because of the small samples in most of the subgroups (e.g., no nonlaunches in the US after 2017 for molecules with major benefit [***Table 3*** and ***Appendix 6, Table S8***]).

Sensitivity analyses

When using December 2015 as the effective date (i.e., the uncertain period was defined as 2016–2021), the 2-year launch proportion by therapeutic value showed a similar trend except that the proportion for molecules with moderate benefit increased in Canada but decreased in the US and the other-countries group (***Table 3***). The coefficient of the interaction term of the country and period variables (3.79 [SE 1.66]; p = 0.02) when comparing the US with Canada suggested that changes in log odds of launching molecules with major benefit after 2015 were different between the 2 countries (***Appendix 6, Table S8***). However, after further imputing missing ratings using proxy measures,no detectable difference was observed between the change in Canada and the change in the

Variable	No. (%) of molecules				
		Main analysis		Sensitivity analysis	
	Overall n = 349	Before uncertain period (2012-2017) n=242	Uncertain period after 2017 n = 107	Before uncertain period (2012-2015) n=162	Uncertain period after 2015 n = 187
No. of comparators in Canada*					
0	46 (13.2)	31 (12.8)	15 (14.0)	26 (16.0)	20 (10.7)
1–4	209 (59.9)	148 (61.2)	61 (57.0)	103 (63.6)	106 (56.7)
> 4	94 (26.9)	63 (26.0)	31 (29.0)	33 (20.4)	61 (32.6)
High price (in the top 10%)					
Yes	91 (26.1)	67 (27.7)	24 (22.4)	43 (26.5)	48 (25.7)
No	258 (73.9)	175 (72.3)	83 (77.6)	119 (73.5)	139 (74.3)
First-year sales in the US					
> $20 million	187 (53.6)	137 (56.6)	50 (46.7)	92 (56.8)	95 (50.8)
≤ $20 million	162 (46.4)	105 (43.4)	57 (53.3)	70 (43.2)	92 (49.2)
ATC classification first level					
B: Blood and blood forming organs	22 (6.3)	12 (5.0)	10 (9.3)	8 (4.9)	14 (7.5)
J: Antiinfectives for systemic use	55 (15.8)	40 (16.5)	15 (14.0)	24 (14.8)	31 (16.6)
L: Antineoplastic and immunomodulating agents	117 (33.5)	75 (31.0)	42 (39.3)	50 (30.9)	67 (35.8)
N: Nervous system	28 (8.0)	15 (6.2)	13 (12.1)	8 (4.9)	20 (10.7)
Other ATC	127 (36.4)	100 (41.3)	27 (25.2)	72 (44.4)	55 (29.4)
A: Alimentary tract and metabolism	53 (15.2)	48 (19.8)	5 (4.7)	35 (21.6)	18 (9.6)
C: Cardiovascular system	11 (3.2)	8 (3.3)	3 (2.8)	8(4.9)	3 (1.6)
D: Dermatologicals	10 (2.9)	8 (3.3)	2 (1.9)	4 (2.5)	6 (3.2)
G: Genitourinary system and sex hormones	4 (1.1)	2 (0.8)	2 (1.9)	2 (1.2)	2 (1.1)
H: Systemic hormonal preparations, excluding sex hormones and insulins	5 (1.4)	3 (1.2)	2 (1.9)	1 (0.6)	4 (2.1)
M: Musculo-skeletal system	10 (2.9)	6 (2.5)	4 (3.7)	2 (1.2)	8(4.3)
P: Antiparasitic products, insecticides and repellents	1 (0.3)		1 (0.9)		1(0.5)
R: Respiratory system	17 (4.9)	14 (5.8)	3 (2.8)	11 (6.8)	6 (3.2)
S: Sensory organs	8 (2.3)	4 (1.7)	4 (3.7)	2 (1.2)	6 (3.2)
V: Various	8 (2.3)	7 (2.9)	1 (0.9)	7 (4.3)	1 (0.5)

Table 1. *Characteristics of molecules included for 2-year launch.*

Abbreviations: ***ATC:*** *Anatomical Therapeutic Chemical.*
*******The molecules in the same ATC fourth level that were sold in Canada in the quarter after the global first launch.*

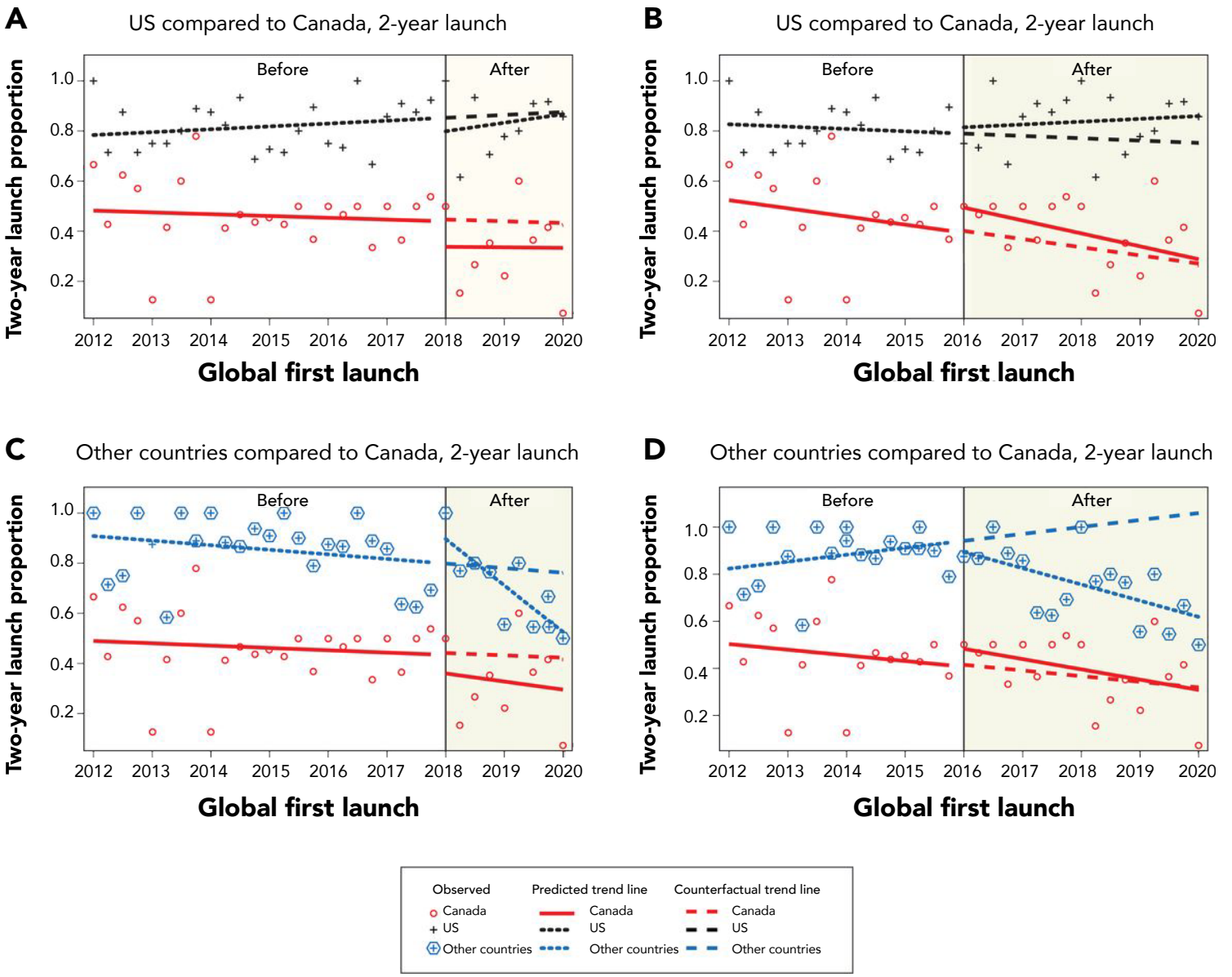

Figure 2. *Observed and predicted quarterly 2-year launch proportion of new molecules in the United States (A and B) and other countries (C and D) compared with Canada. The period of uncertainty starts in 2018 in parts A and C and in 2016 in parts B and D. Two-year launch proportion indicates the proportion of new molecules launched in a specific country or a group of countries within 2 years of their global first launch. The other-countries group includes Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, Switzerland, and the United Kingdom. The counterfactual trend line is an extrapolation of the trend line before the uncertain period, representing what would have occurred had the policy uncertainty not happened.*

US or the other-countries group for each therapeutic benefit subgroup (***Appendix 6, Tables S8*** and ***S9***).

We observed some differences in the logistic regression results among subgroups when using December 2015 as the effective date, compared with our results using December 2017. The coefficient of the interaction term between country and uncertain period was –0.81 (SE 0.40; p = 0.045) for the subgroup with price not in the top 10% and –1.07 (SE 0.45; p = 0.02) for the subgroup with first-year US sales greater than $20 million, suggesting that the decrease of the log odds of launching these molecules in the other-countries group was greater than in Canada (***Appendix 6, Table S7***).

Compared with the 2-year launch analyses, the analysis of log odds of 1-year launching also suggested no detectable differences when comparing the US and the other-countries group with Canada (***Table 2***).

Appendix 6, Table S4 presents the logistic regression results for 2-year launch by comparing each specific country with Canada. The coefficients

	Two-year launch				One-year launch			
	US		Other countries		US		Others countries	
Model parameters* (models in which December 2017 was used as the effective date)	**Coefficient ± SE**	**p value**	**Coefficient ± SE**	**p value**	**Coefficient ± SE**	**p value**	**Coefficient ± SE**	**p value**
Uncertain period after 2017	-0.59±0.30	0.05	-0.48±0.26	0.06	-0.04±0.28	0.9	-0.10±0.25	0.7
Before uncertain period (2012-2017)	Ref.		Ref.		Ref.		Ref.	
Comparison country	2.29±0.22	<0.001	2.21±0.23	< 0.001	2.91± 0.24	< 0.001	2.29±0.19	< 0.001
Canada	Ref.		Ref.		Ref.		Ref.	
Comparison country x Uncertain period†	0.75±0.42	0.08	-0.28±0.36	0.4	0.47± 0.37	0.2	-0.29±0.31	0.4
Comparison country x Before Uncertain period†	Ref.		Ref.		Ref.		Ref.	

	Two-year launch				One-year launch			
	US		Others countries		US		Other countries	
Model parameters* (models in which December 2015 was used as the effective date)	**Coefficient ± SE**	**p value**	**Coefficient ± SE**	**p value**	**Coefficient ± SE**	**p value**	**Coefficient ± SE**	**p value**
Uncertain period after 2015	-0.30 ± 0.27	0.3	-0.20 ± 0.23	0.4	-0.02 ± 0.26	0.9	-0.04 ± 0.24	0.9
Before uncertain period (2012-2015)	Ref.		Ref.		Ref.		Ref.	
Comparison country	2.26 ± 0.27	< 0.001	2.45 ± 0.28	<0.001	2.84 ± 0.28	< 0.001	2.41 ± 0.25	< 0.001
Canada	Ref.		Ref.		Ref.		Ref.	
Comparison country x Uncertain periodt	0.49 ± 0.36	0.2	-0.59 ± 0.35	0.09	0.43 ± 0.35	0.2	-0.39 ± 0.31	0.2
Comparison country > Before uncertain period†	Ref.		Ref.		Ref.		Ref.	

Table 2. *The impact of the uncertain-policy period on log odds of launching in the United States and other countries compared with Canada in main and sensitivity analyses.*

Notes: *Other countries = Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, Switzerland, and the United Kingdom.*

Abbreviations: Ref.: *reference category,* ***SE:*** *standard error.*

**Generalized estimating equation logistic regression adjusted for the first level of Anatomical Therapeutic Chemical, number of comparators in Canada, high price, and first-year sales in the US. The first row indicates the difference in log odds of launching between the uncertain period and before the uncertain period in Canada; the third row indicates the difference in log odds of launching between the comparison country and Canada before the uncertain period; the fifth row indicates the difference between the change of the log odds of launching during the uncertain period (v. before) in the comparison country and that in Canada.*

†The multiplication sign indicates an interaction term.

	No. (%)											
	Before uncertain period (2012-2017) n = 242				Uncertain period after 2017 n = 107				US v. Canada†		Other countries v. Canada†	
Therapeutic benefit rating*	Total	Canada	US	Other countries	Total	Canada	US	Other countries	Coefficient ± SE	*p* value	Coefficient ± SE	*p* value
Overall	242	109 (45.0)	197 (81.4)	203 (83.9)	107	33 (30.8)	88 (82.2)	75 (70.1)	0.75 ± 0.42	0.08	-0.28 ± 0.36	0.4
Major	24	11 (45.8)	22 (91.7)	21 (87.5)	16	5 (31.3)	16 (100)	10 (62.5)	NA	NA	-0.88 ± 1.24	0.5
Moderate	45	34 (75.6)	42 (93.3)	44 (97.8)	12	8 (66.7)	10 (83.3)	11 (91.7)	NA	NA	NA	NA
Little to no	107	60 (56.1)	95 (88.8)	96 (89.7)	40	20 (50)	40 (100)	33 (82.5)	NA	NA	-0.48 ± 0.70	0.5
Missing rating	66	4 (6.1)	38 (57.6)	42 (63.6)	39	0 (0)	22 (56.4)	21 (53.8)	NA	NA	NA	NA
	Before uncertain period (2012-2015) *n* = 162				Uncertain period after 2015 *n* = 187							
Overall	162	72 (44.4)	131 (80.9)	140 (86.4)	187	70 (37.4)	154 (82.4)	138 (73.8)	0.49 ± 0.36	0.2	-0.59 ± 0.35	0.09
Major	13	7 (53.8)	12 (92.3)	13 (100)	27	9 (33.3)	26 (96.3)	18 (66.7)	3.79 ± 1.66	0.02	NA	NA
Moderate	34	24 (70.6)	32 (94.1)	33 (97.1)	23	18 (78.3)	20 (87.0)	22 (95.7)	NA	NA	NA	NA
Little to no	71	39 (54.9)	63 (88.7)	63 (88.7)	76	41 (53.9)	72 (94.7)	66 (86.8)	1.17 ± 0.73	0.1	-0.09 ± 0.65	0.9
Missing rating	44	2 (4.5)	24 (54.5)	31 (70.5)	61	2 (3.3)	36 (59.0)	32 (52.5)	-0.42 ± 1.19	0.7	-0.51 ± 1.17	0.7

Table 3. *Number and proportion of new molecules launched within 2 years of their global first launch by country, policy period, and therapeutic benefit.*

Abbreviations: NA: *not applicable (regressions could not be estimated owing to small samples and sparseness),* ***SE:*** *standard error.*

*****First based on the highest rating from the Patented Medicine Prices Review Board, the Institute for Quality and Efficiency in Health Care in Germany, and the independent French medicine bulletin Prescrire International, and then the breakthrough therapy designation by the Center for Drug Evaluation and Research of the US Food and Drug Administration.*

†*Coefficient and standard error for the interaction term in the generalized estimating equation logistic regression, including uncertain period, comparison country, and interaction between uncertain period and comparison country, adjusted for the first level of Anatomical Therapeutic Chemical, number of comparators in Canada, high price, and first-year sales in the US.*

of the interaction terms suggested greater decreases in Norway (–0.69, SE 0.31; p = 0.03) and Sweden (–0.63, SE 0.29; p = 0.03) than in Canada. The findings from main and sensitivity analyses comparing the US and the other-countries group with Canada are summarized in ***Table 4.***

Interpretation

All analyses showed similar changes or even greater decreases in 2-year or 1-year launch after policy-uncertainty effective date in the other 12 comparator countries as a whole and in Norway and Sweden, compared with Canada. Almost all analyses showed similar changes in launches in the US and Canada. These findings suggest no important negative impact on launch from the policy uncertainty in Canada.

However, an exception was observed among new molecules with major benefit. When we used our main analytic approach, the 2-year launch proportion appeared to decrease substantially in both Canada and the other-countries group after the 2017 effective date but increased in the US. The logistic regression results also suggested a detectable difference in launches

	Uncertain period after 2015		Uncertain period after 2017	
Analysis	**US**	**Other countries**	**US**	**Other countries**
Interrupted time series: 2-year launch*	No	No	No	No
GEE logistic regression: 2-year launch†	No	No	No	No
Subgroups: 2-year launch†				
ATC: Blood and blood forming organs	NA	No	NA	NA
ATC: Antiinfectives for systemic use	No	No	No	No
ATC: Antineoplastic and immunomodulating agents	No	No	No	No
ATC: nervous system	No	No	No	
Other ATC	No	No	No	No
No. of comparators: 0	No	No	No	No
No. of comparators: 1-4	No	No	No	No
No. of comparators: > 4	No	No	No	No
High price in the top 10%	No	No	No	No
Price not in the top 10%	No	No	No	More launches in Canada
First-year sales in US> $20 million	No	No	No	More launches in Canada
First-year sales in US < $20 million	No	No	No	No
Major therapeutic benefit	NA	No	Fewer launches in Canada	No
Moderate therapeutic benefit	NA	NA	NA	NA
Little to no therapeutic benefit	NA	No	No	No
Imputed therapeutic benefit rating‡				
Major therapeutic benefit	No	No	No	No
Moderate therapeutic benefit	No	NA	No	NA
Little to no therapeutic benefit	NA	No	No	No
GEE logistic regression: 1-year launch†	No	No	No	No

Table 4. *Result summary by uncertain period, comparison country, and analysis method.*

Abbreviations: ATC: *Anatomical Therapeutic Chemical,* ***GEE logistic regression:*** *generalized estimating equation logistic regression adjusted for the first level of ATC, number of comparators in Canada, high price, and first-year sales in the US,* ***NA:*** *not applicable (regressions could not be estimated owing to small samples and sparseness),* ***No:*** *no detectable difference between Canada and the comparison countries.*

*****Based on the 95% confidence interval of the difference between expected absolute changes over policy periods in Canada and the comparison country.*

†*Based on p value < 0.05 for the coefficient of the interaction term of comparison country and uncertain period in the GEE logistic regression; fewer launches: the decrease of the log odds of launching in Canada was larger; more launches: the decrease of the log odds of launching in Canada was smaller.*

‡*Further imputed by the designation of first-in-class and priority review by the US Food and Drug Administration.*

comparing Canada and the US, using 2015 as the effective date. Despite these observed differences, we were unable to test the difference statistically using logistic regression when we used 2017 as the effective date, because of the 100% launch proportion in the US after 2017.

The observed potential early impact of the policy uncertainty on the 2-year launch for molecules with major benefit in our study mainly depended on the country with which Canada was compared. The US is no longer considered as a comparator country by PMPRB because it does not have effective policies to constrain medicine prices.[13] We chose to include the US as a comparator because patients and health care providers in Canada are more likely to be aware of the availability of new medicines in the US (v. in other countries) and may wonder why certain medicines are available in the US but not in Canada.

Only Lexchin has compared the launching trend in Canada with another country and assessed the therapeutic value of the molecules that were not launched in Canada.[6,36] One of these studies found that the annual proportion of submissions to Health Canada among the drugs approved by the US FDA decreased from 2014 to 2021 but that this decrease was not different before and after 2017.[36] However, Lexchin did not compare the change before and after the publication of the proposed amendments in Canada with the change in other countries.[36] A separate study showed the same declining trend in Australia from 2011 to 2020 but did not compare the difference before and after 2017.[6]

Compared with previous studies, we found a greater number of medicines with major or moderate benefit that were not launched in Canada, during a similar period. Among the 117 medicines that were not launched in Canada after 2015 (i.e., 2016–2021) in our study, 18 were rated as having major benefit and 5 as moderate benefit. Gaudette and colleagues found only 1 medicine with nonquantifiable added benefit, which was considered as little to no benefit in our study, out of 75 medicines that were not submitted to Health Canada from 2016 to February 2023.[5] Of 116 medicines not submitted to Health Canada in 2014–2021, Lexchin found 4 with major benefit and 2 with moderate benefit.[36] These differences could be attributed to different therapeutic rating approaches: IQWiG used by Gaudette and colleagues; IQWiG and *Prescrire International* used by Lexchin; and PMPRB, IQWiG, *Prescrire International* and FDA breakthrough therapy designation (if required) used in our study. Both previous studies focused on medicines approved by the FDA or the European Medicines Agency (EMA). We chose to use the first sale date to define the launch consistently across the 14 countries using IQVIA MIDAS data, which reflected the timing and speed of both approval and actual marketing. Furthermore, we compared the proportion of medicines launched in Canada with the US and other countries by therapeutic benefit ratings, which was not done in the previous studies.

Limitations

One limitation of our study is that we did not assess time to launch or launch lag because of the short observation periods. Instead, we assessed the launches in Canada within 2 years and 1 year of global first launch, a coarser measure of the launch speed. We also could not conduct some subgroup analyses because of the small number of launches or nonlaunches in each subgroup and in some individual countries.

Samples were small, particularly in subgroup analyses, which may have decreased our ability to detect an impact of the policy uncertainty. The many subgroup analyses conducted increased the likelihood that some of the differences we found might have been due to chance. Had we used a significance level of a p value less than 0.1, logistic regression results would have suggested that the decrease in 2-year launch in Canada tended to be greater than in the US and France among all samples, and in the US among the subgroups with nervous system ATC, 1–4 or more than 4 comparators, price not in the top 10%, first-year US sales $20 million or lower, or drugs that conferred little to no benefit (***Appendix 6, Table S10***). The decrease in 2-year launch in Canada might be smaller than in the other 12 countries as a group.

Our results could be affected by unobserved or unmeasured factors. The COVID-19 pandemic may have had an impact on the launch decision or submission for market approval by pharmaceutical companies, market approval time by regulatory agencies, and time from market approval to sales,[59] which could be associated with fewer launches. It is also possible that in an effort to dissuade the government or PMPRB from following through with the proposed regulatory amendments, industry followed through on its claim[6,60,61] and did not launch medicines

in Canada, which might lead to the observed reduction in launches during our study period. Furthermore, some policies or changes in the comparator countries could have affected their drug launches. For example, the implemented *21st Century Cures Act* in December 2016 enables the US FDA to modernize clinical trial designs including the use of real-world evidence, which could speed the review of novel medical products.[62] The share of orphan drugs among new approvals by the US FDA, EMA, or Health Canada increased from an average of 33% in 2009–2014[43] to 47% in 2016–2021.[44] Special health technology assessment or reimbursement considerations are applied for orphan drugs in some countries such as Canada, Germany, the Netherlands, Sweden, and the UK.[63–65] The Netherlands implemented a "lock" system in 2015 that could postpone the reimbursement of new medicines with disproportionately high costs per treatment or a high budget impact.[66] To minimize the potential confounding effect, we applied a quasi-experimental design using the US and other countries as the comparison group. However, our estimates could be biased if the impact of the COVID-19 pandemic or other unmeasured confounders differed by country.

Conclusion

The PMPRB's regulatory amendment process created a period during which pricing policies in Canada were highly uncertain. No negative impact of this uncertainty on new patented medicine launches in Canada was observed when comparing Canada with all other countries, except for medicines with major therapeutic benefit. The observed reduction in launch proportion for new medicines with major therapeutic benefit in Canada and other countries but not in the US requires close monitoring and further investigation.

Competing interests: Wei Zhang is leading a project funded through a grant-in-aid received by the University of British Columbia (fund recipient) from Pfizer Canada. Wei Zhang is not the fund recipient, and this project is not related to the topic of the paper. No other competing interests were declared.

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Requests for data can be sent to IQVIA Canada.

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Disclaimer: This article is based on internal analysis by the authors using IQVIA MIDAS quarterly sales data for 2012–2021, which were obtained under licence from IQVIA and reflect estimates of marketplace activity. Copyright IQVIA. All rights reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not necessarily those of IQVIA.

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Information on the Latest Drug Approvals and Reimbursement Milestones

Arcutis Canada's submission for **Roflumilast Cream** 0.15% was accepted for review by Health Canada for the treatment of atopic dermatitis in adults and children 6 Years of age and older.

EMPAVELI™ (pegcetacoplan) has obtained formulary listing in Ontario. This significant milestone follows the recent provincial formulary listings received in Quebec, British Columbia and Alberta.

Paladin Labs announces the approval of **WAKIX® (pitolisant hydrochloride tablets)** for use in pediatric patients in Canada.

Health Canada grants approval of the Eye-Tracking Neurological Assessment for Multiple Sclerosis **(ETNA™-MS)**, developed **Novartis**, by for use in tracking disease progression in people living with MS.

Ferinject®, manufactured by **CSL Vifor**, is approved by Health Canada for the treatment of iron deficiency anemia in adult and pediatric patients and iron deficiency in adult patients with heart failure.

VELSIPITY™, developed by **Pfizer Canada**, receives Health Canada approval for adults with moderately to severely active ulcerative colitis**.**

TELUS Health 2024 Drug Trends Report: Diabetes medications maintain top reimbursed expense position; ADHD drugs surge.

Health Canada authorizes **Roche Canada's Tecentriq® SC (atezolizumab, solution for subcutaneous injection)**, the first cancer immunotherapy subcutaneous injection, for multiple cancer types.

Nora Pharma receives Health Canada approval for **Niopeg®**, a biosimilar of **Neulasta®.**

Health Canada Approves **KEYTRUDA®**, manufactured by **Merck Canada Inc.**, as a first-line treatment for adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Quebec's **INESSS** recommends **BEYFORTUS®**, developed by **Sanofi-Aventis Canada Inc.**, for the prevention of RSV for all infants 8 months of age and younger.

NURTEC ODT®, manufactured by **Pfizer Canada Inc.**, is now available in Canada for the treatment of acute migraine.

Health Canada approves **Novartis Pharmaceuticals Canada's Cosentyx®**, a biologic therapy, for the treatment of adults with moderate-to-severe hidradenitis suupurativa.

Pfizer Canada announces availability of **ABRYSVO™** in Canada for immunization of pregnant individuals and adults ≥ 60 years of age.

Takeda Canada Inc. concludes a letter of intent with the pan-Canadian Pharmaceutical Alliance for **LIVTENCITY®** (maribavir) for the treatment of adults with a post-transplant cytomegalovirus infection.

Health Canada approval for **APRETUDE (cabotegravir tablets and extended release injectable suspension)**, developed by **ViiV Healthcare**, for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV.

Health Canada approves **Merck Canada Inc.'s KEYTRUDA®** for adult patients with locally advanced unresectable or metastatic biliary tract carcinoma, in combination with gemcitabine-based chemotherapy.

QULIPTA™ (atogepant), maufactured by **AbbVie Canada**, is now approved by Health Canada for the preventive treatment of chronic migraine in adults.

Truqap™ (capivasertib), developed by **AstraZeneca Canada Inc.**, plus **fulvestrant** is now available in Canada.

Novo Nordisk Canada Inc.'s Wegovy® (semaglutide injection) is now available in Canada.

Health Canada authorizes **Lilly's Ebglyss™ (lebrikizumab)** for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older.

Takeda's HyQvia® is approved as replacement therapy for primary humoral immunodeficiency and secondary humoral immunodeficiency in pediatric patients 2 years of age and older.

Awiqli® the world's first once-weekly basal insulin, developed by **Novo Nordisk Canada Inc.**, is now available in Canada.

ZILBRYSQ™ (zilucoplan injection), developed by **UCB Canada Inc.**, is now approved for adults with generalized myasthenia gravis (gMG) in Canada.

CSL Behring announces positive reimbursement decision in Canada for **HEMGENIX® (etranacogene dezaparvovec)**, the first gene therapy for Hemophilia B.

Health Canada authorizes **Alecensaro® (alectinib)**, manufactured by **Hoffmann-La Roche Limited (Roche Canada)**, as the first and only adjuvant treatment for people with ALK-positive early-stage lung cancer.

Health Canada grants marketing authorization for **TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)**, developed by **Vertex Pharmaceuticals Canada Inc.**, for people with cystic fibrosis aged 2 years and older with certain rare mutations.

Health Canada approves **AstraZeneca Canada Inc.'s Tagrisso®** with the addition of chemotherapy for patients with EGFR-mutated advanced lung cancer.

Canadian Provinces and Territories commit to the health of older adults by broadening access to **PREVNAR 20**, manufactured by **Pfizer Canada.**

Health Canada authorizes **RYBREVANT® (amivantamab)**, developed by **Janssen Inc.**, in combination with **Carboplatin** and **Pemetrexed** as the only targeted first-line treatment approved for patients with non-small cell lung cancer with EGFR Exon 20 Insertion Mutations.

Kye Pharmaceuticals announces the availability of **QUILLIVANT® ER Chewable Tablets** for the treatment of children with ADHD.

Health Canada authorizes **Vabysmo® (faricimab injection)** developed by **Roche Canada** for the treatment of macular edema secondary to retinal vein occlusion.

Sanofi's Fluzone® High-Dose Quadrivalent vaccine remains preferentially recommended to protect adults 65 years of age and older against influenza.

Health Canada grants full approval to **Jemperli** developed by **GlaxoSmithKline Inc.** for the treatment of patients with recurrent or advanced dMMR/MSI-H endometrial cancer.

Roche Canada and the pan-Canadian Pharmaceutical Alliance (pCPA) successfully complete negotiations for **COLUMVI® (glofitamab for injection)** for the treatment of Diffuse Large B-cell Lymphoma.

Quebec's Committee on Immunization recommends the use of RSV vaccines, including **GlaxoSmithKline Inc.'s AREXVY**, for older adult populations at risk of severe outcomes.

AbbVie's EPKINLY™ receives first-ever time-limited reimbursement recommendation by Canada's Drug Agency.

Christine Lennon: From the Bench to the Boardroom

Christine Lennon, the general manager of Incyte Biosciences Canada, speaks about why lateral career moves can pay off, the secrets to start-up success, and why she has no regrets turning down a prestigious and perk-heavy job to build a biotech company from the ground up.

Can you tell us about your background?

I was born in Montreal to immigrant parents. My dad moved here from England and my mother was first-generation Ukrainian. I did my undergraduate degree in science at McGill University, where I met my husband. Then, I started working for Sandoz, which later merged with Ciba-Geigy to become Novartis. In those days, anybody who had an MBA was getting promotions. In the first five years of marriage, my husband and I both pursued MBAs, and had two daughters. We were living with milk crate furniture for a little while. But I was always drawn to health care and helping other people.

Now, as the general manager of Incyte, what are the traits that you look for when you're hiring?

Incyte Canada is only four years old. We're looking for people who are passionate, who don't mind rolling up their sleeves. Even as the general manager, I've been the coffee maker, the person trying to find an appropriate place for us to work during a pandemic, and the person filing drug submissions to Health Canada. I was recently speaking with an employee who is early in her career, who's brilliant, and has worked for a number of other companies in the past few years. I asked her what drew her to Incyte, and she said, "I don't want to have to stay within my narrow lane. In the future, I may want to move into another area, like market access for example, and at Incyte, I can get a taste of different career paths." We're trying to create a culture where people feel they can speak up if they see potential for improvement, and where people feel comfortable stepping outside of their roles. We're trying to create a culture where everyone is working together and supporting each other, like an orchestra.

> ***"We built the company from our kitchen tables. We had to find the people who can help us solve the challenges we've faced. It's still 100% "solve on."***

I love Incyte's slogan "Solve on" because that says people within the organization are focused on solving problems and thinking outside the box.

It's quite honestly the way we live. In a big organization, there's a department for every process and a designated person for each task. At Incyte, myself and some of the other initial employees in the organization had to find the people who could help us solve the challenges we've faced. We built the company from our kitchen tables. We've relied heavily on feedback from the clinician and patient community, as well as virtual calls with Incyte personnel in the U.S.A., Europe, and Japan. It still is 100% 'solve on'.

Incyte has two areas of focus in science and partnerships. One is hematology-oncology, including solid tumors. Another is inflammation and autoimmunity. Incyte Canada has 35 ongoing trials. Considering we're a company of 43 people, this shows we're very committed to R&D.

> ***I've made lateral moves to gain different kinds of experiences. My advice is to work at smaller companies and bigger companies, and to work in both early- and late-stage development. You want to do cross training around the boardroom table, so to speak.***

It's a brilliant strategy to involve local investigators early. What advice would you give to someone who wants to follow in your footsteps, and become a general manager of a biotech company?

My advice is to follow your passion. I had an opportunity at one point in my career to lead up corporate communications and investor relations for a major airline, and I had to make the hard decision to turn it down because I thought, I don't really know if I'm going to love that work, compared to being able to bring innovative treatment solutions to people. A mentor at the time advised me to think about, "What is going to get you up and going, not the first day or the second day, but years later?" He helped me think about what kind of company culture I was looking to work within. I really appreciated my mentor walking me through how they would go about the decision. My family was biased. They were already thinking of the trips they would book with the airline points that would have been included as a perk of the job.

Sometimes, I've had to make lateral moves to gain different kinds of experiences. I didn't have enough business development experience, so I took a lateral move, working for CDP Capital as an advisor, and, boy, I was drinking from a firehose. I learned so much. Those years of experience gave me the grounding I needed to be a VP of Business Development at Neurochem (now GSK). My advice is to work at smaller companies and bigger companies, and also to work in both early-and late-stage development. You want to do cross training around the boardroom table, so to speak. You don't have to be excellent at every aspect of the business. Rather, you should be able to appreciate the different points of view around the table.

Photo by the Centers for Disease Control and Prevention (CDC) on Unsplash

It seems like mentorship has played an important role in your career.

I've been in environments where companies match you with a mentor. I didn't always find that helpful. I appreciate mentors who don't tell me what to do but help me work through the problem. I've also had mentors where I've told, "This is the direction I would like to go in my career." They would then have their ears and eyes open and when they would hear of an opportunity, they would flag it for me. I enjoy mentoring others as well. People reach out to me

and say, "Can I ask you this question? Can you help me through this?" It's my pleasure to help.

In 2024, what advice would you give to Canadian companies at the early stage of commercial development on how they can raise capital and find success?

If the clinical results are unexpected, you need managers that can recognize when something isn't working, and pivot. Investigational drugs can fail in the pipeline. That doesn't mean that you can't bring forward a different version of the product.

It's also important to seek very clear strategic direction from your investors. What are they looking for? What milestones are they expecting, in which time frames? You want to make sure the goals are aligned between the investors and the developers.

You also want to make sure you know what you'll do when it's clear that a drug is effective. Some companies don't have experience commercializing a drug, so they may need a strategic partner to facilitate phase 3 trials. In the later-stage setting, getting feedback is key. You may think you have an exceptional therapy, but patients and clinicians can help you deliver an even better product or find a more optimal market.

You raise excellent points, about the importance of being nimble and goal alignment. Some investors are looking to cash in after that phase 1 or phase 2 or proof of concept and others are committed for the long-term. Can you tell us about some start-up successes that you've followed in your previous role in the venture capital space?

Clementia Pharmaceuticals is one success story, in which I was involved with when I was helping one of the venture capital groups that were early backers of Clementia. Clarissa Desjardins was working at Montreal Heart Institute, when a drug was shelved because it didn't have the results a major company was seeking in the cardiovascular setting. She recognized that the drug had benefits in a rare disease, Fibrodysplasia ossificans progressiva (FOP), which causes children's connective tissue to turn into bone. She approached the Business Development Bank of Canada, and said, "I really believe in this, but in order to license it, I need money." Her company, Clementia, went on to transform the treatment for FOP, and was purchased by Ipsen in 2019. The success of Clementia demonstrates that innovations can be repurposed.

There have been many cases of serendipitous discovery, where scientists notice that a drug has a different effect than they were expecting. With cyclosporin, scientists at Sandoz were hoping it would be effective as an antibacterial drug. When it failed in this regard, the company was keen to abandon the project. But scientist Jean-Francois Borel was passionate about developing the molecule, because, in early studies, he noticed the drug had immunosuppressive properties. His determination to bring cyclosporin to market eventually ushered in a new era of solid organ and bone marrow transplantation. There are many great stories of people who just wouldn't take "no" for an answer, and as a result, they changed the lives of countless patients.

"There are many great stories of people who just wouldn't take "no" for an answer, and as a result, they changed the lives of countless patients."

Speaking of advocating to bring innovative therapies to patients, I'd love to hear your perspective on how we can get therapies to patients sooner in Canada.

We need Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH; now known as Canada Drug Agency), Institut National d'Excellence en Santé et Services Sociaux (INESSS), and the pan-Canadian Pharmaceutical Alliance (pCPA), to sit together with the various patient associations, and find ways to move away from the sequential process, where each agency must complete its review process before the next one can start. Expediting the approval and reimbursement process not only helps existing best-in-class therapies get to patients, it also

encourages further investment into drug development. We can learn from the many countries that are getting life-saving innovations to patients much more quickly than Canada.

Canada represents about 2% of the global market. The reality is that, within the Canadian operations of global pharmaceutical companies, we compete with countries around the world for resources. If we don't enable the conditions for Canadian research and development, with tax credits, fair regulatory approval processes, and other policies, the pharmaceutical industry will invest far fewer resources in Canada.

No discussion on healthcare would be complete these days if we didn't talk about the potential applications for AI and healthcare. What use cases for AI in healthcare most interest you?

Drug discovery is a big area, and there's a lot of potential in data mining previously completed clinical trials. AI could also help organizations to data mine and analyze patient support programs for therapeutic insights. For patients, AI can play a role in providing access to medical information in a timely fashion, in their own language. I don't think AI on its own will always be 100% accurate, so we do have to make sure it's incorporated in a legal, ethical, and safe way. But to the extent we can expedite therapeutic development and expedite health technology assessments, yeah, let's bring it on.

My last question: If you could have dinner with any 3 people,who would be at your table?

Unfortunately, we lost our mom 13 years ago to sarcoma. She was quite young at the time. We recently lost our dad, after a long battle with colorectal cancer. We found the letters they wrote each other when they were dating, and discovered things we didn't know. I would like to ask them more questions and learn a bit more about their life and why they made the decisions they did. It would be fun for me to know how they approached life when they were at my age. I would want my two grandmothers as well. My maternal grandmother came over from the Ukraine as a young woman on a ship and she didn't speak any English. I'd like to know, how did she manage? My paternal grandmother, who was of Irish descent, lost her mother very young. I didn't think of it as a child, but now I'd like to know what it was like to live through the First World War and Second World War. I think one of my projects one day will be to write up as much as I can about the family history for my own kids and their kids. I am more curious than ever about those journeys.

Christine Lennon, General Manager of Incyte Biosciences Canada

In April 2020, Christine became the first General Manager and employee for Incyte Biosciences Canada. Prior to Incyte, Christine was CEO of Epigene Therapeutics, a spinout of Neomed, now Admare Bioinnovations. Prior to that, she spent eight years with Novartis as Canadian Commercial Head, Solid Tumors/Rare Disorders; General Manager - Oncology, Novartis Ireland; Head of Policy, Market Access, Stakeholder Relations, Novartis Oncology Canada. Christine also held leadership roles with Neurochem, Shire (now Takeda), BioChem Pharma and with the National Research Council of Canada (NRC) Industrial Research Assistance Program. Christine has been an advisor to life sciences startups and an executive-in-residence and advisor to healthcare venture capital teams at Business Development Bank of Canada (now Amplitude Ventures) and at Caisse de Dépôt et Placement du Québec. Christine holds an MBA and BSc from McGill University and her Institute of Corporate Directors designation (ICD.D) from Rotman School of Management, University of Toronto. Christine serves as a judge and mentor for McGill's Dobson Centre for Entrepreneurship and McGill's Desautels MBA School. Christine is a McGill Scarlet Key Award Recipient and was named a Healthcare Businesswomen Association Luminary in 2022. Christine is a Board member of Montréal inVivo, Innovative Medicines Canada, Research Canada and Incyte Biosciences Canada.

Trusting an Experimental Therapy

Christopher Bunter's Journey to Health

Christopher Bunter, an Edmonton-based junior high school teacher and award-winning chef, was diagnosed with Crohn's disease in his 30s. By the time of his diagnosis, his health situation was so dire that he was close to requiring a colectomy – the surgical removal of his colon. He spoke to Hypothesis about his diagnostic journey, starting an experimental drug, and combating stigma around Crohn's disease.

When did you find out you had Crohn's disease?

In my 20s, I had a bout of abdominal pain and blood in my stool. I didn't get a diagnosis at that time, however, and my symptoms went away. But they came back again in my 30s. I saw my family doctor and he recognized the urgency of my symptoms and sent me to a gastroenterologist within 24 hours. The gastroenterologist did a colonoscopy and diagnosed me with Crohn's disease. After the test was done, the doctor explained that had I not sought care, I would have lost my colon within two to three weeks.

That would have completely changed my lifestyle and career path. At the time I was diagnosed, I had just begun to embark on a teaching career, after having worked for many years as a chef. It would have been difficult to be leading a classroom if I required the lifestyle adjustments and care required after a colectomy.

Photo by Nathan Dumlao on Unsplash

You were able to get into a clinical trial that gave you access to medication that has made a world of difference for you. But it must have been a bit daunting to try an experimental drug. What was it like to make that decision?

My gastroenterologist recommended the clinical trial to me, and I agreed because I had a great deal of trust in him. If I didn't opt for the experimental drug, the alternative treatment would have required me to get an injection every six weeks and take time off work for that. The alternative drug was also very expensive. For a teacher, taking time off work means writing plans for the substitute teacher and disrupting the class.

Around the same time I started the trial, I was dealing with another diagnosis, rheumatoid arthritis. On top of having to go to the bathroom numerous times a day, I was dealing with joint pain flare ups and taking steroids. The doctor explained that the experimental medication could treat the inflammation that was leading to both Crohn's and rheumatoid arthritis. At first, my symptoms didn't change. I suspect that I was in the placebo or low-dose group of the trial. We won't know for sure, because the trial was blinded. Then, I was moved into the 'open label' part of the trial, where everyone receives the active medication. Within two weeks of taking the medication in the open label study, everything was working as it should. I was able to taper off the steroids completely.

> ***"I'm a junior high school teacher. If it weren't for my treatment, I don't think I'd be able to do my job."***

That's great to hear. How are you doing now?

According to my last scope, everything seems to be in remission. I'm really fortunate. As a junior high school teacher, it would be very difficult for me to do my job if I was facing severe digestive symptoms. You can't just leave 30 kids in a classroom to go to the bathroom.

The role of the caregiver is often overlooked, but they're so vital in patients' day-to-day lives. Can you talk about the role that your family has played in your medical journey?

My wife has been a huge help. She's the type of person who wants to do as much research as she can. Afer my first scope, she was worried that my medical condition would drastically change our lives, but she stood by me every step of the way. She takes the time off work to come with me to appointments. Our son is three years old now and when he was younger, I was suffering

with Crohn's and rheumatoid arthritis flare ups. I wasn't able to help the way that a father should. She had to pick up all the slack and make sure that everyone was looked after. She would have to go out and get groceries and supplies and take our son with her because I couldn't take care of him at home alone when I was very sick.

> ***The symptoms of Crohn's can be embarrassing, but if we don't talk about it, people might not get the help they desperately need.***

You're an advocate for Crohn's patients and families. Can you tell us more about that?

When I was receiving the medication through the trial, I met other Crohn's patient online and in the community. They wanted to know about my experience on the drug. Based on my experience, they were excited when the drug was available on the market, and they could try it as well. Patients want to hear directly from their fellow patients – we intimately understand the burden of a disease. That's why I've raised awareness about the disease and the medication I'm taking. I've shared my story in informational videos. The symptoms of Crohn's can be embarrassing, but if we don't talk about it, people might not know about it, and they might not get the help they desperately need.

On a lighter note, I understand you entered a cooking contest where you were awarded the fourth best hamburger in the world. That's amazing!

That was something I pursued before my symptoms started, while I was still working as a chef. In 2017, my team won second in the burger category at the Canadian Food Championships, which qualified us to compete at the World Food Championships in Alabama. We were on a tight budget, so we had to package all the ingredients in a bag and fly to the airport. We were competing with other teams that had sponsors and brought equipment worth tens of thousands of dollars. But we believed in ourselves. We'd worked together for so long and had perfected our burger. Thanks to my medication, I get to enjoy making and eating the fourth-best burger in the world up to this present day.

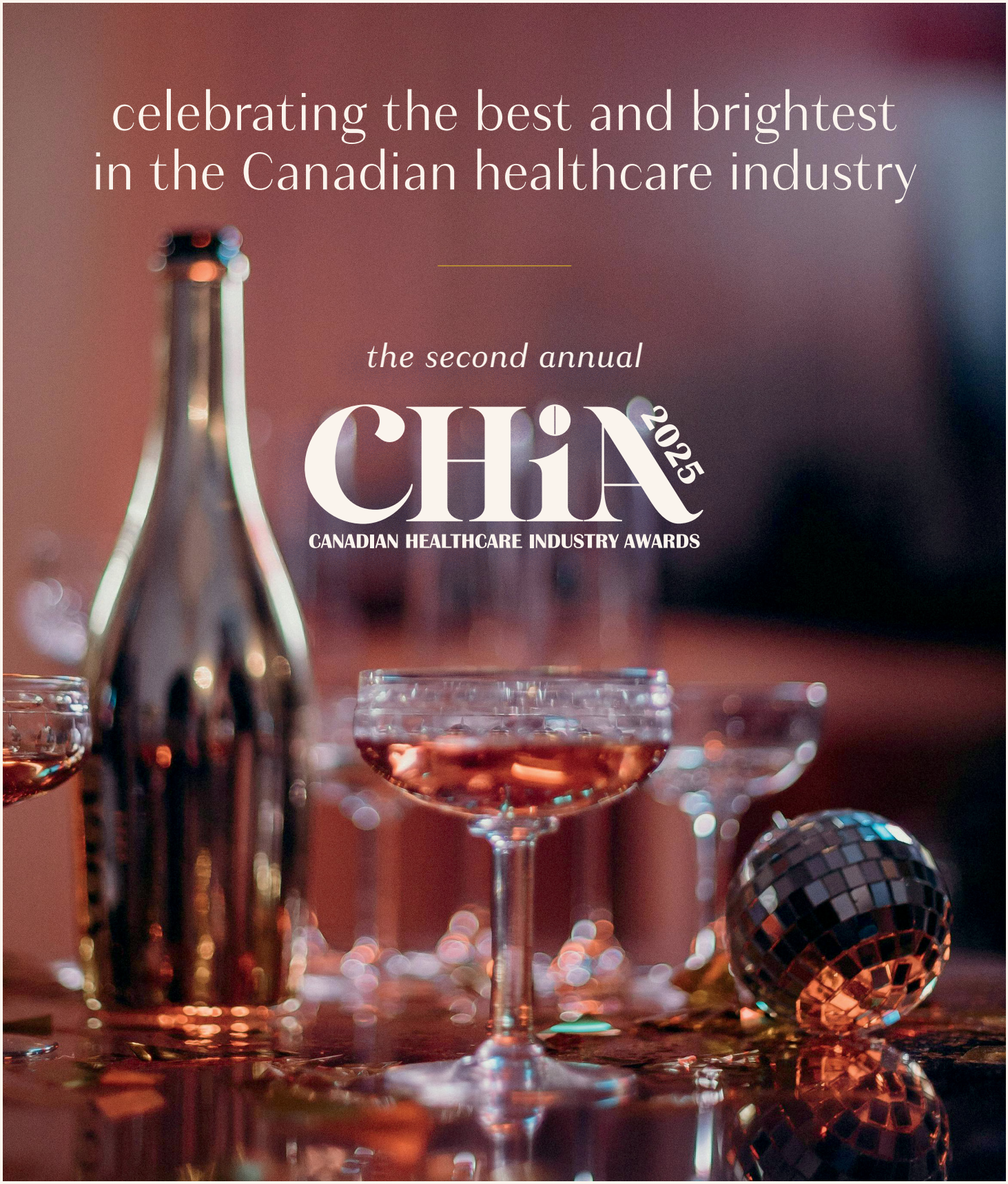
Christopher Bunter

crohn's colitis

About Crohn's and Colitis Canada

Fifty years ago, amid frustrations with the medical community's lack of answers to Crohn's disease and ulcerative colitis, a group of parents and loved ones came together, driven by a shared desire for answers, treatments and a better life for themselves and their loved ones to form a foundation. In 1974, Crohn's and Colitis Canada began. That grassroots movement marked the beginning of major contributions to the field of inflammatory bowel disease (IBD), funding groundbreaking research, valued support programs and pushing forward impactful advocacy efforts. Thanks to generous supporters like yourself, over $150 million has been raised to fund world-leading research over the last fifty years, transforming the field of IBD. For the 322,000 Canadians living with Crohn's disease and ulcerative colitis, your donation provides hope that they are not alone in their journey with inflammatory bowel disease (IBD). Donations to Crohn's and Colitis Canada enable research breakthroughs, program advancements and increased awareness of the challenges those affected by Crohn's and colitis face. Every project your donations help fund ensures more Canadians can access the answers and treatments they need to live healthier lives.

https://crohnsandcolitis.ca/



Nominations for the second annual Canadian Healthcare Industry Awards are now open. For more information please visit canadianhealthcareindustryawards.com

Reserve your table now — contact john@catalytichealth.com.

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Who's Doing What and Who's Going Where

Khang Ha has started a new position as Medical Science Liaison, Rare Diseases (Central) at ***Takeda Canada Inc.***

Sophie Rochon has embarked on a new role as Vice-President, Market Access at ***Otsuka Canada Pharmaceutical Inc.***

Terra Konst has begun a new position as Senior Brand Manager, Women's Health at ***Pfizer***.

Leandra Wells has recently joined ***Galderma*** as Country General Manager, Canada.

Chris Todd has assumed a new role as Associate Marketing Director at ***Arcutis Biotherapeutics, Inc.***

Fabio Ferraro is now the Director of Marketing and Creative at ***Bayshore Specialty Rx.***

Arima Ventin has started a new position as Head, Market Access and Government Affairs Canada at ***AbbVie***.

Virginie Bernier has recently joined ***Medexus Pharmaceuticals*** as Vice President, Hemato-Oncology for US and Canada.

Jean-Claude Beaudoin has assumed the role of Vice President Commercial & Canadian Operations at ***Medexus Pharmaceuticals***.

Karen Heim has assumed a new role as VP & General Manager of ***Alexion Canada***.

Dr. Joss Reimer was installed as ***CMA [Canadian Medical Association]*** president.

Paulina Knap was recently hired as a global meetings & events project manager with ***AstraZeneca***.

Simon Duong has started a new position as Senior Manager, Market Access and Reimbursement at ***Gilead Sciences***.

Reina Skaff has embarked on a new role as National Sales Director, IBD in Canada, at ***Johnson & Johnson Innovative Medicine***.

Marnie McCormick has begun her new role as Vice President & General Manager, Canada at ***BioSyent Inc.***

Venessa Cocuzzoli has assumed a new position as Head of Customer Engagement, Pharmaceuticals at ***Bayer***.

Monika Russel-Szymczyk has recently rejoined ***Novo Nordisk*** as Value Strategy and Payer Engagement Associate Director within the global diabetes market access team.

Kimberly Leonard has started a new position as Franchise Head, hematology-oncology at ***AstraZeneca***.

Aaron Hart is now the Commercial Lead, Mature Brands at ***Takeda Canada Inc.***

Martina Kilian has recently been hired by ***Daiichi-Sankyo Canada*** as a Senior Marketing Manager supporting their breast cancer and pan tumour portfolios.

Dimitri Piplakis has started a new position as National Sales Manager at ***Sobi Canada Inc.***

Holly Palladino has begun her new role as Senior Brand Manager at ***Lundbeck***.

Karlee Hourtovenko has recently joined the ***GSK*** Canadian Leadership Team as Chief of Staff.

Roshel Sachdeva has embarked on at a new position at ***Sanofi*** as Franchise Head, General Medicines, Autoimmune Type 1 Diabetes.

Robert Tam is starting a new position as General Manager at ***Taiho Pharma Canada, Inc.***

James Tidman has begun his new role as Customer Engagement Specialist (Immunology) at ***Novartis***.

Partick Menard is now the Manager of Sales, National Region at ***Ferring Pharmaceuticals***.

Please submit your selection for our "People on the Move" section, celebrating the advancements of your colleagues, for upcoming issues via email to info@catalytichealth.com.