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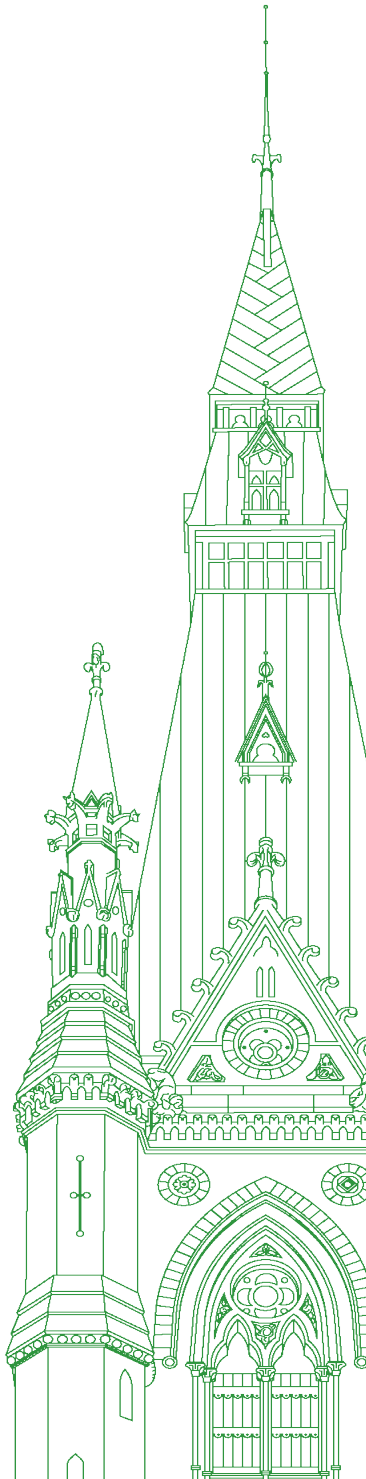

Chair: Mr. Ron McKinnon

Standing Committee on Health

Friday, June 4, 2021

● (1315)

[*English*]

The Chair (Mr. Ron McKinnon (Coquitlam—Port Coquitlam, Lib.)): I call this meeting to order.

Welcome, everyone, to meeting number 41 of the House of Commons Standing Committee on Health. The committee is meeting today to study the Patented Medicine Prices Review Board's guidelines.

I would like to welcome the witnesses: as an individual, Dr. Steven Morgan, professor, School of Population and Public Health from the University of British Columbia; from BIOQuébec, Ms. Anie Perrault, chief executive officer, and Monsieur Paul Lévesque, president and chief executive officer of Theratechnologies Inc.; from Breast Cancer Action Quebec, Sharon Batt, co-founder, and adjunct professor in the Department of Bioethics at Dalhousie University, and Ms. Jennifer Beeman, executive director; and from Cystic Fibrosis Canada, Kelly Grover, chief executive officer.

I will now invite the witnesses to—

Ms. Sonia Sidhu (Brampton South, Lib.): I have a point of order, Mr. Chair.

The Chair: Ms. Sidhu, go ahead on a point of order.

Ms. Sonia Sidhu: [*Technical difficulty—Editor*] encourage witnesses to complete a conflict of interest disclosure form. I understand that some witnesses today may have already done so. For anyone who may not have done so yet, I would ask them to do so as soon as possible with the clerk of the committee.

This has to do with whether a witness has an economic interest or acts as an officer or a director of any outside entity whose financial interest would reasonably appear to be affected by the addition of the witness's testimony in any report that may be written by the committee on that matter. Witnesses should also disclose any personal, business or volunteer affiliation that may give rise to a real or apparent conflict of interest.

Thank you, Mr. Chair.

The Chair: Thank you, Ms. Sidhu.

We will carry on with statements by our witnesses.

Before we start, I will mention that I have cards. I will display a yellow card when we're near the end of your time slot. I will display a red card when your time is effectively up. If you see the red card, you don't have to stop instantly, but do try to wrap up. Thank you very much.

We'll start with you, Dr. Morgan. Please go ahead for six minutes.

Dr. Steven Morgan (Professor, School of Population and Public Health, University of British Columbia, As an Individual): Thank you very much. I appreciate the opportunity to speak to you today.

By way of introduction, I am an economist by training, and I am a full professor of health policy at the University of British Columbia. I think it's important to note, for instance, that I've published over 150 peer-reviewed research papers on pharmaceutical policy. I've won literally millions of dollars in peer-reviewed research grants in Canada and the United States. I have served as an expert on expert advisory committees concerning matters related to pharmaceutical pricing and access for the World Health Organization and the OECD.

I'll keep my opening remarks very brief, as I prefer to use the available time to help fill knowledge gaps that you might have identified as important to your work.

I will start by expressing my support for reforms to our patented medicine price regulations. The old regulations were never designed to provide significant protection against high prices in Canada. They were designed on the false premise that, if Canada paid about the same amount for pharmaceuticals as countries with high levels of pharmaceutical R and D, then Canada would also become a country with high levels of pharmaceutical R and D.

That was never going to happen, and, sure enough, it didn’t. As I wrote during the 10-year review of the PMPRB in 1997, there was much to fix in the regulations from their outset, but the need for regulatory reforms has become even greater in recent years.

Two trends are important here. First, the pricing of pharmaceuticals has become entirely secretive worldwide. Drugs are priced like cars at a dealership. There is the list price, which everyone knows is higher than anyone should really pay, and then there is the actual price, negotiated in secrecy between the seller and each individual buyer.

Paradoxically, it was the widespread use of international reference pricing regulations that was the main reason that secrecy has now become the norm in pharmaceutical pricing. That is, so many countries were using international comparisons of list prices to determine the maximum prices that should be charged within their countries that manufacturers decided to go with confidential prices and confidential price negotiations as a means by which they could charge the most they possibly could in every market. In order to do that, they had to inflate, that is, to raise, list prices in every market. The benchmarking of list prices to international comparisons is now the norm, and, frankly, it is no longer enough.

This brings up the second reason for regulatory modernization. That is the excessive prices that are now frequently asked for for many medicines, especially for medicines that are specialized drugs for treating serious conditions. Excessive patented drug prices are indeed possible, because patents give manufacturers temporary monopolies over the sale of particular medicines.

The potential for abuse of the resulting market power is high, because consumers of patented medicines, also known as “patients with medical needs”, can suffer and might even die if they are unable to afford a treatment. By legally limiting the net-of-confidential-rebate prices that a manufacturer can even ask the Canadian health care system to pay, new patented drug price regulations could prevent the worst cases of excessive pricing and, at the same time, speed up negotiations over final prices and the terms of coverage for Canadians. Patients would get the medicines they need more quickly, and our health care system, ideally a system with universal pharmacare incorporated within it, would likely be able to afford to cover more of those medicines.

Industry will oppose these reforms, and they will provide funding to patient groups willing to oppose the reforms, too, but that doesn’t mean the regulations are wrong. If anything, it means that, unlike the original 1987 versions of the PMPRB regulations, the proposed reforms might actually work.

Thank you. I look forward to any questions you have.

● (1320)

The Chair: Thank you, Professor.

We go now to BIOQuébec.

Ms. Perrault, I presume it is, go ahead for six minutes, please.

[*Translation*]

Ms. Anie Perrault (Chief Executive Officer, BIOQuébec): Thank you, Mr. Chair.

Ladies and gentlemen of the committee, thank you for welcoming us and allowing us to participate in this important and strategic discussion.

My name is Anie Perrault, and I am the chief executive officer of BIOQuébec.

BIOQuébec is an industry association that represents Quebec-based companies. They are biotechnology companies involved in research and development, contract research companies, preclinical and clinical research companies and venture capitalists. So we have a presence along the entire innovation spectrum, from research to commercialization.

I'm here because our members are concerned, even more so because of the COVID-19 pandemic. The Patented Medicine Prices Review Board (PMPRB) was created in the 1980s with a limited oversight role. Its purpose was to prevent the abuse of an exclusive right, the patent. That is the purpose of the Board.

Regulating drug prices is the responsibility of the provinces, which are in charge of health care and, as in Quebec, a drug insurance program—

● (1325)

[*English*]

Mr. Marcus Powlowski (Thunder Bay—Rainy River, Lib.): Chair, I have a point of order.

I was listening in French and then I tried going to the English, and the level of sound of both the speaker and the translator is the same. For those who are listening in English, I don't know how and if you can hear what's being said.

The Chair: Mr. Powlowski, thank you for your point of order.

I wonder if the clerk could just quickly check with the translation booth to make sure we're all squared away.

Ms. Jennifer O'Connell (Pickering—Uxbridge, Lib.): Mr. Chair, it was fine on mine.

Marcus, sometimes if you unplug your headset and plug it back in, it might help.

The Chair: Thank you. We will proceed.

I apologize to the witness.

[*Translation*]

Ms. Perrault, go ahead.

Ms. Anie Perrault: Thank you.

[*English*]

As long as you stop the clock for these six minutes, I'm going to be fine.

[*Translation*]

Regulating drug prices is the responsibility of the provinces, which are in charge of health care and, in Quebec, a public drug insurance program. In our opinion, there are already ways to monitor prices. These include the pan-Canadian Pharmaceutical Alliance (pCPA) and the negotiation of listing agreements.

Innovation takes time, resources and, most importantly, good nerves. It is a combination of financial risk, business strategy and scientific knowledge. It takes place in a stable, predictable context that considers the local market and the global environment.

I would like to emphasize that the financial risks that our entrepreneurs take, particularly in the biotech sector, are much higher than in any other sector. A biotech company invests for years—on average 15, 16 or 17 years—before it knows whether the molecule it is working on will become a drug that will be approved and put on the market.

The rise of precision medicine and targeted therapies means that it costs every bit as much to develop a drug. It benefits smaller populations, which increases the risk. The PMPRB's new regulations would upset this delicate and complex balance. In our view, the new regime could well thwart major investment projects. Putting innovative drugs on the market could be jeopardized, and there could be repercussions for patients. The new regulations also mean that a company can no longer know in advance how it will recoup its investments.

Under these circumstances, who would risk a major health care innovation project in Canada?

The proposed reform is, in our view, misguided, ill-founded and ill-advised. We are trying to emerge from a health crisis that highlights the importance of the government supporting the life sciences sector, not stifling it as the reform does.

In our view, there is no worse time to destabilize the ecosystem. This ineffective regulation must be withdrawn, or at least suspended, and the discussion should be revisited with a clear head.

We need to think about the PMPRB's contribution. We agree with it, but it needs to be done as part of a reflection on the life sciences ecosystem, not only on the reform of drug pricing. We need a comprehensive life sciences strategy that will include aspects tied to the health of Canadians, to access to innovation, to research and to the economic development of the entire country.

Quebec has a strategy like that, but Canada does not. We must stop thinking in a vacuum, which is what the reform currently does. The pandemic has taught us one important thing, namely that the life sciences sector, the sector that is now giving us hope for a more normal life with the vaccine it has developed, is a productive sector. The government must work with the sector, not against it.

With me today is Paul Lévesque, president of Theratechnologies, a Quebec-based biotech company that has developed and marketed two drugs for HIV patients. It is currently developing other drugs for use against cancer and liver disease.

Mr. Lévesque joined Theratechnologies with 35 years of experience in the biopharmaceutical industry. He has spent half of his professional career outside of Canada, in Europe, Asia and the United States. As global president, he led the rare disease unit in New York.

We will be happy to answer your questions today, but first I would like Mr. Lévesque to explain why it is important for him, as the head of a proud Quebec company, to be here today.

Mr. Lévesque, the floor is yours.

Mr. Paul Lévesque (President and Chief Executive Officer, Theratechnologies Inc., BIOQuébec): Thank you, Ms. Perrault.

Good afternoon, everyone.

I am pleased to join you today through technology.

[*English*]

As a former CEO of a Canadian biopharma firm, it is my role today to tell you that if this reform goes forward, it will contribute to delaying and reducing the amount of innovation and innovative therapies that make it to Canada. I'm absolutely convinced of that. I sit in one of those seats, and I can assure you that this is what would happen.

How can I say that?

Imagine for a moment that you have a Tesla, which costs $100,000 apiece in the U.S., but the reform is asking us to have it at $50,000 apiece in Canada. Therefore, an entrepreneur like me, facing that situation just like the head of Tesla, would decide not to launch the Tesla in Canada anymore. That's what would happen, because of cross-border trade, because of the fact that it would put undue pressure on the two markets. That's what this reform will do, so people sitting where I sit today will actually decide not to launch.

Does this mean that we cannot reduce the price of pharmaceuticals in Canada? The answer is no, because this is just the wrong reform for doing it. If you want to have lower prices, you have to get to the negotiation table with provinces and find creative ways to reduce prices based on targeted populations, based on performance, where pharma companies can make sure that we're held accountable for the performance of our medicines.

The point is that what you have on the table now is the wrong reform to do whatever you want to do.

I just want to wrap up here and I'll be very happy to answer your questions. There are ways to bring innovative medicines at good prices in Canada, but this is the wrong way to do it. I have a lot of ideas. We have not exhausted the ideas, but we have to get out of that box and find other solutions.

Thank you very much.

● (1330)

[*Translation*]

The Chair: Thank you, Mr. Lévesque and Ms. Perrault, from BIOQuébec.

[*English*]

We'll go now to Breast Cancer Action Quebec, and Ms. Sharon Batt, co-founder.

Please go ahead for six minutes, please.

Ms. Sharon Batt (Co-Founder, Adjunct Professor, Dalhousie University, Department of Bioethics, Breast Cancer Action Quebec): Thank you, Mr. Chairman and committee members, for inviting us to present at these hearings.

Thirty years ago, four of us started Canada's first breast cancer advocacy group because we believed in the potential of these groups to support and promote the needs of patients. Unfortunately, in the mid-1990s the government withdrew funding from patient groups, and many turned to the pharmaceutical industry for support.

For the past 20 years, I have researched these partnerships, as have many others. A large body of evidence now exists to show they compromise the potential of groups to inform drug policy. The research shows that through financial support and social relationships the industry has captured a large segment of the global patient advocacy movement. By “captured”, I mean that these patient groups express a consistent narrative that aligns with industry interests. We now have two discourses on drug prices within the patient advocacy movement. This difference is starkly evident in the organizations that have intervened about the PMPRB regulations and guidelines.

We believe the new PMPRB regulations and the proposed guidelines will be effective tools to cap the constant upward spiral of drug prices that prevents increasing numbers of patients from gaining access to needed drugs. Excessively high prices distort the allocation of health resources. They threaten the sustainability of health care systems on which all patients depend. At issue in these guidelines are the rules that determine whether many Canadians can afford to pay for their prescription drugs.

Many reports over many decades have recognized that an effective universal health care plan must cover essential drugs, and recent polls show that 86% of Canadians support a national pharmacare plan. We are alarmed by the extent of opposition to the PMPRB by pharma-funded patient groups. Their voices are completely out of proportion to those of the independent patient groups, groups that work with low-income people and other civil society groups that support a national entirely public pharmacare program.

When the PMPRB revised and weakened the first version of its guidelines, we were dismayed. Was this pullback based on evidence or on the intense lobbying by the industry and patient advocacy groups? Drug policy analysts in all countries recognize that the pharmaceutical industry is pricing new drugs at whatever the market will bear. Many of these expensive drugs do not improve patients' survival or their quality of life. Some have been recalled because of the level of harm to patients.

Patient advocacy groups have a responsibility to press for reforms that will limit these harms to patients and threats to our health system. This is hard if you're in a partnership relationship with an industry that benefits from high prices. This is why Breast Cancer Action Quebec will not accept any funding from pharmaceutical companies, nor does any of the groups or advocates with whom we collaborate.

Canada needs transparency laws that will allow the public to examine the relationships the industry has cultivated with patient groups. We do know these relationships are extensive, not only in Canada but in all high-income countries. The industry strategies used to cultivate patient advocates, including paying for dinners, media training and unrestricted educational grants, have been used for decades to cultivate physicians. They work. They may even be more effective with patients than they are with physicians, given the vulnerability of patients and their more limited resources.

The new cystic fibrosis drug Trikafta and its precursor drugs are a flashpoint for much of the anger directed to the PMPRB. From the evidence we've seen, these new CF drugs are that rare product: a breakthrough treatment. We want Canadian CF patients to have them, but simply being an effective drug doesn't justify price gouging. Drugs are supposed to work. Otis Webb Brawley, the former chief medical officer of the American Cancer Society, argues that “patient groups get money from the drug and device companies because they...[make] claims so outrageous that even special interests dare not make them”. Some of the claims that cystic fibrosis and rare disease patients are making about the PMPRB fit that description. I refer to tweets like, “@DougPMPRB You are promoting the death and suffering of Canadian citizens and the blood is on your hands.” I also refer to the emotionally charged images in the ad series, “Stop changes to the PMPRB regulations”, which was sponsored by 13 patient organizations called “Protect Our Access”.

The PMPRB didn't block Vertex from bringing Trikafta to companies sooner; that was the company's decision. Notably, patient advocacy groups in other countries have challenged Vertex directly, as they should, and not their cash-strapped public health programs.

Patient charities supported by the pharmaceutical companies often develop financial assistance programs to help patients pay for the excessively high-priced drugs. This doesn't solve the problem of patient access to high-cost drugs. It serves to maintain an unsustainable drug pricing system that is enormously profitable to pharmaceutical companies. It keeps drug prices high.

● (1335)

In conclusion, partnerships between pharmaceutical companies and patient organizations contribute in myriad ways to inflate drug prices and to skew patients' advocacy in favour of the industry. Canada needs a national, publicly funded drug plan and policies to support it.

Breast Cancer Action Quebec recommends that the new PMPRB guidelines go into effect on July 1, 2021.

I thank you. Jennifer and I are happy to answer any questions.

The Chair: Thank you, Ms. Batt.

We will go now to Cystic Fibrosis Canada.

Ms. Grover, please go ahead for six minutes.

Ms. Kelly Grover (Chief Executive Officer, Cystic Fibrosis Canada): Hello. Thank you for inviting us here today.

I am the CEO of Cystic Fibrosis Canada.

Cystic fibrosis is a fatal disease affecting over 4,300 Canadians who die far too young. We are, however, at a time of extraordinary change for this disease, as there are now drugs that can help 90% of our community live much longer, healthier lives. The next best thing to a cure is on our doorstep.

When we first put forward our submission to this committee, we wanted to discuss the opportunities and the challenges we saw with respect to the implementation of the PMPRB changes. We wanted to stress that we agreed with the goal of lowering drug prices and the changes to the comparator countries, but we had concerns about the additional pharmacoeconomic elements. While we stand behind that thinking, today I need to share the serious concerns we have about the approach and the conduct of the PMPRB.

Drug policy is important. It can have a life-or-death impact. With a drug policy change of this magnitude, it was our expectation that the PMPRB would ensure there was meaningful consultation with those most affected. However, in our experience and in the experience of many other patient groups, this was not the case. Our submissions were sent into what felt like a vortex. Ultimately, they were never reflected in the minimal revisions made by the PMPRB, nor were explanations given for their chosen direction.

Last week we learned of activity at the PMPRB that solidified our concerns about the value placed on patients. We learned through an ATIP request that the PMPRB had developed a communications strategy to discredit four groups. Three of these groups were patient groups, including the cystic fibrosis community. To quote the PMPRB strategy, “opponents of the reforms have been more vocal about the potential negative impacts of their implementation and are spreading disinformation through organized public relation campaigns.” Further, it's noted that “the CF community… have aggressive public relation strategies that are aligned with the messaging promoted by the industry.”

I want to make a specific point here. The word “disinformation” is highly inflammatory and was a deliberate vocabulary choice by PMPRB officials. We now understand that if you dare to disagree with the PMPRB, they won't simply refute your point of view. They will villainize your efforts.

As the CEO of a nationwide organization dedicated to serving people with a fatal disease who now have an opportunity to access life-changing medications, I cannot fully convey the dismay and concern I have that a federal agency deems this community to be an opponent and a threat to be discredited. To specifically target the credibility of this community—children and young adults who are fighting for their lives—is beyond what I could comprehend as reasonable or appropriate for a federal agency. These families felt that these changes stood in the way of their access to new life-saving medications, so they spoke up.

Members of Parliament who disagreed with the PMPRB's directions should also be concerned, as they, too, were characterized as spreaders of disinformation. This characterization should be very concerning to the members of this committee, as the role of elected representatives is to assess policy direction.

My final remark is with respect to another ATIP request that showed calculations conducted by the PMPRB on two cystic fibrosis drugs if the guidelines were implemented. The calculations indicated that the manufacturer would be required to reduce its price by 99%. We found this to be of keen interest. Why? It's because time and time again the PMPRB told us that our concerns were not valid and that the impact on industry was overblown. Whatever you think about the pharmaceutical industry, we believe that most of us can agree that there isn't a company in any sector that would raise its hand to come to a country that requires a 99% reduction in price.

● (1340)

These examples illustrate an agency that we have grave concerns about. As I noted earlier, we support the government's goal of lower drug prices. However, we believe this must be accomplished in a transparent, credible and consultative manner, where all parties are listened to and, frankly, those with the most at stake—Canadian patients—respected. This has not been the case with the PMPRB.

It is incumbent on the Standing Committee on Health to stay these guideline changes and to call on the Auditor General and the Integrity Commissioner to review the activities of the PMPRB.

Thank you.

The Chair: Thank you, Ms. Grover.

We'll start our questions with Mr. Kmiec, please, for six minutes.

Mr. Tom Kmiec (Calgary Shepard, CPC): Thank you, Mr. Chair.

I'd like to start with Cystic Fibrosis Canada because you mention some public information that I released once I had obtained it.

My experience has been that patient advocacy groups like yours and others are usually made up of teenagers who have a particular condition, and parents who are very active in it because it's very personal to them. I have three kids with a rare disease. I have a daughter who passed away just a few years ago from a different rare disease, so it's personal to me as well.

Can you tell me whether the people involved as advocates are paid lobbyists or parents?

Ms. Kelly Grover: Thank you for your question.

People living with cystic fibrosis who advocate are just free agents. They are parents of kids who are sick. They are adults now who are living longer lives, which is a wonderful moment.

I just want to stress that the drug available for these people is for 90% of a fatal disease, and it adds 10 years of life. They are fighting hard. They saw barriers, so they spoke up. This is an amazing community, and I'm so pleased to lead Cystic Fibrosis Canada on their behalf.

Mr. Tom Kmiec: Kelly, when the documents came out, a communications plan accused your group and other patient advocacy groups, and actually parliamentarians like me, of engaging in disinformation. Allegedly, we are deceitful and are lying, which is what the PMPRB accused us of. How does that make your organization and the people you represent feel?

● (1345)

Ms. Kelly Grover: I was talking to my team about this today. I feel sad. I feel really let down. We are a 60-year organization that was built by parents. Now our board chair is a parent of somebody living with cystic fibrosis. We are so committed to changing the course of this disease and doing the work that's needed.

There is rhetoric out there that we don't speak about Vertex the manufacturer, and that we don't do this or don't do that. I'm here today for the moms and dads living with cystic fibrosis.

We have such an opportunity to change the course of this disease, and I'm a bit saddened that it's come to this. It's really about slagging each other. I think we should all come together, figure this out and ensure that people who have a game-changing drug are able to get access in Canada. I think we all could champion that.

It makes me very sad and just frustrated, frankly. I know that's how the parents felt. They felt very slagged—if I can use that word—and really disrespected, and they're frustrated.

Mr. Tom Kmiec: In these internal documents they accused parliamentarians like me of lying. You responded on May 24 in a letter you sent to the President of the Treasury Board and to the Integrity Commissioner. You specifically cited major concerns that the PMPRB had violated the policy on communications and federal identity, section 4.1, and also the cabinet directive 6.10.2 on the management of communications, which is supposed to be done objectively in a non-partisan fashion.

Do you have any concerns about the neutrality and professionalism of the PMPRB executive?

Ms. Kelly Grover: That letter didn't come from us. It came from a sister organization called the Canadian Cystic Fibrosis Treatment Society.

I'm not going to speak to the leadership of the PMPRB. I think the staff probably work hard there and try to do the best they can.

What I do think is that they didn't have a sound consultation process, one that I would expect would have been more of a to and fro and not a didactic, one-way process. I think patients and people living with disease have a lot to offer. There are many things that I could say about the consultation—and I can submit them later. I think you could have had a more meaningful discussion on the changes.

As Cystic Fibrosis Canada, we've said that we do agree with the lower drug prices and with some of the guideline changes, and then we think that maybe you should wait and see, try some out, see how it goes and learn from the experience.

I think it just becomes very didactic and black and white.

I can't speak to the leadership. I'm sorry that I'm answering you in a bit of a roundabout way.

Mr. Tom Kmiec: That's okay.

On the public consultation—because that was going to be my next question—I have emails that I made public in an effort to share with the public what I found out.

I would like to know, do you think these public consultations were done impartially, now that we know about the emails they were sharing amongst themselves as follow-up to these meetings, and whether the PMPRB guidelines should go ahead July 1 or whether they should be directed to redo the public consultation in a fair and open manner?

Ms. Kelly Grover: We think the consultation should be redone in a fair manner. We've been public about that. We don't think that was done.

Mr. Tom Kmiec: Mr. Chair, how much time do I have?

The Chair: You have 40 seconds.

Mr. Tom Kmiec: This will be my last question.

There are other patient organizations you've spoken to with regard to PMPRB. On a go-forward basis, do you feel the PMPRB will give your organization a fair shake, in light of the fact that they have this $56,000 communications project they're working on to discredit you and other patient advocacy groups?

Ms. Kelly Grover: I think the PMPRB is not set up to work with patient organizations, and they feel threatened by people when they speak up. When parents felt that there could be a barrier to their drug, they spoke up. I think you have to be prepared for that when you're forward-facing and you're changing drug policy that is life and death for people.

They were not prepared for that, and they felt it was very offensive.

I'm not condoning disparaging remarks. However, when people are feeling a sense of panic, they are going to talk to who they think is in the way of access to their drug, and that is what they did.

● (1350)

The Chair: Thank you, Mr. Kmiec.

We'll go now to Ms. Sidhu for six minutes.

Ms. Sonia Sidhu: Mr. Chair, I would like to thank all of our witnesses for being here today.

I will start my questions with Dr. Morgan.

Dr. Morgan, I know you have written about different models for pricing drugs and how they can better serve patients. Can you speak to how, with models based on fixed costs, a patient's ability to pay might apply in Canada? Is there room for such a system in the PMPRB's proposed model?

Dr. Steven Morgan: I'm not particularly clear on what you mean by models based on fixed costs. Actually, some of the other witnesses have mentioned....

I think everybody is opposed to excessive pricing of medicines, pricing that can't be defended on the basis of value for money in the health care system. For instance, pouring millions of dollars into treatment for a particular patient or a few patients is money that is not being used to meet other health care needs, including the other needs of the patients with the same disease.

Also, we know that we don't want to be providing excessive returns to investment in pharmaceuticals if there are other investments and innovations in health care that might deliver as much or more of a return to the health system.

There's a desire to stop excessive pricing, and there's also a desire to make sure that pricing reflects something approximating the value to health systems. We've heard, even today, that the best strategies are to set upper limits on what prices could reasonably be in a system that tries to reflect return on investment to R and D and value for money in health systems. Then, frankly, you need to let the buyers and sellers of medicines negotiate prices.

This is something that Canada lacks a strong capacity for, because we have a fragmented and uncoordinated system of private insurance in this country that lacks both the technical skills and moral authority to make value-for-money decisions in a health care system that is otherwise publicly financed.

Canada needs public agencies to do the negotiations of the final prices, those confidential net-of-rebate prices that make sense in terms of value for money. Increasingly, that also means engaging in risk-sharing agreements with manufacturers that address the real and significant uncertainty about whether products work as well in the real world as they are promised, based on often very small clinical trials.

Canada has the opportunity to build back capacity in the Canadian drug agency, which is currently in the process of being established at the federal level, and in partnership with the provinces and other national agencies and provincial agencies, concerning health technology and price negotiation.

Ms. Sonia Sidhu: Thank you.

Affordability is an important concern for everyone. An issue that regularly comes up when I speak to my residents, Bramptonians, is how increasing drug costs and insurance premiums impact their budget. As we all know, the government is working to move forward to establish the fundamental elements of Canada's pharmacare.

To what degree do you believe that lower drug prices will result in an overall saving for Canadians, and on their insurance premiums, if the new guidelines are introduced?

Dr. Steven Morgan: The new PMPRB guidelines will affect prices to some degree in Canada, but it is important to recognize that if you bring down the list prices of medicines in Canada you may not have as dramatic an effect on the final net-of-rebate prices. For example, let's just pretend the list price of a medicine is $100 and the manufacturers and provincial drug plans have negotiated that a price of $70 is actually value for money, which is about right in terms of the average rebate that they negotiate on behalf of public health systems in Canada. Now, imagine that PMPRB regulations brings the list price down to $90, not $100, and the final price to the provinces is going to continue to be $70. The private insurance companies are going to save the $10 reduction in the list prices, but the net savings to Canadians in terms of the public programs is ultimately determined by price negotiation power.

The exception to that rule is with these very expensive drugs for drugs that treat very serious conditions. We've heard some examples with CF treatments, and there are other examples across the spectrum of needs of patients, where, because there are just one or two medicines that truly, effectively treat a given condition, the prices can be so high that there is no such thing as people paying cash or buying the medicine at the pharmacy. Pricing is entirely arrived at by negotiation between public plans and the buyers. It's in those negotiations where the PMPRB regulation has significant potential to prevent the systems that we have for our public health care from being abused in the sense of being held captive against really excessive price asks by manufacturers.

I'll just add—I know the chair has raised a yellow flag for the time allowed—that this is one of the reasons why countries around the world are paying close attention to what's happening here in Canada with these regulations. I think there are countries around the world.... I say this as a person who, for the last 15 years, has hosted an annual meeting of people responsible for pricing, regulation, and health technology assessment, in about a dozen high-income countries, and I know that the members of that group—known as the “Vancouver group” because I'm their host—have often reflected on these regulatory reforms that are under way in Canada. They see them as potentially valuable even in their systems.

● (1355)

The Chair: Thank you, Ms. Sidhu.

[*Translation*]

Mr. Thériault, you have the floor for six minutes.

Mr. Luc Thériault (Montcalm, BQ): Thank you, Mr. Chair.

When an organization responsible for promoting a reform and holding consultations plans to discredit the stakeholders and the people involved in the consultation, I think that things are starting badly and could end up worse. As I read all of the submissions, I see points of convergence that stand out, and that is what we should focus on today.

For those who are concerned about conflict of interest, there is an organization called Research Canada, which represents academic health science centres, universities, colleges, associations of research societies, charities, networks of centres of excellence, organizations in the biopharmaceutical sector, in short, a number of "institutional people", if I can put it that way, who have the same concerns as you, Ms. Perrault.

The organization states: "In essence, the federal government is flying blind into the implementation of its PMPRB reforms..." That's on page 2 of the brief, for people who are going to ask me where I got it. It comes to the conclusion: "in the absence of an inclusive consultation that not just the guidelines..., but the PMPRB reforms as a whole, may prove unaffordable for our economy, our health system and our most vulnerable patients."

What do you think?

Ms. Anie Perrault: I'm assuming that question is for me?

Mr. Luc Thériault: Yes, it is.

Ms. Anie Perrault: In our opinion, the current reform clearly seems to have been designed in a vacuum, whereas our ecosystem works horizontally. The ecosystem is a chain of innovation from research in academia to, hopefully, the commercialization of new drugs. Along that chain, there are many players, including us, the biotech companies, and the clinical and preclinical research organizations. We all work in an integrated way. If we affect one of the links in the chain and weaken it, the whole chain will be weakened.

Unfortunately, changes to regulations are being made in Ottawa in a vacuum, based solely on the price of drugs, when the life sciences ecosystem is much more than that. It is research, innovation, economic development, clinical research and the application of the innovation to patients. This is much broader and the broader consultations have not been held in Ottawa.

In Quebec, we are working with the Québec Life Sciences Strategy, which is the responsibility of two ministers: the Minister of Health and Social Services and the Minister of Economy and Innovation. This already shows the integration and an understanding of our ecosystem, where stakeholders work horizontally, not in isolation.

So that is very important. We are certainly disappointed to see the lack of consultation with all the partners in the reform, whether it is us, the biotech companies, the patient groups, the people in clinical research, and above all, the provinces, because they are the ones responsible for health care in this country.

Right now, the Quebec government is officially opposed to those changes to the PMPRB. The Ontario government has expressed reservations. The Alberta government has expressed reservations. You can't put a strategy like that in place without including those who are going to implement it, like the provinces.

● (1400)

Mr. Luc Thériault: Actually, we have the Quebec life sciences strategy, but no such strategy exists for all of Canada. As you were saying, because of that lack of strategic and holistic vision, the price of drugs is seen strictly as a cost rather than an input from a therapeutic perspective.

The PMPRB claims that it will have no impact on drug accessibility and claiming otherwise will fuel a pro-pharma campaign, if not a misinformation campaign.

What is your opinion about the matter?

Ms. Anie Perrault: I'll tell you what I think about it and I'm also going to ask Mr. Lévesque to comment and tell us what he would do, as the head of a company, if he had to make decisions about drugs that he was working on.

Market access is a key factor in the innovation chain. When you restrict that access, in Canada, unfortunately it's sure to have a negative impact on the ecosystem.

Here at home, we're already seeing less clinical research being done. Fewer innovative drugs have been launched around the globe and none of those drugs have been launched in Canada. I'm not talking about a company deciding to have its drugs approved in Canada, I'm talking about them deciding to not even launch them in Canada. So patients won't be able to benefit from them.

So there will certainly be repercussions. We're convinced that there will be negative repercussions. We haven't considered that entire chain.

As the CEO of a company working on drugs right now, perhaps Mr. Lévesque could answer this question.

Mr. Paul Lévesque: If a Canadian drug is half the price of its U.S. equivalent, we will not be able to launch it. I can tell you that right now.

I have to deal with situations like that. No one else in the company makes those kinds of decisions but me. If a drug sells for $100,000 in the United States, nobody pays that, by the way, so that means it's negotiable. A list price in Canada at 50% of the U.S. price is unsustainable. We can't work in that environment.

All I can tell you is that, 20 years ago, the Canadian pharmaceutical industry was vibrant, but it's become marginalized over time because of policies like the ones we have on the table. This policy is going to result in fewer and fewer innovative drugs being introduced in Canada at a time when, as someone said earlier, a lot of these very high-value drugs are coming. We will be able to treat diseases with gene therapies that we couldn't treat before.

For cancer and all kinds of diseases, this reform comes at a very bad time. We're emerging from a pandemic, and you saw the value the industry was able to create.

[*English*]

What I think is right at this time is to nurture the pharmaceutical industry so that they have something homegrown that can help you out. Today you need a vaccine; tomorrow you're going to need an antibiotic. Who's going to do it, the government?

You need a strong pharma industry. Does that mean that you have to pay super high prices? The answer is no. Get a reorganization; get a reform. Dr. Morgan said that. We can be more efficient in the way we negotiate at the provincial level.

However, this is the wrong reform at the wrong time. We are actually trying to impact the wrong variable in the whole equation.

[*Translation*]

I hope I've answered your question well, Mr. Thériault.

Mr. Luc Thériault: Thank you, Mr. Lévesque.

Mr. Chair, you are on mute.

I could have taken the opportunity to ask another question. See how disciplined I am?

[*English*]

The Chair: I'm wise to those things, but thank you. I apologize for being on mute.

[*Translation*]

Thank you, Mr. Thériault and Mr. Lévesque.

[*English*]

We'll go now to Mr. Davies, for six minutes.

Mr. Don Davies (Vancouver Kingsway, NDP): Thank you.

My first questions are for Dr. Morgan.

In 1987, Bill C-22 amended the Patent Act to expand the patent rights of patentees of medicines. Those amendments included, among other things, an extension of the patent term from 17 years from the date of the issuing of the patent to 20 years from the date of filing of a patent application. To ensure that the prices of patented medicines are not excessive during the expanded period of market exclusivity, that bill also amended the act to create the PMPRB.

As a general statement, would you say that pharmaceutical prices in Canada are excessive?

● (1405)

Dr. Steven Morgan: Yes. In comparison with international comparators, most notably those in Europe and Australasia, there's no question that we pay higher prices. In comparison with what private insurance companies in the United States pay and what national agencies like the Veterans Health Administration pay in the United States, unquestionably our prices are excessive in Canada.

Mr. Don Davies: Thank you.

I see figures putting Canada either third or fourth in the world, depending on the source, in terms of the prices Canadians pay for pharmaceuticals. Is that accurate?

Dr. Steven Morgan: Yes, approximately. In fact, that's an account of list prices. If you looked at comparator countries, high-income countries with universal health care systems, Canada is probably one of the highest price-paying markets for pharmaceuticals even after you account for the negotiations that our provinces undertake. That's because a significant proportion of our medicines are purchased by private insurers or by uninsured Canadians, both of which have little or no negotiating power with manufacturers.

Mr. Don Davies: Thank you.

I understand the order of priority is that the United States pays the highest; I think Switzerland is second highest; and Germany or Canada, third highest.

Of the countries that pay lower costs—I guess there are 210 countries in the world—do the Belgiums, Frances, New Zealands and so on have less access to medicine than Canada does?

Dr. Steven Morgan: That's a great question. People throw out these statistics and these stories, frankly, about drugs that don't come to market in Canada. The fact is that drugs go to market in a few places in the world in very large numbers, and then in other markets around the world, they go to market basically on the basis of whether the drug is truly a breakthrough that will earn market share. In places such as Germany and the United States, the legislation of those countries is set up to give manufacturers every incentive to bring anything to market, regardless of how clinically promising it is, but ones that are clinically promising end up in markets around the world.

The literature on this, which I recently did a systematic review on, is quite poor internationally because most of it is funded by pharmaceutical manufacturers. As a consequence, most of that literature has what we call a commercial bias, a bias that says that any drug in any market at any price is a good thing. The reality is that it's effective drugs that countries want, and effective drugs get to every market of the world.

Mr. Don Davies: Dr. Morgan, I really want a direct answer, if I could, because there seems to be a thesis developing that if we go through with these PMPRB reforms and they reduce the price of drugs, Canadians won't get access to those drugs.

I'm asking in a real world environment, where there are many countries that already pay less for drugs than Canada does, are they getting worse access to drugs than Canada is?

Dr. Steven Morgan: No. One only needs to look at, for instance, the United Kingdom, a country that pays less than us, gets more medicines on its market and actually has higher research and development in the pharmaceutical sector, so there you go.

Mr. Don Davies: Thank you.

Ms. Batt, in your view, will these PMPRB reforms discourage clinical trials in Canada?

Ms. Sharon Batt: In my opinion, I haven't seen evidence that it will, but obviously it's up to the companies where they do their clinical trials. I'm not sure how important the PMPRB guidelines are to those decisions, but I don't have....

Mr. Don Davies: Okay. I'll move to the next question.

In your view, will PMPRB reforms discourage new drugs from coming to Canada?

Ms. Sharon Batt: No. As Dr. Morgan said, I don't see evidence that the really good, important drugs won't come here. There's going to be the demand. I don't see how the provinces are not going to want to welcome drugs that are actually going to make a difference.

Canada is certainly a smaller market than the United States, but it's not a trivial market. We're spending a lot of money on drugs. I don't know why the companies would walk away from our market just because their prices are reduced a bit.

Mr. Don Davies: I think we've seen the media reports that the pharmaceutical industry offered the Canadian government $1 billion to delay bringing the PMPRB reforms in. According to an industry estimate, they say the regulations would reduce drug companies' revenues by about $19.8 billion over 10 years.

Do you think the opposition of the pharmaceutical industry to these reforms is based more on their interest in their own profits or on their concern that Canadian patients won't get access to drugs?

● (1410)

Ms. Sharon Batt: I think they are concerned about their own profits. Certainly the United States is very concerned about high drug prices too, and is looking to Canada. If Canada gets an effective reform in place, I think there's certainly some concern on the part of the companies that the United States could follow suit. The dynamic between the two countries is very interesting and is very likely a factor in the drug companies' opposition to these new guidelines.

Mr. Don Davies: Thanks.

I have a quick question for Dr. Morgan.

Dr. Morgan, what percentage of research is created from publicly funded research, like in universities, that goes into new molecules? Can you give us a rough estimate?

Dr. Steven Morgan: I don't have the number off the top of my head. I know that Chris McCabe will be speaking later with this committee. He might have that number. It's a significant percentage, particularly if you include tax expenditure subsidies, which we provide for the private investment, in addition to government grants and non-profit organizations sponsoring research itself.

Mr. Don Davies: Is there a ballpark estimate?

Dr. Steven Morgan: I don't want to give you a number without having the statistics in front of me.

The Chair: Thank you, Mr. Davies.

That ends our first round of questions. We'll start our second round at this point with Mr. d'Entremont for five minutes, please.

Mr. Chris d'Entremont (West Nova, CPC): Thank you, Mr. Chair.

I want to thank the witnesses for being here today.

I would say at this point that we've taken hundreds of *mémoires* from organizations that have presented to us. I think they're as diverse as the views we see here today. Quite honestly, this is meeting two of a three-meeting process. We're getting close, I believe, to the end of our process, where we need to have an idea of what we're going to recommend, and yet we have PMPRB changes going in place in just a few weeks. It's hard to synthesize a lot of the things we're seeing before us.

It was six months ago that we had our last meeting. We invited the PMPRB to be at this meeting to bounce some of these thoughts of them and for consultations. Unfortunately, they didn't want to be here today, which I find a bit awkward, as we're trying to find ways, to my mind, to help them come up with the best piece of rules and regulations in order to do that.

We talked a lot about pricing today, but we had the issue on the other side of the equation. We talked about the patient side.

Kelly Grover, thank you so much for being here on behalf of CF patients. I get a lot of folks from the patient groups talking to us. I know Tom will probably ask a few more questions on this if he gets the opportunity, but have you had an apology from PMPRB for what was truly their attack on patient groups? I find it difficult that we're attacking patient groups right now.

Ms. Kelly Grover: Thanks for your question. We've met with many of you, and you've met with your constituents, and we thank you for that.

We, CF Canada, didn't ask them for an apology, but there was another letter this week that was written to another patient group that was called out. There was a letter written—and I was copied on it—by the board chair of the PMPRB, and I think that's when what I said before.... I'm sorry to keep talking about my feelings, but I felt just really disappointed and sad about the letter and its tenor. On my part, if I had a communications plan after doing something wrong, or whatever, I might have started with this: “I'm sorry you felt that way and here's where we're coming from.” But that was not it. The tenor of the letter was almost like they doubled down. They're very offended by the patient groups. Dr. Batt spoke to some of the language online. They're very offended by that. There's no consideration of where patients are coming from. There's no understanding of that or trying to empathize with them.

On top of that, I found it curious in their note that they stated that they are the experts on this and that's what they advise government on. I found it curious their use those words, because I thought this was a consultation process, whereby we all bring in Dr. Morgan's suggested things and we are all bringing our voices to the PMPRB to make these the best guidelines. I might be a bit naive about that, and I'm not trying to play that card with you right now, but if that was the point, that you were just information gathering from all of us and it wasn't a consultation process, then call it that. But that wasn't what it was called. If you look at their consultation principles, it's about meaningful discussion and debate, and that didn't happen.

I don't expect there to be an apology to us, to be honest. I'm not going to waste my time on that. We were invited here, we've written our letter and that's that.

● (1415)

Mr. Chris d'Entremont: All right. Thanks, Kelly.

The other side of this.... We have patients on one side and, from a health system standpoint, the patients should be number one on that. In the time I spent there, it was about patient service and trying to find better ways so that people could get their treatments, drugs and whatever they possibly needed from our health care system.

We also have the other side. I see that Minister Champagne actually is out there trying to bridge a few gaps right now. Because of the way the PMPRB is coming down, he's reaching out to research and development and drug companies.

[*Translation*]

I would like to ask Ms. Perrault a question.

Ms. Perrault, where do investments for research in the pharmaceutical industry come from?

Ms. Anie Perrault: Thank you for the question, Mr. d'Entremont.

Investments come from a number of sectors. At BIOQuébec, our members are not large pharmaceutical companies. They are biotechnology companies that do clinical and preclinical studies. They are part of the ecosystem.

However, the ecosystem is very different from what it was 10 years, 15 years, 20 years ago. It has changed quite a bit and is now much more horizontal. The large pharmaceutical companies are now involved in academic research, biotech and clinical trials. Venture capital comes from a number of countries. It's international. It's not true that we work in a vacuum. We work in a much more horizontal way. Research is indeed publicly funded. Governments are still very much involved in basic research, but a whole ecosystem exists around that.

I would even add that, if public funds are going to allow research to be done—and the research we do in Canada is of high quality—I'd like Canadians to be able to benefit from it. At the end of the day, the drug is probably going to have been developed in several places around the world. Research will have been done all over the place, but certainly Canadians will have contributed. In the context of the current pandemic, Canadians contributed significantly to the preclinical trials for the RNA vaccines, which, by the way, were done largely in the Montreal area.

It would be unfortunate if Canadians could not benefit. That may happen later. Some countries receive drugs very quickly. Other countries, including Canada, will also receive them, but when? Will they get them in the middle third, in the final third of the timeline? I'd like Canadians and Quebecers to be able to benefit as quickly as possible.

This reform, which is only about drug prices, should be about the whole ecosystem and how it can benefit Canadians. Patients should be reaping the benefits of the research, the innovation, the clinical research and the drugs. So you need to take a holistic view.

The Chair: Thank you, Ms. Perrault.

Thank you, Mr. d'Entremont.

[*English*]

We go now to Mr. Van Bynen.

Mr. Tony Van Bynen (Newmarket—Aurora, Lib.): Thank you, Mr. Chair. Thank you to this panel for joining us today.

I think that all of us can agree that this is a very important discussion. I appreciate everyone's taking the time to join us.

My questions will be directed to Dr. Morgan.

Canadians have access to some of the best doctors and nurses, hospitals and treatments in the world, all of that through our publicly funded health care systems. This includes the incredible team at Southlake Regional Health Centre, where I had the pleasure to volunteer as a board member for many years and to gain some insight into the health care sector.

We've learned that some Canadians, particularly those with rare diseases, have difficulty affording the medications they need. Budget 2021 reaffirmed that the government will proceed with its announced plan to provide ongoing funding of $550 million for the program for high-cost drugs for rare diseases. How do you think this investment will help Canadians currently living with rare diseases now and in the future?

Dr. Steven Morgan: Thanks. That's a great question.

There are a few things under way. The federal government is consulting to try to develop something of an actual strategy around rare diseases. Canada has lacked that to date. I think that's very promising. There's funding for the medicines when patients need them, but there are also the various mechanisms that need to be put in place for the assessment of medicines as they come to market, and to support both manufacturers and patients in navigating often complex and uncertain information about whether the medicines are going to work or not.

The $500 million that's dedicated towards helping provinces pay for expensive drugs for rare diseases is an important step in the process of developing a truly comprehensive national pharmacare program. For patients with rare diseases, I think it's a clear signal that they will not be left behind by a pharmacare program that is designed to cover all of the medicines Canadians need. I know there was a lot of fear at the outset of discussions about national pharmacare that patients with rare diseases would become the second or third in line after the patients with more common conditions like diabetes, asthma and other such things.

● (1420)

Mr. Tony Van Bynen: I'm looking at an article entitled “Pricing of pharmaceuticals is becoming a major challenge for health systems”. In that article it is said that “The pharmaceutical sector can potentially abuse market power because of the inelasticity of demand for necessary medicines.” Can you expand on that, please?

Dr. Steven Morgan: Yes, absolutely. The idea of having a patent as a mechanism for incentivizing research and development typically comes from markets where the price that a consumer is willing to pay is based on the idea that the consumer can always walk away from a transaction on a voluntary basis and not be harmed unduly by doing so. Unfortunately, in the context of necessary medicines, particularly for serious diseases, patients can't walk away. As a consequence, patients and their families would pay virtually anything for effective life-saving treatments. As a consequence, patients and their families and their organizations would try to convince governments to pay anything for effective life-saving treatments. This gives patent holders in the pharmaceutical market very unique market power, which the patent system really wasn't designed to provide. That's why safeguards like PMPRB regulations are a useful tool to make sure that there's incentive for innovation, but not an opportunity to abuse the market power of the patent.

Mr. Tony Van Bynen: Thank you.

One conversation we're hearing lately is about patents in relation to the COVID-19 vaccine. I'm curious to hear your thoughts about the patent process in relation to pharmaceutical drugs. Can you identify any areas where Canada could improve or further encourage pharmaceutical companies to develop their drugs in Canada?

Dr. Steven Morgan: If you want an innovation strategy on R and D in the pharmaceutical sector, you have to improve the productivity of the R and D itself. Manufacturers locate their research and development investments based on science. If you want good scientific research conducted in Canada, invest in Canadian science, invest in data platforms, invest in clinical trial networks, those kinds of things.

Paying higher prices isn't necessary to attract R and D, and countries like the United Kingdom prove that. You can actually have effectively managed drug budgets and significant pharmaceutical investment. Focus on science. Put the investments into the scientific enterprise in Canada. That's where you're going to get your best return on innovation policy.

Mr. Tony Van Bynen: Thank you.

That's a great segue to my next question, which I'd like to direct to either Ms. Perrault or Mr. Lévesque from BIOQuébec.

I know that supporting Canada's biotechnology and life sciences industry is a priority for this government that goes beyond responding to COVID-19. Budget 2021 proposes to invest $2.2 billion towards growing and strengthening our domestic life sciences sector, including $92 million for adMare BioInnovations, which is based in Montreal, to support company creation, scale-up and training activities in the life sciences sector.

What impact do you think these investments will have on Canada and Quebec's life sciences and biotechnology industries?

Ms. Anie Perrault: I can answer that.

Do you want to go ahead, Paul, on this one?

Mr. Paul Lévesque: No, go ahead. I'll complement you.

The Chair: Let's make it a quick response. We're way, way over the time.

Ms. Anie Perrault: Okay.

Actually, Mr. Van Bynen, I applaud the investment that the Canadian government has made recently in the sector. My point today is that the ecosystem is much larger than just drug prices. It's about much more than that. We don't have a Canadian life sciences strategy right now. It does not exist. I think we should have one. We should take the opportunity that the pandemic is giving us, and the rebound that the economy should take, to actually think about putting in place a Canadian life sciences strategy that will take into consideration drug prices but also much more than just that.

● (1425)

Mr. Tony Van Bynen: Thank you, Mr. Chair.

The Chair: Thank you, Mr. Van Bynen.

Mr. Kmiec, please go ahead for five minutes.

Mr. Tom Kmiec: Thank you, Mr. Chair.

Mr. Lévesque, I'm reading here an email from PMPRB executives from December 5 after a meeting they had with industry groups. In it, one of them says that "industry has been sucking Canada for decades". From all the discussions I've had here, you don't seem to do that. You provide jobs. You're in R and D. You do work.

What do you think of that coming from an executive at the PMPRB responsible for stakeholder relations?

Mr. Paul Lévesque: The life science sector is important. If we haven't actually drawn that learning from the pandemic, I don't know what is important to take from it.

I don't represent a multinational. I'm a homegrown pharmaceutical company. We don't have a lot of those. As Dr. Grover was just saying, in the U.K. they get some benefits from the industry despite having low prices. They have a homegrown company. AstraZeneca is from there. It's a multinational that is homegrown in the U.K. What is the equivalent in Canada? There is none. That's the point: We're one of them.

Mr. Van Bynen had a very good example a moment ago in his question when he said, well, we are providing a lot of money in that sector. That is true. We're being helped in terms of income tax credits and in all kinds of areas, but we cannot sell. We are having a hard time getting reimbursed by the government. It's like supporting an industry manufacturing two-by-fours when you don't want the two-by-fours to be sold in your territory. That's the way I feel as a Quebec homegrown pharmaceutical company.

Yes, you need to continue to nurture and put money where it can have an impact, but quite frankly, I don't need that much money. I would like to have access to the Canadian market, just as I have access to the U.S. market and access to the EU market. What I'm telling you is that I'm very proud of being here. The model we have here in Quebec is that a lot of the research comes from the local university. We've made deals with them. We catalyze, in a way, their Canadian—

Mr. Tom Kmiec: Thank you, Mr. Lévesque. I'm sorry to interrupt you. I want to ask one more question of Cystic Fibrosis Canada.

Mr. Paul Lévesque: Okay.

Mr. Tom Kmiec: Kelly, I have the May 27 letter you sent. The PMPRB refused to show up today to testify. We can all make assumptions on why they refused to show up. In your letter, you call for a stop to the changes the PMPRB is trying to introduce through the guidelines, and also for conducting "a full investigation of the agency and its work". You sent this to the Prime Minister.

Have you heard back from the Prime Minister or anyone in the government? What type of investigation did you have in mind?

Ms. Kelly Grover: We have not heard back from anyone.

Just thinking and listening to everyone, I sort of want to stress something. We were called out as a patient organization for spreading disinformation and being an opponent, yet we agreed with some of the changes made by the PMPRB, so I find this very curious and wanted to make that clear.

We also were asked to be part of a consultation, and we took our time. We are very busy. We are trying to get a drug funded in Canada, which is no small feat for a rare disease, so I wanted to make that clear.

In terms of the investigation, it is outlined in the CF treatment society letter. We would be looking for the guidelines to be stayed while we look at the conduct of the PMPRB, how they are consulting with patient groups, and then how they maligned us in this, or intended to. They maligned us in the document. Whether the document was put into action, I couldn't say.

As I said earlier, the board chair doubled down on this, and so did Mr. Clark, who was asked about it in a media report. There is nothing wrong with combatting...or doing a communications plan. Calling people liars and spreading fake news about those who are trying to do the best they can as a charity and for the community, I find really concerning. I think you should be concerned. I think the Prime Minister should be concerned, and I think the health minister should be concerned.

● (1430)

Mr. Tom Kmiec: Thank you for that. I have one last question.

Obviously, you're talking to other patient advocacy groups in the lead-up to the implementation of these regulations on July 1. Should that come about? Should the government not delay it further or maybe stay them, like you asked them to do, to conduct an investigation of the PMPRB?

What will you do in the six months afterward to advocate on behalf of the families who are affected by cystic fibrosis? Do you trust the PMPRB to conduct the implementation?

Ms. Kelly Grover: I am going to answer the last question and come back.

We don't trust the PMPRB for the implementation. They are doing consultations on the evaluation right now. None of us knew about it, because it was promoted on Twitter, and we're not on Twitter all the time, so that was a bit of a problem.

As for what are we doing to do, honestly, we only have so much time and so much energy, and so does this community. We need to get Trikafta into the hands of people who live with this disease. That is not going to be through the PMPRB now, so we have to turn our attention over to our provincial partners and hopefully see this drug funded. We are concerned about the future of cystic fibrosis drugs at this time, but, as I said, we're going to keep our eye on it.

Also, Dr. Morgan spoke about the rare disease framework. Obviously, we are interested in that as well.

There's only so much time and energy. The priority is getting this drug here now.

The Chair: Thank you, Mr. Kmiec.

We go now to Dr. Powlowski for five minutes.

Mr. Marcus Powlowski: First, let me start by saying that nobody should ever question the integrity of parents of sick children in doing what they're doing. Certainly, I don't think anybody is lying. I think, however, there might be some disagreement as to how to best help Canadians, including Canadians with cystic fibrosis. In passing, I would note that one of my kids' best friends has cystic fibrosis and certainly would like access to Trikafta.

I have a question for Ms. Grover. Hopefully she can be fairly brief. Vertex was refusing for a long time to ask Health Canada for approval for Trikafta. I know Cystic Fibrosis Canada has been advocating and lobbying for these changes to the PMPRB to be withdrawn. Has Vertex at any time asked Cystic Fibrosis Canada to lobby the government on this issue?

Ms. Kelly Grover: No.

Mr. Marcus Powlowski: Have they told Cystic Fibrosis Canada that the reason they weren't asking for approval from Health Canada was a result of the proposed changes to PMPRB, and that unless those changes were withdrawn, they wouldn't submit the drug for approval?

Ms. Kelly Grover: They didn't tell us that, but it was said publicly.

Mr. Marcus Powlowski: I would like to now address my questions to Professor Morgan. If there is time, I will also give Ms. Grover an opportunity to respond.

Professor Morgan, in your opinion, do you think drug companies are using patient advocacy groups basically to do the lobbying for them in order to further their own business interests, and by refusing to put an application before Health Canada for their drug Trikafta, are they not holding sick Canadians with cystic fibrosis hostage to their demands?

What are pharmaceutical companies really afraid of? It might be because these changes.... I've heard they're really afraid that these changes to the PMPRB would basically allow other jurisdictions to figure out the actual price our country was paying for drugs, and what purchasers were paying in our country.

This is a jealously guarded secret. As you've said previously, they don't want countries to know what other countries and other jurisdictions, other buyers, are paying for their drugs. With these changes to the PMPRB, it would allow HTA and pharmacoeconomics in the PMPRB to set a maximum price based on HTA and a maximum QALY saved.

When PMPRB was looking at the actual price that it would allow for a drug, this would allow other countries to figure out the price that Canada and purchasers in Canada were paying for the drug.

● (1435)

Dr. Steven Morgan: You've bundled a couple of questions. I appreciate that, because I literally have to run after responding to this.

PMPRB's net-after-rebate price restrictions on economic analyses would not necessarily disclose the final prices in Canada, because it sets a maximum price that the manufacturer could ask payers in Canada to pay. Payers might well negotiate even lower prices. The fact that these medicines have very high sticker prices, which are covered in other countries, is certainly a reflection that those countries are getting rebates.

My own research shows those rebates are often more than 50% off. For very expensive drugs, they can be in the order of 80% to 90% off the list price. Internationally, everyone knows this is happening, but we don't know the exact numbers. The regulations are not going to disclose corporate secrets globally.

In terms of investments in patient organizations, Ted Marmor, a famous political scientist who studied health policy in the United States, used to use the line that nothing that is regular is stupid. Manufacturers make investments in patient organizations when they need to pursue particular aspects of their overall public relations strategy. Some of that is good will, and some of that is providing resources to voices that can help them build their cases. If those voices turned against the manufacturer, and were as vocally critical of the manufacturer as they are of drug plans that might not want to pay the price that is being asked, you'd find that the resources and the funding for the charities would dry up.

I'm very sorry to the committee, and to you, Mr. Chair, but I must go.

Thank you, and good luck with the rest of the hearing.

Mr. Marcus Powlowski: Do I have time?

The Chair: Mr. Powlowski, your time is up.

Thank you, Doctor Morgan. I appreciate your time with us.

[*Translation*]

Mr. Thériault, you have the floor for two and a half minutes.

Mr. Luc Thériault: Mr. Chair, in response to his question, I urge Mr. Van Bynen to read page 3 of the Research Canada paper on government investment matters. It states:

> We believe that if we do not get this right they may threaten to undermine the government's historic investments in research and innovation, constrain an increasingly vibrant health research and innovation ecosystem and market for high-quality jobs, and will ultimately restrict patient access to lifechanging treatments.

It is not the industry saying this, it's the people doing basic research. Somehow, there has to be a compromise. To get it right, those researchers first recommend delaying the implementation date of July 1. Second, a roundtable should be established to bring partners together to find common ground for the rest of the implementation process.

For example, they could decide to delay implementation and act on the recommendations from the papers, which, at the moment, show a consensus. They recommend reviewing the reference basket of countries and then sitting down with all the stakeholders, whether it's representatives from patient organizations, the research community, life sciences, the Institut national d'excellence en santé et en services sociaux, INESSS, which is doing important work, the Canadian Agency for Drugs and Technologies in Health, CADTH, the American Pharmacists Association, and obviously the PMPRB. They all want to discuss and really consult this time. We would also have representatives from the pharmaceutical and biopharmaceutical industries at that table.

Who would be against doing it that way? Wouldn't that be the way to go right now, faced with this mess, these distortions, these relationships and this jumping to conclusions? Do you really believe that they are going to get results if they don't do it like I just suggested to you, using an approach that's in line with Research Canada's?

Mr. Lévesque, would you be willing to sit at such a roundtable? Is that a solution, in your opinion?

Mr. Paul Lévesque: Yes, it's a solution.

As I have been saying since earlier, the list price, the catalogue price, is one issue. I see agreement that people are paying too much for drugs in Canada. I'm a taxpayer like everyone else and I have nothing against motherhood and apple pie. However, in my opinion, the price that counts is the price the provinces pay—in other words, a negotiated price.

I do feel we need to sit down at the table and be creative. It's been said that we haven't followed through on creative ideas. However, I don't see how a reform that simply sets a list price at half the U.S. price because the reference basket changes is going to fix anything. That's just the list price.

● (1440)

Mr. Luc Thériault: Thank you.

Ms. Grover, would you agree to sit at the roundtable?

You can just say yes or no.

[*English*]

Ms. Kelly Grover: Yes.

[*Translation*]

Mr. Luc Thériault: Thank you.

Ms. Anie Perrault: I'd like to say to Mr. Thériault that some key partners are missing from that roundtable, and I mean the provinces.

The Chair: Mr. Davies has the floor.

[*English*]

Mr. Davies, please go ahead. You have two and a half minutes.

Mr. Don Davies: Thank you.

When we undertook the study, the analysts from the Library of Parliament told us this about the PMPRB:

> ...an independent quasi-judicial body whose mandate is to regulate the prices of patented prescription and non-prescription medicines to ensure that the prices are not "excessive" during [the] period of market exclusivity. It does not have a mandate to set the prices of patented medecines [sic] sold in Canada.

Dr. Batt, in a joint written submission to the committee, you said:

> When independent stakeholders and industry representatives hold "divergent and even diametrically opposing points of view," the PMPRB's responsibility is not to strike a "balance" between the demands of industry and policies that serve the public interest. The PMPRB's role is to come down firmly on the side of the public. It is not to protect the payers... and it is definitely not to make concessions to an industry that is far too powerful.

I wonder if you can expand on what you think the role of the PMPRB should be.

Ms. Sharon Batt: I see the PMPRB as a consumer protection organization. I have worked for a consumer protection organization in Quebec, where I was one of the editors of their consumer protection magazine. The concept of a consumer protection organization is that industry is very powerful and that individual citizens are not particularly powerful, and they need the government to step in and take their side when there is a contest between a powerful industry and the public interest.

Mr. Don Davies: Thank you.

I have a very quick question. Given that there seems to be broad consensus that prices are excessive in Canada, and given that it's the PMPRB's job to regulate that and it clearly hasn't, what do you think of the latest PMPRB reforms? Should we go ahead with them or not?

Ms. Sharon Batt: Yes, we recommend that the reforms go ahead. They've already been delayed twice, so I hope they're not going to be delayed again.

Mr. Don Davies: Thank you.

Also, I want to make a brief comment, if I may, because I think it is important.

I'm starting to hear more and more that health care is a provincial responsibility. That is actually not correct. In the Constitution of Canada, subsection 92(7) gives to the provinces "The Establishment, Maintenance, and Management of Hospitals, Asylums". Actually, constitutionally, health care is a shared responsibility according to the Supreme Court of Canada, so I think it is important we remember that it's a very important role for both the federal government and the provinces, and not exclusively the provinces.

Thank you, Mr. Chair.

The Chair: Thank you, Mr. Davies.

We started late and I've made an allowance for that. We have used up our hour and a half pretty much for this panel.

I'd like to thank all of the witnesses for sharing your time with us today, your expertise and helping us with our study.

That being said, I now suspend so we can bring in the next panel.

Thank you, all.

● (1440)

_____(Pause)_____

● (1445)

The Chair: We will now resume the meeting.

Welcome back to meeting number 41 of the House of Commons Standing Committee on Health. The committee is meeting today to study the Patented Medicine Prices Review Board guidelines.

I'd like to introduce the witnesses at this point. From Innovative Medicines Canada, we have Pamela Fralick, president, and Declan Hamill, vice-president, legal, regulatory affairs and compliance. From the Institute of Health Economics we have Dr. Christopher McCabe, chief executive officer and executive director. From the Liv-A-Little Foundation, we have Erin Little, president, and J. Scott Weese, professor.

I will now invite the witnesses to present their statements.

Just as a matter of procedure, when you're nearing the end of your time I'll display a yellow card and when your time is up I'll display a red card. When you see the red card, you don't have to stop instantly, but do try to wrap up.

Thank you very much.

With that, we will go to Innovative Medicines Canada for six minutes.

Please go ahead, Ms. Fralick, I presume.

Ms. Pamela Fralick (President, Innovative Medicines Canada): Mr. Chair and honourable members, thank you for the opportunity to present today. I'm joined, as you've just heard, by Declan Hamill, our vice-president for policy, regulatory and legal affairs.

We are here on behalf of Innovative Medicines Canada, which represents 47 member companies from the innovative medicines and life sciences sectors. The pandemic continues to underscore the importance of innovative medicines to the health of Canadians. Most importantly, it is demonstrating why timely access to innovative treatments and vaccines is so critical.

It's also one of the reasons we are calling on the government to suspend for the duration of the pandemic the implementation of the Patented Medicine Prices Review Board's regulatory changes, which are set to come into force on July 1.

The government has previously cited COVID-19 as a primary reason for delaying the implementation of the PMPRB's regulatory changes. I think we can all agree that the same rationale applies today. More importantly, delaying these regulatory changes will also ensure that we all have the time needed to re-evaluate the desired policy outcomes, the effectiveness of the consultation process and the premise on which the PMPRB's new regulations were developed.

Since the changes were first proposed, there has been a strong consensus among industry representatives and many stakeholders that the consultation activities were not intended to inform decision-making. From initial steps, which included a 2018-19 steering committee and working group, through to later stages, many points of concern were raised and disregarded.

The lack of meaningful engagement led industry to undertake serious actions, including two Federal Court legal proceedings and a constitutional challenge in Quebec. Most recently, in its submission to the Quebec Court of Appeal, the Attorney General of Quebec submitted that the proposed PMPRB changes infringe on provincial jurisdiction and that therefore all the regulatory changes should be disallowed.

Providing the appropriate time and process to consider any PMPRB regulatory changes will also ensure that any decisions are based on accurate understanding of where Canada stands regarding the price of medications compared to those in other key countries. Contrary to PMPRB's assertions, Canadian drug prices are in the middle of the current list of those of comparative countries, not at the top.

Overall, median international prices were 16% higher than Canadian prices. Increases in the annual Canadian price of patented medicines have been on average less than the rate of inflation as measured by the consumer price index.

Further review will also demonstrate that the price of innovative medicines is not the primary cost driver for Canadian public and private drug plans as PMPRB claims. Rather, increased drug use by Canada's aging population and the related growth in chronic diseases are the primary cost drivers, not the price of medicines. Although the need for Canadians to have access to the most innovative medicines and vaccines is clear, the PMPRB regulatory changes will impact the market incentives that encourage early access availability in Canada.

Information obtained through an access to information request shows that PMPRB's analysis concludes that prices for certain medicines will drop between 90% and 99%. There is a point at which price reductions make it not commercially reasonable for companies to introduce drugs for approval in Canada or alternatively that they will be introduced significantly later. This is already an issue in Canada.

Independent data sources show that Canadians have access to only 48% of all new medicines launched globally, which means we are behind countries like the U.K., Germany, Japan, and France. This gap in access will increase if the proposed PMPRB changes proceed.

Additional time to consider PMPRB regulatory changes will also provide an opportunity to reflect on the true breadth of the Canadian biopharmaceutical sector's economic contributions. According to a recent report from Statistics Canada, the sector generates almost $15 billion in economic activity and $2 billion annually in R and D spending. Calculations based on this data put the industry's ratio of R and D to sales ratio at 8.8%, which is more than twice that reported by PMPRB, which uses a 1987 definition of research and development.

To be clear, our industry is not opposed to modernizing PMPRB, but we believe it can be done in a way that maintains patient access to new treatments and medications, builds on Canada's talent and expertise, and attracts international investment.

A vibrant life sciences sector in Canada starts with clear and balanced policy objectives. We believe a whole-of-government approach involving Health Canada, Innovation Science and Economic Development, Finance and International Trade is essential. It also includes fair and accurate reporting on patented medicine pricing, on understanding the real cost drivers to the system and prioritizing the value of saving lives.

● (1450)

IMC and our international counterparts remain committed to working with the federal government and all stakeholders. Our global CEOs have reached out to the Prime Minister on several occasions over the past three years, hoping to engage in collegial and collaborative dialogue, and to this day remain keen to develop a productive working relationship.

Thank you for this opportunity to speak with you today. I respectfully request that the committee recommend that the government delay the implementation of the PMPRB’s regulatory changes.

We look forward to answering your questions.

The Chair: Thank you.

We go now to the Institute of Health Economics.

Dr. McCabe, please go ahead for six minutes.

Dr. Christopher McCabe (Chief Executive Officer and Executive Director, Institute of Health Economics): Thank you, Mr. Chairman and honourable members. It's a privilege to be able to address you today.

Canada spends over $15 billion on pharmaceuticals each year. Therefore, how we decide prices is a crucial issue of public policy. I think it's useful to identify the principles that should guide public policy in this space.

The first principle I would propose is that governments do have a responsibility to pursue good value in how they spend taxpayers' dollars. The second is that all Canadians are equal before the law. The third is that we here in Canada look after our neighbours.

The new PMPRB regulations consist of two components: the revision of the reference price basket of countries and the adoption of a form of value-based pricing for some drugs.

I view the first change as uncontroversial. It ensures that Canadian prices will remain in line with our economic peers, most of which receive larger industry investments than we do. The removal of the U.S. from the basket is reasonable, given that the U.S. is recognized as a global outlier for pharmaceutical prices and its prices drive significant access problems in their own country. Given the remaining reference basket of countries have very good access to pharmaceutical products, any changes in the supply of drugs to Canada after the implementation of the new regulations cannot, I would argue, credibly be attributed to a reduction in our prices.

The adoption of a modified value-based pricing for category I pharmaceuticals is more controversial. Patient groups are legitimately concerned that innovative drugs will not be brought to Canada, and the pharmaceutical industry has raised equally legitimate questions about its impact on investment in developing future innovative therapies.

In its pure form, value-based pricing is a way of operationalizing the principle of equality. Value-based pricing sets the price for a product to ensure that the health gained from buying the product is at least equal to the health lost by other Canadians that results from diverting health care funds from their current activities to pay for it.

The importance of caring for our neighbours drives a divergence from this pure form. The PMPRB's version of value-based pricing will sacrifice equality to ensure patients in need can access highly effective innovative treatments. For breakthrough treatments, the PMPRB regulations will establish prices that sacrifice at least six years of good health for other Canadians for each year of good health the new innovation produces.

It is legitimate to ask whether this 6:1 trade-off is sufficient to attract investment in developing future innovations. By setting a value-based price, the PMPRB—essentially on behalf of Canada—is signalling to future investors our willingness to pay for future products, which they will take account of. Is the proposed value-based price sufficient to encourage investment to address unmet needs?

Dr. Aidan Hollis of the University of Calgary evaluated the recent highly effective innovative therapies for cystic fibrosis to examine whether the prices the manufacturers would like payers to pay were required to achieve acceptable returns on investment. His detailed evaluation established that standard pharmaceutical industry target returns would have been achieved with prices approximately one-tenth of those that the manufacturers wanted to charge. The evidence does not support this concern that the implementation of the new PMPRB regulations will impact upon investment in the development of novel pharmaceuticals.

The PMPRB is concerned with protecting Canadians from excessive—as distinct from abusive—pricing. Value-based pricing is a robust operationalization of the concept of "excessive". When we spend over $200 billion a year on health care, the idea that the price for any single technology is unaffordable is not credible.

"Excessive" can be operationalized by considering whether what we have to give up to pay for a new drug is justified by what we gain. As a starting point, giving up more than you gain is excessive unless there are extenuating circumstances—hence, value-based pricing. Having a conceptually robust operational definition of "excessive" strengthens the PMPRB's processes and provides greater certainty for manufacturers and investors.

The revised regulations are consistent with important Canadian values—

● (1455)

The Chair: Pardon me, Doctor.

I stopped your time. I want to ask you to raise your microphone to about the level of your upper lip. You're getting a lot of popping and so forth, and it is very difficult to hear.

Please carry on. I'll resume your time at this point.

Dr. Christopher McCabe: The revised regulations are consistent with important Canadian values of value for money, equality and caring for our neighbours. The available evidence, while limited, does not support the concerns that the change in the return on investment will damage investment in future innovations. The experience of countries in the reference price basket, in accessing innovative pharmaceuticals, does not suggest that Canadian patient access should be impacted by price reductions.

There may also be benefits to industry and patients. Aligning PMPRB's regulations with the methods used by payers to evaluate drugs should expedite the currently lengthy price negotiation process, allowing companies' products more time on market with reimbursement.

Further, the downstream pressure on prices will strengthen companies' incentives to be more efficient in development, manufacturing and marketing of their products. Companies that can always pass costs on to the price taking consumer are unlikely to be as efficient as those that cannot.

In addition, the downward pressure on average prices will allow payers to provide coverage for more drugs for more Canadians from the same limited resources, and in the long-term should reduce the costs of prescriptions to Canadians.

Thank you, and I'm happy to answer any questions.

The Chair: Thank you, Doctor.

We'll now go to Ms. Erin Little, for six minutes, please.

Ms. Erin Little (President, Liv-A-Little Foundation): Mr. Chair and members of the committee, thank you for the opportunity to appear before you to share my personal views about the Patented Medicine Prices Review Board and my personal experiences as a rare disease advocate.

My name is Erin Little. I am the president and co-founder of Liv-A-Little Foundation.

Liv-A-Little Foundation was founded in 2013, two years after our daughter, Olivia, was diagnosed with the rare disease cystinosis. We are a volunteer-run organization committed to supporting the advancement of treatments and, ultimately, a cure for cystinosis.

Procysbi is an excessively-priced drug that was flagged by the PMPRB in 2017. It's a perfect example of how the PMPRB protected patients. I have provided you with the PMPRB statement of allegation regarding Procysbi.

The Cystinosis Research Foundation funded every bench study and early clinical trials at UCSD, which resulted in the development of a slow-release form of cysteamine. In 2016, Raptor Pharmaceutical was bought by Horizon for $800 million. Procysbi is the result of a business deal, not R and D. How many other companies are using this same business model to build their portfolios?

As members of Parliament argue about the PMPRB spending $56,000 to invest in an effective communication plan, I would recommend they be more concerned that in 2020, Horizon's CEO raked in $21.63 million U.S., which is more than the PMPRB's annual budget. Let us be honest, the PMPRB can use all the help it can get when it comes to educating patients and Canadians on what and why it does what it does.

In 2019, Recordati brought the new, non-patented drug Cystadrops to the Canadian market with a sticker price of $120,000 a year. No patent meant no protection from the PMPRB review board. Cystadrops is another example of taking an old drug, tweaking the delivery mechanism and marking it up by 4,000%.

Recordati's GM and I were discussing the price. He admitted the drops would be expensive and then proceeded to tell me that all they're asking for is a little bit more from each taxpayer to cover the cost of a small population of patients. I sat there in dismay for two reasons. First, I was in shock that pharma prices drugs based on what the market will bear and not on what it cost to make them. The second was that I am one of those taxpayers.

What are we going to do about this? Are we printing money to continually pay for high-cost drugs? If we are, then let's print it for clean water, for the 215 bodies just found, for the homeless, for the kids who go to school hungry, for mental health services and for LTC homes. When we pay for excessively priced drugs, the money needs to come from someplace, which means someone else goes without. If and when we hold big pharma accountable to charge what the drug is worth instead of what the market will bear, we all win.

We are all familiar with the term “grooming” when it's referencing sex trafficking children, but no one is yet talking about how pharma is grooming advocates. Grooming is when someone builds a relationship, trust and emotional connection with someone so they can manipulate, exploit and abuse them.

In November 2017, Horizon Pharma invited us and a select few Canadians to a round table meeting. The meeting wasn't about our concerns; it was about building a common advocacy voice shaped by Horizon. I have provided you with the agenda from that meeting along with a letter of intent. That meeting is an example of grooming patients.

Horizon has also created the platform RAREis on Instagram. RAREis gives patients, advocates and families a place to share their stories and be heard. This is a perfect example of building trust and emotional connection with vulnerable advocates, which leads to manipulation and abuse. The repercussions of these relationships mean that advocates turn against our government.

In October 2018, I sat at this table and heard what it would cost to keep Olivia alive based on the average life expectancy at that time. It was hard to hear this, as a mother who wants nothing more than to outlive her child. I also understand why she had to bring that cost to the committee's attention: High-cost drugs are not sustainable in our health system.

I want to share with you the current cost faced by two different families living with cystinosis. Family A has a Procysbi cost of $56,000 a year and Cystadrops is $120,000. For family B, Cystagon costs roughly $18,000 a year and compounded drops are just under $3,000. All four of these drugs are made with cysteamine.

The first evidence regarding the therapeutic effect of cysteamine on cystinosis dates back to the 1950s. The delivery is changing, but not the ingredients. Is the change in the the delivery mechanism worth a 4,000% increase?

In conclusion, I support the implementation of the new guidelines and I strongly suggest we look hard at advocacy groups that are funded by industry and question whether they are being groomed by the industry. I strongly believe that every patient deserves to access drugs that are safe, effective and affordable.

Health Canada needs to do a better of job of listening to the patients, caregivers, and organizations not funded by pharma. We once trusted our child's life in the hands of a Canadian organization only to be betrayed, as their agenda was to support the industry. This organization happens to receive funding from both pharma companies treating cystinosis patients in Canada.

● (1500)

I will end with this. I am not against for-profit companies, but I am against the greed, manipulation and control they hold over the lives of every Canadian. Our child like many others would die without access to these drugs. I remember the days when I feared if Olivia would live. Now I fear if she will be able to afford to stay alive.

Thank you, and I'm willing to answer questions.

● (1505)

The Chair: Thank you, Ms. Little.

We'll start our round of questions now. I believe we'll start with Monsieur d'Entremont.

Go ahead, please, you have six minutes.

Mr. Chris d'Entremont: Thank you very much, Mr. Chair.

Where do we go from here? The PMPRB has been around for a while. We were talking about it on our first run-around. We've had some very good testimony here today—very emotional.

Ms. Little, thank you so much for your presentation on that as well.

It's hard to figure out where to start on this one. Maybe a quick question here is on how a lot of concepts are getting caught up in our discussion here. We've got expensive drugs, rare diseases and a rare disease strategy issue that we need to be talking about. I don't know if it belongs in here. It does, but it doesn't. We have the issue of pricing that belongs in here and it doesn't. We have the issue of this pharmacare that's been promised to Canadians on a number of different occasions. That's caught up in here. It's hard to figure out.

Maybe I'll go to IMC for a few minutes.

Where do you think things should go from here? If the government has already twice held back from expanding the regulations.... I have to figure out how to actually ask this question correctly. Do we hold them off again? I ask because I'm sure that holding them off twice now has created even more challenges within the system, because the system is probably very anxious on how pricing is going to happen, how the reviews are going to happen, how PMPRB is going to work. So is holding it off for another six months conducive to the companies? Maybe that's the first question for Pamela.

Ms. Pamela Fralick: Through the chair, thank you very much for that question.

It's not about delay for delay's sake. It never has been. It is about reaching a better outcome than we feel is possible through the current regulations that are being proposed. Without taking up time on this call, I have a pile of correspondence that has gone to ministers and the Prime Minister from us at the association, from our global CEOs, requesting that dialogue. We believe, as Monsieur Lévesque mentioned in the previous session, that better solutions are possible. That, to me, is what the delay is about. It's to have that time, especially with this kind of a hearing that this committee is so generously offering to those of us interested in this issue. Let's truly get to that discussion that will lead to a better outcome than what is currently on the table.

Mr. Chris d'Entremont: I have a simple question. Are drug prices too expensive in Canada?

Ms. Pamela Fralick: I'd love to quote some data back to you from PMPRB reports, because I think there's a bit of a discrepancy between some of the sound bites that you might hear versus the data from the actual reports.

There are three comments I could make. The first point is that only three of the countries in the current basket of countries have prices below Canada's. The price difference is quite minor. The second point would be that relative prices have declined over time. I mentioned this in my opening comments. Prices in Canada have been around 20% below the median of the PMPRB7 for the past year. That's the lowest they've been in the history of the PMPRB. The last comment I would make is that the PMPRB says that U.S. prices are a global outlier and that this makes Canada's prices appear lower than they are. However, even when the prices are only compared with European countries in the PMPRB7, Canadian prices are still in line with that median, according to the last five PMPRB annual reports.

You can argue, do we still want them lower? That's another question. But in terms of what you've heard through the media and statements from PMPRB, I would just add that additional information.

● (1510)

Mr. Chris d'Entremont: Maybe the last question will go to Dr. McCabe, because I'm going to run out of time quickly.

We talk about value-based pricing. Would you try to expand a little bit on that? We have what the listing price is, we have what the sale price is and we have this whole negotiation that goes on in-between. What can patients actually pay, or are we still continuing to be worried about what provinces can pay or what plans can pay? There is a whole bunch of different payers. Who do we actually work with here?

Dr. Christopher McCabe: I think this is really important, and it's what I've focused on. The PMPRB is setting this maximum price, and it's the only location where the whole of Canada can actually have a conversation about good value for money. Once the PMPRB maximum price is set, then all of the payers, the HTAs and all of that, come into play. It's not part of this discussion, to be honest. If it helps you then not to say, “Okay, let's just talk about it: Is this is a way of establishing a price that is not excessive?”—because that's its function....

As I tried to outline, using value-based price is a nice way to operationalize that concept of “excessive”. Once you have “non-excessive” prices, then the rest of the market can work as it does currently. I hope it doesn't, because I think there are much bigger efficiencies for industry, patients and health systems by dealing with the fact that it typically takes18 months to two years from Health Canada approval to getting a reimbursed invoice. I think there are much bigger gains to be had by re-engineering that process. But Canada as a whole does need an operationally robust definition of an “excessive price”. I think that's what this is about, and if we can all focus on that, it will help us.

Mr. Chris d'Entremont: You have 40 seconds left there—maybe 30.

There you go.

The Chair: You're finished. Thank you very much.

We go now to Dr. Powlowski for six minutes.

Mr. Marcus Powlowski: My questions are for Professor McCabe.

In the previous panel, we heard from Cystic Fibrosis Canada, a group that has strongly advocated for us to drop the proposed changes to the PMPRB. Let me ask the same question I asked somebody on the previous panel. Are some drug companies, in your opinion, using patient advocacy groups to further their own financial interests? Are at least some drug companies, by refusing to apply for Health Canada approval—as Vertex was doing for some period of time—not holding sick Canadians hostage to their demands? Certainly, part of their demands is that they don't like the changes to the PMPRB. That's one question.

I'd like to pose my second question now in case your answer to the first one is overly lengthy. What can we do when companies refuse to ask for Health Canada authorization of life-saving drugs? What can we do in the example that Ms. Little gave? A drug is no longer under patent; however, the drug company is asking for really excessive prices.

I would suggest that in TRIPS, the Agreement on Trade-Related Aspects of Intellectual Property Rights, there is a realization that intellectual property rights shouldn't trump all other human values. As a result, within the TRIPS WTO agreement, there are the TRIPS flexibilities. One of the TRIPS flexibilities is compulsory licensing, which allows the government to give a licence to a non-patent holder. They do have to compensate the patent holder. In your opinion, when we're getting predatory behaviour by some drug companies that would seem to be holding Canadians hostage, should we not reconsider reinstituting legislation that would allow us to do compulsory licensing?

Thanks, Professor.

Dr. Christopher McCabe: I'll try to be quick.

To your first question, pharmacy companies are doing exactly what we asked them to do. We have set up society and asked them to maximize their profits. That has a lot of good things about it. They're doing what we asked them to do as a society. If we want them to do different things, we should change the legislation.

They have a coincidence of interest with patient groups, and least in certain forms. Some patient groups choose to work with them and others don't. That's their right—their right of free speech. I'm not going to judge them. I think all of us probably have people in our family who we've lost too early or in horrible circumstances. I'm not going to judge those things. I think people are exercising their rights of free speech and doing what we asked them in looking to maximize their profits. We just need to recognize that it's what we're dealing with.

The second question is about the role of compulsory licensing. I think compulsory licensing is there as a protection for when the system fails, and sometimes the system does fail and sometimes governments have to be willing to use it to create incentives for people and stakeholders in these sorts of processes to engage effectively and to find solutions.

I do believe if the system is abused and there is no willingness to move away from that abuse by the patent holder, it is within government's right to use compulsory licensing. However, whenever that happens, it's proof that the system has failed and we should be looking to find out why the system failed.

● (1515)

Mr. Marcus Powlowski: What would you suggest in response to Ms. Little's point about the price that the drug company is asking for the treatment of her daughter's cystinosis? The system would seem to have failed if they're asking for $100,000 and there's nothing we can do about it.

If, for example, Vertex is not bringing the drug to market, does that not suggest to you that the present system is failing?

Dr. Christopher McCabe: I would say that both of those are credible examples of the system failing, and the government should take seriously its responsibilities to its citizens and certainly entertain the use of it.

The U.K. government did entertain the use of its rights around a very expensive breast cancer drug, which helped to trigger a negotiation that otherwise might well not have happened. These tools are there for a reason and are used sparingly but effectively, and I wouldn't criticize anyone who used them in both of the cases you identified.

The Chair: Pardon me, doctors.

Dr. Powlowski, I'm going to stop your time.

Dr. McCabe, could you move the mike a bit farther away from your mouth? We're getting a lot of popping. It's really harmful to the interpreters to try to deal with that.

Dr. Christopher McCabe: I do apologize.

Is that better?

The Chair: Say a few things. Tell us about the weather.

Dr. Christopher McCabe: I feel like I've talked enough already. Is that better?

The Chair: To my ear, it's better. I'll look to the clerk to see if it's good.

It's a little *comme ci, comme ça*.

Dr. Christopher McCabe: I'm sorry to be such a troublesome witness.

The Chair: Well, it's not you; it's your mike. Let's forge ahead as we are.

Dr. Powlowski, you have one minute left.

Mr. Marcus Powlowski: We had a witness in the previous panel who suggested that the results of these changes to the PMPRB would be like Tesla getting $100,000 for its vehicle in the United States but in Canada only getting $50,000 for the same vehicle, so why is anyone going to want to sell in Canada?

We've also heard, I think on this panel, too, people talking about reductions in profits. These will result in a reduction in their asking price from 90% to 92%.

Professor McCabe, with those particular examples, is this legislation that draconian that it's going to cause such a loss of profits for a pharmaceutical company?

Dr. Christopher McCabe: It is a very strong set of regulations, and we need to remember that old saying that "Hard cases make bad law." There will be extreme cases where the mismatch between the price that is asked and the value that is delivered is very large.

We have to ask ourselves, do we want to pay massively over value? Do we want to sacrifice a lot more of other Canadians' health to avoid these reductions in revenues?

You only get that if actually the expected value, how it impacts on patients' health, is completely out of kilter with the price that the manufacturers are asking to be paid, yet if you are out kilter on your ask, you will see a very large reduction. That's not necessarily a bad thing, because I don't think any of us want taxpayers' money to be paid for low-value technologies, which is what will be the case in that circumstance.

● (1520)

The Chair: Thank you, Doctor.

[*Translation*]

Mr. Thériault, you have the floor for six minutes.

Mr. Luc Thériault: Thank you, Mr. Chair.

We have a situation where people are claiming that we need to implement the reforms as they stand and that the pharmaceutical companies are indeed bluffing. They believe that the drug companies are not going to leave, that clinical trials are going to continue and that patients will face no consequences, even though we have no innovation strategy, even though we separate health from innovation and from research and development, and even though we have no really effective rare disease strategy in place. Some people feel that there will be no impact. Some people feel there are risks.

Ms. Fralick, I'd like to know what Canada represents in the global market. We can always target Vertex, but if it simply didn't start clinical trials here, we would have access to those drugs six to eight years down the road, right?

No one is going to be able to single out anyone, because it's a global free market. Am I mistaken?

Ms. Pamela Fralick: Thank you for the question. I will answer in English, if I may.

Mr. Luc Thériault: We are having interpretation issues. Did you switch to the English channel?

[*English*]

Ms. Pamela Fralick: I'm going to speak in English. I haven't changed my channel.

The Chair: I'll stop the clock here, Mr. Thériault.

You can put the interpretation on whatever channel you want to hear, and then you may speak in whichever language you wish. The interpreters will interpret accordingly.

Ms. Pamela Fralick: It's been fine until now.

[*Translation*]

Mr. Luc Thériault: Mr. Chair, can we start over? I will quickly repeat my question.

What weight does Canada carry on the global market?

Can we really believe that companies are bluffing when they say there will be fewer clinical trials?

[*English*]

Ms. Pamela Fralick: There are many elements to your question. We already lag behind our international peers in terms of the numbers of new products launched. This would be my first point. It's critical that the PMPRB does not further erode Canada's status in that global market.

At the moment, Canadians only have access to 48% of all new medicines launched globally. That compares with 64% in Germany and 60% in the U.K. We've talked about that before and there is, of course, more in the U.S. Only 25% of all medicines are available in Canada within the first year of international launch compared with a higher percentage in Germany, the U.K. and the U.S.

There is also a time lag that has been referred to. I'll include that in my comments because you're asking about the international status of Canada. Canadians wait an average of 17 months from the first international launch, whereas medicines are available far sooner in other countries—for example, 11 months in Germany, 12 months in the U.K. and four months in the U.S., so we're already at a disadvantage.

You asked specifically about clinical trials, but if there's time, I'll add a bit more. The industry, first of all, is extremely important to Canada in its support of clinical trials. Between 65% and 75% of clinical trials initiated in Canada in every quarter since 2015 have sponsored by industry.

According to the data we have been collecting, there's been a decrease of about 20%, compared with the previous three years, in clinical trials being launched in this country. Some of that might be due to COVID. I know that someone raised that point, but we're looking at data across quite a period of time.

I have other data points on impact, but I will stop there in deference to your question.

● (1525)

[*Translation*]

Mr. Luc Thériault: You alluded in your presentation to an ineffective consultation process. You aren't the only one pointing that out. We've heard that grievance from a number of stakeholders. You said that the die had already been cast and that the reform had been determined in advance.

What makes you think that everything was predetermined?

I know there were two delays. I understood that you didn't want a third delay, roundtable or no roundtable, because a six-month delay would only draw out the uncertainty for six months. That would not help matters.

So what do you feel needs to be done with respect to the process?

[*English*]

Ms. Pamela Fralick: I want to recall something that I heard from the Secretary of the Treasury Board, Peter Wallace, early in his tenure when he was appointed to address that question. He talked about how important it is for government not just to listen and walk through a consultation process, but also to hear. That is the piece that we all fear has been missing in this process. We cannot state that the number of steps haven't been taken—they have—but we have not been heard.

Early in the process, I did submit a letter, which I can make available to this committee. The letter outlined our numerous concerns with the process and why we felt we were not being heard. Perhaps the most compelling data point is that 80% of 112 submissions to PMPRB's most recent consultation are opposed to or have expressed concerns about the guidelines, yet minimal changes have been made over the course of the four-year process.

Thank you.

[*Translation*]

Mr. Luc Thériault: Do I have any time left, Mr. Chair?

The Chair: You have 10 seconds left.

Mr. Luc Thériault: I will come back to it in the second round.

The Chair: Thank you, Mr. Thériault.

[*English*]

We'll go now to Mr. Davies for six minutes.

Mr. Don Davies: Thank you.

Ms. Little, first of all, thank you for sharing your very personal experience, and best wishes to your daughter.

You made reference to the fact that the molecules involved in the medicine that helps your daughter were discovered in the 1950s, and if I understand correctly, all that changes is that a pharmaceutical company takes the same molecule, changes the delivery system and charges, if I may say, an outrageously expanded amount of money for it.

Can you explain that in detail to us?

Ms. Erin Little: Yes.

The active ingredient, cysteamine, is in all four of the products that I previously talked about. With cysteamine, the hardest part of almost any treatment, if you ask any patient, is the side effects. The side effects of cysteamine are from all drugs. When they took Cystagon and turned it into Procysbi.... Cystagon has to be given every four hours and Procysbi has to be given every two hours.

I wholeheartedly support this drug being here in Canada and Canadians having access to it. If Olivia were a 26-year-old woman managing a relationship and career, of course I would want her to have a drug that makes compliance easier. The problem is that all of the side effects are still the same: gastro upset, making patients smell, loss of or poor appetite, gas, bloating...just horrendous things that nobody wants to deal with.

The difference between Cystagon and the Procysbi was that they enteric-coated the latter, so it releases differently. Is it worth that? That's not for me to decide, but a drug—an active ingredient—that's been around for decades and was first introduced as a treatment in 1994 for patients...I find it unjustifiable and with the—

Mr. Don Davies: What was the price difference as a result of that change?

Ms. Erin Little: The drug is based on weight, I just have to point out. There is the two-year-old who takes Procysbi for $56,000 a year versus Olivia who takes Cystagon at $18,000 a year. If Olivia were on Procysbi, she would have to take a higher dose, which would result in more money.

The compounded eye drops that have been safe, effective and on the market for years are $3,000 a year. The new drops are $120,000 a year. Again, they do offer easier compliance, but the drug is the same.

● (1530)

Mr. Don Davies: I understand that you had some concerns about clinical trials. Can you explain to us your views on clinical trials and their importance?

Ms. Erin Little: Yes, and I'm going to speak only to our rare disease because it is the only disease I represent.

We are very fortunate that a cure for cystinosis is on the horizon. In 2019, a clinical trial opened that uses gene and stem cell therapy, which, again, will hopefully result in a cure. The clinical trial is in the States. Right now, the pharmaceutical company AvroBio is taking the time to take the clinical trials global. I know they're in Europe and they're moving to other locations in the States. They are not coming to Canada.

I will say, however, that the first patient to go through the clinical trial in the fall of 2019 was a Canadian male. We are still being offered clinical trials. I think this is where we need to hear more from patients. We need to hear the stories behind the words and the numbers.

Mr. Don Davies: Thank you.

Dr. McCabe, approximately what percentage of the money going into research to discover new drugs is publicly funded?

Dr. Christopher McCabe: That's an incredibly difficult question to answer, because—

Mr. Don Davies: I'm sorry, but Dr. Morgan told me to ask you.

Dr. Christopher McCabe: I'll thank him for that the next time we're having a beer, hopefully.

I don't have that figure at hand, but, undoubtedly, the basic and increasingly early translational work for pharmaceuticals and advanced medicinal therapies draws heavily on public dollars. I think the COVID vaccines are a fantastic example of how a great deal of investment from the public sector was then picked up to take through phase three trials, which the pharmaceutical industry are absolutely astoundingly good at, but it takes both. The proportions vary a lot.

I'm sorry. That's not a helpful answer.

Mr. Don Davies: No, that's good.

I'm going to spend a bit of time on the last one, because I think Trikafta is a very interesting example of this. I think every single Parliamentarian wants every single Canadian who needs Trikafta to get access to it, and that's not happening today.

Here's a brief history of it. We know that it was a research team at the Hospital for Sick Children at the University of Toronto that discovered a CF gene in the 1980s. It was the Canadian Cystic Fibrosis Foundation and clinics that identified almost all of the research subjects from families in Canada. They donated blood samples. The Canadian Cystic Fibrosis Foundation and the Canadian Institutes of Health Research supported the research. CFF gave $150 million to Vertex in 2000 to do the research.

When the company finally launched the precursor to that, Kalydeco, they priced it at $294,000 annually for two pills a day. Twenty-nine researchers contacted them; they wrote Vertex's CEO to express their dismay and disappointment that this successful drug was diminished by this “unconscionable price”, in their words.

Aidan Hollis, whom you reference, studied Vertex's pricing for Kalydeco and Orkami—a precursor as well to Trikafta—estimates that the company's profits from the two drugs will be $21.1 billion. He concludes that the high prices are not justified by costs or the need to support the innovation. The price seems more designed to reward shareholders.

My question is, what can we do to get Trikafta into the hands of Canadians? Is it time that the Canadian government used compulsory licensing? If this company won't apply to Health Canada to make this drug available, should we exercise our right to compulsory license that drug? Finally, how many times has the Canadian government used compulsory licensing?

Dr. Christopher McCabe: I don't know how many times the Canadian government has used compulsory licensing.

I think the magnitude of benefit of Trikafta to the Canadian CF population is so large that it would be legitimate for the government to consider using its compulsory licensing power if Vertex persists with not bringing it to Canada.

Again, I would hope that would not happen, because it would be a failure of the system.

● (1535)

The Chair: Thank you, Mr. Davies.

That wraps up round one. We will start round two. I believe it's with Mr. d'Entremont.

Mr. d'Entremont, please go ahead for five minutes.

Mr. Chris d'Entremont: Thanks a lot, Mr. Chair.

We get to the basis here: expensive drugs and access to certain drugs.

Maybe to Ms. Fralick, how do we make sure that drugs are available and bring down the prices?

Those are the two things that need to happen here. Drug pricing needs to go down, and Canadians need to have access to those drugs. Where's that middle in terms of where PMPRB is and where pharmaceutical companies are?

Ms. Pamela Fralick: We, as an industry, have pulled together on at least two occasions. I guess what we found was a good way forward and have presented this to government. I know that one of the honourable members of this committee did cite one piece of one of those offers, but it was an isolated piece that was really part of a comprehensive package that we felt would help government meet its policy needs. Again, it's still to ensure that Canadians get access to the drugs they need.

The government has not expressed an interest in that, which is why I continue to come back to my plea, if you will, and my most compelling point. There needs to be a dialogue, not just with industry and governments. I fully support having patients part of this. It has been part of our mantra over the last couple of years.

Mr. Chris d'Entremont: Within it, then, we should have some kind of table or place where the PMPRB can be a listener or chair the meeting—whatever it is we want them to do—and bring these different folks to that table.

Ms. Pamela Fralick: Yes.

Mr. Chris d'Entremont: Who should be at the table? You're saying that patient groups and pharmaceutical companies should. Who else should be there?

Ms. Pamela Fralick: The whole-of-government needs to be there. I did reference that in my opening comments.

At the moment, the PMPRB is within the Health umbrella, and everything we do has been put over to Health. Whenever we write to another department, it is sent over to Health, so we're stuck with a struggle between dealing with the cost containment debate with Health Canada, and on the other side with ISED—Innovation, Science and Economic Development Canada. We have a wonderful report that was done in 2018 by HBEST, the health and biosciences economic strategy table. We have a more recent one done a few months ago by the Industry Strategy Council. All of these promote the life sciences as an economic driver for the health and well-being of Canadians.

We're struggling as an industry. We're working very positively with Minister Champagne and have over the years with others, like Minister Bains, to try to encourage investment to come to Canada, but the cost containment policies really make it difficult for our CEOs to compete at the global level.

Mr. Chris d'Entremont: People at the table should include provinces as well. I was a provincial minister. A lot of times we had an opportunity to help set prices or purchase different kinds of drugs. Avastin was one decision that happened during my time. It was a few million dollars, and we had to make a decision on where we were going on it.

We funded it, by the way.

How do the provinces play into this? I ask because they are not necessarily a part of the PMPRB. They are a part of the other program.

Ms. Pamela Fralick: They do pay for the drugs, many of them, so they have a vested interest. We've had wonderful conversations with many of the provinces. Anie Perrault, earlier in this session, talked about the life sciences strategy in Quebec. We have had very good conversations in Ontario and with Nova Scotia, Alberta and British Columbia—you can go right across the country.

I think there's a way to do that. There has to be a will. I think that's the main issue. As Paul Lévesque said, with the pandemic, it's the wrong reform for the wrong time. Everyone is consumed with the pandemic, so let's start with a coalition of—hopefully—the willing and then figure out from there if we are missing anyone at the table.

Mr. Chris d'Entremont: Is there a part of these regulations that you would say you could phase in? We could continue to discuss a few of the finer points, but could a number of those recommendations actually be brought in immediately?

Ms. Pamela Fralick: I think this would be a beautiful start to a conversation. The concern is about the extreme nature of the impact of the regulations as they currently sit. The statistic that was just quoted a moment ago—the 90% and 99%—comes from a PMPRB assessment. It's not an industry assessment. We don't have a line of sight on all of those data that the PMPRB has been working with, so let's get to the table and discuss the art of the possible, as opposed to being so estranged and the relationship being.... I've used words like not “ideal” and “fractured”. You've seen that in the press when I've used them. We can do better.

● (1540)

Mr. Chris d'Entremont: I'm guessing I'm out of time.

The Chair: Yes, you are out of time. Thank you very much. You can be co-chair, perhaps.

We go now to Ms. O'Connell.

Ms. O'Connell, please go ahead for five minutes.

Ms. Jennifer O'Connell: Thank you, Chair.

Thank you to all the witnesses for appearing.

Ms. Little, thank you for your testimony and for sharing your daughter's story. You spoke toward the end of your opening statement about—forgive me for paraphrasing, but it stuck with me—how at first you thought about your daughter accessing these drugs to save her life and, as she gets older, how you worry about whether she can afford to sustain these life-saving medicines. That's the piece that I think a lot about when we're having this conversation.

It's this issue of whether drugs will come here, but I often wonder, even if the drugs come here with outrageous prices, how does that make them any more accessible for the average Canadian, unless they're independently wealthy? I see so many GoFundMe pages fundraising for individuals to get some of these drugs. Could you just speak a little more about that experience and the availability to access them even if drugs do come here?

Ms. Erin Little: This is something we always think about as a family. One, we're very fortunate that my husband does have a great benefits package. When Cystadrops came onto the market, the insurance company lay in the weeds to see if the government was going to cover it before the company made the decision. The insurance company just sat and waited, and thankfully, we didn't have to go without the drug in that time period.

In Ontario, though each province as we know is different.... From what I know, every family in Canada has received coverage for cystinosis. We're very lucky. We're an ideal population. There are roughly only 100 of us and not 5,000. It would be a different story, and we'd have a different battle if....

The family I mentioned in my testimony does have Procysbi and the eye drops covered. They have insurance. Their insurance package isn't as nice as our family's. Some of the drugs that treat our children are not covered, because they are supplements, but if they do not get these supplements, they will go into renal failure. One family still pays out $230 a month for these supplements.

The excessively priced drug is one thing. How do I raise my child? Do I have to raise my child for her to take a job in a company, so she can get a good benefits package versus doing something she's passionate about? As Canadians, I don't think we should have to think about that as a family. She should have every equal opportunity and access to treatments. She was born this way. This wasn't lifestyle; this wasn't an accident. This is how she was born.

This is why we need to be concerned. Just because Canada covers these drugs now, doesn't mean it is going to 20, 30 or 40 years from now.

Ms. Jennifer O'Connell: It leads to the fight that even if these drugs get approved.... We look at Trikafta, and CF is a good example. Even when the drugs come through that approval process at Health Canada, the next fight is, are the provinces and territories going to cover them, or is private insurance going to cover the costs?

It just feels that when drugs are approved for use here, the fight begins over who's going to pay for them, because they're so expensive in many cases.

Ms. Erin Little: Yes.

Ms. Jennifer O'Connell: Thank you for that perspective.

Dr. McCabe, I want to ask you if you have a position on something that was mentioned in an earlier panel. An earlier witness talked about the threat that pharmaceutical companies will leave Canada if this happens, because we're a small jurisdiction, but she said that Canada's not a trivial market. Although we're not as big as the U.S., we're certainly not trivial.

Do you have thoughts on that?

● (1545)

Dr. Christopher McCabe: Yes, we're not a trivial market, and certainly not when we work in a pan-Canadian way.

No disrespect to Prince Edward Island, but in global terms, its population means that some people might describe it as unimportant. We are tens of millions of people, and when we work together, we are a substantial market that will generate a lot of revenue and profit for companies. Given that they're profit maximisers, I wouldn't expect them to leave.

There are many things we can do, and should look to do, such as complementary policies to make us a better place for companies that are indeed focused to be here—and that has to do with research infrastructure that we don't currently have.

The reason the U.K. does so well and can get away with its low prices is not just that it has domestic global companies, but has the most amazing research infrastructure. As it showed with COVID, it can run 30,000 or 40,000 high-quality patient trials at almost the drop of a hat. We couldn't do that here.

In terms of keeping the companies here, I don't think it's about prices—and that's what the literature says. Companies locate on the basis of other things.

Ms. Jennifer O'Connell: Thank you so much.

The Chair: Thank you, Ms. O'Connell.

We go back to the Conservatives at this point and Mr. d'Entremont

Mr. Chris d'Entremont: The provinces of Quebec, Ontario and Alberta have again been calling to hold off the changes to PMPRB. Where do we think that's going?

I know a lot of these questions are for IMC, but it represents the industry. Where are the provinces, and how is that going?

Ms. Pamela Fralick: Just to clarify this, when I mentioned Alberta, it was not in terms of supporting a delay in the PMPRB. They may or may not. They haven't voiced that to us, but they have certainly voiced an interest in being competitive in the life sciences world. That's the piece that I've noticed. Ontario and Quebec have been very, very active for decades. That's where most of the industry is located. In the Atlantic provinces, the conversations I've been having with them, and again, right across the country, reflect that they truly want to be competitive.

I would just add that Canada certainly isn't trivial, but it is only 2% of the global market. It's very difficult for us to compete on that stage and bring industry and various other pieces of the life sciences sector here. We need to be on our A-game.

Mr. Chris d'Entremont: A lot of the patient groups have said that some of this research will go offshore or go to another country. It could take a number of years before we see some of these innovative medicines show up for Canadian patients. How real is that threat? Is it a real threat, or is it truly just because of this global market that we seem to find ourselves in?

Ms. Pamela Fralick: I prefer not to use the word “threat”, because none of the companies, none of our members, have ever viewed this as a threat. Rather, it's a reflection of the reality of the situation.

I can comment quantitatively. I have an advantage that you don't and that no one on this committee does. You're looking at lagging indicators in the reports that come out with data that's a couple of years old. I get to talk with these companies on a daily basis. While I can't name companies—I can name one, but I'll save that for my third comment—I can tell you that at least six planned drug launches by our member companies have been delayed, including drugs for rare diseases, because of the uncertainty around PMPRB. We know that only 15 of 54 drugs that have been approved by the U.S. FDA have even been submitted to Health Canada for approval. I have a list of 39 drugs, and not just on rare diseases—they include cancer, Parkinson's and HIV—that have not been submitted to Health Canada for approval specifically because of the uncertainty around PMPRB. This is not for other reasons.

That's quantitatively; I gave you a few numbers there.

Qualitatively, Life Sciences Ontario did a survey of companies and executives just a couple of months ago: 35% say they've already delayed bringing new treatments to Canada; 96% anticipate that these new rules will drive decisions to delay or not bring new treatments to Canada; and 90% say that the reform will reduce research, clinical trials and innovation.

My last point, if you want a very specific example, is the letter that was submitted to this committee by a member company, Medicago. It states very clearly that as a Canadian company—we've all heard about Medicago, and are so proud to have a homegrown company—when it comes to the launch, it may not be here in Canada. It's because of PMPRB.

● (1550)

Mr. Chris d'Entremont: Is it because of the rules that are being proposed for PMPRB or is it the continued delay of those regulations?

Ms. Pamela Fralick: For clarification, it is the PMPRB regulations, the new regime that is scheduled to come into effect on July 1, in just three weeks' time. That is what is causing the problem.

On the PMPRB itself, we are very happy to work with government to modernize it. Interestingly, by the way, while many pieces of PMPRB were overhauled—it wasn't just modernized, it was overhauled—the actual definition the PMPRB uses for R and D investment was not touched. It took Statistics Canada and its report back in May to provide much more current data than what PMPRB uses from its 1987 definition.

Mr. Chris d'Entremont: Turning now to Ms. Little, I'm the father of a diabetic, so I have some of the same problems. Right now he's on my plan, but as he ages out, he needs to find employment. He needs to be able to work through his disease and be able to get some kind of coverage.

Maybe you could explain your daughter's disease a little bit more as well.

Ms. Erin Little: With Olivia it's genetic. She also lives with chronic kidney disease, and....

Go ahead, Mr. Chair.

The Chair: You can finish your answer, if you'd like.

Ms. Erin Little: Okay.

Olivia lives with chronic kidney disease. Chronic kidney disease is a lifelong circumstance until it leads to a kidney transplant. So on top of cystinosis, which is what the high-cost drugs treat, she has a lot of treatments for renal issues that are not covered. Even things like OHIP+ do not cover somebody like my daughter. These are ongoing worries that we have.

The Chair: Thank you, both.

We'll go back now to Ms. O'Connell for five minutes.

Ms. Jennifer O'Connell: Thank you, Mr. Chair.

Earlier in the meeting, in the first panel, we heard some testimony regarding the PMPRB's being asked to appear.

I just want to correct the record while I have a chance. The PMPRB was only invited yesterday. My understanding is that they would be happy to appear. I think it is important, given the testimony we heard today in the first panel, that we invite the PMPRB.

That said, I move that the Standing Committee on Health hold an additional meeting on the Patented Medicine Prices Review Board guidelines—as we were initially scheduled to do—in place of one of the meetings to be scheduled during the regularly scheduled meeting slots prior to the end of day on June 21, 2021; that the clerk invite the PMPRB to appear as a witness; that the meeting take place for two hours; and that, in addition to the PMPRB witness, each party be allowed to invite one witness for this meeting on the Patented Medicine Prices Review Board's guidelines.

The Chair: Thank you, Ms. O'Connell.

I find that this directly relates to the business at hand. Therefore, I would rule it in order.

I see that we have Ms. Rempel Garner with her hand up.

Please go ahead.

Hon. Michelle Rempel Garner (Calgary Nose Hill, CPC): Thank you, Chair.

I will note that the Liberals wasted two meetings filibustering our programming motion earlier this week. They also wasted meetings in September filibustering this. We wanted to have more meetings on PMPRB. I think this is one of those things where the Liberals are putting it forward because we did lose meetings.

For the witnesses who are here today, that is what happened.

I will note that the meetings that this this motion is trying to replace would allow any political party to put forward any witness they want. So if there are additional witnesses on any particular topic, political parties can do that.

The other thing I will note is that I tried to get the regulator in front of the committee today. We asked for anybody from the regulator to show up, and they declined.

I think this is theatre. We have a motion set....

I deeply appreciate the testimony of the witnesses, particularly by Ms. Little. I thought that your testimony was very compelling.

At the same time, I would also note that it was the members of the Liberal party who wasted two meetings filibustering a programming motion to which they didn't have any substantial amendments. The amount of heavy lifting that went on behind the scenes between opposition party members was enormous. We could have had another round of questions today.

I will be voting against this motion, because we literally just spent three meetings going through a programming motion that could have been condensed into five minutes of debate—so, no.

● (1555)

The Chair: Thank you, Ms. Rempel Garner.

[*Translation*]

Mr. Thériault, you have the floor.

Mr. Luc Thériault: Thank you, Mr. Chair.

I am quite surprised at my colleague's proposal, especially since I recall a meeting where she found it inappropriate—to use a neutral word, which she does not often do—to interrupt a session with witnesses. She knows how important this issue is to me, and she always knows that, according to the rules, I have very little time to ask questions. I don't believe she has given any of her time to me. I have eight and a half minutes of speaking time, while her party enjoys several more minutes.

She has just prevented me from using my two and half minutes, when we had agreed on a way to operate during this saga as to how we would organize our work going forward. We came up with a compromise, which was to hold a three-hour meeting so that we could provide instructions to the analysts and make a minimum of recommendations before the reform comes into force on July 1. Unless my colleague tells me today that the government is delaying the reform, her manoeuvring means that we may not get there, when I've already made that compromise. I was the one who proposed this study and I don't understand why she is doing this.

From the beginning, we heard testimony from PMPRB representatives about the reform, which took time at the meetings. I can barely figure out what is accurate or inaccurate in the various testimonies.

I'm very surprised at my Liberal colleagues' manoeuvring, which I interpret as a lack of respect for me and for the witnesses here today. I feel it's a shame, because I have never been disrespectful to anyone around the table. I'm very disappointed, and I'm going to remember this.

The Chair: Thank you, Mr. Thériault.

[*English*]

We'll go now to Mr. Davies.

Mr. Don Davies: I'd very much like to add my voice to what my colleague, Mr. Thériault, just said.

Last week the Liberals were extremely opposed to a motion that was being made while we still had witnesses here and lectured all opposition members on that. Here they are doing the same thing. I don't know why this motion couldn't have been left until after we heard from the witnesses. It would have been easy to do that.

Secondly, just this week, we had a meeting on Monday of our subcommittee on agenda to set the agenda. On Wednesday, we had a Standing Order 106 meeting to confirm the agenda. We had two full meetings this week that were hours in length and the Liberals never once made any indication that they wanted to have another meeting. They had every opportunity to call the PMPRB to this meeting if they wanted. We had eight witnesses. Each party was entitled to call any two witnesses they wanted today and the Liberals did not.

Incidentally, and as my colleague Ms. Rempel Garner said, we have four more meetings scheduled where each party has the opportunity to call any witness they want at each of those four meetings. In one of the meetings they have two, so the Liberals could easily call the PMPRB to one of those meetings, if they want.

This motion is not only is insulting to the witnesses and has not only has robbed Mr. Thériault and myself of our chance to ask our final.... I also only have two and a half minutes to go, with Mr. Thériault. We've been robbed of our chance after the Liberals got their time.

All for what? It's all to call a witness, which they could have done for today and can do in the next three weeks, at this point. That's unacceptable conduct. It's disrespectful to the witnesses and it's disrespectful to the members of this committee.

I'm not sure...this is in order. I've received no notice of this meeting. We're not in committee business. It would be nice if the members of this committee would serve notice as the other ones did.

I remember last week when the Conservatives submitted a motion on the Wednesday for the Friday, the Liberal members of this committee didn't think that was acceptable. Well, I was just served notice of this five minutes ago, orally. I don't think this is appropriate conduct.

Again, I would ask my honourable colleague to withdraw this motion. If she believes that the PMPRB is an important witness, then use one of their witness slots they have in the next three weeks to call them.

● (1600)

The Chair: Thank you, Mr. Davies.

Seeing no further hands raised, we can call the vote. If we do this quickly we will have time for Mr. Thériault and Mr. Davies' testimony.

I would ask the clerk to call the vote on this motion.

(Motion negatived: nays 6; yeas 5)

The Chair: I will carry on with the questions.

[*Translation*]

Mr. Thériault, you have the floor for two and a half minutes.

Mr. Luc Thériault: Thank you, Mr. Chair.

Ms. Fralick, as I understand it, you want to delay the implementation of the reform, which comes into effect on July 1. You want it to be more than just a delay. You also want a roundtable to bring together the various partners, some of whom I named earlier. In response to Mr. d'Entremont, you kind of said all there is to say.

You also pointed out the inconsistency between the government's recommendations in the 2018 report by the Department of Innovation, Science and Economic Development, which reflected all that drive to stimulate the biotech innovation sector, and a reform that is strictly in the hands of Health Canada. As Ms. Perrault said earlier, the department has only a perspective in a vacuum, whereas we should have a broader understanding of the life sciences and take action on all levels.

What people want—I imagine it is what you want too—is to set up a roundtable. However, would you agree to a compromise, a phased implementation? It would mean going ahead with the reference list of countries, which appears to be a concession, from what I've seen in a number of papers, and establishing the roundtable, then sitting down and discussing the rest of the issues.

Would you agree to that proposal, Ms. Fralick?

[*English*]

Ms. Pamela Fralick: Thank you.

Through the chair, I think that would be a good departure point for the discussion. If we can get to that table with the appropriate government officials and whoever else should be there—we can determine that—then I think that would be a very useful point of departure and would generate a great deal of good discussion.

● (1605)

[*Translation*]

Mr. Luc Thériault: Thank you for your answer, Ms. Fralick.

I read in some briefs that simply changing the reference basket of countries could lead to 20% to 30% in savings.

Do you have those numbers as well? Are they realistic, Ms. Fralick?

[*English*]

Ms. Pamela Fralick: There are several figures floating around. The first estimate by PMPRB, by the government, came in at about $8 billion or $9 billion over 10 years. They readjusted that. It went up to $13 billion. An independent third party did another assessment. It's about $19.8 billion over 10 years. Yes, the basket change alone would save considerable dollars and resources for Canadians.

[*Translation*]

The Chair: Thank you, Mr. Thériault.

[*English*]

We go now to Mr. Davies for two and a half minutes.

Mr. Don Davies: Ms Fralick, we've heard—and I think we all have an imperfect understanding of this—that there seems to be this very curious way of drug pricing in Canada, such that drug companies publish astronomical list prices that nobody actually pays. Then behind closed doors the pharmaceutical companies negotiate significant discounts—we've heard at this meeting that these are between 50% and 90%—that nobody can ever find out.

Can you explain that as an industry practice and tell us whether you think that's a wise way to come to pharmaceutical pricing in Canada?

Ms. Pamela Fralick: Unfortunately, as an association representative, I'm not privy to the individual negotiations that take place between companies and governments—

Mr. Don Davies: That's the problem—nobody is. That's not just with governments; it's also with insurance companies.

Ms. Pamela Fralick: Yes, “private payers”, I should have said more appropriately. I just don't have a line of sight on that. Unfortunately, I can't help you.

Mr. Don Davies: The reason I ask is that it's not just an issue of expanding comparator countries. I don't think anybody can argue that expanding the present system—which has, I think, five to seven countries with two of the expensive two and 11-country comparisons that's much more representative—is....

Also, aren't there fundamental issues of transparency? How do we set appropriate pricing in this country if pharmaceutical companies are negotiating secret agreements, and then any attempt to shine a light on those agreements so that we can find out what actually is being paid is being resisted by the pharmaceutical industry? Who benefits from having private, secret prices paid when drugs are such a public necessity in this country?

Ms. Pamela Fralick: Again, through the chair, you're dealing with sensitive commercial issues. As an association representative, we don't have guidance, policies or best practices that direct how payers and companies deal with this, but understanding that this is a tension, I think if we were to get to a table, this is another point that could be discussed.

Mr. Don Davies: That's the point. It's not just a private commercial transaction. The public grants a patent to private companies, which then have 20 years of protection. Someone has to protect the public interest in this, otherwise a pharmaceutical company could say, “We want a billion dollars a pill, and if you don't pay it, we're just not going to make the drug available.” That clearly can't happen.

I'm going to go to Ms. Little for my last question.

Ms. Little, should we proceed with these PMPRB changes, and what would be the impact on your family and your daughter of those reforms going ahead?

Ms. Erin Little: Yes, I do believe we need to move forward. They might not be perfect, but they're progress and that's what we need.

Mr. Davies, I'd like to answer your question, but I just want to say one thing.

Ms. Rempel Garner, I appreciate your calling my testimony today “compelling”. As a patient, I'm not here to be compelling. I, too, run an organization and sometimes I feel that I am dismissed because I tell a story, but I tell the story that everybody at this table serves. We are the customer of this product.

Somebody once said to me that our story is a bit like being suddenly cast adrift in a vast and stormy sea in a lifeboat surrounded by unmarked ships that are being piloted by either the Mexican drug cartels or the Coast Guard, but there is no way of knowing which is which. Sometimes that's how we feel, with government on one side and pharma on the other. Even within the advocacy space, we need to know that we are being supported and that our children and our patients are being protected.

For that reason, I do feel that we need to move forward.

Thank you.

● (1610)

The Chair: Thank you, Mr. Davies.

Thank you to the committee members for all of your great questions.

Certainly, thank you to the witnesses for sharing with us your time today and your expertise and helping us with our study.

That said, I believe our business is done today and I declare the meeting adjourned.