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# Standing Committee on Health

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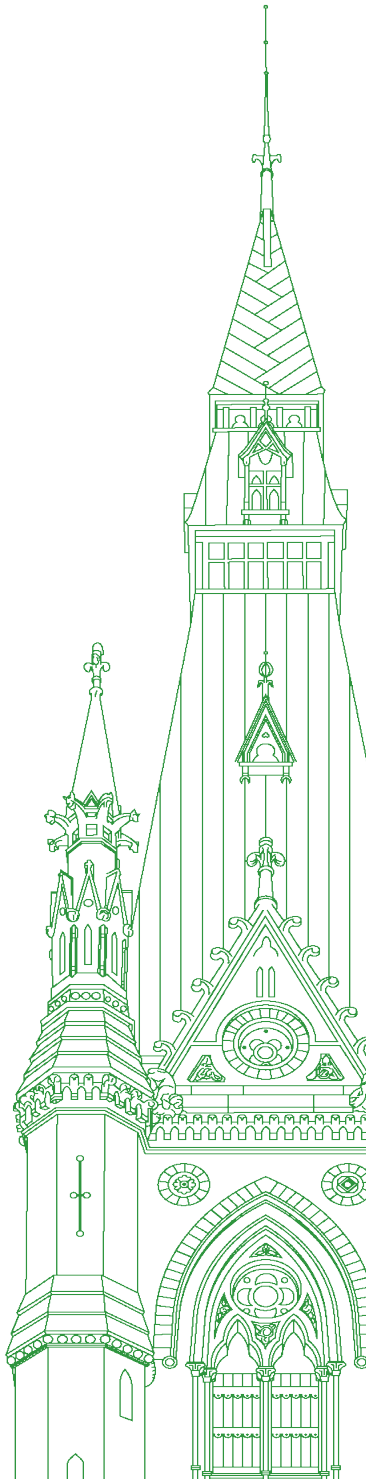

Chair: Mr. Ron McKinnon

# Standing Committee on Health

**Friday, November 27, 2020**

● (1305)

[*English*]

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

Welcome, everyone, to meeting number nine of the House of Commons Standing Committee on Health. The committee is meeting today to study the emergency situation facing Canadians in light of the second wave of the COVID-19 pandemic, for the first hour, and the Patented Medicine Prices Review Board's guidelines for the second hour.

I want to thank the witnesses for appearing today. For the first hour, from the House of Commons, we have Philippe Dufresne, Law Clerk and Parliamentary Counsel; and Michel Bédard, deputy law clerk and parliamentary counsel.

For the second hour, from the Patented Medicine Prices Review Board, we will have Dr. Mitchell Levine, chairperson; and Douglas Clark, executive director.

I would like to start the meeting by providing you with some information following the motion that was adopted in the House on Wednesday, September 23, 2020.

The committee is now sitting in a hybrid format, meaning that members can participate either in person or by video conference. All members, regardless of their method of participation, will be counted for the purpose of quorum. The committee's power to sit is, however, limited by the priority use of House resources, which is determined by the whips.

All questions must be decided by recorded vote, unless the committee disposes of them with unanimous consent or on division. Finally, the committee may deliberate in camera, provided that it takes into account the potential risks to confidentiality inherent to such deliberations with remote participants.

The proceedings will be made available via the House of Commons website. So you are aware, the webcast will always show the person speaking rather than the entirety of the committee.

To ensure an orderly meeting, I would like to outline a few rules to follow.

For those participating virtually, members and witnesses may speak in the official language of their choice. Interpretation services are available for this meeting. You have the choice, at the bottom of your screen, of floor, English or French. Before speaking, click on your microphone icon to activate your own mike. When you are done speaking, please put your mike on mute to minimize any interference.

As a reminder, all comments by members and witnesses should be addressed through the chair. Should members need to request the floor outside of their designated time for questions, they should activate their mike and state that they have a point of order. If a member wishes to engage in debate, they should use the “raise hand” function. This will signal to the chair their interest to speak and create a speakers list. In order to do so, they should click on “participants” at the bottom of the screen. I should note that people who want to respond to points of order or raise their own points of order consequent to a given point of order should not use the “raise hand” function. Just use a hand gesture or speak up with a point of order statement.

When speaking, please speak slowly and clearly. Unless there are exceptional circumstances, the use of headsets with a boom microphone is mandatory for everyone participating remotely. Should any technical challenges arise, please advise the chair. Please note that we may need to suspend for a few minutes as we need to ensure that all members are able to participate fully.

For those participating in person, proceed as you usually would when the whole committee is meeting in person in a committee room. Keep in mind the directives from the Board of Internal Economy regarding masking and health protocols. Should you wish to get my attention, signal me with a hand gesture or, at an appropriate time, call my name. Should you wish to raise a point of order, wait for an appropriate time and indicate to me clearly that you wish to raise a point of order.

With regard to a speakers list, the clerk and I will do the best we can to maintain a consolidated order of speaking for all members, whether they are participating virtually or in person.

With that, we'll invite the law clerk, Mr. Dufresne, to make a statement.

You have 10 minutes, please.

**Mr. Philippe Dufresne (Law Clerk and Parliamentary Counsel, House of Commons):** Thank you, Mr. Chair and members of the committee, for your invitation to appear today to discuss the motion that was adopted by the House of Commons on October 26, which provides that this committee “undertake a study on the emergency situation facing Canadians in light of the second wave of the COVID-19 pandemic”.

As the Law Clerk and Parliamentary Counsel for the House of Commons, I'm pleased to be here today to address any questions that the committee may have with respect to the House's motion and the role it prescribes for my office. I hope that my answers—

[*Translation*]

**Mr. Luc Thériault (Montcalm, BQ):** Sorry, Mr. Chair.

The pace is much too fast. There is indeed interpretation, but the brain can't grasp the content. It isn't just words. The meaning must be interpreted as well.

If you could slow the pace down, I'd be very grateful.

[*English*]

**The Chair:** Thank you, Monsieur Thériault.

Monsieur Dufresne, please continue. I will allow extra time for your statement if you need it.

**Mr. Philippe Dufresne:** Thank you, Mr. Chair.

As the Law Clerk and Parliamentary Counsel for the House of Commons, I am pleased to be here today to address any questions that the committee may have with respect to the House's motion and the role it prescribes for my office. I hope that my answers will assist the committee.

[*Translation*]

As you know, the House's motion includes an order for certain documents from the Government of Canada to be provided to my office no later than November 30. This includes documents from the Office of the Prime Minister; the Privy Council Office; the Office of the Minister of Public Services and Procurement; the Office of the Minister of Health, Health Canada and the Public Health Agency of Canada. This also includes all documents relating to the COVID-19 vaccine task force and its subcommittees; the Government of Canada's COVID-19 vaccine distribution and monitoring strategy; and the government's communications with the World Health Organization concerning the Global Public Health Intelligence Network.

The motion states that the Clerk of the Privy Council Office may request an extension of up to seven additional days by writing a letter to the committee.

[*English*]

The House's motion expressly excludes from its order the minutes of meetings of the cabinet and its committees. It also requires that all documents provided in response to the order be vetted by my office for matters of personal privacy information and national security, and that the category of documents relating to the COVID-19 vaccine task force and its subcommittees also be vetted for information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations between the government and a third party.

The motion provides that my office is to complete this work within seven days of receipt of the documents from the government, and to provide them to the Speaker for tabling in the House of Commons at the next earliest opportunity. Upon being tabled, the documents are to be permanently referred to this committee. I confirm that my office has not yet received documents in response to the order.

● (1310)

[*Translation*]

The order allows the government to exclude any minutes of meetings of cabinet and its committees.

For all the other categories of redactions—personal privacy, national security and information that, if disclosed, could reasonably be expected to interfere with contractual or other negotiations between the Government of Canada and a third party—the order is clear that my office must vet those redactions.

[*English*]

In our view, the House's order does not preclude the government from proposing what it feels the redactions on those grounds should be, but my office needs to see the documents and make the final determination about what is provided to the House and to this committee in accordance with the order.

It is up to this committee, and ultimately the House, to determine whether it is satisfied with documents provided in response to the order, with the government's approach and with any redactions made. This is consistent with the House's role as the grand inquest of the nation.

[*Translation*]

In terms of the process and resources, my office has 15 counsel, along with two paralegals and other employees, including jurilinguists, the publications team, translators, administrative assistants and an articling student, for a total of 35 employees.

My office provides comprehensive legal and legislative services to Parliament, the Board of Internal Economy, the House and its committees, members of Parliament and the House Administration. It's also responsible for drafting private member’s bills and motions to amend government bills, and for the printing the bills as they progress through the legislative process. In some sense, it provides similar types of legal and legislative services to the House that the Department of Justice provides to the government.

In response to the House's order, we've taken steps to acquire additional resources in anticipation of receiving a very large volume of documents for review and redaction.

[*English*]

My office has reviewed the House's order and made the necessary preparations so that we can respond and begin our work as soon as we receive the documents. We have established a project team to prepare for the receipt of documents, led by the deputy law clerk and parliamentary counsel, legal services, Monsieur Michel Bédard, who is with me today.

The project team has carefully reviewed the text of the House's order and developed an internal process for uploading, organizing, reviewing and redacting documents. As mentioned, we've taken steps to acquire additional resources in anticipation of receiving what we expect will be a very large volume of documents for review and redaction. This includes hiring two additional legal counsels to assist with this work as required.

We have taken steps to mobilize and leverage our existing resources in anticipation of this work.

The House's order states that we are to complete our work within seven days of receipt of the documents. We understand this to mean calendar days. We are then to provide the redacted documents to the Speaker, who will table them, and they will then be referred to the committee.

At this stage, while I do not know how many documents we will receive from the government in response to the House's order, I understand it is expected to be a very large number of documents.

Indeed, in his testimony before the finance committee on Tuesday this week, the Clerk of the Privy Council, Mr. Ian Shugart, suggested that it could be millions of pages. Given the unprecedented volume of documents, we are expecting that this will represent a significant amount of work and full-time, dedicated resources.

[*Translation*]

I'm prepared to devote close to 100% of my office's resources to the review and redaction of documents for the seven-day period set out in the motion.

This means that all our other activities—including the provision of legal advice and drafting of private member's bills—will be severely curtailed or delayed, except those services that are essential.

Since the House is sitting, those essential services include the preparation of government bills; the publication of bills tabled in the House; the reprint of bills at the request of a committee; the printing of parchment copies; the drafting of amendments to legislation at all stages; and responses to requests for urgent legal advice.

Now let's see how many pages we could process in seven days.

Basically, if all counsel each review between 300 and 500 pages a day, we estimate that we could process up to 50,000 pages in the first seven days following the receipt of the documents.

This estimate is based on the 6,000 pages that the government recently sent us in response to a production order by the Standing Committee on Finance.

● (1315)

[*English*]

In this case, the volume of documents could be exponentially more than that, and the scope of redactions my office has to vet is also larger. Of course, these estimates may change depending on the volume and type of documents we receive in response to the House's order. The approach the government takes may also impact our estimated timelines.

Should the volume of the documents provided go beyond what my office can complete in seven days, I will immediately inform and seek guidance from the committee with respect to the way forward.

With that, my colleague and I would be pleased to answer any questions.

**The Chair:** Thank you, Mr. Dufresne.

I would like to advise the committee that we have received a letter from the Clerk of the Privy Council requesting the seven-day extension as provided for in the motion. I would ask at this time if the committee is willing to make that letter public. I would ask if there is unanimous consent to do that. If there is anyone who wishes to dissent from that decision, please indicate that.

Seeing no dissent, I declare that on unanimous consent we have determined that we can release that letter to the public. Thank you all very much.

We go now to our rounds of questions for the six-minute rounds. We'll start with Ms. Rempel Garner.

Please go ahead for six minutes.

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

To the law clerk, I want to thank you and your team for all the work you're doing. I also want to thank your team for all the work that you do for all of us parliamentarians on a day-to-day basis with private members' bills and legal advice. You're an integral part of Parliament, so thank you.

I have one quick question. Have you received any of these documents to date from the government?

**Mr. Philippe Dufresne:** No, we have not. Not as of today.

**Hon. Michelle Rempel Garner:** Have you given any thought to perhaps prioritizing certain sections of the documents for review upon receipt?

**Mr. Philippe Dufresne:** Our goal, once we receive documents, is to see whether we can do what we have received within the timelines. If we are not able to do so, then we would advise the committee and seek the committee's guidance as to what it wishes to do about any prioritization in terms of providing the documents.

If we are dealing with the magnitude that we understand we will be dealing with, it will be physically impossible to review all of those documents in the timeline, so the question of priority would come up at that stage, but in my view, this priority is up to this committee to determine.

**Hon. Michelle Rempel Garner:** Thank you. Those were my thoughts exactly.

With that, Mr. Chair, I move:

> That the Chair be instructed to present the following report to the House forthwith, provided that dissenting or supplementary opinions, pursuant to Standing Order 108(1)(b), shall be filed with the clerk of the committee within 24 hours of adoption of this motion:
>
> The Standing Committee on Health has met pursuant to its Order of Reference of Monday, October 26, 2020, and recommends the following:

> That the Law Clerk and Parliamentary Counsel, when vetting documents under subparagraph (aa)(ii) of the Order adopted by the House on Monday, October 26, 2020, be instructed to prioritize the vetting in the following order: (a) documents, produced by the Public Health Agency of Canada in response to paragraphs (y) and (z) of the Order, concerning vaccines; (b) all other documents, produced in response to paragraphs (y) and (z) of the Order, concerning vaccines; (c) documents, produced in response to paragraph (w) of the Order, concerning rapid testing; (d) other categories of documents which may be specified, from time to time, by the Standing Committee on Health; and (e) all other documents; that all documents be circulated to the committee in both official languages; and
>
> That the Standing Committee on Health may, on the request of the Law Clerk and Parliamentary Counsel, grant one or more extensions of the deadline, prescribed by subparagraph (aa)(ii) of the Order adopted by the House on Monday, October 26, 2020, for his vetting of documents, provided that he shall provide the Committee with a weekly status report on the vetting process.

Chair, while the clerk is here, I think we've heard a lot of interest in the Canadian media, putting it mildly, on the vaccine production process and distribution, etc. The documents that are going to be relevant to the committee could be prioritized, as the clerk just said. What this would do is, per the clerk's suggestion, give him some directions on what to prioritize first and foremost, and produce first and foremost. It would also give him the ability to come back to our committee at future points.

What I'm thinking here is that we prioritize the topics that are first and foremost in the minds of Canadians and that I think have been in front of Parliament the most frequently over the last few months and are probably the most material to our response to COVID, so that we can look at those in an expeditious manner, and then allow the clerk to come back to committee and essentially tell us how it's going. I think this is an elegant solution to perhaps some challenges that have been outlined. It would allow us to move forward as parliamentarians and to be able to scrutinize the government's response—the adequacy of it—while providing some direction and clarity.

I will note this. I do find it odd that the clerk has not received any documents yet. For the PCO, in a letter today, which is now public—and I can speak to this—to say that there is a substantive quantity, to quantify that volume and not to have passed anything to the clerk to date, is odd.

Again, I would like to commend the clerk and his team for helping parliamentarians do their job. It is my hope that the committee will support this motion so that we can give him some direction on what to prioritize, and then what we can be scrutinizing in the first order.

Thank you.

● (1320)

**The Chair:** Thank you, Ms. Rempel Garner.

I'm not sure if we have the authority to give direction to the clerk on prioritization of documents or whether we can attempt to modify that order of the House, but my first inclination is that this is in order, so I would ask if members of the committee are fully aware of what the motion is here.

Ms. Rempel Garner, I wonder if you could send a copy of that—

[*Translation*]

**Mr. Luc Thériault:** Sorry, Mr. Chair, but I can't hear the interpretation. Maybe you aren't speaking loud enough. Obviously, there's an issue with the interpretation. Not only am I unable to keep up with you in real time, but there are very long pauses. Maybe there's a sound issue or your microphone isn't lowered. Either way, I'd like to understand what you're saying.

[*English*]

**The Chair:** Mr. Thériault, did you get translation of Ms. Rempel Garner's motion? Yes.

It's just me you can't hear. Okay, I apologize.

My initial concern is whether we have the power to give direction to the clerk and whether we can modify the House motion in this way.

I would ask the law clerk himself if he could advise me on this matter.

**Mr. Philippe Dufresne:** Certainly, Mr. Chair.

It seems to me that there is the House order that provides for timelines. I understand Ms. Rempel Garner's suggestion was that the committee would report to the House, so I wonder if the purpose is to have the House ultimately adopt that report as an order.

You quite rightly point out that the House order exists and it provides certain requirements, so if this committee wishes to suggest modifying that, it seems that would give rise to a necessary change to the House's order.

● (1325)

**The Chair:** Thank you, Mr. Dufresne.

Okay, my understanding now is that this will be a request to the House to change its order accordingly, to reflect the priorities that Ms. Rempel Garner has proposed.

Are we ready to debate this motion?

Mr. Kelloway.

**Mr. Mike Kelloway (Cape Breton—Canso, Lib.):** Thank you, Mr. Chair, colleagues and clerk. It's good to see you here.

I am very keen, as I know all of us are from all our respective parties, to get to work here. We have witnesses here today with important testimony. I would really like to actually focus on the agenda before us.

For that reason, I move that the debate be now adjourned.

**The Chair:** Thank you, Mr. Kelloway.

The question is, shall the debate be now adjourned on Ms. Rempel Garner's motion?

Mr. Clerk, I will ask that you take a vote.

(Motion negatived: nays 6; yeas 5)

**The Chair:** The debate will carry on.

We'll go now to Ms. Rempel Garner.

**Hon. Michelle Rempel Garner:** Thank you, Chair.

I just want to agree and clarify that the intent of my motion is what the clerk clarified, that this would be reported to the House and then the House would have to dispense with it. Procedurally, I agree with the assessment in terms of how it would move forward.

**The Chair:** Thank you.

Mr. Davies, please.

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

First of all, I think it's an excellent motion. From the beginning, one of the main concerns of the government side—in fact, I think of all of us—has been how we can efficiently get important information to us, given that there could be a large volume. I think this is an excellent way to prioritize, given the realities of the letter I just saw this morning from the Clerk of the Privy Council, Mr. Shugart. He is essentially saying that the government can't provide all the documents in time. I'm hearing from the law clerk that, given the Herculean efforts and extra resources of his office, he can't meet the requirements of the motion in the time period given.

As parliamentarians, the only responsible thing to do is see how we can shape our motion to respond to that reality. I can speak for the New Democrats in that I think we should be focusing on vaccines and rapid testing, which are two issues Canadians are probably most interested in hearing about. I think this is nothing more than an attempt to shape the motion into a more reasonable path forward, so that we can actually get started on getting the documents coming to the committee, as the House wanted.

In light of Ms. Rempel Garner's last comment, I was a little unclear about the way forward, too. I think she and the chair are right that this has to go back to the House. However, at the end of the clerk's speaking notes, after taking us through the practical difficulties of processing the information in time, he says:

> Should the volume of the documents provided go beyond what my Office can complete in 7 days, I will immediately inform and seek guidance from the Committee with respect to the way forward.

If I may, it might help all committee members to put that question to the clerk and ask him to explain that. I read that to mean that, given that the motion has passed to refer these documents to the committee, perhaps this committee can work with the law clerk on getting an efficient path forward, so that we can get documents coming to the committee in an orderly fashion, given the practical and pragmatic realities of the volume of documents.

Can I ask the law clerk that? Can this committee simply work with you, or does this have to go back to the House?

● (1330)

**Mr. Philippe Dufresne:** Thank you for the question, Mr. Davies.

My remarks really dealt with the practical way of raising a concern if the amount of documents is so significant that we know we are not able to meet that timeline.

Ultimately, at the end of the day, in terms of a path forward, it seems that a change to the House's order would be required. The committee would not have the authority on its own to simply approve something that would go against what the House has ordered.

In terms of next steps to address a concern, the approach that's being put forward now would seem to address that, which is by having the committee propose something to the House so that ultimately the House can make the decision.

**Mr. Don Davies:** Thank you.

**The Chair:** Thank you, Mr. Davies.

Thank you, Mr. Dufresne, for your counsel.

We go now to Mr. Fisher, please.

**Mr. Darren Fisher (Dartmouth—Cole Harbour, Lib.):** Thank you very much, Mr. Chair.

Although I don't support this motion, we have the law clerk in front of us for an hour, as requested by the Conservatives—which we supported. We're happy to have you here today.

It's now 2:32 here in Nova Scotia, so it's 1:32 there. We're not going to get all the questions in that we'd hoped to get in, so this seems like just another one of those things thrown in the way—a monkey wrench in the middle of this.

I guess, with the 45 seconds or so since I've printed this motion and looked at, we won't support this motion. We also won't speak to it, because I think it's important—and out of respect for the law clerk—that we get rolling on this so that we can ask these questions. Probably a couple of members now will lose their opportunity to speak to this.

I will say that we debated this all day in the House of Commons and we passed it. I think we should respect the motion the House sent to us. However, like I said, I think the important thing right now is getting to Mr. Dufresne.

**The Chair:** Thank you, Mr. Fisher.

Mr. Davies.

**Mr. Don Davies:** Just quickly, I would like to respond to Mr. Fisher's comments. We do have the law clerk here, and after giving his statement, the nub of his testimony or statement so far is that he does not have the resources necessary to actually implement the motion that was passed by the House.

I think the motion by Ms. Rempel Garner is directly on point, because we're dealing with the substance of the matter before us.

The other thing that I must say is troubling, and is in the back of my mind, is that essentially what we're hearing from the government, from the Clerk of the Privy Council and now from the law clerk, is that the government cannot respect the order of the House. That's what we're hearing.

Mr. Fisher referred to respecting the motion of the House. Well, the motion of the House is clear. We've asked for all these documents. We've given a timeline, and the House passed it. What we're really hearing the government say is that they are not going to do it. The question is, can't they, or won't they?

I think it's a question of resources. The law clerk has clearly indicated that they've put in additional resources and hired additional staff to do it. Even with that, it's not sufficient. There is a reference to millions of documents. I have no idea where that comes from. I have no means of assessing whether that's accurate or not. I don't know if that's rhetorical spin or if that's based on data.

The other way to go is to say that the House of Commons passed a motion ordering the government to produce those documents, and it's up to the government to produce whatever resources are required in order to comply. I don't know that it lies in the mouth of the government to say that it can't do it or it won't do it.

● (1335)

**The Chair:** Mr. Davies, can you to speak more specifically to Ms. Rempel Garner's motion?

**Mr. Don Davies:** Thank you, Mr. Chair.

I'm speaking directly to the motion, because the motion is predicated on the witness's statement that, given the resources he has, he cannot provide all the documents that have been ordered by the House to come to this committee. Ms. Rempel Garner's motion is an attempt to respond to that in a very responsible way by saying, let's prioritize them.

I support the motion, because I think we should prioritize them. That's a rational, reasonable and sensible way to deal with the matter, but I'm also raising the underlying question, which is, why isn't the government able to send all the documents, even if it is a million documents? That's a question of resources. It's a tough job to do, but it's not an impossible job to do.

I raise that for my colleagues to consider, in lieu of simply expecting the government to comply with the order. I suppose we can take appropriate procedures after that, if they don't. I think this motion is very rational and reasonable.

I'll conclude by saying that I listened to Liberals in the House oppose the motion in the House to produce documents, and one of their prime arguments was that there were too many documents and it would be too difficult for the government to comply. Here we have a motion in front of us that seeks to prioritize them and focus on vaccines and testing. Let's at least get those documents going, and we can give the government more time for the rest of the documents. Now I hear the Liberals saying they don't agree with that, so that's pretty tough to understand.

I'll be supporting this motion, and I thank my colleague for bringing it forward.

**The Chair:** Thank you, Mr. Davies.

Seeing no further hands raised, we shall now proceed to vote on the motion.

(Motion agreed to: yeas 6; nays 5)

**The Chair:** We can carry on with Ms. Rempel Garner.

**Hon. Michelle Rempel Garner:** Thank you, Chair.

Mr. Dufresne, after the House adopted this motion or right prior, a lot of concern was put forward by the government, particularly around section (aa) and section (y) of the motion, which says that the documents will be “additionally vetted for information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations between the Government of Canada and a third party, by the Law Clerk and Parliamentary Counsel”.

I read your CV. It's very extensive, and anybody who has an understanding of the role of the law clerk.... I've interacted with your office many times in my career as a parliamentarian. There's a lot of expertise there.

Are you confident about your team's ability to essentially get that part of the motion done, in terms of what it demands around confidentiality, etc.?

**Mr. Philippe Dufresne:** Absolutely, Ms. Rempel Garner. We have a full legal team with knowledge and experience on a range of legal topics. As indicated in my opening statement, we are, in a sense, the department of justice for the House, providing legal, litigation, drafting services for the House, obviously with smaller resources.

In terms of specific information that we may not have, factual information we may not have that the government would have, the government could raise that with us and bring it to our attention, and we would expect that it would do so, if it has concerns about the disclosure of information.

● (1340)

**Hon. Michelle Rempel Garner:** One of the things the procurement minister said was that if you had an inability to do the job, Canada wouldn't get a vaccine. I won't make you comment on the minister's comment, but are you confident that you can keep confidential the information that, let's say, Pfizer had concerns about?

**Mr. Philippe Dufresne:** We will be implementing what the House has ordered and the grounds the House has provided in its motion. It has provided, as one of the grounds, the protection of information the disclosure of which could interfere with the government's ability to contract or negotiate with third parties. From our standpoint, that's a broad ground that's meant to protect against prejudice to the contract ability of government with third parties.

The House has accepted that as a ground. We understand that ground. We understand the legal issues surrounding it and the implications, and we will apply those in our task.

**Hon. Michelle Rempel Garner:** Do you anticipate a delivery schedule for vaccines being something that you would redact?

**Mr. Philippe Dufresne:** We would have to see what is provided to us by the government and we would have to see the context and, again, what concerns may be raised with that. Is the information you're describing something the disclosure of which could interfere with the government's ability to contract or negotiate with third parties? We would expect the concern to be raised. We would consider that very carefully.

**Hon. Michelle Rempel Garner:** Quickly, has the PCO, Health Canada or any other government department reached out to you regarding the redaction processes surrounding vaccines, especially with respect to vaccine delivery schedules?

**Mr. Philippe Dufresne:** We were approached by senior government officials to exchange and discuss the practical implications of this motion and complying with the motion. And so, exchanges have been had in terms of what to expect. So yes, there have been exchanges.

**Hon. Michelle Rempel Garner:** Is there any information that you can provide on that exchange to the committee?

**Mr. Philippe Dufresne:** Discussions centred around what the motion required and how best the government could comply with it, and the implications for my office. It was really in the sense of a pragmatic consideration looking at how to meet this task that's set out by the House.

**Hon. Michelle Rempel Garner:** Thank you.

**The Chair:** Thank you, Ms. Rempel Garner.

We go now to Mr. Van Bynen. Please go ahead for six minutes.

**Mr. Tony Van Bynen (Newmarket—Aurora, Lib.):** Thank you, Mr. Chair.

Thank you to our witnesses for joining the committee today and for their very informative statement. Certainly a lot has been mentioned, and it's insightful. I'm sure our committee will be asking you to elaborate on some of that.

First, in your statement you mentioned redactions, and it's clear that it's up to your office to vet them. I'm hoping you could elaborate on your office's redaction process.

**Mr. Philippe Dufresne:** As set out in my statement, we are setting up a team to review the documents, to look at the proposed redactions from the government, if there are any, and really to go page by page, line by line, making sure that given the grounds that the House has identified in terms of the appropriate areas for redactions, those are made, and that the information that needs to be kept confidential is kept confidential.

We would very much go about that in a very meticulous and very careful manner.

**Mr. Tony Van Bynen:** Thank you.

Are there standards for redactions enshrined in Canadian law? Can you expand on the obligations to redact under the Privacy Act?

**Mr. Philippe Dufresne:** In this context, the order and obligations to redact do not come from the Privacy Act. They come from the House's constitutional authority to seek documents and to determine the manner in which...and the public interest considerations that ought to be applied. We could look to those statutes, and if there are similar concepts that are found in those statutes, that can be a guide, but at the end of the day the ultimate ground is the one that the House has adopted.

This is what we would look to first and foremost, but certainly there is legislation, such as the Privacy Act and the Emergencies Act, that has related concepts, and we would look to see how those are consistent and helpful when applying the House's criteria.

● (1345)

**Mr. Tony Van Bynen:** Thank you.

I understand that in addition to the Privacy Act, there are obligations within the Access to Information Act as well. Are these different from those that are outlined in the Privacy Act?

**Mr. Philippe Dufresne:** These are obligations that fall on the government and the executive in terms of what documents can be requested by Canadians, the grounds for redactions and the process for complaints. There are obligations on Parliament and the House itself in terms of proactive disclosures, and there are rights for the protection of private information.

But these statutes are distinct from the House's authority under the Constitution to seek and receive information from witnesses, testimony and documents, and to determine the grounds therefore. Those statutes are not limits to what the committee can request. Obviously, they provide for very important public interest principles that should be considered, but ultimately the committee and the House have the last word.

**Mr. Tony Van Bynen:** Can you give us more information about the obligations required under the Access to Information Act?

**Mr. Philippe Dufresne:** Do you mean the obligations required on the government or on the House? As counsel to the House and as counsel to the committee, I would say that the obligations do not apply to the House and to the committee. So these would be questions really for the government, as to what it is required to do under those statutes, and the government would be best placed really to highlight its obligations in this respect.

**Mr. Tony Van Bynen:** If I could just come back to the redaction process, imagine some boxes full of documents arrive at your office, or documents arrive electronically, what are the steps that you would be going through to determine what should or shouldn't be redacted, and are these items then referred to the government, or has the government highlighted areas that they feel should be redacted and you make the decision?

How is that going to work? I'd like to get a better understanding of that.

**Mr. Philippe Dufresne:** One of the unknowns is that we have not received the documents yet, so one of the things we do not know is whether the government will have proposed redactions or not. If they have, then we would look to those and we would expect to be able to see behind those redactions to what is being proposed to be redacted, what's the information behind it, and then compare that to the grounds that the House has allowed. Is this something that is personal privacy information? Is this something related to national security? Would the disclosure of this information be reasonably expected to interfere with contractual negotiations?

These are really the guiding principles and we would look at that. If there are no proposed redactions, we would nonetheless look at the documents ourselves to see whether there's information there that is problematic. But in terms of the national security and the interference with contracts involving the Government of Canada, we would expect that the government would be raising concerns on those and we would look at those.

**Mr. Tony Van Bynen:** Given the prioritization, I haven't seen the details on what was proposed or adopted just today. Would the focus on the vaccines, etc. be one of the areas where there might be a high risk of interfering with contractual negotiations?

**Mr. Philippe Dufresne:** In its motion, the House really linked the vaccine development and the contractual negotiations. It said that this ground of "information the disclosure of which could reasonably be expected to interfere" would apply with respect to paragraph (y). Paragraph (y) is the paragraph on the vaccine task force.

I think the House accepted and understood that when you're dealing with this vaccine development issue, there is a risk that there is contractual information that needs to be kept confidential so that it doesn't harm that relationship between the government and the vaccine developers. The House has agreed that this is a valid reason to keep information confidential.

If the prioritization results in those types of documents being looked at first, I would expect to see that ground come up. I would expect that this is where you would see this issue being raised as information that should be kept confidential.

● (1350)

**The Chair:** Thank you, Mr. Van Bynen.

We go now to Monsieur Thériault.

[*Translation*]

You have the floor for six minutes.

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

Mr. Dufresne, thank you for giving a clear presentation and clear answers.

I don't have many questions. I found Mr. Van Bynen's questions very useful. However, I'm not sure whether you addressed all my concerns.

First, when I read the letter from the Clerk of the Privy Council, I was a little stunned to see that there could be millions of pages. According to the calculation that you provided today, it would take at least 20 days of diligent and ongoing work to produce the documents for the House and the committee. This is on top of the fact that, in his letter, he says that the documents would be sent as they are. In other words, we don't know how much of the documents are in English or French, so we can't estimate how long it may take to translate them. The documents must be provided in both official languages. This unknown variable seems quite important. It may also apply, but in a much more limited way, to the motion undertaken today with respect to the sequential processing of information.

I'm also wondering about the Clerk of the Privy Council's decision to exclude confidential business information. Perhaps you can shed some light on this. I thought that he was sending you all the relevant documents.

The motion that we passed states that information may be redacted in cases where full disclosure could reasonably be expected to interfere with contractual or other negotiations between the government and a third party. This relates to your judgment and the analyses of your legal proceedings, not to the Clerk of the Privy Council.

Didn't the House order basically instruct the Clerk of the Privy Council to send us all the documents?

**Mr. Philippe Dufresne:** Your interpretation of the motion does indeed reflect what I noted in my remarks. The motion stated that the grounds related to the confidentiality of the information or possible prejudice to contract negotiations were justifiable. However, the redaction must be approved by me or my office.

The House established that these grounds were justifiable. However, ultimately, the House must be satisfied with the application of these grounds. As I said, I would have expected the government to identify the information that must be protected based on these grounds, since it certainly has the information on hand. However, the House established that, at the very least, my office would approve the information. To do so, I must be able to see the information and the proposed redactions.

In his letter today, the Clerk of the Privy Council said that he'll exclude certain information based on these grounds. We haven't received the disclosure yet, so I'm not sure what this will mean exactly. Will it mean that we can obtain the documents and feel satisfied that the redaction was done properly? I don't know. In any event, I also noted this reference in the letter.

**Mr. Luc Thériault:** Okay, thank you. This clears things up. I have full confidence in your work. I know that you'll be able to tell us whether excluding certain documents, as the Clerk of the Privy Council intends to do, is justified.

I don't have any more questions.

● (1355)

**The Chair:** Thank you, Mr. Thériault.

[*English*]

We will now go to Mr. Davies.

Mr. Davies, you have six minutes.

**Mr. Don Davies:** Thank you, Mr. Chair, and thank you to the clerk for being here.

It seems as though we've really focused on this, but I want to be absolutely clear. Mr. Clerk, is it your view that the documents must come to your office in unredacted form?

**Mr. Philippe Dufresne:** My view, Mr. Davies, is that the House has allowed the exclusion of cabinet minutes. The minutes of meetings of the cabinet and its committees are to be excluded from this order, so those would not be considered at all by my office. However, the motion otherwise requests that the documents be vetted by my office for the other three grounds, which are privacy and personal information, national security and interference, or what "could reasonably be expected to interfere with contractual or other negotiations".

The motion uses the word "vetted", and from my standpoint this would require that my office be able to see the information behind the redaction and agree or not to make redactions. Again, I suspect there's much information that we would give significant weight to, but the motion as it's written requests that it be vetted by my office.

**Mr. Don Davies:** Thank you.

If the documents do come to your office redacted by those three criteria, in your view would that be in compliance with the motion as passed by the House?

**Mr. Philippe Dufresne:** If they come to my office redacted, I would be in a situation of reporting it to the committee, because it makes it difficult, if not impossible, for my office to vet and to determine whether the redactions are valid. Some of them may seem like valid redactions to us, and sometimes we're almost 100% certain, but for others, we would not be able to know. I would therefore not be in a position to report to you and the House that we've done the vetting as asked and give the documents. I would have to indicate that I'm not able to do it, or I'm able to do some vetting, but for what has already been redacted I could not, unless my office was shown the originals.

**Mr. Don Davies:** I understand now.

I'll tell you the basis for my concern. I've just had a chance to read the letter from Mr. Shugart, the Clerk of the Privy Council, that was sent this morning. It suggests to me that they are going to withhold documents on the criteria of confidential business information. This strikes me as foreshadowing that they intend to redact information, I would say, in violation of the motion.

To that point and the issue of his description of withholding information on the basis of confidential business information, is that, in your view, the same as the wording in the motion passed by the House? There is a redaction criterion for information "which could reasonably be expected to interfere with contractual or other negotiations between the Government of Canada and a third party". Is that the same as confidential business information?

**Mr. Philippe Dufresne:** They're not the same words, obviously, and we would look at any proposed redaction in a given document. That said, the House's criterion says, "information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations between the Government of Canada and a third party." If the Government of Canada has committed contractually to respecting confidentiality with respect to certain information, an argument could be made that making it public could reasonably interfere with the contractual or other negotiations.

That's what we would look at to find out what the information is and why it meets that test, but you're correct that confidential information is not the test. The test is whether the disclosure of that information could reasonably be expected to interfere with contractual or other negotiations.

**Mr. Don Davies:** Mr. Clerk, you've done this kind of job before. Is it possible for the government to send you documents in waves of information? In other words, would it be possible for the government to send you documents that it already has so that you could start to get the work under way to execute the motion, as opposed to waiting?

● (1400)

**Mr. Philippe Dufresne:** I don't want to indicate what's possible or not for the government to do. That would be for them to say. I can say that certainly my office can start looking at documents as soon as we receive them in terms of sequencing, but I really can't say what the government can or cannot do.

**Mr. Don Davies:** This is my final question. In July, the Standing Committee on Finance adopted an order for the production of documents related to the WE Charity matter, and the committee directed the government to provide the documents in unredacted form to the Office of the Law Clerk and Parliamentary Counsel—that was you—for redaction according to the parameters set out in that production order.

However, in a letter to the clerk of the finance committee, you indicated that the government had once again redacted the documents prior to providing them to your office. In testimony before the Standing Committee on Finance, Mr. Shugart said the following:

> I'm afraid that it is a fact that if the executive branch were to give all of the documents of cabinet confidence or commercial sensitivity or solicitor-client privilege or national security to the law clerk, it would be, in a sense, waiving that privilege, because the law clerk is a servant of the legislature, not of the executive.

So, if the government does this again with respect to the present directive—i.e., it redacts for reasons not stipulated in the motion or it does the redaction—what would your view be of whether that would be conforming to the motion of the House and the privileges of this committee and the House?

**Mr. Philippe Dufresne:** In the instance that you refer to, with respect to the finance committee, we received documents; we looked at what they were, and we reported to the committee as to the concerns we had and the fact that we were not able to do what the House had asked us or what the committee had asked us to do in that instance.

That's exactly what we will be doing in this instance. Once we receive the documents, we will review them to see what has been provided and whether that is consistent with what the House has ordered. The House has ordered that certain things be excluded, namely minutes of cabinet and its committees, but that other redactions be made by my office.

We'll have to wait and see what we receive. We will advise the committee in terms of the implications of that, but I don't want to do that before I've received and seen what is in fact provided.

**Mr. Don Davies:** Thank you. Those are my questions.

**The Chair:** Thank you, Mr. Davies.

That brings us to the end of this section of our meeting.

I would like to thank you, Mr. Dufresne and Mr. Bédard, for your presence here today and for sharing your time and expertise.

With that, we will suspend and bring in the next panel. Thank you.

● (1400)

_____(Pause)_____

● (1405)

**The Chair:** We will now resume the meeting.

For this hour, we are continuing the study of the Patented Medicine Prices Review Board's guidelines.

Returning to us are Dr. Mitchell Levine, chairperson, and Mr. Douglas Clark, executive director.

I'm assuming, gentlemen, that you gave your statement last week. Do you have another statement this week?

**Mr. Douglas Clark (Executive Director, Patented Medicine Prices Review Board):** I do not.

**Dr. Mitchell Levine (Chairperson, Patented Medicine Prices Review Board):** I don't either, although Mr. Clark has some comments in response to some questions that were provided at the end of last session.

**The Chair:** I'll give you a few minutes to make that response.

**Mr. Douglas Clark:** We actually submitted those in writing in both official languages a few hours ago. I thought they would be distributed to members by now. Is that the case?

**The Clerk:** Yes.

**The Chair:** That's perfectly okay.

In that case, we will start straight away with the questions.

We will go to Mr. Kmiec.

Mr. Kmiec, please go ahead for six minutes.

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

I want to go back to what we talked about on Monday, the $15-million threshold before these new PMPRB rules kick in. Can you tell me if that is the list price or the rebate price? How will you know when that $15-million threshold has been crossed?

**Mr. Douglas Clark:** It's actually not $15 million; it's $12 million. It's based on real revenue as reported to us by the patentee. They're required to report that revenue to us, so it will be pretty easy to monitor. About 50% or so of high-cost rare-disease drugs that come to the Canadian market would be unlikely to hit that threshold and actually have sales above $12 million a year.

**Mr. Tom Kmiec:** How was that $12-million threshold set?

**Mr. Douglas Clark:** If memory serves, it was based on a methodology used by a sister organization in the U.S., called ICER, where you basically look at how much we're spending on pharmaceuticals in a given year, how much GDP is increasing, the percentage of GDP increase, and multiply the percentage by the total spend on pharmaceuticals. That gives you some idea of what your budget envelope is to accommodate new drugs coming onto the market. Then you divide by the average number of drugs that are coming onto the market over a period of some years. Typically, it's around 35 new drugs per year. That gives you about a $6-million envelope for any new drugs, and then—

**Mr. Tom Kmiec:** Mr. Clark, I'm sorry to interrupt you. Afterwards, at some time, would you be able to provide that ICER report to the committee? I think that would be of interest.

**Mr. Douglas Clark:** Sure.

**Mr. Tom Kmiec:** The reason I ask is that $12 million is a pretty low bar at the list price of a drug such Zolgensma, which CADTH is trying to determine whether to approve. It's just under $3 million. That's about four patients, four kids with SMA1, and the manufacturer will have already breached that $12 million. However, Zolgensma, just like Trikafta for CF patients, is a game-changing medication. They're going to have to go by these new rules in the PMPRB, which likely means that a $3-million drug that changes the life a little boy or a little girl.... I have two children in mind, Kaysen and Harper in Edmonton. This is a condition that kills children by the age of two.

With this $12-million threshold, were patient viewpoints taken into account and the likelihood of patients dying while these PMPRB rules are implemented?

**Mr. Douglas Clark:** As I said, about 50% or less of high-cost rare-disease drugs that are coming onto the market would meet that threshold. However, it's important to bear in mind that even when that threshold kicks in, for the time being, the new, lower-price ceiling won't be applied by us. As I mentioned at our Monday meeting, we're awaiting a decision on an appeal from the Federal Court of Appeal on that topic. For the time being, the only price ceiling applicable to Zolgensma, assuming it comes to Canada, would be the median international price.

**Mr. Tom Kmiec:** Moving on, then, I was rereading all the briefs. The pharmaceutical companies are upset, obviously, with the PMPRB. You're affecting their revenue. I understand that. However, when I read over all the patient advocacy and briefs from patient organizations, I find zero support for these changes.

Are there any organizations out there that represent patients that are absolutely 100% on board with all these changes? These are organizations that represent patient families and patients across Canada. Do any of them support the PMPRB changes?

● (1410)

**Mr. Douglas Clark:** Yes. There are a number of independent patient organizations that don't accept any funding from outside sources, from industry, and they submitted briefs to the committee. One is Breast Cancer Action Montreal or Quebec. The other one is Independent Voices for Safe and Effective Drugs in Canada. Those are two that come to mind.

Generally speaking, as to where they break in terms of support or opposition to the reforms, there is a correlation between whether a patient group is independent or accepts funding from the private sector. Dr. Levine stated as much in his opening statement, when he said that patient groups are scattered across the divide that separates, on the one hand, payers who are struggling with these very high-cost drugs, and on the other end, the industry, which continues to want to charge these exorbitant prices.

**Mr. Tom Kmiec:** Speaking of high prices, a lot of the different health systems, health insurers across Canada, also submitted briefs. I'm going to draw your attention to Alberta Health Services in my province. Alberta Health Services said that between the first proposal and the revisions in the second proposal, none of their viewpoints were taken into account and none of the revisions they were asking for were made.

Is there a reason that the second version of the PMPRB regulations, the ones to be implemented January 1, completely ignored Alberta Health Services' viewpoints and their submission on the changes needed to the PMPRB regulations?

**Mr. Douglas Clark:** Off the top of my head, I'm not sure what submissions they're referring to. I can tell you that we did make substantive revisions, major revisions between the November and June drafts, and I think those revisions have been instrumental in getting some of our stakeholders to sign on to the new guidelines.

Ultimately, it's important to bear in mind that I've met many times with the folks who are responsible for the Alberta drug plan and it has always been my understanding that they're very supportive of the pCPA. These changes are a direct result of calls from the pCPA, which represents all the provinces, all the public drug plans and the federal drug plan, for stronger federal measures to support them in the difficulties they're currently encountering in trying to negotiate a fair price with monopolists over a life-saving drug.

On the whole, I can't speak to that particular submission. I don't recall exactly what they said, but I know CLHIA submitted a brief as well, and on the whole, public drug plans and private drug plans are uniformly supportive of these changes.

**Mr. Tom Kmiec:** It's interesting that you're bringing up pCPA, because pCPA is the body that negotiates on behalf of—

**The Chair:** I'm sorry, Mr. Kmiec. You're over time.

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

**The Chair:** We go now to Dr. Powlowski.

Please go ahead, Dr. Powlowski, for six minutes.

**Mr. Marcus Powlowski (Thunder Bay—Rainy River, Lib.):** Okay, I think this is really difficult stuff for someone to understand. Let me get this straight. The Patent Act sets out some criteria for the PMPRB to consider in determining the price or what price is considered excessive. The act allows the minister, by regulations, to add other criteria as to what makes the price of a drug excessive.

One of the new criteria is pharmacoeconomics. Is it the PMPRB or the CADTH, the Canadian Agency for Drugs and Technologies in Health, that makes the calculation in terms of pharmacoeconomics?

**Mr. Douglas Clark:** To respond to the first part of your statement, that's absolutely correct. There are criteria in the Patent Act enumerated there, and then there are additional criteria now having been added in by way of regulation by the Minister of Health.

In terms of the actual calculation, what we call the ICER value that will go into our formula, that will be conducted and calculated solely by the CADTH and also on occasion by INESSS, depending on whether there's a report available from INESSS and not the CADTH.

We've been saying this all along. We have no intention of duplicating that work. We are leveraging the existing expertise that we have within the Canadian regulatory ecosystem and are trying to complement it as best we can. We're taking that input directly. We're not making any changes to those numbers. We're simply applying a formula—does the ICER value meet or not meet our pharmacoeconomic value threshold in our guidelines—and then we go from there.

● (1415)

**Mr. Marcus Powlowski:** My understanding of pharmacoeconomics is that, largely, this is a calculation of cost per QALY, quality-adjusted life year, so that's what goes into calculating the ICER.

**Mr. Douglas Clark:** That's correct. “Cost-utility ratio” is the official term.

**Mr. Marcus Powlowski:** My understanding is that this is HTA, health technology assessment. Am I wrong in saying this? I've read that Canada will be the first country that sets a maximum allowable price based on HTA. Is this true?

**Mr. Douglas Clark:** As I said on Monday, no two regimes are alike. Canada, to my knowledge, is the only developed country with a price regulator that regulates pharmaceuticals. The comparison kind of breaks down when you have that information.

There certainly are other developed countries where the reimbursement body won't enter into negotiations with a company unless the price is below a certain ICER threshold. The U.K. and Japan are examples of that.

**Mr. Marcus Powlowski:** In terms of what that threshold is, in terms of a maximum cost per QALY, is there a limit? Is that $60,000? Is that what the limit is?

**Mr. Douglas Clark:** No. The November 2019 draft that we initially consulted on had a $60,000 cost-per-QALY maximum. However, following the extensive consultations that we had with our stakeholders over the course of the ensuing three or four months, we opted to raise that threshold to $200,000 per QALY.

The reality is that we have a cap on the extent of the price reduction, so the degree of cap is a function of how good the drug is, the therapeutic benefit of the drug. The maximum cap on the price reduction would be 50%. For a breakthrough drug, it would be 20%, so as a result of the cap, even new high-cost drugs that don't meet that $200,000-per-QALY threshold, which is a very generous threshold, would still be able to pass our price ceiling because the cap has the effect of increasing the cost-per-QALY threshold.

It's a lot of information that I'm throwing at you, but if you look in the guidelines, you'll see a threshold of $200,000 per QALY.

**Mr. Marcus Powlowski:** Are there many drugs out there that are likely to come before you that are going to exceed the cap?

**Mr. Douglas Clark:** Yes, probably. That's the phenomenon that Dr. Levine was talking about on Monday. We're just getting more and more of those types of drugs that are extremely high-cost. They can be north of $500,000 per QALY, $1 million per QALY, but that's the entire point of having health technology assessment: to try to ensure that we're getting value for money.

Those drugs typically don't get recommended by.... Well, they never get recommended for reimbursement by the CADTH or INESSS unless they condition it on a major price reduction, sometimes in the order of 90%, 95%, 98%, which is the case with the cystic fibrosis drugs that have come to Canada in recent years.

**Mr. Marcus Powlowski:** Now, if some of the drugs we're talking about here are obviously life-saving drugs and we're setting a limit on how much we're willing to pay in terms of a cut-off in cost per QALY, aren't we basically putting a price on life as to what price our government considers acceptable? How much are we willing to pay to save a life?

I would ask.... Maybe this is an unfair question, but from a democratic perspective, to put a value on life by regulation seems to me somewhat undemocratic, if it is done by regulation rather than by going through Parliament. Maybe that's an unfair question. I think it's a bit of a philosophical question.

**Mr. Douglas Clark:** I think it's a fair question, and maybe one that would be better directed to CADTH or INESSS, because that's precisely the type of work they do, along with HTA bodies across the world. They figure out how much we can afford to pay for a quality-adjusted life year. That's the nature of the exercise.

● (1420)

**Dr. Mitchell Levine:** I think one of the things you also have to remember is that the more life-saving, effective or dramatic the improvement of a drug is, the lower the cost per QALY becomes. When you're seeing drugs that are at half a million or a million dollars per quality-adjusted life year, the implication is that either the price is just way off the chart or, in fact, it doesn't deliver on the outcome that one would really hope for.

Really effective drugs, life-saving, life-altering drugs, have lower cost per QALY. That's the way that ratio works.

**Mr. Douglas Clark:** The other thing to consider is that in the absence of some kind of threshold, ceiling or ultimate cap, what is the alternative? The alternative is.... I think a lot of people would say, “Well, you negotiate.” As Dr. Levine pointed out, in Canada prescription medication isn't covered by our health care system, so at best, public payers are wielding 42% of the national buying power of the country.

I think it's trite, but it's also important and it's true, that it's very difficult to negotiate with a monopolist, especially when you don't have a monopsony—even more so when the monopoly is held over a life-saving drug. The alternative to saying that we have to draw the line somewhere is to basically say we'll take whatever price the company thinks is fair and that's what we'll pay. That's not working out so well.

**The Chair:** Thank you, Dr. Powlowski.

We go now to Mr. Thériault.

[*Translation*]

You have the floor for six minutes.

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

When we look at the briefs that we received, it becomes clear that we're dealing with objectively different points of views and interests. I want this study to help us find common ground, to ensure a win-win situation.

I'm advocating for the patients' point of view. I'm not only talking about patients, but about patients with rare diseases, since they're the most vulnerable. I'll play devil's advocate, as I did at the last meeting and as I'll do with all the people who will appear before the committee during this study.

At the last meeting, you told us the following:

> ... the average annual treatment cost of the top selling patented drugs increased by approximately 1,000% and the proportion of high-cost drugs—that is, drugs costing more than $10,000 per year—rose from 5% to about 40% of overall pharmaceutical spending. Yet less than 1% of the population are using these medicines.

However, the brief submitted by the Canadian Organization for Rare Disorders states the following:

> ... the PMPRB continues to use alarmist language to convey the idea that Canada is paying too much for rare disease treatments and conflates drug spending categories to support its position. For instance, in the case of drugs for rare diseases, the PMPRB lumps together oncology medicines with those with true orphan indications to generate larger number to help justify the need for the reforms. In reality, in 2019, non-oncology rare disease treatments represented just 1.9% of the total Canadian medications bill.

What do you have to say about this?

**Mr. Douglas Clark:** Since I don't have the data in front of me, it would be difficult to respond on the spot.

If you want, I can commit to analyzing the data and figures provided by the Canadian Organization for Rare Disorders. I honestly don't know whether this is true or false. I'd need to ask my colleagues to conduct the necessary analysis.

**Mr. Luc Thériault:** You don't know that the total cost of orphan drugs is around $228 million?

**Mr. Douglas Clark:** I don't know whether that's true or false.

I know that very high-cost drugs currently account for 40% of total pharmaceutical spending in Canada.

● (1425)

**Mr. Luc Thériault:** I imagine that this organization can prove its case. They claim that you're lumping these drugs together to boost your statistics. If not, why else would you do so?

**Mr. Douglas Clark:** I don't agree with this claim. It isn't to boost the figures. That's the truth.

**Mr. Luc Thériault:** What's the exact proportion associated with rare diseases? That's the question here.

**Mr. Douglas Clark:** I'll need to give you the answer later, Mr. Thériault. I don't know. I don't have the figures in front of me.

**Mr. Luc Thériault:** Okay.

During the—

[*English*]

**Mr. Douglas Clark:** Mitch, did you want to add something?

**Dr. Mitchell Levine:** Yes. I would like to offer a comment here, because I think we're mixing up two things a little bit. One is that we have high-cost drugs and they're not just orphan drugs. Orphan drugs are often high-cost drugs, but that's not particularly the case. Much of what we were worried about in terms of high-cost drugs, drugs costing more than $10,000 per year, are in fact for common diseases now. These are things like rheumatoid arthritis and rheumatological diseases. Cancer is a common problem. The therapies are very, very expensive.

So I wouldn't say this whole focus is about trying to manage the cost of rare disease as much as it is about trying to manage the cost of very expensive therapies.

[*Translation*]

**Mr. Luc Thériault:** Mr. Clark, I'd like a written answer. I can also respond to the written answer that you sent today.

At our last meeting, I asked for your views on several proposals. One of them was the idea of a more gradual implementation of the PMPRB's new guidelines. The first step would be to implement the new basket of comparator countries. The pharmacoeconomic factors should then be applied after a more extensive consultation. In addition, a multi-stakeholder evaluation and monitoring committee should be created to make the process more objective.

You responded that several of the measures that I referred to would be part of your plan for the future. A number of these suggestions don't pose any issues.

I'd now like you to be a little more specific about which of these measures might apply and, if so, whether they would apply as of the January 1 deadline.

**Mr. Douglas Clark:** I believe that all the measures that you just described will be part of our plan, once the new regime comes into effect in January 2021.

We'll proceed in stages, starting with the implementation of the new price ceilings, which are the result of the new comparator countries.

We'll be able to conduct audits only much later, probably in two or three years. It will depend on the Federal Court of Appeal's decision. The Federal Court of Appeal must determine whether we can obtain the information that we need to check whether patent holders are complying with the new confidential price ceilings.

Right now, that's exactly what we're doing. We're moving forward, one step at a time. First, the new country-specific price ceilings will begin to apply in January 2022. At this time, the confidential price ceiling, or the maximum rebated price, isn't being applied.

In the meantime, we'll mainly be consulting with the patent companies. However, we'll also be working on this issue with other stakeholders, as we move forward.

**Mr. Luc Thériault:** What about the multi-stakeholder evaluation and monitoring committee? Some briefs expressed concern about the fact that—

**The Chair:** Mr. Thériault, your time is up.

[*English*]

We go now to Mr. Davies.

**Mr. Don Davies:** Thank you.

Mr. Clark, in the PMPRB's most recent annual report, you noted the following:

> ...the ratio of R&D expenditures to sales revenues for pharmaceutical patentees in Canada has been falling since the late 1990's, and has been under the agreed-upon target of 10% since 2003. In 2018, it was at 4.0% for all patentees and 4.3% for members of Innovative Medicines Canada.

In your view, Mr. Clark, will the PMPRB regulatory changes being proposed result in lower research and development investment in Canada?

● (1430)

**Mr. Douglas Clark:** Frankly, it can't get much lower, can it?

I think one of the driving forces—the impetus behind these changes—is the realization that back in the day when we chose the basket of comparator countries that we've used since about the late 1980s, we did so on the basis of a policy presumption that we priced in line with countries that have a significant R and D footprint. We've come eventually to emulate that same footprint. In other words, we see an average 20%-25% R and D to sales ratio in those other countries, so if we offer a level of intellectual property protection and price in line with those countries, we'll come to enjoy the same level of R and D. Well, that hasn't exactly panned out.

For the government, I think the underlying rationale for changing the list of countries is that they're choosing to pursue different policy objectives. They've realized that there's no organic connection between the price in a country and R and D intensity. Many of the countries that we compare ourselves to presently have lower prices than we do, and considerably more R and D. I think the emphasis going forward.... The reason we have those new 11 countries is that the primary objective of the policy is to ensure that we're getting prices that are more in line with the OECD median.

**Mr. Don Davies:** Just for the record—and I think I speak for all of my colleagues—we would love to have more research and development in pharmaceuticals done in Canada. I think that's across all party lines.

I wanted to establish whether you have any concerns that these regulatory changes will negatively impact that, and I got my answer.

Similarly, do you think that the PMPRB regulatory changes proposed for January 1 will result in fewer clinical trials in Canada?

**Mr. Douglas Clark:** I guess that's the flip side or another facet of R and D. We don't see any evidence of that.

I will say that clinical trial intensity is going down in developed countries across the board, as industry kind of moves their R and D efforts into emerging markets. We've seen a bit of a decline in Canada in clinical trials recently.

**Mr. Don Davies:** That's under the current regulatory regime.

**Mr. Douglas Clark:** Yes. I guess you could say it's been declining for a couple of years now. The regulations were adopted in August 2019, so I'm not sure how that coincides with that time period. It's actually declining less dramatically in Canada than it is in many of these other countries, including the U.S., which has very high-priced drugs.

**Mr. Don Davies:** I think they're the number one country in the world for prices.

**Mr. Douglas Clark:** They are, almost without exception.

**Mr. Don Davies:** My last question is in this vein. Will the proposed PMPRB regulatory changes result in fewer drug launches in Canada?

**Mr. Douglas Clark:** Again, we tried to address this in the written answers to some of the questions we undertook to follow up on, on Monday. We certainly don't see that. Actual applications—what we call new drug submissions—to Health Canada for new active substances, in other words new innovative medicines, are actually up in the past fiscal year.

Since the regulations were finally adopted, and with these changes coming into force on the horizon, we're seeing an uptick in drugs coming to Canada, not a lowering. Then if you break it down quarterly, which we did in our answer, you see the same general trend. For the most recent quarter, it's actually above the average over the last three years. When you look at it quarterly, it's slightly above, 9.8 versus 9.

**Mr. Don Davies:** I'm going to just say it bluntly, if I can. It almost seems that the pharmaceutical industry—which controls where the R and D goes, where they launch drugs and where they have their clinical trials—is threatening to reduce these things in Canada if the government proceeds with regulatory changes that are geared towards reducing prices that Canadians pay for increasingly expensive prescription drugs, getting our prices more in line with what other countries are paying, and making some changes to improve the pricing process.

Would that be a fair comment?

**Mr. Douglas Clark:** Of course they are, and in doing so, they're just behaving rationally, and they do this in every country that tries to introduce reforms to try to contain pharmaceutical expenditures. It's just the nature of the game.

Again, Dr. Levine made this point in his opening remarks. We are never going to get an industry sector to sign on to changes that will result in their revenues coming down. I keep using the analogy with people that, for five years, we've been asking somebody if they want a haircut and they keep telling us no, and then we keep asking them, “Would you like your bangs cut shorter and a little shorter in the back?” They don't want a haircut, right?

You can consult until the cows come home, but you're never going to get industry to back changes to a regulatory regime that are going to result in less revenue for them. The bottom line is that you have to have a fair process and a transparent process. That's what we think we've managed to do.

● (1435)

**Mr. Don Davies:** The bottom-line question is this: Do you think these changes will help patients in Canada?

**Mr. Douglas Clark:** I do.

**The Chair:** Thank you, Mr. Davies.

That ends round one.

We start round two now.

Mr. d'Entremont, please go ahead. You have five minutes.

**Mr. Chris d'Entremont (West Nova, CPC):** Thank you very much, Mr. Chair. I apologize for being a little late. I was doing a speech in the House. I know Ms. Sidhu was over there as well, so there may be a few different faces before us.

I want to go to where you left off with Mr. Kmiec. When you talked about patient groups that receive funding from pharmaceutical companies, we received a lot of patient groups writing in about PMPRB changes. I'm just wondering what threshold we are supposed to consider on support for our patient groups. It's a difficult one here.

**Mr. Douglas Clark:** It is. I think that's your challenge. I don't know if it's really my place to advise you in that regard.

It's important to understand a little bit of history here. Maybe that would help you at least contextualize it. It used to be that the federal government contributed to charitable organizations like patient advocacy groups, but in the mid-1990s, they decided to no longer fund organizations of that kind if they had a policy-lobbying arm, because the government didn't want to have to engage with an organization that's ultimately giving it grief for a policy that it didn't like. That created a vacuum, and in defence of these organizations, they had to fill that gap somewhere, so industry was only too happy to step in and provide that funding.

It varies across the developed world, but in some countries they continue to fund their patient groups only on the condition that they prove that they're independent from industry. In many of those countries, it's much easier to have a rational, evidence-based discussion about policy changes, in particular policy changes of this kind.

I'm not saying that every patient group that accepts money is biased, and I'm sure they certainly don't feel that way, but there's a lot of research out there to show that, when you take money from someone, it—even implicitly, without your knowledge, subconsciously—impacts your views. There's definitely a correlation, and a pretty strong one, between where patient groups stand on these reforms and the extent to which they accept funding from industry. Whether it's positive, I don't know, but there's definitely a correlation. It's hard to deny if you go through those briefs.

**Mr. Chris d'Entremont:** Yes. I go back to one of the meetings that we've all had with CF Canada. CF Canada said they wanted Trikafta to be covered, but if that became difficult, then they would turn quickly on Vertex as well. I don't think their intention is to necessarily support the pharmaceutical companies, but in the absence of direction, I suppose that you're the target of that.

**Mr. Douglas Clark:** Well, that's an interesting point you raise, because, as I mentioned on Monday, a lot of other countries have struggled with the prices for these new, very promising, life-changing cystic fibrosis drugs. There was a stalemate in many of these countries between the reimbursement body and the company because they wouldn't bring their price down. Some of the patient groups in the U.K. and Switzerland, for example, decided that they were going to switch strategies and seek out a compulsory licence and obtain a generic version of those drugs from a South American country. It was only when that threat was made that you started to see progress made at the negotiation table.

I think that's something for patient groups to consider, not just with respect to this particular product line and this company, but more generally. It doesn't make sense to me that a company that saw its second quarter results go up 62% most recently and made $2 billion selling four cystic fibrosis drugs is not in the hot seat to the same extent as the government because it refuses to bring out product to us unless we pay among the highest prices in the world. It just doesn't seem sensible to me.

● (1440)

**Mr. Chris d'Entremont:** Let me switch gears just a bit. It was in the news yesterday—so I'm sure you're aware of it—that Innovative Medicines, I think, was talking about vaccine production in Canada. They sort of tied it back over to the PMPRB changes. I'm wondering if you had any thoughts on that or if you have seen that report.

**Mr. Douglas Clark:** Yes, I have. I will say that we've adopted a policy on a temporary basis to only look at these vaccines on a complaints basis. If we get a complaint from a provincial or federal minister of health about the price, that's when we'll look at it.

The companies have already committed to providing these products at public, non-commercial, so-called humanitarian or compassionate prices for the duration of the pandemic, so I don't know why they would say that, unless they were saying that their intention was to price excessively in Canada, but that now, since the PMPRB is not going to look at them proactively, they'll bring the drugs here. I don't understand the statement.

**Mr. Chris d'Entremont:** I think it has to do—

**The Chair:** Thank you, Mr. d'Entremont.

We go now to Mr. Kelloway.

Mr. Kelloway, go ahead for five minutes.

**Mr. Mike Kelloway:** Thank you, Mr. Chair.

Hello, colleagues, and hello, witnesses.

I just want to say how insightful I find this conversation, and I know Canadians do as well, with the great questions from all of my colleagues and the answers that follow.

I have three questions. We'll see if we can get through all of them.

The first one is around investments. Several other countries benefit from significant pharmaceutical industry investments while having considerably lower prices than Canada. For example, Belgium receives four times more investment dollars than Canada, despite prices being 20% less.

For both witnesses, can you identify any lessons from the evolvement of the drug regulation processes of our international partners, particularly those within the PMPRB11, that Canada could apply to our own drug regulation processes?

**Mr. Douglas Clark:** I'm not sure whether there's anything we can do within the context of our drug regulatory processes that could change the basic ratio that we're seeing today. The key distinguishing factor or feature between us and these other countries you point to that have lower prices for more R and D is that they have a homegrown industry there. Companies tend to focus their R and D efforts around their international headquarters, and we don't have a homegrown.... We have a homegrown vaccine research facility that now has been purchased by Sanofi, and it's an incredible facility. We have Glaxo for vaccines in Quebec, and Medicago, which is a world-class pioneering vaccine facility.

In the late sixties and early seventies, the government introduced a number of policies that gave rise to a very robust and vibrant generic industry, with Canadian companies that were true powerhouses internationally, but in the late eighties I guess they decided to tie the wagon to a different horse, or bet on a different pony, or however you wish to describe it.

I will say that, in fairness, there's one thing we could do, and that is to harmonize or align our processes so that it's much easier to go from regulatory approval to actual reimbursement and sale. In Canada, it's like a relay race because of overlapping and competing jurisdictional roles, and that's really why I think a lot of people are advocating for a Canadian drug agency that would sort of collapse all these functions into one.

**Mr. Mike Kelloway:** Is that for greater clarity and flexibility? Is that what I'm hearing?

**Mr. Douglas Clark:** I think a one-stop-shop would be ideal, but when you break down many of the dysfunctional and intractable issues in Canada, a big part of the reason we sometimes can't overcome them is that we're a federation. That's my own personal opinion.

I do think there's a lot of goodwill out there, and you've certainly seen different regulatory bodies in the space and different jurisdictions co-operating and collaborating in a way that we've never seen before, because they have to and because of the cost situation they're confronted with. I think it's an opportune time to capitalize on that goodwill and try to take that further and formalize that co-operation and collaboration.

● (1445)

**Mr. Mike Kelloway:** That's fantastic.

This is another question for both of you or one of you.

Price is considered to be a poor determinant of where new medicines are first launched. Many countries with lower drug prices than Canada, including the Netherlands, Sweden, the U.K. and Norway, have obtained earlier access to new medicines. I think this is an important question for all of us, but for Canadians watching, can you explain how the new guidelines will encourage further pharmaceutical innovation in Canada?

**Mr. Douglas Clark:** I don't think we're making that assertion or that claim. We don't have a policy responsibility to encourage innovation. We're an economic regulatory body that ensures that prices of patented medicines aren't excessive. There are a lot of other things going on within government, both federally and provincially. Quebec in particular has an organization, a public-private partnership, called Catalis. They're doing amazing work to try to bring in more clinical trials in that province.

I don't think it's the purview of PMPRB to ensure that its guidelines, regulations and regime in its totality encourage R and D. It would be nice if it did, but we don't have that mandate.

**Mr. Mike Kelloway:** That's fair enough.

Let me go to a third question, if I have time. How much time do I have, Chair?

**The Chair:** You have five seconds.

**Mr. Mike Kelloway:** Well, stay tuned for the next edition. I'll pass.

Thanks so much.

**The Chair:** Thank you, Mr. Kelloway.

We now go back to Mr. Kmiec. You have five minutes, please.

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

Just to go back, I was looking this up online. According to ISED's website, we have 2% of the world's pharmaceutical market, but we attract 4% of clinical trials. Clinical trials, though, are a really important way for patients to get access to drugs that are not approved in Canada or are not for public reimbursement.

Has the PMPRB done any work, or any internal analysis, on what the expected drop in clinical trials will be—over the next, say, one to five years—if these regulations go through, or are they expected to increase? Have you done that analysis? Also, what will the impact be on patients and patient access to some rare-disease drugs, like rare oncology drugs, in Canada?

**Mr. Douglas Clark:** It's true that we are 2% of the world market, but that's not a negligible amount. That makes us a top 10 market, so it's not surprising that we would account for a significant amount of clinical trial development. I will say that pharmaceutical patentees, from the industry, account for a small minority of those clinical trials in Canada. They are the exception. It's mostly other organizations within the health care system that conduct those clinical trials.

I can't say that you reduce the price to this or that amount and it will equal this or that number of clinical trials. I just don't think there's a formula that lands you there magically. All I can say is that we are unable to discern a strong correlation between price and clinical trial intensity. In fact, we see the opposite.

**Mr. Tom Kmiec:** I have a question, then, about the regulations that are to be introduced January 1. Is there any mechanism within the PMPRB that's being planned, or is already set up, that is going to assess the impact of these new regulations, not on price, but on patient access to drugs? Is it going to look at things like how many Canadians are going to the United States or Mexico to get access to drugs? Is it going to look at the number of situations where people go on a GoFundMe page in order to finance a drug that perhaps is approved in Canada but is not up for reimbursement?

What are the metrics that are going to be used, specific to patient access?

**Mr. Douglas Clark:** That's an excellent question.

We're working very hard on what we're calling a guidelines monitoring and evaluation plan. It's a very audacious, ambitious plan. We are going to be reaching out. It has four different buckets of things that we'll be looking at and evaluating. There are many metrics falling into each of those buckets, but the things that you've just talked about do squarely fall into them.

We're going to be reaching out very soon to our provincial and territorial colleagues and counterparts to help us formulate an initial framework, and then we're going to be going to patient groups and academics. We're going to be engaging everybody to help us come up with a very exhaustive, comprehensive plan to make sure that if there are any—

● (1450)

**Mr. Tom Kmiec:** When will it be complete?

**Mr. Douglas Clark:** By the end of fall 2021. Before any impact of these guidelines and regulations makes itself felt, we'll have that plan in place. I can assure you of that.

**Mr. Tom Kmiec:** You're saying the expectation from your agency is that the impact will not be felt between January 1, 2021 and the fall of 2021, before you have this evaluation plan in place.

**Mr. Douglas Clark:** No price changes can take place as a result of the new regime until January 2022. I think that's what I'm saying.

**Mr. Tom Kmiec:** Will you also do an analysis? There's going to be a year lead time going into it, so some companies will obviously be making decisions, and patients are going to be waiting for some of these drugs. They're seeing their friends and people they know travelling to America. Trikafta is a perfect example, because it happens all the time. I just spoke with a patient who is on Trikafta through SAP in Canada, and it's a life-changing experience for her.

How are we going to track situations like hers, where people can't get access to SAP or, after it's approved—if it is approved—are not eligible for it? How will you track that? Will they be part of those metrics showing that these people didn't get access to it?

**Mr. Douglas Clark:** Yes, they absolutely will.

There are 4,300 people in Canada who suffer from this awful disease, and Canada is renowned because of CF Canada's very comprehensive and exhaustive database of all of those patients. That's a great tool for us to rely on in being able to track those things, so absolutely, we will.

**The Chair:** Thank you, Mr. Kmiec.

We will go now to Mr. Van Bynen, for five minutes.

**Mr. Tony Van Bynen:** Thank you, Mr. Chair, and thank you to our witnesses for joining us again today to share their expertise on PMPRB.

We're living in a world where information is easily accessible to everyone at any time, in any form and anywhere. As a consequence, disinformation is easily accessible. It's often said that disinformation will be halfway around the world before the truth has put its shoes on.

Many if not most of us are not familiar with PMPRB. I'd like to take this opportunity to ask what is fact, what is not, and to elaborate where possible.

With this in mind, could you tell the committee whether the following statement is a myth or a fact: “Lower drug prices will lead to a loss of research and development and manufacturing”?

**Mr. Douglas Clark:** There is no empirical evidence to back up that statement, and to the extent that there is empirical evidence, it would suggest a contrary conclusion.

**Mr. Tony Van Bynen:** Thank you.

What are your thoughts on the following statement: “Canada's approach is out of step with that of the rest of the world”? Is this a myth or a fact? How does our approach compare to the rest of the world?

**Mr. Douglas Clark:** It's both a fact and a myth. As I said, no two regimes are alike. Canada is the only country with a universal health care system that doesn't include prescription drug coverage. Therefore, the idea was that we would try to approximate what we would be able to secure by way of our monopsony power, if we were buying on behalf of the total population, by creating a ceiling price regulator.

There is no other country that has a ceiling price regulator in this sector like Canada does, but the new economic factors that we're adopting as part of these regulatory changes are based on pharmacoeconomic value, market size/affordability and based on best practices internationally. I'm not aware of any country where these things are not given prominence in the process for determining whether to reimburse a drug and at what price.

**Mr. Tony Van Bynen:** Thank you.

During these challenging times, something that is on everybody's mind is their job. Is the statement “Some drug manufacturers may be forced to cut jobs in Canada” a myth or a fact? Could you elaborate on that?

**Mr. Douglas Clark:** I think that question should be directed at the companies. I know there's been a lot of attrition in the pharmaceutical industry footprint in Canada in the last 10 or 15 years. I believe the Prime Minister spoke to that in question period a few days ago. Whether this will exacerbate that is not for me to say.

● (1455)

**Mr. Tony Van Bynen:** It sounds to me like the major differentiator is the fact that we're lacking significantly in homegrown manufacturing.

**Mr. Douglas Clark:** That's my personal take on the situation. I shouldn't say that; it's more than personal. The data supports the conclusion that companies tend to focus their R and D efforts, resources and investment in proximity to their international headquarters.

**Mr. Tony Van Bynen:** Thank you.

Many of our international partners have updated the rules to constrain rising drug prices many years ago. The new PMPRB guidelines appear to be quite similar, or drawn directly from those that are already in place in other countries, including those with large pharmaceutical industries, such as the United Kingdom, France, Japan and Australia.

Considering this, would you identify some of the challenges that PMPRB has faced in fulfilling its mandate of protecting Canadians from excessive pharmaceutical prices over the years, and how will these new guidelines help address some of these challenges?

**Mr. Douglas Clark:** We have a number of sort of motherhood, seminal policy documents out there that I think I would refer you to. It's a big question with a long answer, so I think I would refer you, first and foremost, to our 2015-18 strategic plan. It really sets out exactly what you're talking about in writing, and in a way that I hope is accessible to most people.

Going back to Dr. Levine's opening remarks, it's the dramatic shift that we've seen in the nature of the products that are dominating the market. These go from small-molecule drugs that treat common ailments and that arguably are within the means of ordinary people, to complex biologic drugs to treat more rare diseases that clearly are not within the means of anybody and even institutional payers struggle with. That's one big change. It has necessitated a corresponding change to our regime.

There's another big change. Canada pioneered this practice of international reference pricing as a way to ensure we were getting a reasonable and fair price, but since doing that in the late eighties, through the creation of the PMPRB, most other countries have copied that. One of the ways industry has responded, to try to make that a less effective policy, is by negotiating confidential rebates and discounts off the public list price. That has driven pricing underground, which has proven to be another big challenge for us.

The changes that have been made to the regulations and the guidelines go directly to the heart of those changes. The new regulatory tools, the economic tools, the pharmacoeconomic value and market size will enable us to ensure that Canadians are getting value for their money for these products that have nosebleed price tags.

One of the other changes, which is currently before the Federal Court of Appeal, requires patentees to provide us with the information on those confidential discounts and rebates so that we can regulate the true price in the market.

I know that's a long-winded answer, but if you want more information, I'd really encourage you to go to our website. We've been very transparent over the last five years about what the problem is, what our proposed solution is, and the path for getting there.

**Mr. Tony Van Bynen:** Great. Thank you.

**The Chair:** Thank you, Mr. Van Bynen.

**Mr. Tony Van Bynen:** Thank you.

[*Translation*]

**The Chair:** Mr. Thériault, go ahead for two and a half minutes.

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

I would like to come back to the last question I wanted to put to you earlier and did not have time to finish.

Would you agree with a multipartite assessment and oversight committee being created to make the process a bit more objective?

**Mr. Douglas Clark:** I certainly agree with there being a committee, but I don't know whether I would call it an oversight committee. That doesn't seem compliant with the laws and regulations that govern us.

We definitely have a lot of back and forth with other stakeholders to help us do our job properly under the new regime.

**Mr. Luc Thériault:** Like a number of other people, I have a lot of questions about the impact of the new guidelines on the life sciences ecosystem. Quebec has adopted the Quebec 2017-2027 life sciences strategy, which is in fact an economic development tool. The same concern comes up in the brief submitted by the Life-Sciences British Columbia organization.

Regarding the reform you are proposing, people are not seeing a concrete analysis of the direct impacts it would have on the life sciences ecosystem. I am talking about impacts not only on industry, but also on research institutes, teaching hospitals, research organizations under contract and clinical trial sites.

Could you assure us today that you have taken into account the overall impact of the new guidelines? I assume that, in five years, you have had enough time to produce those analyses. If so, how have you integrated this into your thought process and your reform?

● (1500)

**Mr. Douglas Clark:** I think that my testimony today is pretty clear: we think that the data from research does not support some of the claims being made. It's as if the stakeholders were making unfounded statements and are asking us to prove the opposite. To our mind, there is no link between the price and industry's intensity in research and development in Canada. I don't know how else to answer this question.

**Mr. Luc Thériault:** Okay. My understanding is that, in five years, you have not analyzed the economic or overall impacts of the reform on life sciences. Is that right?

**The Chair:** Mr. Thériault, your time is up.

**Mr. Douglas Clark:** No, we have not analyzed the impact on life sciences. However, we have done an analysis on prices, and we believe there will be no impact, as no data....

[*English*]

**The Chair:** Mr. Thériault, thank you.

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

**Mr. Don Davies:** Thanks.

Mr. Clark, I have two and a half minutes. I'm going to ask you three questions and ask you to try to answer them succinctly so I can get them all in.

First of all, generally, what percentage of research dollars that go into patented medicines is publicly funded?

**Mr. Douglas Clark:** That depends on the country. Are you talking about Canada or—

**Mr. Don Davies:** Canada.

**Mr. Douglas Clark:** I don't have that number at my fingertips, but it's a considerable amount. Mariana Mazzucato, an economist, does a lot of work in this area. I can certainly get back to you with that.

For example, in the U.S. Trikafta was developed on the basis of quite a bit of funding from the National Institutes of Health and from the Cystic Fibrosis Foundation. It's not uncommon. In fact, it's more common than uncommon.

**Mr. Don Davies:** Thank you.

I was going to move to Trikafta because, obviously, special access is not working for the many Canadians who are living with cystic fibrosis. I'm wondering how best we should proceed to ensure that CF patients can get access to this life-saving, life-altering medicine. What would you recommend?

**Mr. Douglas Clark:** If I were omniscient and omnipotent, I would do as the government committed to do a few years back and pursue the establishment of a national drug agency. I think that is the single most well-substantiated complaint about penetrating the Canadian market, that it's like a relay race where you have to go through one hurdle after another. You think you're there, and then suddenly you have to submit information to the PMPRB, to CADTH, and finally you get to the public reimbursement point.

So I think more buying power and a Canadian drug agency—

**Mr. Don Davies:** You did briefly mention compulsory licensing. As I understand it, that's the power of the state. When a patent holder refuses to act on a patent and they have access to a life-saving molecule or something of great public interest, it allows the state to act on that patent if the private patent holder won't.

Is that something we could look at? If Vertex will not apply in Canada to make Trikafta available to the patients who need it, is compulsory licensing an option?

**Mr. Douglas Clark:** That's a really good question. As I said, that's what patient groups were threatening to do in the U.K. and Switzerland, and that's kind of what brought Vertex back to the table. That's my understanding.

There are a number of provisions in our Patent Act that allow for compulsory licensing. One—section 65 and section 66—refers to the kind of situation you just described, when the patentee refuses to provide the product on reasonable terms, but there's a much more open-ended provision, section 19 in the act, that allows the government to override a patent for public, non-commercial use or in emergent circumstances.

All of these provisions.... As you probably know, Mr. Davies, Canada used to have a compulsory licensing system in effect that allowed generics to produce patented drugs at any point in the lifetime of the patent, but in the early 1990s and mid-1990s we entered NAFTA and we entered the WTO TRIPS agreement, and those agreements have a lot of standards and restrictions on the degree to which countries can avail themselves of those provisions, so our provisions reflect the language, track the language in NAFTA and TRIPS.

However, it's not an impossibility. When I go abroad and meet with my counterparts, a lot of countries are saying they lack the tools to deal adequately with the types of prices they're seeing and they need to explore this option of compulsory licensing more and see whether they need to make changes to their legal regimes and whether they need to amend the multilateral agreements they've entered into. They're saying, “Have we gotten to a point where we're in the same position that developing countries were 20 years ago with drugs for tuberculosis, AIDS and malaria, where we just can't afford the market price?”

I think developed countries increasingly find themselves in that same situation, so now there's an openness to talking about compulsory licensing more broadly.

● (1505)

**The Chair:** Thank you, Mr. Davies.

That brings us to the end of our questioning for today.

Thank you, Mr. Clark and Dr. Levine, for giving us your time and your expertise today.

Thanks to everyone on the committee for your excellent questions.

With that, we are adjourned.