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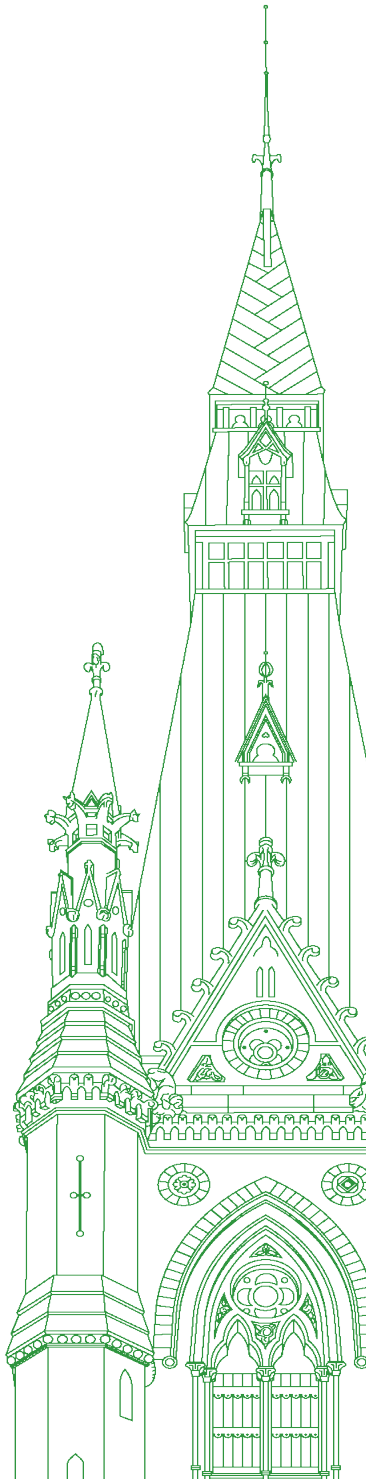

Chair: Mr. Sean Casey

Standing Committee on Health

Thursday, May 11, 2023

● (1105)

[*English*]

The Chair (Mr. Sean Casey (Charlottetown, Lib.)): I call this meeting to order.

Good morning, everyone. Welcome to meeting number 68 of the House of Commons Standing Committee on Health. Today we continue our study of the oversight of medical devices—breast implant registry—with a two-hour panel to hear from patient advocates.

Today's meeting is taking place in a hybrid format, pursuant to the House order of June 23, 2022.

I have a few comments for the benefit of the witnesses.

For those participating virtually—I guess it's Ms. Pratt—make sure that you mute yourself when you're not speaking. You have interpretation on the bottom of your screen of floor, English or French.

Please don't take any screenshots or photos of the screen. The proceedings today will be made available via the House of Commons website.

In accordance with our routine motion, I'm informing the committee that all remote participants have completed the required connection tests in advance of the meeting.

I'd now like to welcome the witnesses who have joined us today.

In the room, from the Breast Implant Safety Alliance, we have Julie Elliott and Terri McGregor. Online, from the Breast Implant Failure and Illness Society Canada, we have Nancy Pratt.

Thank you all for taking the time to appear today.

We're going to start with Ms. Elliot.

[*Translation*]

Ms. Elliott, you have five minutes for your opening address.

Ms. Julie Elliott (Patient Advocate, Breast Implant Safety Alliance): Mr. Thériault and members of the committee, thank you for your invitation.

My name is Julie Elliott, and my health has been negatively affected by breast implants.

However, my story is not important because it's the same as that of thousands of other women. We can grasp the extent of the community of women negatively affected by breast implants on social media. There are more than 250 support groups worldwide, with over 350,000 members identifying as having breast implant illness or potentially having cancer caused by implants.

The Quebec support group for these women was founded following the episode about the dangers of breast implants on the French-language CBC program *Enquête*. Overnight, it became a primary source of information...

The Chair: Ms. Elliott, could you speak a little more slowly for the interpreters? If you happen to need an extra minute, you'll get it.

[*English*]

Ms. Julie Elliott: Thank you so very much.

[*Translation*]

Overnight, it became a primary source of information about breast implants.

Let me give you some examples to illustrate the importance of a breast implant registry.

On March 4, 2019, an article in La Presse reported that 15,000 women with textured implants in Quebec would be contacted by the authorities. However, four years later, most of them were never contacted. Many are breast cancer survivors who have undergone post-mastectomy reconstruction with textured implants. These women have never been contacted by the public health facility where they underwent their reconstruction and learned about it on an informal platform run by women who have also been negatively affected by breast implants.

A few surgeons took the initiative to contact their patients to offer to meet and discuss with them the impacts of textured implants on their health. In Quebec, Dr. Stephen Nicolaidis is one of them. This example raises an extremely important point in creating an implant registry: the mandatory legal retention period for patients' medical records and the responsibility for information sharing.

In Quebec, thousands of patients who have had breast implants are unable to find information about their surgery or their implants because of the 5-year retention period for medical records. In comparison, British Columbia has a retention period of 16 years. A chart illustrating the mandatory retention periods for medical records for each province in Canada is appended.

Another example is the recall of breast implants from the manufacturer Mentor in 2022 by Health Canada, which was ignored and never publicly reported. Discovered by chance, this recall was posted on a Facebook group page. Women came forward, outraged to learn that they had problematic implants, and had it not been for the vigilance of the members of the group, the news would never have been released. A registry would have alerted these patients, just as it would have alerted women with Biocell implants in Canada and the United States sooner than 2019. Let's not forget that the ANSM in France issued a recall in December 2018 for these same implants, and that a registry was set up in 2019.

A national registry of implants would alleviate these problems. Right now, it is us, the patients, who are working to ensure that members of support groups on social media have the correct, scientific and official information. We are the ones who translate the most recent English-language, mostly American, press releases for the benefit of francophone women.

You must realize, dear committee members, that our platforms have literally served as a registry for our members since 2018 and that they do the work that the government and public health agencies are not doing.

However, these women have to find us. It is an absolutely abnormal situation that puts us in the crosshairs of doctors and surgeons, and we are constantly subjected to their condescension, both in person and on social media. Keep these situations in mind and don't forget the effort expended by workers and patients in terms of time and energy and travel. And it must also not be forgotten that they do all this strictly on a volunteer basis.

Do we really need to remind people that public health agencies are responsible for the safety and approval of health products, and warnings about them? The only possible way to provide all participants with the same information at the same time is a computer database for the mandatory declaration of implanting a high-risk medical product that links the public health agency, the manufacturer, the purchasers in hospitals and in private practice, and the patients. A registry like this would be part of the safety and warning system for medical implants. It should be an integral part of the process of accepting a health product and it goes hand in hand with the precautionary principle.

In Canada, the main manufacturers of breast implants are Allergan and Mentor. No matter where these implants are licensed, distributed or sold, they are all manufactured using the same formula, the same ingredients, the same process and the same facilities—only the delivery points differ. Mentor implants come from California and the Netherlands, Allergan implants come mainly from Costa Rica, and formerly from Ireland. They are distributed worldwide. A partial list of compounds and ingredients is appended.

If a manufacturer experiences problems—let's cite the example of Allergan's Biocell implants, which account for 85% of worldwide cases of breast implant-associated anaplastic large cell lymphoma, known as BIA-ALCL; in other words, all countries where the implants have been distributed are affected. It is therefore only logical to believe that if a health agency decides to warn a manufacturer, proceed with a recall or ban a product for safety reasons, the agencies of all the countries where this product is distributed should automatically issue the same warning at the same time.

● (1110)

Despite the borders, the same implants are going into human bodies. And these humans have the right to receive this information immediately and at the same time. In the same way that car manufacturers immediately contact all dealers selling their vehicles when there is a problem or a recall, with only a few days between the moment an automobile problem is identified by the manufacturer and the moment when my dealer contacts me to fix the problem. This is done at their expense, for my safety and their reputation. In Canada, the law requires it, whether the problem is minor or major.

Only a breast implant registry can treat us as well as the vehicles we drive.

Thank you and I am now tabling these documents for the committee.

The Chair: Thank you, Ms. Elliott.

[*English*]

Next, the floor is yours, Ms. McGregor, for five minutes.

Ms. Terri McGregor (Patient Advocate, Breast Implant Safety Alliance): Thank you.

I'd like to thank the committee for today's invitation to testify with the aim of improving patient outcomes.

It's been eight years since I was introduced to the true risk profile of breast implants with my stage 4 diagnosis of breast implant-associated anaplastic large cell lymphoma, or BIA-ALCL. We do this gruelling and unpaid work in an effort to raise a patientcentric perspective among the giants of industry that continue to successfully control the narrative, mislead consumers and leverage the emotional plight of breast reconstruction and our prophylactic mastectomy patients.

A national registry will directly impact health outcomes for patients if, and only if, its architecture and oversight include the following.

First is accountability. Will there be consequences for not doing what's required?

Second is auditability. Will the data be subject to audit by a neutral party so that we will know and be able to vet its credibility?

Last is accessibility. Will advocacy groups, patients and doctors have free access to the data so that we can protect patients from misleading information?

The devil is in the deep-dive details. I empathize with the confusion and complexity for committee members attempting to wrap their comprehension around a 60-year culture of mismanagement and contradictions. We are here to help.

We are subject experts. We are solution-driven and can provide robust recommendations and resources if we are included in the planning stages. We trust that a robust opt-out registry can deliver real-time, real-world outcomes and address issues sooner, in addition to the standard track and trace for notifications.

Who controls the data controls process and the reported outcomes. The effects of undue influence permeate our existing registries, specifically the Canadian device registry I was given in 2009, the Canadian adverse event reporting registry, the NBIR and the Profile registry for ALCL patients.

My lived experience with Health Canada's registry is evidence of the denial and delay tactics of undue influence. Industry has succeeded to date, and the consequences have been disastrous, and not only for patients. We bear witness to the slander campaign directed at plastic surgeons who do not bend to the peer influence of their thought leaders.

What actions did manufacturers take to notify patients in 2011? Why didn't Health Canada invoke its authority to demand that patients be notified in 2011? What punitive consequences has Health Canada issued against device manufacturers that intentionally withheld our BIA-ALCL cancer reports to our governments?

Blind wilfulness is the only reasonable conclusion for implanting surgeons whose self-promoting websites are riddled with misleading, stale-dated and simply false statements. Commerce without ethical context is dangerous and continues to harm patients. I have provided a link for your interest.

Why do we not have answers to rudimentary questions? How many Canadians have breast implants? How many Canadians are affected by the recalled products? Simply put, we cannot manage what we don't measure.

Our recommendations include adopting breast MRI recommendations for implant surveillance in Canada, requiring that breast implant patients be notified of the need for a breast MRI, pausing or limiting the sale of breast implants until an effective registry is created, requiring the participation of—

● (1115)

[*Translation*]

Mr. Luc Thériault (Montcalm, BQ): Excuse me, Mr. Chair, but could the witness perhaps slow down a bit because the interpreters are having trouble keeping up?

Ms. McGregor, as the chair said earlier, if you go past the five minutes, you'll get lots of extra time later.

Could you slow down a bit, please?

[*English*]

The Chair: Did you catch that, Ms. McGregor? The interpreters are having a hard time keeping up with you. If you slow down, we'll give you another couple of minutes.

Ms. Terri McGregor: I'll slow down.

I'm not sure where to pick up, but adopting breast MRI recommendations is critical for Canadians, because that is completely contradictory to both the manufacturers' and the FDA's recommendations.

Next, we suggest that we pause or limit the sale of breast implants until an effective registry can be created.

Also, require participation of patient advocates in developing a registry, as well as in its administration.

As well, pause or limit the sale of breast implants until there is a full investigation of regulatory failures and manufacturer violations, including failure to report injuries and harm and the failure to meet the approval conditions put forward by this committee in 2006; the impact of BIA-ALCL and other implant-associated injuries on our health care system, including the financial burden; the impact on Canadians who cannot access knowledgeable health care for accurate evaluation, accurate pathology testing and treatment for our malignancies; the shortcomings of the current mandatory reporting system; and misleading marketing of breast implants.

We also ask you to extend mandatory adverse event reporting to include private practice breast clinics.

As well, we also suggest that we prohibit manufacturers from selling implants to doctors who fail to provide informed consent, and if manufacturers fail to monitor such doctors with oversight, impose consequences that risk their licence to sell implants.

Also, include photos depicting breast implant adverse events on Health Canada's website.

Last, assess the burden placed on our provincial health care for the sick and injured implant patients. It is unreasonable that device manufacturers and private practice breast clinics profit, leaving the wreckage of health costs to our provinces.

Thank you.

● (1120)

The Chair: Thank you very much, Ms. McGregor.

Next is Nancy Pratt, from Breast Implant Failure and Illness Society Canada, who is appearing online.

Welcome to the committee, Ms. Pratt. You have the floor.

Ms. Nancy Pratt (Patient Advocate, Breast Implant Failure and Illness Society Canada): Thank you.

Hello, Mr. Chair and members of the committee. Thank you for your interest in the creation of a breast implant registry.

I'm a patient advocate with lived experience of unknowingly having recalled breast implants. Recently, long-time women's advocate Anne Rochon Ford, who is now retired, sent me her files, which she saved over decades. Reading through them, I felt disheartened, frustrated and angry because we're still fighting for the same safety issues today as they were back then in the early 1990s. The questions and concerns have been present for a long time. The fears of the risk of cancer have come true.

We shouldn't still have to fight so hard for safety and tracking measures for devices that carry Health Canada's highest risk rating and have known serious issues, ranging from device failures to localized complications, impacts of silicone migration, autoimmune systemic illnesses, and now a known link to cancer, deaths and recalls.

In 2004, a bill to establish a breast implant registry was introduced in the House. How different the situation would be if that had occurred. The result has been wasted decades, leaving Canadians with having to give consent without a clear understanding of the risks they're taking on.

Health Canada licensed breast implants despite having no long-term safety data, without a protocol of care in place and with no one keeping track. Over decades, we have seen that industry claims of safety and incidence of harm have been misrepresented. Implanting class 4 medical devices without keeping track demonstrates disregard for patient safety.

Those profiting from breast implants have deflected responsibility for tracking them. Continuing to do nothing simply isn't an option. It's not fair that the Canadian public continues to be sold devices when concerns about them are not being systematically tracked, researched and evaluated.

I strongly support the establishment of a public mandatory registry. This will assist in post-marketing research and create a system to help contact people if needed.

Many implantations are done in private for-profit clinics and increasingly through medical tourism. It's important that physicians be required to register the implantations done in Canada and that people who received implants elsewhere can register themselves. CIHR should be funded to undertake this project.

Since the 2019 recall of textured implants linked to BIA-ALCL, many affected Canadians are still unaware of the recall. This is unacceptable. Implant wearers of previous decades were similarly unaware of recalls. It has resulted in unnecessary harm and lives lost.

Canadians with breast implants bear the consequences of inadequate oversight without device tracking. Nobody should ever be unaware that a device implanted within them has been recalled or carries a safety warning.

A registry is but one part of the solution. We need directed research dollars to answer the myriad questions that people's experiences with silicone have raised. There are many questions that need answering. This is not a role for the industry, given its history and its obvious conflict of interest.

We hope this time a registry will be created and public research on breast implants will be funded. It will save lives and prevent illness. We are at a time parallel to the 1990s moratorium. If there is no resolve at this point for creating a breast implant registry, then perhaps it's time to hit the pause button and withdraw breast implants from the Canadian market until a registry is created.

● (1125)

Thank you.

The Chair: Thank you, Ms. Pratt.

We're now going to begin with rounds of questions, starting with the Conservatives.

Dr. Ellis, you have six minutes.

Mr. Stephen Ellis (Cumberland—Colchester, CPC): Thank you very much, Mr. Chair.

Certainly I want to thank the witnesses for being here. Also, I want to be very clear that if I ask any questions—and I probably speak for everybody at this committee—that seem personal in nature, it's with our understanding that you have shared your own medical stories out there already. Am I correct in saying that about everybody?

Ms. Terri McGregor: Absolutely, for me.

Mr. Stephen Ellis: Again, it's not like we're going to ask significant medical questions.

Ms. Terri McGregor: Don't hold back, please.

Mr. Stephen Ellis: Don't hold back. Thank you. I appreciate that.

Thank you all for being here. There are so many questions and there is so little time.

I have a few questions about the registry itself. I thought I heard two different things, one from Ms. McGregor and one from Ms. Pratt. I heard about an opt-out registry, and I thought I heard Ms. Pratt say a mandatory registry. Maybe I'll start with Ms. McGregor, and then we'll go to Ms. Pratt.

Could you could talk a bit about that?

Ms. Terri McGregor: I'll qualify that I'm not a registry expert. However, from what we've heard from this committee in previous meetings, I think that it must be mandated and be what I believe is called an opt-out registry. If you really don't want your information there, you have to make a lot of effort to take it out. This is because we see the poor participation, for example, in the NBIR. Hopefully I've clarified that.

Mr. Stephen Ellis: Thank you.

Ms. Pratt, do you agree with that, or do you see it slightly differently?

Ms. Nancy Pratt: I totally agree, absolutely.

Mr. Stephen Ellis: Okay.

Do we have any numbers from around the world? I understand that all of you have travelled extensively around the world to tell of the difficulties you've had. If we have an opt-out registry, how many people would actually opt out of it? I guess I have a concern that if the opt-out numbers are 50%, we'll have a huge issue. Do you have any idea of those numbers?

Ms. Terri McGregor: I don't, but I could draw your attention to the fine print in the NBIR, the U.S. registry. I will tell you that as a citizen in 2023 and with those fears around privacy and about data being hijacked, I thought they went a little bit into too much detail. After I read the instructions for the data, the thought that my data could be sold to a third party sometime in the future, undisclosed to me, I will tell you that, skeptically, I would have said, "Really?" I want my government and regulatory bodies to have it, but this blanket idea that it can be sold to anybody at any time in the future....

I would just suggest that any kind of opt-out language be far more specific and not sort of trigger that general fear of hacking that occurs today.

Mr. Stephen Ellis: I guess it makes sense that we become fearful when we hear that someone is going to sell our data for their own gain. It doesn't really make a whole lot of sense.

Ms. Terri McGregor: That's right, and sold to an unknown party at any time in the future. That, to me, is just far too broad of a stroke.

Mr. Stephen Ellis: Thank you for that.

I'll ask all three of the witnesses this particular question, and maybe I'll have the same answer. I don't know.

Who should pay for the registry? I think one of the hesitancies we see around this table, perhaps, is related to how much it's going to cost the government. I think we need to understand that particular aspect of who should pay. Should manufacturers pay? Should the government pay the full shot? Should there be a shared-payment model? Should patients pay?

If all three of you could comment on that, I'd really appreciate it.

● (1130)

Ms. Terri McGregor: I'll start with that.

My first thought would be to reframe that question and say that we're already paying. I do not know what it cost to treat me at Princess Margaret through multiple rounds of chemotherapy and my stem cell transplant, and I'm continuing on six-month follow-ups.

What we know is that Canadians.... In the study we talked about from Lorraine Greaves—and Nancy can talk to it—Canadian breast implant wearers go to their physicians four times more often than non-implant wearers do. We suspect that's because of these systemic issues that don't directly point to a breast implant. It's just that constant routine of family physician to referral, and then "we can't see evidence" and back.

I would suggest that the infrastructure is already there, because we're paying for it, and we are in complete support of a user fee. If we can do it for tires in Ontario, let's do it with breast implants.

Mr. Stephen Ellis: Ms. Elliott, do you have a different comment or the same?

[*Translation*]

Ms. Julie Elliott: I fully agree with what Ms. McGregor said.

I believe Health Canada and two other organizations fund the Canadian Joint Replacement Registry.

I'd like to expand upon what Ms. McGregor said about the societal cost of her cancer. I personally have never had cancer in connection with breast implants, but I had systemic implant-related problems which began in the first month following surgery, and these problems continued for 10 years.

When the journalist for the French-language CBC program *Enquête* was preparing the episode about the dangers of breast implants, I gave her permission to access all the information in my medical file and all related expenses invoiced to the RAMQ over a period of approximately five years prior to my implants.

In the five years prior to my implants, I went to very infrequently to doctors' offices or hospital emergency rooms. But it became routine as of the first few weeks following the implant surgery.

Over a 10-year period, the total costs were significant. They included loss of income, money that I myself spent on various professional consultations, in addition to the costs invoiced to the RAMQ for the consultation of various medical specialists. The total cost was approximately $750,000 over a 10-year period, $200,000 or $250,000 of which were my out-of-pocket expenses and foregone income. The rest was paid for by society. Personally, it's difficult to total up how much I myself put into it, because I was taking care of my health. I didn't know why I was having health problems.

The Chair: Thank you, Ms. Elliott. That's all the time we have for this round of questions. There will be lots of other questions to come. You'll have an opportunity to provide more details.

[*English*]

Mr. Jowhari, go ahead, please. You have six minutes.

Mr. Majid Jowhari (Richmond Hill, Lib.): Thank you, Mr. Chair.

Welcome to our committee. Thank you for sharing your experience with us. Thank you for the advocacy that you're doing. I'm sorry that you've had the experience that you've had. Once again, thank you for your advocacy.

I'll start with you, Madam Pratt. In the last committee meeting we had, I asked Dr. Morris as well as Dr. Cohen about medical tourism. You also highlighted the fact that medical tourism is trending and is becoming more prevalent.

What are your thoughts around how we can incentivize those who choose to do breast augmentation through the venue of medical tourism to ensure that they would register in such a registry?

● (1135)

Ms. Nancy Pratt: I'm not an expert on this, but I think there has to be a way to reach them so that when they've had their procedure done in another country and they come back to Canada, their doctors should be educated. Health Canada should do an outreach to the colleges so that there's a standard care in place. Their family doctors would be aware to notify them and to let them know that the registry exists and that it would be a good idea if they registered.

Mr. Majid Jowhari: Thank you. What you're suggesting is that most patients have a family doctor, and through their family doctor—

Ms. Nancy Pratt: No.

Mr. Majid Jowhari: —education plays a big role in ensuring that they register.

I'm sorry. You said “no”. Can you clarify?

Ms. Nancy Pratt: To your point about everybody having a family doctor, that's not true. There are so many Canadians, including me, who don't have a family doctor.

If we're calling in to a virtual clinic, even the doctors in those clinics should be updated, through the college, on the standard protocol of care. They should be aware and advise the patient. I guess the problem with that is that if they present to a virtual doctor and it isn't for an issue specific to their surgery, the virtual doctor might not know.

Mr. Majid Jowhari: Thank you very much.

I want to go to Madame Elliott.

You talked about there being basically two large manufacturers and that the onus is on them. I want to spend the rest of the time I have on participation.

My colleague Dr. Ellis talks about the percentage needed in terms of participation, whether it's the patient, doctor, surgeon, clinic or province. Numbers being thrown around are that 90% or 95% participation among patients and doctors is needed. I believe there was a discussion on opting out.

How do we incentivize the patients, doctors and clinics to ensure they do not opt out?

Ms. Julie Elliott: If you are asking me the question, the opt-out should not be an option.

Mr. Majid Jowhari: You're suggesting it should be mandatory.

Ms. Julie Elliott: Yes.

Mr. Majid Jowhari: Okay, we now have a registry system that serves all the purposes we have set. It's mandatory. We have somehow built the agreement across all stakeholders—whether it's the province, federal government, patient, doctor, manufacturer and all those things—to come in.

What will happen if someone decides to go outside of the country to get that procedure done and chooses not to inform the registry?

Ms. Julie Elliott: Actually, that's the problem. The first problem with medical tourism is that a lot of popular countries right now are using breast implants that are not even manufactured here. I've personally talked to plastic surgeons who, right now, are doing business in Montreal removing breast implants or taking care of post-op complications for patients who went outside the country—outside North America—to have their breast augmentation, liposuction surgery or what have you.

That would be the first problem: Most of the time, they're getting breast implants or other types of cosmetic implants that are not even regulated here.

However, we're in 2023. There should be a way for whoever has any kind of implant.... If you come back here and have this type of implant, you're coming back with some information on your implant. There's a registry. You should be able to put those numbers into any kind of registry.

I think Terri would probably be way more efficient than I am at answering that question.

● (1140)

Ms. Terri McGregor: As somebody who ran a business for a long time, I can say that looking for 100% accuracy in this database is an unrealistic expectation.

Canadians who choose medical tourism.... That is an outlier percentage. It is minor. Do we give that patient or their surgeon an option when they land back in Canada and have a problem? Can somebody populate that data? Yes, medical tourism is an issue, but it is far greater an issue in Taiwan and Australia.

At some point.... We're not going to capture 100%, but less than 100% is better than the 0% we're collecting today.

The Chair: Thank you, Ms. McGregor.

[*Translation*]

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

Mr. Luc Thériault: The issue of medical tourism comes up often. I'll give you my opinion on that matter. There's probably an financial saving in going elsewhere. On the other hand, if there's a higher level of safety here with respect to these implants, people wouldn't go elsewhere. Basically, it's our responsibility to provide added value for being operated on here, if we are to justify the extra associated costs. That's just my opinion, however. You can tell me whether you agree or not.

I have a question for Ms. Pratt, who was with us by video conference, to get her back into the discussion.

I asked the Health Canada representatives why they were not being very proactive. I asked Lorraine Greaves, who heads the Scientific Advisory Committee on Health Products for Women, about the virtual meeting held by this committee on February 23, 2021. I asked her whether there had been any progress with respect to the implementation of the recommendations made by the scientific advisory committee. She said that there had been no progress at all.

In the documents you gave to the clerk of the Standing Committee on Health, I saw that you had sent a letter to Health Canada in 2022, I believe, asking for a status report on progress with the recommendations made by the scientific advisory committee.

Did you get a reply?

[*English*]

Ms. Nancy Pratt: I didn't get a response, no. It's concerning.

[*Translation*]

Mr. Luc Thériault: Health Canada, which claims to be very proactive, made a big deal out of setting up a scientific advisory committee. It held one meeting at which breast implants were discussed and made recommendations. Since then, nothing has happened. You followed up in 2022 and still hadn't received an answer in 2023.

How do you explain that? Are you discouraged about it?

[*English*]

Ms. Nancy Pratt: Absolutely, it's hard not to be discouraged sometimes as an advocate, but certainly Health Canada has done minimal changes to this point, so even things like a black box warning and our request to put photos of failed breast implants on their website.... The website itself isn't as informative as it should be.

I want to draw attention to the fact that even though there have been some actions taken, we wrote them a letter asking what substantive changes have been made, and the really important issues are ignored. The issues with breast implants described in the “inconvenient truth” article, like migrated silicone and the chemicals in breast implants, they don't want to take on. These changes that are happening, and not to a good degree, to me are not really making women any safer than they were back decades ago, so they need to address these issues.

● (1145)

[*Translation*]

Mr. Luc Thériault: In the letter, you asked that Health Canada show photographs of some silicone implants to explain to women how the silicone migrates and to make them aware of the problem. In the report on the *Enquête* television program, a famous plastic surgeon cuts a silicone implant in half and says that the product should not be in a woman's body.

Did Health Canada circulate these photographs after your request, as was done for tobacco, for example?

[*English*]

Ms. Nancy Pratt: No, they haven't pursued those actions. The scientific advisory committee made some really great recommendations to Health Canada, and they haven't been pursued either. It's really troubling.

[*Translation*]

Mr. Luc Thériault: Is silicone migration an established fact?

[*English*]

Ms. Nancy Pratt: Yes, absolutely.

All breast implants bleed silicone and chemicals. You have that even if an implant is still intact. It's bleeding silicone. Sometimes a wearer might have their implants removed, but they have silicone uptake in lymph nodes or in surrounding tissue.

Then there's also the issue of rupture. If it's not diagnosed in time—and with no standard protocol of care in place, it's very often not diagnosed in time—silicone can migrate outside of the capsule that surrounds the breast implant and go into the body. I can speak to this because that's something I've experienced.

Just to draw to another point, yesterday there was a comment that silicone is inert. I guarantee you that anybody who has migrated silicone within them will not agree that silicone is inert. I have pain, as do they, in every place where that silicone has migrated within us.

The Chair: Thank you, Ms. Pratt.

Mr. Davies, go ahead, please, for six minutes.

Mr. Don Davies (Vancouver Kingsway, NDP): Thank you, Mr. Chair, and thank you for being here. It's fascinating testimony.

Ms. McGregor, you used the term “true risk profile”. In your view, are Canadian women receiving from their surgeons, at the time they're considering implants, the true risk profile of breast implants?

Ms. Terri McGregor: There are very few absolute answers, but I can absolutely answer: Absolutely not.

As for the true risk profile.... We talk about slick marketing. I have a link to some board-certified plastic surgeons who are also on the executive committee as the thought leaders of their societies. When I read their professional websites today, it sounds like they're saying, “Don't worry, little lady; if you get cancer from these implants, it's not really a big deal. It is 100% curable, and no ALCL patient has ever needed chemotherapy or radiation.”

I can tell you that when I read that blatantly inaccurate misinformation last week, in 2023....

Quite honestly, patients are using these fancy, pretty websites with half-marketing, half-medical information. If I were a patient using that surgeon's website, I would walk away thinking that not only is that information false but also that it is dangerous. This is where patients have no power and no control.

I'm also not in a position to want to put myself in some kind of campaign and then be sued by plastic surgeons. In our social media support groups, we've already had threatening letters from surgeons who disagree with the harmed patients. We're just a lot of volunteers who, for some reason, are now getting letters threatening legal action.

● (1150)

Mr. Don Davies: Ms. Elliott, an August 20, 2019, article from Black Press Media noted that you said that “many plastic surgeons aren't trained to administer explants—a riskier, more complex surgery than implants—and even if they are, they don't always believe patient concerns.”

You were quoted as saying, “A lot of surgeons are trying to convince us—or themselves—that you don't actually need to remove your breast implants in order to get better...[They say] if you're sick, it's not because of your implants. It's everything else but your implants.”

How common do you think that situation is? What is the role of surgeons in this issue, do you think?

Ms. Julie Elliott: How common is it? It's extremely common.

Part of the problem is that when you get breast implants, you go to see a plastic surgeon. When you have problems after your surgery, most of the time you're not going to go back to see your plastic surgeon and say, “Hey, I feel sick.” If you have post-surgical problems and complications, of course you're going to go back to the person who did the surgery on you, but when the post-op healing period from the actual surgery is done, you're going to go back to see your GP or whatever specialist would be the one to give attention to your needs.

Most of the time, if you go back to see plastic surgeons, they're going to tell you that it's not your implants. It's anything else. You're going to see specialists. If you tell them, “I think my breast implants are causing this and this”, if it's not a mechanical problem caused by the implants—which most of the time is caused by capsular contraction—they're almost never going to tell you, “I think it may be your breast implants.”

Mr. Don Davies: Thank you.

Ms. Pratt, in an April 2023 article from CBC News, you noted that a breast implant registry “shouldn't be limited to implants, but should also include other materials like mesh and clips that may also be placed inside the body during implant surgery.”

Can you expand on that?

Ms. Nancy Pratt: Absolutely.

Everything that's placed in the body should be recorded in the registry. What's happening now with the recall of textured implants is that many plastic surgeons are using smooth implants and they're using mesh, which is not approved for use in surgery in breasts. They're using it off label as regulators turn a blind eye.

Mesh has been getting coverage in the news for the difficulties that it has created. It's a high-risk device. It has complications. Now they're cavalierly using this mesh in patients, and often they don't know. Patients don't often have an understanding of what's going into them.

It's not appropriate to follow just the implant. Then later, if the patient has an issue that's mesh-related and there's a recall on that mesh, they can't be notified. They can be notified about the breast implant, but not about the mesh.

Mr. Don Davies: We had some witnesses earlier this week on Tuesday. There was a little bit of a difference of opinion, I think. One person was very clear that there were very concrete links between breast implant illness—BIA-ALCL—and autoimmune disorders from breast implants. With the other witness, I detected that he made it seem like it's not so clearly established.

I want to know your opinion on that. How clear is the evidence of illnesses linked to breast implants, in your view?

● (1155)

The Chair: We're out of time, but we'd like to have a brief response, please.

Who was that directed to, Mr. Davies?

Mr. Don Davies: It was directed to anybody who wanted to answer, but maybe Ms. McGregor can.

The Chair: Ms. McGregor, give a brief response, please.

Ms. Terri McGregor: I don't live in a litigious country, but what I can tell you is that the fear of litigation has not been discussed so far at this hearing. That's all I'm going to suggest.

The fear of litigation to these plastic surgeons is significant, serious and not being discussed.

The Chair: Thank you.

We have Mr. Jeneroux, please, for five minutes.

Mr. Matt Jeneroux (Edmonton Riverbend, CPC): Thank you, Mr. Chair.

I want to bounce around a little bit, but first I'll speak about the litigation piece. Due to a lack of evidence, I would think, because there's no registry, I would hope that some of that would be mitigated. I'm sorry that you're going through that, Ms. McGregor.

I think Ms. Pratt made a very significant point that I didn't really think of until she made it in her testimony. It was the other items included as part of this, the mesh and the clips. Those are also things that we haven't heard yet at this committee and that I suspect would be important for us to consider as we write our report and recommendations.

Mr. Chair, we've had a lot of testimony here about the need for the registry. To go back to a point I've made before, this has been ongoing since 2004. It appears to me that this isn't a partisan issue at all. I firmly believe that a lot of us around this table are supportive of the registry. It's just a matter of where the registry is housed and the logistics of it. Some of this has been pointed to CIHR and to what the orthopedic registry is. We have yet to hear from CIHR. I'm not sure if that's worthy of another meeting or if it's worthy of asking them for a response to something like this. I'm just using my time to indicate that I think it would be very relevant to have CIHR indicate their capability to house something like this registry.

I want to get to medical tourism, but from you guys' testimony, it's scary to think that for the young girls right now, it's not on the reconstructive side but more on the cosmetic side. Where the heck do they go to get information? What do they do? Your organizations are doing good work in trying to get that information out there, but at the end of the day, I would think that the Government of Canada should have some resource or some role in providing a lot of the concerns that have been raised at meetings that we've had so far to someone who's considering going down this path.

On the medical tourism piece, if I have time to go to all three of you, that would be great, but I'll probably start with Ms. Pratt to help me circle this with the registry.

With regard to the tourism, let's say you go down to Colombia and you get the implant put in, and the implant has the problems or issues that we're discussing here at the committee. The registry, I would assume, from how it's being discussed, isn't necessarily tracking that implant in Colombia. Colombia doesn't have a registry. How does that then circle back to the registry that we would like to see put in place here in Canada?

Ms. Nancy Pratt: As I think Terri mentioned, there should be an option for them to register themselves, but there has to be awareness. Health Canada has to take a more leading role in making sure that this kind of information is available. Canadians should be able to get that information at Health Canada's website. There needs to be an outreach.

● (1200)

Ms. Terri McGregor: One of the things we haven't discussed is immigration. I've dealt with many immigrants who had their surgeries done in their original countries but have now landed in Canada. Again, for those patients, is there not an option somehow for them or for a physician to upload that data? When I have patients who are Colombians who are immigrating or are in an effort to immigrate, those patients are now deathly ill but, in my personal experience, they have to fly back to Colombia for their surgery.

I just wanted to mention that we have this immigration cohort that hasn't been discussed yet.

Mr. Matt Jeneroux: Madam Elliott, you have about 10 seconds, I guess, if there's anything to add on that point.

Ms. Julie Elliott: On medical tourism, my opinion goes the same way as Terri's. When a patient comes back.... Right now, what's very trendy is that those women are going to Morocco or Turkey more than Colombia. If I'm talking about Quebec, those patients go to Morocco and Turkey. When they come back, a lot of them—I cannot give you a percentage—are coming back with complications.

The cost of it comes back to our health care system. They spend that money outside, which is okay, because it's medical tourism. It costs them $4,000, and they have a trip. They go sightseeing. They get breast implants and something else. They come back and they have complications. They're sick. They have breast implants that are unknown.

For the surgeons who have them under their care here in the medical system, it's a puzzle. It's a problem. There should be something.... I don't know how. I'm not a business person at that level. If someone comes back, there should be a way to track those surgeries to help the health care professional when they come back, and there should be a way for those women to have those implants tracked. If something happens in the country of origin of those implants, how will those women know what's happening with those implants if they keep them?

In my group, we have so many women coming in, because a few days, months or weeks later they have all kinds of problems with those implants. They have mesh inside. They have long sutures and have so many problems.

The Chair: Thank you, Ms. Elliott.

Next is Ms. Sudds, please, for five minutes.

Ms. Jenna Sudds (Kanata—Carleton, Lib.): Thank you very much, Chair.

Thank you to all three witnesses for being here and for sharing your experience, your expertise and the work that you're continuing to do. It's obviously so crucial as we attempt to tackle this study.

I wanted to pick up on two things. The first thing I wanted to go back to was from you, Ms. McGregor. You had mentioned a list of three recommendations. The first one that I think I caught was adopting breast MRI surveillance. Can you speak a bit about what that should or could look like, and about the impact that you believe that would have?

Ms. Terri McGregor: I can tell you that my surgery was in 2009. My surgeon did say, “Terri, these should last around 10 years”, and I made a mental note saying, “Save another 10 grand, Terri, because in 10 years you may have to get these replaced.” I also know, as a Canadian woman, that every 10 years I have a different thought and belief system because I have evolved. I actually thought that I might just want them out because maybe in my 50s I won't want these things. I think I'm typical.

What is devastating to me is that nobody in Canada—whether it's Health Canada or it's the manufacturers' inability to get that information to Canadians, including my implanting surgeon—told me to do anything until I had a problem. However, that is completely contradictory to all the manufacturers, and I think there are four that are licensed in Canada. Their own label says that we are to get implant surveillance, and there's some debate on when. Right now, the FDA standard is that you should be having your first preventive maintenance after your fifth year of surgery. To me, this is no more difficult than with your vehicle. We have preventive maintenance for these implants, because these things—silent ruptures, gel bleed, and intracapsular and extra-capsular ruptures—could be identified sooner.

I believe it comes down to the fact that we have a lack of private MRI resources. I don't believe that our government should be paying for an MRI for an elective surgery that I had. I think the problem is that we don't have privately paid MRIs.

● (1205)

Ms. Jenna Sudds: Thank you very much. It's very insightful as we look to recommendations as the report is completed and written. Thank you for that.

I had another question in that vein, but I know I have limited time, so I'm going to go to my other point.

As all three of you were speaking—but particularly you, Ms. McGregor—what came to mind is the role of the plastic surgeon and the industry, so to speak, or the profession. You made the comment slightly offhand about it being half marketing and half medical. I get it. I've seen these sites, and you're very accurate in saying it in that way.

This leads me down the road of what should be done further—whether it's in regulations or whatnot, or whether it's at the government level or at an association or professional level—that could better keep track of and hold plastic surgeons responsible. I'm taking the registry slightly aside from that comment, because obviously that's under discussion, but there seems to be more. There's a bigger issue at hand here.

I'm wondering, and I'll open the question to others as well, what recommendations you have to hold these professionals to account and to a higher level.

Ms. Terri McGregor: That's a fantastic question. I've asked that question of the ASPS, the American plastic surgeon association, when I landed on websites that are so dangerous. They are literally dangerous to patients.

I will tell you that I sent off a request to ASPS to ask what we can do about this, because this doesn't represent your organization with any credibility. At the time—and it may have changed—I was told that since I didn't have an MD behind my name, I was not able to complain about any misleading information.

At this point, I would tell a Canadian consumer today, whether she's a breast reconstruction patient or an augment patient, this is “buyer beware”, and that very pretty, glossy half-medical half-marketing information is dangerous and is misleading through omission. It is literally a selection of omission and wordsmithing.

Personally, I spent three years on and off Health Canada's website. Health Canada's website was a major decision-making tool for me, and it is why Health Canada became a target after my diagnosis. It's because I wasn't an impulsive 20-year old but was in my forties, and the fact that Health Canada had chosen to withhold that information was unacceptable to me, because I thought that was my oversight safety.

The first time somebody said to me, “Well, Terri, you never went to the FDA's website,” my mouth literally dropped, because it would never have occurred to this intelligent woman, as a Canadian, to go over to the FDA and to the States to read about breast implants. It didn't even cause me a thought.

The Chair: Thank you, Ms. McGregor.

[*Translation*]

I'm now giving the floor to Mr. Thériault two and a half minutes.

Mr. Luc Thériault: Ms. Elliott, if we can't rely on the industry, which never did the studies it was supposed to carry out when the moratorium was conditionally lifted in 2006, and we can't count on the surgeons, because it's impossible to know whether they are practising informed consent in a consistent fashion, then although we can rely on associations like yours, it's not enough. In this particular instance, responsibility falls to Health Canada, which is responsible for the safety of women, and for product certification and safety. If a high-risk product or instrument is involved, and there doesn't appear to be enough conclusive data, then the precautionary principle has to apply. That would mean more warnings, not fewer.

Do you think that the Health Canada site has improved since 2019? Has it done enough to be considered comparable to an organization like the Food and Drug Administration, the FDA?

● (1210)

Ms. Julie Elliott: I'd have to say no. It hasn't done enough and the Health Canada website hasn't improved. If you wish, I can give you two examples.

First, manufacturers' sites and the FDA site recommend that women who have implants should undergo an MRI, magnificent magnetic resonance imaging, three to five years after surgery. I can't remember the exact number of years stated. That's not recommended anywhere on the Health Canada site. We're not talking about mammography or ultrasound, but an MRI. That is stated at the Mentor and Allergan manufacturers' sites and on the FDA site, but it's still not mentioned at the Health Canada site. It's a manufacturer's recommendation. Why on earth isn't it on the Health Canada site?

I'll give you another, somewhat more personal, example. You'll understand why. In 2021, Health Canada started a blog containing data on Canadian monitoring of BIA-ALCL.

Mr. Luc Thériault: That's lymphoma.

Ms. Julie Elliott: Yes, it's breast implant-associated anaplastic large cell lymphoma, a form of cancer linked to textured breast implants.

I was contacted by a woman from Health Canada. I can't tell you which committee she was on, because I don't have the email in front of me here. She asked me if I would like to revise their article for their data blog. I'm a patient. I'm a representative and a patient. I don't have the letters MD after my name. That shows how information can be altered. I was asked to revise the PDF file that Health Canada was going to put on its blog and on its social networks page. There were major mistakes in it.

So they asked me, not a specialist, to revise the article. They asked me, a patient.

Mr. Luc Thériault: And yet there is the Scientific Advisory Committee on Health Products for Women.

Ms. Julie Elliott: I found two major mistakes.

For example, the original version said that BIA-ALCL was linked only to textured implants. I had to tell them that was not the case, and that textured expanders were also involved, not just the implants themselves. I had to explain to them that in their very minimal blog, they should also warn patients who had undergone breast reconstruction surgery.

I can't remember the other mistake, because it was two years ago, after all.

Is the information at the Health Canada website adequate? No.

Information at the website of the Food and Drug Administration, the FDA, is also probably inadequate. In fact both sites are equally short of information.

An enormous amount of work and effort is needed at health Canada. For the precautionary principle, right now, given that the two studies by Allergan and Mentor…

[*English*]

The Chair: Thank you.

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

Mr. Don Davies: Ms. Pratt, I want to follow up where I ended my last questions.

We've heard about the linkage between breast implants and three major conditions: the BI illness, the BIA-ALCL—in other words, the cancer that's associated—and autoimmune disorders.

In your view, how clear is the evidence that those illnesses are linked to implants?

Ms. Nancy Pratt: I think there is absolutely no doubt, and I think we're asking the wrong question.

I think the question isn't whether BII is real, for instance. We've seen, since implants were introduced in the sixties, that within a year, those symptoms were already being manifested. Through six decades, wearers have developed the same symptoms.

From my perspective, the question should be how the industry so masterfully convinced individuals who are medically and scientifically trained to buy into their narrative. It should just make sense that when you're implanting a device that has chemicals inside it, and the silicone doesn't stay encased in there—and as I said earlier, it's certainly not inert, as I can attest, given what I feel in my body—I think we're asking the wrong question. The question is, how did medically and scientifically trained people become so willing to step out of what is just common sense?

● (1215)

Mr. Don Davies: Let me tell you why I ask. I ask because if there is a clear link—at least when it comes to cosmetic applications—I am asking the theoretical question of whether we should be allowing the sale in Canada of products that are clearly linked. They're carcinogenic and they are linked to other very serious illnesses. Given those health concerns, why are we allowing that product to be licensed and sold and implanted in people in Canada if that link has been established?

Ms. Nancy Pratt: I think that's a great point.

I think that until they have addressed the issue of migrated silicone and its impact.... And again, I can tell you that I live with the impact of it daily. I am in pain 24-7 from the silicone in me.

I think until they have addressed the inconvenient truth of breast implants, there should be a pause. I don't feel they should be available until they have taken appropriate action.

The Chair: Thank you, Ms. Pratt.

Next we have Dr. Kitchen, please, for five minutes.

Mr. Robert Kitchen (Souris—Moose Mountain, CPC): Thank you, Mr. Chair.

Thank you all for being here and sharing your stories with us and helping us as we move forward on this.

I realize I have little time, and I have so many questions I want to ask, but I'm going to apologize to you all right now initially.

What we've heard today is basically a conversation in which we've talked about CIHR and the registry they have. I'd like, Mr. Chair, to propose a motion that we extend our meeting one more day to hear from CIHR on their orthopaedic registry so that we can have that information here.

I see a lot of consensus around the table, so I'm hoping we can very quickly get approval for that.

The Chair: The motion is in order. It is to add a meeting to this study for the purposes of hearing from CIHR.

The debate is on the motion.

Go ahead, Dr. Hanley.

Mr. Brendan Hanley (Yukon, Lib.): Thank you, Mr. Chair.

Greetings to everyone.

I think there may be some confusion between CIHR and CIHI. I stand to be corrected, but my understanding is that the orthopaedic registry is actually with CIHI, the Canadian Institute for Health Information.

Can we get clarity on who holds what and who has already appeared, and then revisit what our need is?

The Chair: We have Dr. Kitchen and then Dr. Ellis.

Mr. Robert Kitchen: If that's the case, it's a friendly amendment. Just for clarification, if it is CIHI or CIHR, I'm comfortable with that.

The Chair: We've heard from CIHI.

Go ahead, Dr. Ellis.

Mr. Stephen Ellis: Thank you, Chair.

The new information that has come to light is to understand how we can move this study forward. To me, it makes sense to hear from whichever government agency it is to ask how much this is going to cost, what the orthopaedic registry costs, etc., if we're going to use it as a template to move this forward.

In deference to the witnesses, the issue, as I see it, hasn't been moved forward in the 20 years that this issue has been coming here. I think hearing from a government agency that may or not be responsible for this is important and germane.

The Chair: Dr. Hanley is next.

Mr. Brendan Hanley: Given it's CIHI, and we did already hear from CIHI and Health Canada, and some of those very questions were posed, and we did hear their opinions, perhaps in light of all that we've heard, we may want to revisit that. I'm certainly open to that consideration. Perhaps there are other witnesses within CIHI who might speak to that, but just to be clear, they have already appeared and spoken to this issue.

● (1220)

The Chair: Are there any further interventions?

[*Translation*]

Mr. Thériault, you have the floor.

Mr. Luc Thériault: I'd appreciate it if people could avoid using initials, because that often makes it difficult for the interpretation. It would be better to give the full name of institutions so that we can hear them and know exactly what we're talking about.

The Chair: I see.

The initials used in the motion were CIHR, but I don't know its precise meaning.

Can someone here tell us?

[*English*]

Mr. Stephen Ellis: It's the Canadian Institutes of Health Research.

The Chair: Okay. In English, the Canadian Institutes of Health Research is the wording in the motion.

We have Mr. Jeneroux, please.

Mr. Matt Jeneroux: Thanks, Mr. Chair.

With regard to the Canadian Institute for Health Information—in English, for Mr Thériault—if the sponsor of the motion is open to it, in light of a lot of evidence we've heard over the course of the last little while, having a submission on whether this is something they've taken some extra steps on maybe since hearing from a lot of the patient advocates, but also a lot of the surgeons as well, I'm not sure if it's within the committee's right to...I don't want to say "demand" any sort of information or whether to politely ask them if they could submit something.

If there is a way to do that, getting more of their information on the record will help us have a better report. That would be beyond their first intervention, when they came and didn't have a lot of the information that we have today.

The Chair: Go ahead, Dr. Kitchen.

Mr. Robert Kitchen: Thank you, Mr. Chair.

I'm agreeable to that, because when we heard from them before, we did not get that information to know exactly what the registry entails, what questions were being asked, what questions they may be asking of the patients.

That can be done in writing. I'm agreeable to that, as opposed to having them attend another meeting, if that would be the case.

The Chair: Are there any further interventions?

The motion is to invite the Canadian Institutes of Health Research to appear. Are we ready for the question?

Go ahead, Mr. Jeneroux.

Mr. Matt Jeneroux: I am sorry to complicate things, Chair, but can I make an amendment to have the Canadian Institute for Health Information provide its response to testimony when it comes to the registry?

I am looking at the clerk on whether this is in order or whether we can do that. I've never, I guess compelled somebody to testify before, so I'm not totally sure whether that's right.

In essence, it's that the Canadian Institute of Health Information provide, in light of testimony that's happened over the course of the set number of meetings, additional information on the capabilities of a registry within their organization.

● (1225)

The Chair: The amendment so substantially changes the motion that I'm going to suggest that the original motion either be withdrawn or defeated. The original motion was to invite the Canadian Institutes of Health Research to appear. The amendment is to invite the Canadian Institute for Health Information to submit a brief.

I see it as being so different that it isn't really an amendment. It changes the whole character. I know we're trying to get at the same information, but the manner is so different.

Can we have unanimous consent to withdraw the original motion?

(Motion withdrawn)

The Chair: Everyone is okay with that.

Now we have a new motion to invite the Canadian Institute for Health Information to provide a written response to the testimony that's been given. Is that it, in essence?

Mr. Matt Jeneroux: Yes, I think that exact wording.... We want them to focus on the housing of the registry within their organization.

The Chair: Does everyone understand the question?

Go ahead, Mr. Jowhari.

Mr. Majid Jowhari: MP Jeneroux, are you specifically asking what the current capabilities of the CIHI are as they relate to the registry?

Mr. Matt Jeneroux: Through the chair, yes, because they house the orthopaedic joint registry. We've heard so much testimony on this that people say, “Well, if you can do that, why can't you do this?”

I hope that's clearer.

Mr. Majid Jowhari: Thank you for the clarification.

The Chair: Is there discussion on the motion?

All those in favour of requesting that information from CIHI?

(Motion agreed to [*See Minutes of Proceedings*])

The Chair: The floor goes back to Dr. Kitchen.

Mr. Robert Kitchen: Thank you, Mr. Chair. I appreciate that.

I apologize to all three of you for that, but it's procedure, and we need to get it done.

We've heard a lot of conversation about the report from Health Canada. We've heard that patients are to report issues to Health Canada and that surgeons are to provide that information such that we have that safety, that approval and those warnings that they could possibly put out.

What I'm hearing from you is that Health Canada isn't the organization that should be doing the registry. Am I correct in that?

I'll start with Ms. McGregor.

Ms. Terri McGregor: The political infrastructure of this is beyond my scope. If I can simplify it, if Health Canada's mandate is the safety of our population, their mandate is oversight. We get called in to state the problems, and we have solutions, but unfortunately we never seem to be invited to the discussion table.

I'll use the CSPS. I've been called in the media Canada's leading expert on BIA-ALCL, and whoops, I forgot to go to medical school.

I say that because it's fantastic to stand in front of a podium and speak at a medical conference. I have co-authored two articles with Mark Clemens. When I heard that there was a working group for BIA-ALCL at Canadian plastic surgeons, I asked if I could simply attend a meeting and share the real-world evidence, because these Canadians were finding us on social media and in our cancer support groups. To be denied....

I don't want to just present; I want to be part of it. The CSPS national BIA-ALCL committee of physicians won't even invite us to the table, but I want to let you know what's happening with these 60 Canadians.

Mr. Robert Kitchen: Thank you, Ms. McGregor.

Ms. Elliott, do you have any comments on that?

Ms. Julie Elliott: If I have time, I will leave it to Terri, if you don't mind.

Mr. Robert Kitchen: Okay, thank you.

Ms. Pratt, do you have any comments?

Ms. Nancy Pratt: I'm not an expert on this.

Mr. Robert Kitchen: Thank you very much.

As a practitioner, when I first started out in practice and patients came to see me, the fact that they came was consent. Then, over time, it came to a point where I had to give consent to my patients in a written form. I would show them in writing that this is consent for treatment. Then it became informed consent; not only would I show that to them, but I'd also have them sign it.

As you see, there's been a progression over the years, going back 30-odd years of practice, but ultimately we see those things. Ultimately, when we talk about practitioners providing that information to patients and who are receiving the service, I'm assuming that we're still seeing that aspect, that same progression.

Is that correct? Would you agree with that?

● (1230)

Ms. Terri McGregor: As for informed consent, I would remind everyone that this is an elective surgery, not a life-saving device. The other place that we're seeing these patients having to give consent is with our reconstruction patients, who are making these decisions in the middle of active breast cancer.

I'll defer to Julie for the rest of that.

Ms. Julie Elliott: Right now, if a patient goes into a surgeon's office to get a breast augmentation, the informed consent that they have in front of them is about the surgical part of it, most of the time. Rarely, it's anaesthetic. Do you know that you may have systemic symptoms or that there's a slight chance that you can get BIA cancers? Rarely. Most of the time, it's about surgical complication outcome, mechanical complications, the part about anaesthesia and that's it. That's the informed consent that patients have these days.

The Chair: Thank you.

Mr. Robert Kitchen: Could I, very quickly—

The Chair: That's all you have.

Mr. Robert Kitchen: —ask you whether you would provide to the committee your thoughts on what should be included in the registry? That would be greatly appreciated.

I'm sorry, and thank you, Mr. Chair.

The Chair: It's no problem at all.

Dr. Powlowski, you have five minutes.

Mr. Marcus Powlowski (Thunder Bay—Rainy River, Lib.): My understanding is that in 2019, Allergan issued a voluntary recall of its breast implants.

Maybe I have this all wrong here. I went to the Health Canada website. There is a recall policy for health products. I would have thought this policy would apply to breast implants, but correct me if I'm wrong. It requires that the responsible party, which I assume is Allergan, is expected to take action in a manner that is prompt. They are expected to have a recall procedure. They are expected to maintain distribution records that allow tracing of the devices.

To Ms. Elliott specifically, I think you said that there were 15,000 people in Quebec who had implants. A lot of them hadn't been contacted. What exactly did Allergan do? Perhaps I'm wrong in my interpretation of the medical devices regulations and our recall policy for health products, but it would seem to me that they have an obligation to be doing that. What, if anything, did they do, to your knowledge?

I know they're not here, but you can say it from your perspective?

Ms. Julie Elliott: My perspective is based on my experience of having a group of close to 2,500 women in Quebec. There are a few dozen who have textured devices and should have received some kind of information about the fact that their implants were recalled. Very few of those patients who received textured implants as part of a reconstruction following mastectomy received a letter from the health care centre where they had their surgery. It's very few of them.

I asked the women in my group, "If you receive a letter, please let us know. We want to know how many of you got that letter." I think that among all those patients, there was only one who had textured implants for aesthetic reasons only—not part of a reconstruction—who got a letter from.... I don't remember whether it was from her plastic surgeon or Allergan, but there was only one.

Of course, not all women with breast implants or textured breast implants are part of the French-Canadian group. It represents only a small portion of the women with textured implants and breast implants in general. A minority were contacted. Close to 0% were contacted by the manufacturer to let them know they had a defective device implanted.

● (1235)

Mr. Marcus Powlowski: Do any of the other witnesses know whether women who received these implants were contacted by the manufacturers?

Ms. Terri McGregor: I can answer that.

Public commentary from manufacturers, specifically Allergan, says they have taken robust—I believe that's the term they used—activity to try to contact us. What I know as a patient, whether I'm silicone or saline, or smooth or textured, is that implant manufacturers have very robust warranty data. If you look at my Canadian device registry, it was dual-purpose. It was their warranty.

We can't get an answer from the Canadian sales and distribution teams for Allergan and Mentor on exactly what actions they took to reach out and contact women. That question has landed on crickets.

What I can tell you is that this committee will be receiving a copy of my 2009 Canadian device registry. The black-box warning at the bottom of my registry specifically sets that responsibility with Allergan—that Allergan will contact me if there's a safety, efficacy or performance issue. Why cancer didn't raise somebody's alarm bell to say that it was a material change.... I wanted to know—

Mr. Marcus Powlowski: No, sorry. Can I—

Ms. Terri McGregor: Who was the trigger for that? Where is the trigger point from Health Canada to get them to issue those warnings?

Mr. Marcus Powlowski: Well, I'd like to jump in there, because the recall policy for health products on the Health Canada website says that the regulatory operations and enforcement branch of Health Canada monitors recalls and assesses the effectiveness of responsible parties. It also says that should a responsible party fail to effectively conduct a recall, the branch may take compliance and enforcement actions.

To your knowledge, did they take any such action, and have they monitored this recall?

Ms. Terri McGregor: That was part of our recommendations. What consequences has that department levied on these manufacturers that have completely defied any of the conditions, the laws put in place to protect us? Thanks for the question.

The Chair: Thank you, Ms. McGregor.

We will go to Mr. Aboultaif for five minutes, please.

Mr. Ziad Aboultaif (Edmonton Manning, CPC): Thank you. I have three short questions for each one of you to answer, and then one question.

How would you rate the quality of information you received when consulting with professionals prior to the operation?

Let's start with Ms. McGregor.

Ms. Terri McGregor: Sorry?

Mr. Ziad Aboultaif: How would you rate the quality of information received from the surgeon prior to the operation?

Ms. Terri McGregor: What I would suggest is that the surgeon is also motivated to sell me, and there are a lot glossy products—

Mr. Ziad Aboultaif: I am asking about the quality of information received. How do you rate it? Good? Bad?

Ms. Terri McGregor: Ugly.

Mr. Ziad Aboultaif: Okay.

Ms. Elliott, would you comment?

Ms. Julie Elliott: Are you asking about quality of information about the breast implants?

Mr. Ziad Aboultaif: Yes, I'm asking about the information received prior to the operation.

Ms. Julie Elliott: Do you mean information about the actual device?

Mr. Ziad Aboultaif: Overall.

Ms. Julie Elliott: Okay. He told me—and I remember—"Do your homework." This was in 2007. What tools did I have in 2007?

I went on Google or whatever, and what did I find out about that? I found that there could be post-op complications, so I came back to him and said, "Well, there's a slight chance I can die from the surgery. I can have post-op complications," and he said, "Well, you did your homework."

Mr. Ziad Aboultaif: Okay.

I'll ask Ms. Pratt, please.

Ms. Nancy Pratt: I got my implants back in 1991, and I was told when I got mine that they would be lifetime devices. The plastic surgeon actually said that when I died, my body would decay, but my breast implants would be shiny new in the casket.

Today I would say that there's really mixed messaging when Canadians go to consult with plastic surgeons about implants. A lot of them—not all plastic surgeons—do double-talk and say, "Oh, but, you know, the risk is really low," so the messaging is not adequate.

● (1240)

Mr. Ziad Aboultaif: If a loved one told you they wanted breast implants, how would you respond? Answer yes or no, please.

Ms. Terri McGregor: Run for your life in 2023.

Mr. Ziad Aboultaif: Ms. Elliott?

Ms. Julie Elliott: You're putting your life at risk.

Mr. Ziad Aboultaif: Ms. Pratt?

Ms. Nancy Pratt: I absolutely agree with Terri. Run for your life.

Mr. Ziad Aboultaif: One of you said that a registry is only a partial solution. Do you believe that there will be a risk-free implant at all?

Ms. Terri McGregor: No, I think that's asking for a perfect world, and I don't think there will ever be a risk-free implant. What we're asking for is the transparency on the other flip side of that equation. We just want balanced information. I want to be an informed consumer and not the fooled Canadian that I felt like.

Mr. Ziad Aboultaif: Ms. Elliott, would you comment?

Ms. Julie Elliott: May I speak in French?

Mr. Ziad Aboultaif: Yes, indeed.

[*Translation*]

Ms. Julie Elliott: In schools of dentistry, future dentists learn that teeth that are screwed in, dental implants, carry a risk of lymphoma.

[*English*]

Mr. Ziad Aboultaif: Thank you.

Ms. Pratt, would you comment?

Ms. Nancy Pratt: Sorry; can you repeat the question?

Mr. Ziad Aboultaif: The registry is only a part of a solution. Do you think we can eventually have risk-free implants?

Ms. Nancy Pratt: I don't see that happening. I think anything implanted into the body is at risk for complications, but certainly, if they're going to be on the market, track them.

Mr. Ziad Aboultaif: Okay. Here's my final question. Health Canada's roles are supposed to be information, responsibility and liability. Health Canada needs to provide information. We agree on that.

Now, on responsibility, if the information is there, who is going to be responsible for the decision on whether or not to continue with the implant? Is it the patient?

Ms. Terri McGregor: I'm sorry. I'm misunderstanding your question.

Mr. Ziad Aboultaif: The question is, if the information is provided on Health Canada's website, and let's say there's a registry—

Ms. Nancy Pratt: Balanced information.

Ms. Terri McGregor: That's right.

Mr. Ziad Aboultaif: If it's balanced information, and if the decision of the patient is to go for the implant, who's responsible for that decision?

Ms. Terri McGregor: Ultimately, it's the consumer.

Mr. Ziad Aboultaif: Is it the consumer, Ms. Elliott?

Ms. Julie Elliott: I'm not necessarily sure that my answer is going to....

Allergan and Mentor failed to provide long-term safety studies on breast implants. Their long-term safety studies were dropped after three and four years. How come breast implants are still on the market?

To me, that answers the question, because consumers right now in North America should not have to decide which breast implants.... Right now, with no long-term safety studies done, there should not be breast implants on the market to choose from.

Mr. Ziad Aboultaif: Thank you.

The Chair: Thank you, Ms. Elliott.

Go ahead, Ms. Brière, please, for five minutes.

[*Translation*]

Mrs. Élisabeth Brière (Sherbrooke, Lib.): Thank you, Mr. Chair.

I'd like to congratulate our three witnesses and thank them very much for having been here this afternoon to share their experience with us. It will greatly help us make progress with this file.

I'm going to shift the discussion somewhat. I'd like to hear what you have to say about transgender women, many of whom may well have had implant surgery.

Do you have any data about complications or unfortunate incidents experienced by this group?

Ms. Julie Elliott: My group does not operate as a centre for statistics, but it's fairly representative. I'm talking about my group, as well as other communities working on breast implant diseases and BIA-ALCL in general.

Transgender women are probably the most psychologically ill-treated group of patients, and they also experience the most medical cognitive dissonance. That's because they are women who frequently take hormones to achieve what they are looking for in terms of identity. It involves a medical implant, a foreign body. Any foreign body can have consequences. Transgender women who have breast implants are therefore experiencing systemic symptoms related to the implant surgery, like women who are not transgender.

The problem is that if they ask their health professionals about it, as we have all done, most of the time they will be told that their problem is hormone related. They are told that it's caused by something they did to their body. And yet, transgender women who have decided to have their breast implants removed, had their symptoms resolve after a while, as they do for other women.

I personally don't see any difference between transgender and non-transgender women: with breast implants, they both experience the same systemic problems, and the same cases of breast implant-associated anaplastic large cell lymphoma.

● (1245)

Mrs. Élisabeth Brière: Thank you.

[*English*]

Ms. McGregor, would you like to add something?

Ms. Terri McGregor: I just want to add that I am in a global collective of women with BIA-ALCL. Right now, about 250 of us from around the world sit in a private Facebook support group because nobody else wanted us. The breast cancer website said, “Goodbye.” Lymphoma said, “Who are you?” We have two transgender patients. One is a transgender influencer and has been quite public with her story, if you want more information.

Mrs. Élisabeth Brière: Thank you.

Ms. Pratt, would you like to add something?

Ms. Nancy Pratt: I don't really have anything to add, other than that I have heard there are complications happening and I would imagine that they will have the same complications as anybody.

Mrs. Élisabeth Brière: Thank you.

[*Translation*]

Ms. Elliott, on a French-language CBC program, you said that doctors should give patients a card, but that the card might be lost or in certain instances never issued.

Where do we stand between the card and the introduction of a registry?

Ms. Julie Elliott: I'd like to make sure that I've understood the question. Do you mean that the card would replace the registry or that the registry would replace the card?

Mrs. Élisabeth Brière: Yes.

Ms. Julie Elliott: It's easy to lose a card. You could lose it while moving or if you're wallet is stolen. We recommend that people keep it with them in the event of something like an accident. But a document can never replace a registry.

A card can be useful for situations where a file might be destroyed after five years, as is the case in Quebec. The only physical evidence left about the implants is the card. However, a registry would solve all problems pertaining to the card, registration problems, and the destruction of medical records after a certain number of years. The time period before records can be disposed of varies greatly from one province to another. It mustn't be forgotten that when there are breast implants, as I mentioned earlier, if any complications arise that are not postoperative, you don't return to see the surgeon.

Unless there are mechanical complications, women rarely return to see their plastic surgeon. Indeed, five, six or even 10 years might go by. In Quebec, if plastic surgeons have not seen their patients again after five and a half or six years, the files are destroyed. That means there is no more tangible trace of the implant unless the person remembers the manufacturer's name. In such instances, they can call the manufacturer and asked them to find their file. The problem is that patients do not always remember who the manufacturer was. They can often remember whether the implants were saline or silicone, but most of the time they don't remember the external texture or the manufacturer.

● (1250)

The Chair: Thank you, Ms. Elliott.

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

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

Dr. Morris felt that unless it was mandatory for plastic surgeons to contribute to the registry, it wouldn't work. He said that there would have to be a high participation rate.

I'd like to clear up the earlier confusion.

I understand that you would like surgeons and manufacturers to be required to participate. Moreover, you were in agreement with the idea that women should be able to opt out. Have I understood properly?

[*English*]

Ms. Terri McGregor: I think we all agree on mandatory, but I don't feel that I'm in a position to say.... Perhaps there is a 1% reason.

Breast implants are a very personal choice, and what I know from most Canadians is that there are people in this room who have acquaintances in their life who have breast implants that you don't know about. Our culture is very private. We do not want to discuss that, so if there is a percentage who don't want to be in, I don't feel that I'm in a position to say that those women don't deserve that choice.

[*Translation*]

Mr. Luc Thériault: In fact, earlier on, I was talking more about the right to opt out rather than a requirement to register, that is to say that all women would be registered by default and not that they would have to register in order to participate. The purpose is not to know why they would want to opt out, but to consider all women to have registered, and allow them to opt out for a variety of reasons. My understanding is that you are in favour of this principle.

In view of all the problems you mentioned today, do you think that Health Canada should create a proper consent form containing all of the information, as well as the surgeon's and the patient's signatures, as evidence that the patient gave her informed consent and was informed of all the risks associated with the implants?

[*English*]

The Chair: Be brief if you can, please.

[*Translation*]

Ms. Julie Elliott: What's needed is a mandatory standardized informed consent form. It should be in the same format, with the same questions, and the same information for everyone. There should also be consequences for private practice surgeons who do not complete the form with their patients.

The Chair: Thank you, Ms. Elliott.

[*English*]

Mr. Davies, you have two and a half minutes, please.

Mr. Don Davies: Thank you.

After hearing a lot of testimony, I'm still finding myself a little bit unclear about the state of research in this area. I'm totally convinced, by the way, that the three illnesses are linked and that we should act regardless, based on the precautionary principle.

I'm just wondering about this: In your view, Ms. Elliott, should the federal government provide targeted funding to support research related to breast implant illness? It would seem that if there is any confusion in the literature or in the profession among surgeons, this should be resolved immediately by funding absolutely strong clinical trials and research.

My mind was going to the exact same place my colleague Mr. Thériault was going. Even if we don't have crystal-clear causes or evidence yet, it would seem to me that based on the precautionary principle, Health Canada should require all surgeons to issue a standard warning that lists at least the possibility of the three illnesses. Is that something you think Health Canada should be doing?

● (1255)

Ms. Julie Elliott: Of course.

Mr. Don Davies: My final question is on the gendered nature of this issue.

This committee is going to be looking at women's health in another study that's coming up. I'm just wondering.... I can't help but say that this has been going on since the sixties. I think you mentioned cars being recalled, and I think we do have a registry of implants for everything else.

Is it possible that this reflects a larger societal issue about the way we treat women's health by not taking women seriously, by denying their anecdotal complaints, by dismissing them and by being so slow to act when we see clear ties?

Ms. Terri McGregor: You know, it's hard for me to not jump out of my seat and answer that question.

I understand that there's a hierarchy in medicine, but I will suggest that somewhere in this private practice industry of plastic surgery, we see a patriarchal hierarchy of medicine gaslighting female patients. If anyone would ever wanted to write a Ph.D. or case theory, I would strongly suggest that they use private practice breast implant surgeons as that cliché model.

Mr. Don Davies: Ms. Elliott, do you have a comment on that?

Ms. Julie Elliott: I'm going to express myself in French.

[*Translation*]

It's just that I don't want to get the date wrong.

In 1988, Health Canada dismissed a scientist because he had said that breast implants ought not to be on the market, and that they should be withdrawn immediately. I provided you in the appendix with the URL for an article about this. Health Canada dismissed the scientist because he wanted to publicly release the Health Canada records indicating that these implants should not be on the market.

The Chair: Thank you, Ms. Elliott.

[*English*]

We started a little bit after 11, so we probably have five or six minutes left.

Dr. Ellis has agreed to two more short rounds, so maybe we'll do two and a half minutes from Dr. Ellis and two and a half minutes from Dr. Hanley, and then we'll look to adjourn.

Dr. Ellis, you have two and a half minutes.

Mr. Stephen Ellis: Thank you very much, Mr. Chair.

Thank you to the witnesses for being here and giving this interesting testimony.

My colleagues talked about Health Canada requiring certain things for consent, but we know the consent law in Canada is between a physician and a patient, so that would present some difficulties. The only reason I want to bring that forward is that I think it's important that we not offer people false hope of what may or may not change. I think we need to live in reality here, and that's important.

I have a couple of things on medical tourism and immigrant Canadians, people coming here from other countries who have had implants inserted. I guess I look at that.... That's going to continue to create a significant problem for all of us with respect to a registry, which means that perhaps there is a requirement for that interim step. I know my colleague Madame Brière talked a bit about this, a card or an online registry where people could put their information as an interim step, because we have no jurisdiction over physicians in other countries and how to make them become part of our registry.

Do you have any thoughts about that? Would that make sense? What if we compelled the manufacturers to have a website on which women could then enter their information, saying, “Yes, I had Allergan XYZ. It was a textured, silicone-based implant,” etc.? At least that would provide some protection for folks coming here to understand what may happen.

Could you quickly give a few comments on that idea?

Ms. Terri McGregor: I don't know how we get that information to the patient, but that patient should simply have an upload option. I really don't think it's that complicated.

Ms. Julie Elliott: Manufacturers are manufacturing serial numbers. They have lists of those serial numbers. They can divide those lists per country, per province or state, per city, per buyer.

● (1300)

Mr. Stephen Ellis: Again to Ms. Pratt, through you, Chair, could you provide a short answer, please?

Ms. Nancy Pratt: I really don't have anything to add to that. I would agree with Terri's comment.

The Chair: Thank you, Dr. Ellis.

The last short round of questions will come from Dr. Hanley.

Mr. Brendan Hanley: Thank you.

First of all, I want to thank the three of you for appearing today. It's one thing to go through the personal experience; it's another to tell the story of that and to be an advocate. You've each done that in an amazing fashion, and have for many years, so thank you.

I want, in the interest of time, to zone in on a couple of questions.

Ms. McGregor, you referred to the impulsive 20-something-year-old. Do we have enough filters to limit or to....

In this age of cosmetic, aesthetic surgery availability and the influence of industry, are too many women being led into implants without enough information? Is there too much societal pressure? Can you comment on that?

Ms. Terri McGregor: That's difficult.

I guess I was referring to myself in general. In my twenties I made decisions differently from the way I did in my thirties or forties or fifties.

As far as the influence is concerned, Julie, maybe I'll let you pick that up.

Ms. Julie Elliott: If I remember correctly—and correct me if I'm wrong—manufacturers of cosmetic products, aesthetic products, are not supposed to do direct marketing to consumers, yet if you go on Instagram, you see direct publicity for Botox or breast implants.

Who's on Instagram and TikTok? You see that 20-year-old, and there is a label—Juvéderm, Allergan, Botox. Any 20-year-old who sees that can say, “I can have access to breast implants or Juvéderm” and is going to be attracted to that.

I think that whoever is in charge of looking at that particular issue should be looking at what's happening on social media right now.

Mr. Brendan Hanley: Ms. Pratt, do you have a final comment?

Ms. Nancy Pratt: When I started advocating, one of the reasons was that in my daughter's group of peers, there were quite a few who already had breast implants or were considering them.

To start, when they get their implants and they're really happy, they then convince somebody else to get it done. Health Canada doesn't have the right information there. Manufacturers are showing them these high-gloss images. On Health Canada's website, they should have pictures of what a lymph node with silicone looks like. What does a really badly ruptured implant look like? They should be encouraged to consider....

Lots of them are very health conscious, very environmentally aware of chemicals, but they're having chemicals implanted within them. I say this because I did it. That was me. I was a fitness nut, and I had these in me. There can be a disconnect.

I think manufacturers and plastic surgeons and Health Canada should have more responsibility for making sure there is an awareness of the reality of breast implants and what can happen, what can go wrong.

The Chair: Thank you, Ms. Pratt, and thank you, Dr. Hanley.

To all of our witnesses, thank you so much for being with us and sharing your personal stories, and for your advocacy. We share your hope that what you have done here today will make a difference, and that's what we are all seeking to do. Thank you for doing your part in that regard.

Colleagues, just before we wrap up, you should be aware that the witnesses here today have submitted several supporting documents for their presentations, and we're still waiting for some translations. Once that's done, they will be circulated as soon as possible.

The plan for Tuesday was to schedule some time for drafting instructions on the breast implant registry. That may be premature, given the motion that was adopted today, but if you want to start giving some thought to what you would like to see in the report in terms of recommendations, etc., we could possibly have a preliminary discussion on that on Tuesday.

There will also be some time in camera for committee business so that we can plan the agenda for the coming weeks. You will receive, before Tuesday, a summary of the studies that are currently under way and upcoming, as well as a proposed calendar showing a potential work plan.

Finally, the documents from the PMPRB study are about 350 pages. They're still in translation. We don't have a firm date for when they will be available.

That's it by way of updates. Is it the will of the committee to adjourn the meeting?

Some hon. members: Yes.

The Chair: We're adjourned.